No. 09-152 JUN 1 - 2010

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 VACCINE INJURED PETITIONERS BAR ASSOCIATION, THE GEORGE WASHINGTON UNIVERSITY LAW SCHOOL VACCINE INJURY CLINIC, AND ZENORIA PHILLIPS DELOATCH, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF MOSHELLA F. ROBERTS, AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

Amicus curiae, the Vaccine Injured Petitioners Bar Association (hereinafter "Petitioners Bar") is a voluntary bar association comprised of attorneys who represent petitioners in the National Vaccine Injury Compensation Program (hereinafter "Vaccine Program" or "Program"). Members of the Petitioners Bar have assisted the families of children and adults who have suffered adverse effects from vaccinations since the inception of the Vaccine Program. The organization and its members have a professional responsibility to ensure that the families of the vaccine-injured receive justice as Congress intended – swiftly, with generosity and certainty. To that end, members of the Petitioners Bar have testified before Congress numerous times concerning vaccine injuries and the Vaccine Program. It is in the performance of their professional duties that these *amici* feel compelled to describe to this Court the injustice worked upon a small group of petitioners by the lower court's decision – an injustice never intended by Congress.

Amicus curiae, The George Washington University Law School Vaccine Injury Clinic was established in 1994 at the suggestion of several judges of the U.S. Court of Federal Claims who saw a need for additional knowledgeable counsel in vaccine injury cases.

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represents that it authored this brief and that no person or entity other than *amici* or their counsel made a monetary contribution to the preparation or submission of the brief. Counsel for *amici* represents that counsel for all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amicus* briefs have been filed with the Clerk.

The Vaccine Injury Clinic represents the families of young children in vaccine compensation proceedings through its law student-attorneys. Through the efforts of its students and faculty, the Vaccine Injury Clinic has obtained compensation for children with severe mental and physical disabilities and has prevailed in appeals to the U.S. Court of Appeals for the Federal Circuit on significant vaccine matters.

Amicus curiae, Mrs. Phillips DeLoatch is a mother who lost her healthy child four days after receipt of the Gardasil vaccine. Mrs. DeLoatch is a petitioner in the Vaccine Program seeking justice for the loss of her daughter. Mrs. DeLoatch's case exemplifies a vaccine claim that may not be adequately resolved within the Vaccine Program, thereby requiring resort to the tort system. Should Mrs. DeLoatch opt out of the Vaccine Program, and allege in a traditional tort suit that her daughter's death could have been avoided with an alternative design, she would be precluded from pursing her claim by the Third Circuit's opinion below. As a result of the Third Circuit's interpretation of the National Childhood Vaccine Injury Act of 1986 (hereinafter "Vaccine Act" or "Act"), families of vaccine-injured children, like Mrs. DeLoatch, could find themselves without remedies in either the vaccine court or the tort system.

These *amici* would respectfully submit that the members of Congress did not intend for children to fall through the cracks in the system they created. As Senator Robert T. Stafford explained, "Our obligation is not to the drug companies nor the doctors. Indeed, our highest obligation is not even to the parents who may have suffered grievously; our highest obligation is to the children." *Hearing on S. 827 Before the S. Comm. on Labor & Human Res.*, pt. 1,

99th Cong. 16 (1985). Senator Paula Hawkins echoed this sentiment in her written statement to the House Subcommittee on Health and the Environment, "But I think it is equally important that in our desire to assure a continuous supply of childhood vaccines, that we are not stampeded into modif[y]ing the bill to the detriment of the injured children. They are and must remain our first priority." *Hearings on H.R. 5810 Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Commerce*, 98th Cong. 354 (1985).

Amici submit this brief in hopes that their experience and perspectives will assist the Court in understanding the practical implications of the decision on review.

SUMMARY OF ARGUMENT

Congress created the National Vaccine Injury Compensation Program to ensure that all children injured by vaccines would receive compensation quickly, easily, and with certainty and generosity. To meet these goals, the Vaccine Program limits the scope and timing of compensation proceedings. Evidence is limited. Motion practice is limited. There is no discovery as a matter of right.

In theory, such limits streamline the compensation process to the benefit of families enduring the financial and emotional costs of vaccine injuries. However, not all claims can be fully and fairly adjudicated within the Vaccine Program. For example, for the families of those injured by vaccines that have not been widely studied, the publicly available information necessary to support a claim in the Vaccine Program does not exist.

