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 OF *AMICI CURIAE* PATRICIA A. BUFFLER, DIEGO T. BURIOT, JOSE CORDERO, RONALD E. GOTS, RONALD HART, STEVEN H. LAMM, ANGUS NICOLL, ONORA O'NEILL, SAMUEL OSHER, JAMES D. WATSON AND RICHARD WILSON IN SUPPORT OF RESPONDENT

MARTIN S. KAUFMAN*
* *Counsel of Record*
Atlantic Legal Foundation
2039 Palmer Avenue
Larchmont, New York 10538
(914) 834-3322
Counsel for Amici Curiae

July 30, 2010

QUESTION PRESENTED

Does Section 22(b)(1) preempt vaccine design-defect claims categorically, or must a vaccine manufacturer also show, case by case, that the side effects at issue could not have been avoided by some differently designed vaccine?

TABLE OF CONTENTS

TABLE OF CONTENTS (cont'd)

TABLE OF AUTHORITIES

Page

CASES

STATUTES and REGULATIONS

TABLE OF AUTHORITIES (cont'd)

Page

TABLE OF AUTHORITIES (cont'd)

Page

TABLE OF AUTHORITIES (cont'd)

Page

INTEREST OF *AMICI*

Amici are scientists who are deeply interested in this case and its impact on the quality of healthcare, particularly the broad availability of affordable and effective preventative measures, specifically vaccines, at reasonable cost. *Amici*'s concerns are informed by decades of experience and accomplishment in their respective fields of scientific endeavor. They submit this brief to emphasize the critical role played by vaccination in fostering public health.[1]

Patricia A. Buffler is Professor of Epidemiology at the School of Public Health of the University of California at Berkeley, and is Dean *emerita* of the School of Public Health of the University of California at Berkeley. Among many honors and activities in the field of epidemiology, Dr. Buffler is a Fellow of the American College of Epidemiology, and was President of that organization in 1991-1992. She is a member of the Institute of Medicine of the National Academy of Sciences and a Fellow of the American Association for the Advancement of Science.

Diego T. Buriot, M.D., M.P.H., is a consultant in international health. He is presently World Health Organization ("WHO")-Pan American Health Organization Special Advisor for Haiti. Over the past

---

[1] Pursuant to Rule 37, the parties have consented to the filing of this brief; their letters of consent are on file with the Clerk of the Court. In accordance with Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. *Amici* submit this brief in their individual capacities; the views expressed are not those of the institutions with which they are affiliated.

twenty years he has held several WHO senior positions and provided leadership expertise and negotiation skills in a wide variety of situations both at global and country levels. He established and led, as Director, the WHO Communicable Disease Surveillance (CSR) Office in Lyon, France, dedicated to the strengthening of epidemiology and laboratory capacities in developing countries. Dr. Buriot was, until 2006, Special Advisor to the WHO and he worked on issues related to bio-security, emerging infections, research on communicable diseases, and on issues related to complex emergencies. Dr. Buriot is a graduate of the University of Paris (M.D.) and Harvard University (M.P.H.). He is Board Certified in Pediatrics and Infectious Diseases. He began his career as Assistant Professor of Paediatrics in Paris and subsequently worked at the Centers for Disease Control and Prevention on the Combating Childhood Communicable Disease Project. He has worked extensively in Africa, the Middle East and the Commonwealth of Independent States (CIS) (former Soviet Union countries) to develop and review national communicable diseases control programs. He served in an advisory capacity to several international organizations, including the World Federation of Scientists and United Nations Economic, Scientific and Cultural Organization. Dr Buriot is the author of over 50 original publications, reviews, and book chapters on global health issues.