Mrs. Phillips DeLoatch's experience in the Vaccine Program illustrates how the limits put in place by

Congress to provide swift justice to the vaccine-injured can become barriers to justice. Mrs. DeLoatch represents her daughter's estate as a petitioner in the Vaccine Program. Mrs. DeLoatch lost her daughter after she received the cervical cancer vaccine, Gardasil. There are currently five other families in the Vaccine Program who have similarly lost their daughters after a Gardasil vaccination.

To prove how the Gardasil vaccine caused her daughter's death, Mrs. DeLoatch needs specific studies and information on the vaccine, which information is currently held only by Gardasil's manufacturer, Merck & Company, Inc. In traditional tort claims, the litigation tool of discovery could be used to obtain this information. Because of the restraints on discovery built into the Vaccine Program, such a tool is not available to Mrs. DeLoatch and she has been denied discovery from the vaccine manufacturer. Acknowledging the damaging effect of her inability to obtain discovery on her claim, the Special Master in Mrs. DeLoatch's case has informed her that she may leave the Vaccine Program and file suit against the vaccine manufacturer to pursue her claim.

Without the information she must obtain from the manufacturer, Mrs. DeLoatch cannot proceed in the Vaccine Program. To obtain this information, Mrs. DeLoatch must leave the Program and file a traditional tort suit against the manufacturer showing that her daughter's death could have been avoided through a safer design. The manufacturer will undoubtedly defend this design defect suit by arguing that Mrs. DeLoatch may pursue her claim only in the forum of the Vaccine Program. Pursuant to the Third Circuit's ruling, Mrs. DeLoatch and petitioners

like her have nowhere to go to seek justice. Such a result is the antithesis of Congress's intent in creating the Vaccine Program.

ARGUMENT

I. CONGRESS CREATED THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM TO PROVIDE SIMPLE AND SPEEDY JUSTICE FOR THE FAMILIES OF VACCINE-INJURED CHILDREN.

Congress established the National Vaccine Injury Compensation Program in 1986 as a means to provide swift justice to the families of children and adults injured by vaccines. *See* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, tit. III, 100 Stat. 3743, 3755 (codified as amended at 42 U.S.C. § 300aa *et seq.*). From its inception, the purpose of the Vaccine Program was to "establish a simple, no-fault, low transaction cost, nonadversarial, and effective national program for assuring the provision of just compensation to children and others who have sustained vaccine-related injury." H.R. 5810, 98th Cong. § 2(b)(1) (1984); *Hearings on H.R. 5810*, *supra*, at 5.

A. Prior to the creation of the Vaccine Program, families, already emotionally and financially stressed by their children's injuries, had to seek relief in the traditional tort system with its delays and inconsistent results.

In creating the Vaccine Program, Congress recognized that some individuals inevitably suffer adverse reactions to vaccines. *See* H.R. 5810, *supra*, § 2(a)(2); *Hearings on H.R. 5810*, *supra*, at 57, 117 (statements of Rep. Henry A. Waxman). Families can be devastated by such vaccine injuries. An adverse vaccine

reaction can cause a range of disabilities, paralysis and even death. *See* H.R. Rep. No. 106-977, at 2 (2000). To provide for their injured child or parent, a family may face enormous expenses, including residential care, therapy, medical equipment, and drugs. *Id.* Before the creation of the Vaccine Program, families had to turn to traditional tort litigation in an attempt to seek compensation for these overwhelming medical expenses. *Id.*

In the 1980s, Congress became concerned that families were subject to years of emotional and financial stress in their efforts to seek relief through the traditional tort system. *See, e.g., Hearing on H.R. 1780, H.R. 4777, and H.R. 5184 Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Commerce*, 99th Cong. 1-2 (1987) (statement of Rep. Henry A. Waxman); H.R. Rep. No. 99-908, pt. 1, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6347. Testifying before the House Subcommittee on Health and the Environment, Dr. Martin Smith, President-Elect of the American Academy of Pediatrics explained, "Yet, when a small percentage of serious injuries inevitably occurs, we abandon those children to the slow, tedious, uncertain tort process for appropriate compensation." *Hearings on H.R. 5810, supra*, at 5. Describing the stresses placed upon parents, Dr. Smith stated, "Under the present system, parents are forced to revisit over an extended period of time the tragedy that has occurred with their children and relive a difficult emotional crisis. The needs of these children are immediate. They cannot wait 6 to 8 years for a possible settlement." *Id.*

After years of hearing from countless experts like Dr. Smith, as well as the parents of injured children, members of Congress agreed on the need for a simple

and speedy compensation program for vaccine-injured children. Senator Paula Hawkins, speaking on behalf of the Senate Committee on Labor and Human Resources, stated, "I believe we all agree on the need to modify the current method of compensating children for injuries. I think these children have an urgent need and deserve simple justice quickly." *Hearing on S. 2117 Before the S. Comm. on Labor & Human Res.*, 98th Cong. 290-91 (1984). At a hearing conducted by the same committee in 1985, Senator Hawkins challenged her colleagues to move forward with a compensation program, saying, "it is time we ... provide just and expedited compensation for those few children who are injured by an adverse reaction." *Hearing on S. 827*, pt. 1, *supra*, at 6.

B. Congress designed the Vaccine Program with restrictions to the timing of proceedings and the scope of evidence to be considered for the purpose of ensuring a swift and generous resolution of vaccine claims.

In crafting the Vaccine Program, Congress sought to provide the swift justice called for by its members and the parents and doctors who participated in its hearings. In its report on the Vaccine Act, the House Committee on Energy and Commerce set forth the Act's purpose: "to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, pt. 1, *supra*, at 3, *reprinted in* 1986 U.S.C.C.A.N. 6344. As this Court noted in *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995), "For injuries and deaths traceable to vaccinations, the Act establishes a scheme of

recovery designed to work faster and with greater ease than the civil tort system."

The Vaccine Act initially required that a judgment be rendered "as expeditiously as practicable but not later than 365 days after the date on which the petition was filed." Vaccine Act § 2112(d)(3), 100 Stat. 3762. To assist the courts in meeting this one year deadline, the Act included a vaccine injury table that created a presumption of vaccine-related injury in certain circumstances. *Id.* § 2114(a), 100 Stat. 3764. The Act also provided for special masters to assist the court in quickly addressing the petitioner's compensation claim. *Id.* § 2112(c), 100 Stat. 3761. *See also Shalala v. Whitecotton*, 514 U.S. at 270 ("Special masters in the Court of Federal Claims hear vaccine-related complaints which they adjudicate informally, within strict time limits, subject to similarly expeditious review." (citations omitted)). While the Act authorized special masters to require information and testimony as may be reasonable and necessary to determine entitlement to compensation, it limited discovery as a matter of right. *See* Vaccine Act § 2112(c)(2), 100 Stat. 3761-62; R.U.S.C.F.C., App. B, Vaccine Rule 7 ("There shall be no discovery as a matter of right.").

Thus, Congress designed the Vaccine Program with compassion for the families who would participate in the Program. As Senator Orrin G. Hatch stated in his Opening Statement to the Committee on Labor and Human Relations, "It is compassion which drives this legislative process; it is concern for children and their health." *Hearing on S. 827*, pt. 1, *supra*, at 1. The Program was designed to provide simple and speedy relief for families enduring the financial and emotional struggles attendant to serious injuries –

injuries their children had received as a result of mandatory vaccinations. It was designed to provide swift justice for those families.[2]

II. NOT EVERY CASE CAN BE FULLY AND FAIRLY LITIGATED WITHIN THE CONFINES OF THE VACCINE PROGRAM.

The Vaccine Program can deliver the swift justice Congress intended. It can provide a relatively quick resolution for the families of those injured by vaccines. In some cases, however, the Program, as designed, cannot provide swift justice. Mrs. Phillips DeLoatch is the petitioner in one such case. Her experience provides a stark illustration of how the Program cannot fully resolve all vaccine claims.

A. Mrs. Phillips DeLoatch suffered the loss of her daughter after receipt of the Gardasil vaccine and now has learned that her case is one where the Vaccine Program cannot deliver swift justice.

Mrs. DeLoatch is the personal representative of her daughter's estate. *See DeLoatch v. Sec'y of Health & Human Servs.*, No. 09-171V, slip op. at 1 (Fed. Cl. Apr. 27, 2010). Moshella F. Roberts, Mrs. DeLoatch's daughter, passed away in April 2008, shortly after receiving the Gardasil vaccine. *Id.* at 2. Moshella was 20, a young woman who worked in home health care. *Id.* Four days after receiving the Gardasil vaccine, Moshella was found dead. *Id.* Moshella had no previous health problems.

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[2] In its Report on the Act, the House Committee on Energy and Commerce noted, "without such quick and certain conclusion of the proceedings, the compensation system would work an injustice upon the petitioner." H.R. Rep. No. 99-908, pt. 1, *supra*, at 17, *reprinted in* 1986 U.S.C.C.A.N. 6358.