Jose Cordero, M.D., M.P.H. is Dean of the University of Puerto Rico Graduate School of Public Health. Prior to his appointment as Dean, Dr. Cordero was an Assistant Surgeon General of the United States Public Health Service. In 1994, Dr. Cordero was appointed deputy director of the National Immunization Program, where he made important and long-lasting

contributions in many areas of one of the nation's most successful public health programs. He was the founding Director of the National Center on Birth Defects and Developmental Disabilities ("NCBDDD") at the Centers for Disease Control and Prevention ("CDC") in Atlanta, Georgia. He served in that capacity since the establishment of the NCBDDD, was created by the Children's Health Act of 2000. NCBDDD is a leading international institution devoted to research and prevention of birth defects and developmental disabilities and health promotion of people of ages living with disabilities. Dr. Cordero worked for 27 years at the CDC and has extensive public health experience in the fields of birth defects, developmental disabilities, and child health. Dr. Cordero's work has been published in many national and international journals.

Ronald E. Gots, M.D., Ph.D. specializes in toxicology and environmental medicine. He is Principal of the International Center for Toxicology and Medicine and Medical Director and President of the National Medical Advisory Service. He is Adjunct Professor of Pharmacology at Georgetown University School of Medicine. He has been Coordinator of the Pharmaceutical Class Labeling Project of the U.S. Food and Drug Administration, Medical Director and Examining Physician of the Occupational Health Units, Bureau of Economic Analysis, Census Bureau and Immigration and Naturalization Service, Senior Investigator/Chief in the Department of Gastroenterology, Walter Reed Army Institute of Research.

Ronald Hart is Director Emeritus of the National Center for Toxicological Research. He was a Distinguished Scientist in Residence, United States Food and Drug Administration. Dr. Hart was Adjunct Professor of Cancer Prevention at the Strang Cancer Research Institute of Rockefeller University and Professor in the Department of Radiology at Ohio State University. He also was Chairman of the United States Interagency Committee on Environmental Health and Related Topics and was a principal author of the Technology Transfer Act, 1986. Dr. Hart developed the first direct proof that DNA damage was a cause of cancer (1974), established much of the modern basis for the role of food intake on aging, degenerative disease occurrence and chaired the White House Consensus Policy on Chemical Carcinogenesis.

Steven H. Lamm, M.D., D.T.P.H. is a medical doctor and holds a diploma in tropical public health and a master of science degree in biophysics. He is board certified in pediatrics, occupational medicine, and preventive medicine. He is a charter fellow of the American College of Epidemiology, and a winner of the Annual Prize of the Society for epidemiologic research. Dr. Lamm is on the attending faculties of the Johns Hopkins University-Bloomberg School of Public Health (Health Policy and Management) and the Georgetown University Department of Pediatrics (Epidemiology). He has conducted studies on vaccine safety for thirty years, including studies in the United States, Europe (Poland), and South America (Amazon). He is Clinical Assistant Professor of Pediatrics at Georgetown University School of Medicine. He was Senior Epidemiologist in the Epidemiology Branch of the National Institute of Child Health and Human Development of the National Institutes of Health; he

was also an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention.

Angus Nicoll is head of the Influenza Program of the European Centre for Disease Prevention and Control. ("ECDC") and is a Professor at the London School of Hygiene and Tropical Medicine.

Onora O'Neill CBE, FBA, F. Med. Sci., Hon. FRS is a Harvard trained philosopher whose work focuses on ethics and political philosophy, including medical and research ethics. She was Principal of Newnham College, Cambridge University from 1992 to 2006, is professor *emerita* in the Faculty of Philosophy in Cambridge University, and was President of the British Academy from 2005 to 2009. She is an independent (non-party) peer in the U.K. House of Lords (Baroness O'Neill of Bengarve). She is a past chair of the Nuffield Council on Bioethics, and has served on House of Lords Select Committees dealing with Stem Cell Research, Genomic Medicine, Nanotechnology and Food and Behavioural Modification, and is a Trustee of several U.K. charities that work to improve public understanding of science, including the Nuffield Foundation (chair); Sense About Science; and the PHG Foundation.

Samuel Osher, **M.D**. is a physician with the Harvard University Health Service, and Clinical Instructor in Medicine at the Harvard Medical School. His clinical interests include preventive care and hypertension.

James D. Watson is a Nobel Laureate in Medicine (1962) (with F.H.C. Crick and M.H.F. Wilkins), and co-discoverer of the structure of DNA. Dr. Watson has also been awarded the John Collins Warren Prize of the Massachusetts General Hospital, the Albert Lasker

Prize of the Public Health Association, the John J. Carty Gold Medal of the National Academy of Sciences, and the Presidential Medal of Freedom. He earned his Ph.D. in Zoology, and has been awarded numerous honorary degrees. He was director and president of the Cold Spring Harbor Laboratory of the National Institutes of Health, and is currently Chancellor *emeritus* of the Cold Spring Harbor Laboratory.

Richard Wilson is Mallinckrodt Research Professor of Physics *emeritus* at Harvard University and immediate past Director of the Regional Center for Global Environmental Change at Harvard University. He is an Affiliate of the Center for Science and International Affairs and the Center for Middle Eastern Studies at Harvard University. Professor Wilson is a past Chairman of the Harvard University Department of Physics. He is a founder of the Society for Risk Analysis. Professor Wilson has been a consultant to the United States government and foreign governments on toxicology, epidemiology, public health and safety, nuclear safety, and risk assessment. Professor Wilson's areas of expertise include elementary particle physics, radiation physics, chemical carcinogens, air pollution, ground water pollution, and human rights. He is the author of more than 880 published papers on subjects including carcinogenic risk, statistical distributions of health risks, cancer risk management, public health, environmental pollution, and risk benefit analysis, including RICHARD WILSON & EDMUND A. C. CROUCH, RISK-BENEFIT ANALYSIS (2nd ed. 2001).

STATEMENT

Both the briefs by the petitioner and the respondent in this case emphasize the issue of whether federal law preempts state law, but they say little about the public health and scientific issues which the law should, and in this case does, address. These public health and scientific issues are fundamental in many ways. It is important that the scientific and public health considerations that underlie that intent be fully considered. The Court will no doubt wish to divine the intent of Congress in enacting the relevant legislation.

Mankind constantly faces the issue of how to balance the rights of an individual and the role of society and its institutions. It is vital to emphasize, and to consider especially carefully, the situations where the motives, the risks, and the rewards are different. Vaccination is one of these issues.

A. The Importance of Vaccination

Vaccines are among the most effective tools available for preventing infectious diseases and their complications and sequelae.[2]

---

[2] "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. NO. 99-908, pt. 1, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 ("1986 House Report"). For example, between 1934 and 1984, diphtheria, tetanus and pertussis ("DTP") vaccines helped reduce reported cases of pertussis by 99%. J. Bass & S. Stephenson, *The Return of Pertussis*, 6 PEDIATRIC INFECT. DIS. J. 141 (1987).

There can be no doubt of the fantastic success of vaccination since it was first introduced over two centuries ago, and became standard and widespread, and in many instances mandatory, more than a century ago. Primarily because of the availability of vaccines to protect against many infectious diseases, most of us will no longer die from infectious disease but from other causes. Indeed, in one case, smallpox, the disease was eradicated in the last half century, except for a handful of laboratory samples.

High immunization coverage has resulted in drastic declines in vaccine-preventable diseases, particularly in many high- and middle-income countries. Vaccination is one of the greatest public health achievements in the United States during the twentieth century. A reduction in the incidence of a vaccine-preventable disease often leads to the public perception that the severity of the disease and susceptibility to it have decreased. S.B. Omer et al., *Vaccine Refusal, Mandatory Immunizations, and the Risks of Vaccine-Preventable Diseases*, 360 NEW ENG. J. MED. 1981 (2009); *see also* R. Chen & B. Hibbs, *Vaccine Safety: Current and Future Challenges*, 27 PEDIATR. ANNALS 445 (1998). Immunizations have eradicated smallpox world-wide; have eliminated poliomyelitis in the Americas; and have controlled measles, rubella, tetanus, diphtheria, Haemophilus influenzae type b (Hib), and other infectious diseases. We know that vaccines have dramatically reduced the number of people who get infectious diseases. Without vaccines, epidemics of vaccine-preventable diseases would return, resulting in increased and unnecessary illness, disability, and death. History shows that in times of high vaccine coverage and very low incidence of vaccine-preventable diseases, it is common and very easy to shift attention