After performing an autopsy the day after her death, the medical examiner ruled Moshella's cause of death to be undetermined. *Id.* Convinced that the administration of the Gardasil vaccine played a role in her otherwise healthy daughter's death, Mrs. DeLoatch filed a petition in the Vaccine Program. *Id.*

B. Typically, a vaccine proceeding moves relatively quickly through the process of gathering medical records and medical expert opinions to the causation hearing.

Typically, a petition for compensation in the Vaccine Program is supported by the injured party's medical records and medical expert affidavits. *See* Office of the Special Masters, U.S. Court of Federal Claims, Guidelines for Practice Under the National Vaccine Injury Compensation Program at 5-7 (2004) (hereinafter "Special Masters Guidelines"), *available at* http://www.uscfc.uscourts.gov/sites/default/files/OSMGuidelines1104.pdf. The respondent in the proceeding, the Secretary of Health and Human Services, as represented by the attorneys of the Department of Justice, has the opportunity to review the medical records and obtain its own medical expert opinions regarding whether the injury claimed is vaccine related. *Id.* at 8-9. *See also* 42 U.S.C. § 300aa-12(b)(1). At such point, the respondent may choose to concede that the injury is vaccine related and the parties move on to the question of the amount of compensation to be paid. *See* Special Masters Guidelines at 8-10.

If the respondent refuses to concede that the injury claimed was caused by or related to the receipt of a vaccine, then the special master presiding over the petition conducts a causation hearing to determine

that issue.[3] *Id.* at 12-14. At the causation hearing, the special master considers the medical records, the testimony of the petitioner's family and the opinions of the medical experts. *Id.* For the most part, there is no discovery or motion practice by the parties. *Id.* at 11-12. The parties proceed to hearing with the medical records, limited testimony and expert opinions. *Id.* at 12-14. There is no right to interrogatories or depositions. *See* H.R. Rep. No. 99-908, pt. 1, *supra*, at 17, *reprinted in* 1986 U.S.C.C.A.N. 6358. This is how Congress's swift justice is achieved.

As would be expected under such a system, the opinions of medical experts become paramount to the outcome of a petitioner's claim. Experts, in turn, rely heavily on both their own medical experience and the body of medical literature that may explain the relationship between a particular vaccine and adverse reactions that have been associated with that vaccine over time.

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[3] This discussion presumes that the case does not involve an injury listed on the vaccine injury table and is thus an "off table" case. Off-table cases comprise the majority of cases filed in recent years. *See* U.S. Dep't of Health & Human Servs., National Vaccine Injury Compensation Program Strategic Plan 1, 5 (2006). At this point in time, every Gardasil case must be an off-table case, as no compensable injuries have been added to the vaccine injury table since Gardasil became covered by the Vaccine Act. *See* Health Res. & Servs. Admin., U.S. Dep't of Health & Human Servs., *National Vaccine Injury Compensation Program – Vaccine Injury Table* (effective date Nov. 10, 2008), *available at* http://www.hrsa.gov/vaccinecompensation/table.htm#a; 42 C.F.R. § 100.3 (2009); Vaccine Injury Compensation, 73 Fed. Reg. 59,530 (Oct. 9, 2008) (amending 42 C.F.R. § 100.3 to remove an item from the vaccine injury table).

C. Medical experts cannot formulate well-founded opinions where vaccines, such as Gardasil, have not been well studied, resulting in a petitioner's inability to prove his case.

When a vaccine has been studied and administered for a number of years such that possible adverse reactions have been identified, the relevant medical literature is available and accessible by the medical experts. However, with the introduction of numerous new vaccines in recent years and ongoing, incomplete studies of the safety of such vaccines, there are times when the medical literature is not sufficiently developed for use by a medical expert in formulating an opinion.

Vaccine injuries are almost always difficult to detect and sometimes difficult to define. In most cases, there are no objective medical tests available to clearly demonstrate the role the vaccine has played in causing injury. *See, e.g., Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) ("The DPT vaccine leaves no 'footprint' evidencing that it was the catalyst for a particular injury."). Often, vaccine injuries manifest themselves in complex neurological or immunological disorders. *See, e.g.*, Michael E. Horwin, Comment, *Ensuring Safe, Effective and Necessary Vaccines for Children*, 37 Cal. W. L. Rev. 321, 329-30 (2001). Due to the fact that adverse vaccine reactions affect a statistically small group of people, it is usually impossible for the medical community to track trends that allow them to identify adverse reactions with anything approaching scientific certainty. Physicians and scientists are hampered in these efforts by the weaknesses of the Vaccine Adverse Events Reporting System

("VAERS"), which, as a passive, voluntary reporting system, may lack complete or relevant information. *See* H.R. Rep. No. 106-977, *supra*, at 9.