away from the real benefits of vaccines to potential vaccine risks. *Vaccines: Finding the Balance Between Public Safety and Personal Choice: Hearing Before the H. Comm. on Govt. Reform*, 106th Cong. 84 (Aug. 3, 1999) (hereinafter "*Hearing*") (statement of David Satcher, M.D., Ph.D., Assistant Sec'y for Health and Surgeon General) *available at* http://www.hhs.gov/asl/testify/t990803a.html (last visited July 29, 2010).

Vaccines which protect against disease by inducing immunity are widely and routinely administered around the world based on the common sense principle that it is better to keep people from falling ill than to treat them once they are ill. Suffering, disability, and death are avoided. Immunization has million of deaths each year. World Health Organization, *Immunization Against Diseases of Public Health Importance* (Mar. 2005), available at http://www.who.int/mediacentre/factsheets/fs288/en/index.html (last visited July 29, 2010). Contagion is reduced, strain on healthcare systems is eased, and money is frequently saved and can be used for other health or other public services.

An immunization campaign carried out by the World Health Organization (WHO) from 1967 to 1977 eradicated the natural occurrence of smallpox. When the program began, the disease still threatened 60% of the world's population and killed every fourth victim. Eradication of poliomyelitis is within reach. Since the launch by WHO and its partners of the Global Polio Eradication Initiative in 1988, infections have fallen by 99%, and some five million people have escaped paralysis. Between 1999 and 2003, measles deaths dropped worldwide by almost 40%, and some regions

have set a target of eliminating the disease. Maternal and neonatal tetanus will soon be eliminated in 14 of 57 high-risk countries. *See* World Health Organization, *Immunization Against Diseases of Public Health Importance* (2005), *available at* http://www.who.int/mediacentre/factsheets/fs288/en/index.html (last visited July 29, 2010).

Routine vaccination is now provided in all developing countries against measles, polio, diphtheria, tetanus, pertussis, and tuberculosis. To this basic package of vaccines, which served as the standard for years, have come new additions. Immunization against hepatitis B is now recommended by WHO for all nations, and currently is offered to infants in 147 of 192 WHO Member States. Immunization against Haemophilus influenzae type b is recommended where resources permit its use and the burden of disease is established; it is provided in 89 countries (only in selected parts of two of those countries). Yellow fever vaccine is offered in about two-thirds of the nations at risk for yellow fever outbreaks. Routine immunization against rubella is provided in 111 countries. In industrialized countries a wider span of protection is typically provided than in developing countries, often including vaccines against influenza, predominant strains of pneumococcal disease, and mumps (usually in combination with measles and rubella vaccine). World Health Organization, *Immunization Against Diseases of Public Health Importance*, *supra.*

In the United States vaccination programs have eliminated or significantly reduced many diseases. However, these diseases still exist and can once again become common, and deadly, if vaccination coverage does not continue at high levels. Vaccine-preventable

diseases have many social and economic costs: for example, sick children miss school and parents may have to take time off from work; these diseases also result in doctor visits, hospitalizations, and even premature deaths. *See* Centers for Disease Control and Prevention, *What Would Happen If We Stopped Vaccinations?* (July 7, 2010), available at http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm (last accessed 07-29-2010).

Immunization is considered among the most cost-effective health investments.[3] There is a well-defined target group; contact with the health system is only needed at the time of delivery; and vaccination does not require any major change of lifestyle.

B. The Societal Interest In Vaccination

Thus, there is a strong societal interest in encouraging widespread vaccination, an interest that can best be fostered on a national level. A decision to vaccinate is a decision to help protect not only individuals, but also to protect entire communities from

---

[3] In the mid-1990s, vaccines to provide "basic" coverage for tuberculosis, polio, diphtheria, tetanus, pertussis, and measles cost about $1.00 per child. Inclusion of vaccines for hepatitis B and Hib raises the vaccine cost to $7.00 to $13.00 per child (not including administration and injection equipment) in the developing world. When vaccine administration is included, the costs amount to between $20.00 and $40.00 per child. *See* World Health Organization, *Immunization Against Diseases of Public Health Importance* (2005), http://www.who.int/mediacentre/factsheets/fs288/en/index.html (last visited July 29, 2010). In addition to the health benefits to individuals and the community, "Billions of medical and health-related dollars have been saved by immunizations." H.R. Rep. No. 99-908, at 4.

diseases spread by person-to-person transmission. A decision to not vaccinate puts the individual and the community at risk. When immunization programs achieve high levels of "community" immunity or what scientists sometimes refer to as "herd" immunity (the indirect protection of a community, including unvaccinated individuals), the likelihood that an infected person will transmit the disease to a susceptible individual is greatly reduced. Community immunity provides indirect protection to children who may be too young for certain vaccinations or have other health problems that prevent them from being immunized, yet are still susceptible to the disease. For example, children under one year old are too young to receive the measles vaccine but receive some protection from the vaccination of older individuals. Children who cannot be vaccinated with some vaccines for medical reasons such as childhood leukemia are also protected. *See Hearing, supra.* These groups are often more susceptible to the complications of infectious diseases than the general population of children and depend on the protection provided by the vaccination of children in their environs. *See* K.A. Poehling et al., *Invasive pneumococcal disease among infants before and after introduction of pneumococcal conjugate vaccine,* 295 JAMA 1668-74 (2006).

As Surgeon General David Satcher stated at a Congressional Hearing in 1999, "Protecting our society from debilitating and deadly diseases that can be prevented through the administration of vaccines is a cornerstone for ensuring the health and well-being of our citizens. Vaccines are highly effective in preventing death and disability, and save billions of dollars in health costs annually." *See Hearing*, *supra.*

C. The Unavoidable Risks of Vaccines

Notwithstanding the enormous benefits of vaccines, experts recognize that "[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 MORBIDITY AND MORTALITY WEEKLY REP. 1 (2006) *available at* www.cdc.gov/mmwr/pdf/rr/rr5515.pdf (last visited July, 29, 2010)

Even when vaccines are properly manufactured and administered, a small number of children may suffer serious adverse reactions. *See See* H.R. REP. NO. 99-908 at 4, 6. Despite these risks, public health officials and physicians' organizations have consistently advised that it is safer to take the required inoculations than to risk the health consequences of contracting the diseases immunizations are designed to prevent and "in light of the overall success of immunization programs, the Federal government continues to support . . . immunizations to children." *Id.* at 6. The benefits of vaccination clearly outweigh the comparatively small risk of injury.

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, the length and quality of life of countless children has also been increased and significant savings in direct and indirect costs have been realized. Thus, the finding of Congress 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), was fully justified.

In passing the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1, *et seq*. (The "Vaccine Act" or the "Act"), Congress was responding to a concern that fear of enormous exposure to tort liability would significantly reduce the availability of essential vaccines. Congress was also mindful of the need to provide for fair and efficient compensation for those who were injured by vaccines.

The Vaccine 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 correctly recognized, the Vaccine Act furthers that vital objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 248 (3rd Cir. 2010) (emphasis added).

ARGUMENT

PREEMPTION OF STATE COURT ACTIONS BASED ON DESIGN DEFECT CLAIMS IS ESSENTIAL TO EFFECT THE INTENT OF CONGRESS IN ENACTING THE VACCINE ACT

Mankind clearly needs to, and for the most part wants to, continue and expand vaccination. The motive for society is clear – to develop "herd immunity." However, since an individual can obtain much of the advantage of the "herd immunity" without being vaccinated, so long the neighbors are, and since every vaccine has side effects (hopefully affecting only a small number of people, largely at random) there is a small incentive for an individual not to be vaccinated, although the un-vaccinated individual remains at some risk.

Public health experts and authorities recommended a no-fault compensation program to compensate anyone who suffered these side effects and thereby to reduce the incentive for an individual to refuse vaccination. Recognizing this, Congress, in 1986, passed the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1, *et seq*.

A. The Objectives of the Vaccine Act

"[T]wo overriding concerns" prompted passage of the Vaccine Act: "the inadequacy -- from both the perspective of vaccine-injured persons as well as vaccine manufacturers -- of [a tort law] approach to compensating those who have been damaged by a vaccine," and "the instability and unpredictability of the childhood vaccine market," due to vaccine

manufacturers' inclination to leave the market out of fear of potentially enormous tort liability. H.R. REP. NO. 908, at 7.[4]

The Vaccine Act thus had two goals. One goal was to ensure the continued supply of essential childhood vaccines by reducing the burden of litigation that had driven a number of vaccine manufacturers from the market, threatening the nation's vaccine supply. A second goal was to provide a streamlined and liberal administrative compensation scheme for those children who suffer from the rare side effects of some vaccines. Thus, the Act is designed to encourage "development and distribution of vaccines that will further enhance the public health" and to compensate individuals injured by such vaccines. H.R. REP. NO. 908, at 7.

B. The Compensation Scheme

Congress addressed the need for adequate and efficient compensation by establishing the National Vaccine Injury Compensation Program ("VICP") as an alternative to personal injury lawsuits, under which children injured by certain vaccines would receive "fair and expeditious" compensation for their injuries. *Id.* at 12; 42 U.S.C. §§ 300aa-10, *et seq*.

A person seeking compensation for an injury caused by a vaccine covered by the Vaccine Act must file a

---

[4] "The number of childhood vaccine manufacturers [had] declined significantly," H.R. REP. NO. 99-908, at 4, while those that remained "question[ed] their continued participation in the vaccine market." This "unstable and unpredictable childhood vaccine market," *id*. at 5, led to "a short term crisis of availability of DTP vaccine." *Id*., at 7.

petition with the Court of Federal Claims ("CFC"), which refers the petition to the an office of special masters appointed to hear vaccine injury claims (known as "Vaccine Court"). 42 U.S.C. §§ 300aa-11(a)(1)-(2), 300aa-12(c), 300aa-21(a). The Secretary of Health and Human Services is the respondent and vaccine manufacturers are not parties to the proceedings. *Id.*, § 300aa-12(b)(1). The award of the Vaccine Court is reviewable by the CFC and by the U.S. Court of Appeals for the Federal Circuit. 42 U.S.C. § 300aa-12(c)-(f).

A claimant is entitled to compensation if he or she has suffered an injury set forth in the "Vaccine Injury Table" (a "Table injury"), unless it can be shown by a preponderance of the evidence that the injury was not caused by the vaccine. *Id.* §§ 300aa-11(b), (c), 300aa-13(a)(1), 300aa-14.[5, 6]

Awards cover medical costs, lost earning capacity, and pain and suffering. 42 U.S.C. § 300aa-15(a). To ensure that claimants can afford legal representation, the VCIP allows recovery of reasonable attorneys' fees even if there is no award to the claimant if the claim was brought in good faith and on a reasonable basis. 42 U.S.C. 300aa-15(e). Awards are paid from a "Vaccine Injury Compensation Trust Fund" funded by an excise tax on the manufacture of vaccines covered by the Act.

---

[5] The Vaccine Injury Table is a list of vaccines and the injuries presumed to be caused by those vaccines. (*See* 42 C.F.R. § 100.3)

[6] A claimant 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. 42 U.S.C. § 300aa-21(a).

26 U.S.C. § 4131 (imposing an excise tax on certain types of vaccines); *id.* § 9510 (creating a trust fund)

After the Vaccine Court has issued a final judgment, a petitioner may accept or reject it. 42 U.S.C. § 300aa-21(a).[7] If the claimant rejects the CFC's judgment the claimant may bring a civil action against the manufacturer, 42 U.S.C. §§ 300aa-11(a)(2)(A), 300aa-21(a)-(b); such actions is governed by state law, subject to the Vaccine Act's limitations. 42 U.S.C. § 300aa-22.

The criteria for accepting a claim are important.[8] The adequacy of compensation is important. The criteria should, and probably will, change with time. However, this is not an issue before the Court in this case.

C. The Preemption Provision

An important element for ensuring the continued and affordable supply of vital vaccines is the preemption provision of the Vaccine Act, 42 U.S.C. § 300aa-22(b)(1), which provides that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death," except "as provided in subsections (b), (c) and (e) of this section." 42 U.S.C. § 300aa-22(a), 22(b)(1).

---

[7] A claimant may withdraw a petition if the special master or the CFC fails to render a judgment within specified time limits.

[8] In the case at hand, *amici* know of no good evidence that DPT vaccines cause seizures and do not question the judgment of the Vaccine Court on this issue.

Section 22(b)(1) establishes limits on state law civil tort liability. The provision bars state law tort liability against manufacturers of childhood vaccines for all claims except for those based on manufacturing defects and failures to warn:

> 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).

The Third Circuit correctly recognized that the Vaccine Act furthers that vital objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 248 (3rd Cir. 2010) (emphasis added). Section 300aa-22(b)(1) bars state law tort liability of manufacturers of childhood vaccines for all possible claims except manufacturing defect and failure to warn claims.

Vaccine preparation and labeling are subject to approval by the Food and Drug Administration ("FDA") and it would be absurd if the uniform national standards were replaced by individual state procedures and approvals. While we must acknowledge that FDA's procedures can never be perfect, and constant improvements are to be sought, with expected reduction of side effects, it would defeat the purpose of the national policy to encourage development and production of vaccines for a manufacturer to be liable

even if the manufacturer complied with FDA approved procedures.[9]

An interpretation of the Vaccine Act that would allow design-defect claims to be asserted in state tort litigation would frustrate Congress's purpose. Vaccine and immunization policy involve complex decisions balancing safety and effectiveness. Jury trials in 50 jurisdictions would likely produce inconsistent decisions about whether a vaccine design is defective and thus the basis for substantial exposure to damages. Even a few jury verdicts finding a design defect could quite possibly result in withdrawal of that vaccine from the market.

National public health policy decisions should not be made in state court litigation over whether a vaccine was manufactured according to its FDA approved design, or whether a manufacturer has complied with applicable regulations and provided FDA with all required information before and after a vaccine's licensure so as to enjoy presumptive protection from failure to warn claims under 42 U.S.C. § 300aa-22(b)(2).[10]

---

[9] More logical perhaps, but in the view of *amici* still not sensible, would be to hold a physician liable if he fails to choose the "best" of all vaccines approved by the FDA.

[10] Federal versus state jurisdiction has important public health implications which have changed over time. The states have traditionally had the authority to take forceful (even draconian) action in the interests of public health and safety. *See, e.g.*, *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), in which the Court endorsed the rights of states to pass and enforce compulsory vaccination laws and which served as the foundation for many state public health laws; *see also Zucht v. King*, 260 U.S.

(continued...)

CONCLUSION

In making the decision in this case, *amici* urge the Court to be mindful of the importance of vaccination to individual health and to the public good by ensuring that there is an adequate supply of vaccines available at reasonable cost and the importance of a uniform national policy encouraging the availability of safe and effective vaccines.

The decision of the Court of Appeals should be affirmed.

July 30, 2010

Respectfully submitted,

MARTIN S. KAUFMAN*
** Counsel of Record*
Atlantic Legal Foundation
2039 Palmer Avenue
Larchmont, New York 10538
(914) 834-3322
mskaufman@atlanticlegal.org
Counsel for Amici Curiae

---

[10](...continued)
174 (1922), in which the Court, deciding a case filed by a girl excluded from a public school (and later a private school) found school immunization requirements to be constitutional. Courts have been generally supportive of the states' power to enact and implement immunization requirements. Increasing interstate and international travel has made the federal role increasingly relevant and important. At the time of the SARS epidemic in China, for example, travelers from China were questioned, and in future situations travelers are likely to be checked for fever with simple thermometry. This would be far harder to do at every state border if it were not conducted at the port of entry.