For these reasons, the system of swift justice embodied by the Vaccine Program can grind to a halt when faced with a dearth of medical literature relating to a vaccine or injury. Lacking relevant literature, the parties' experts cannot develop or test theories of causation. The experts may have no supportive medical literature to corroborate their testimony. Lacking their experts' opinions, the parties and the special masters cannot proceed to the causation hearing.

This is exactly the situation in which Mrs. DeLoatch finds herself. Gardasil has been widely touted as the first vaccine developed to prevent cervical cancer. *See* News Release, U.S. Food & Drug Admin., FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus (June 8, 2006), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108666.htm. It was approved by the Food and Drug Administration ("FDA") on June 8, 2006, in a fast-track review process. *Id.* *See also* Judicial Watch, Inc., *A Judicial Watch Special Report: Examining the FDA's HPV Vaccine Records* 3-4 (2008) (hereinafter "Judicial Watch Special Report"), *available at* http://www.judicialwatch.org/documents/2008/JWReportFDAhpvVaccineRecords.pdf. The vaccine had been on the market less than two years when Moshella Roberts received her shot. Little medical literature addressed adverse reactions to the Gardasil vaccine at the time of Moshella's death. Little more has been published since her death. And so Mrs. DeLoatch and her med-

ical experts find themselves at the forefront of a new area of research and study – not a desirable place to be when studies take years and one is seeking swift justice.

Gardasil is the trade name for the Quadrivalent Human Papillomavirus Recombinant Vaccine, which was created and is marketed by Merck & Company, Inc. (hereinafter "Merck"). *See* Barbara A. Slade et al., *Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine*, 302 J. Am. Med. Ass'n 750, 750 (2009). It is licensed for use in girls between the ages of 9 and 26 and is administered in a series of three shots. *Id.*

Gardasil is designed to prevent young women from being infected by four specific strains of Genital Human Papillomavirus ("HPV"). *See* Judicial Watch Special Report at 3. There are more than 30 strains of HPV. *Id.* In most cases of HPV, the body's immune system will fight off the virus. *Id.* However, if the body's immune system is not able to fight off the virus, some strains of HPV will cause genital warts and other strains will develop into cervical cancer. *Id.* Gardasil guards against two strains of HPV that can cause genital warts and two strains that may lead to cervical cancer. *Id.* It is unknown how long Gardasil provides such protection before a booster shot is required, although Merck has estimated at least 2.5 to 3.5 years. *Id.* at 12.

As part of its approval of Gardasil, the FDA required that Merck conduct a safety surveillance study that would include 44,000 vaccinated subjects who would be followed for 60 days for general short-term safety. *Id.* at 13. *See also* Letter from Norman W. Baylor , Ph. D., Director, Office of Vaccines, U.S. Dep't of Health & Human Servs., to Dr. Patrick Brill-

Edwards, Director, Worldwide Regulatory Affairs, Merck & Company, Inc. (June 8, 2006), *available at* http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm111283.htm. Merck was also required to follow these young women for six months following their vaccinations to monitor for new autoimmune disorders, rheumatic conditions, or thyroiditis. *Id.* The study was to be completed by June 30, 2009, and submitted to the FDA by September 30, 2009. *Id.* Although past due at this point, this safety surveillance study has not been released and is listed by the FDA's website as delayed. *See* U.S. Food & Drug Admin., Postmarket Requirements and Commitments, *available at* http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm (updated quarterly, last updated Apr. 30, 2010) (hereinafter "FDA Postmarket Requirements").

While Merck has not completed its study of the Gardasil vaccine, there have been two publications that have reviewed adverse reactions to Gardasil as reported in the VAERS database. In June 2008, Judicial Watch issued its Special Report on Gardasil in which it cited 38 reports of Guillain-Barre Syndrome, 78 reports of genital warts, and 18 reports of deaths following receipt of the Gardasil vaccine as reported in the VAERS database. *See* Judicial Watch Special Report at 4, 14-15. In June 2009, Judicial Watch updated its review and reported a new total of 47 deaths associated with Gardasil as reported in the FDA's VAERS database. *See* Judicial Watch, Inc., *Vaccine Adverse Effects Report System (VAERS) Cumulative Deaths Report* 1 (2009), *available at* http://www.judicialwatch.org/files/documents/2009/vaersdeathsALL_20090616.pdf. Of those 47 deaths

reported, at least 27 listed the cause of death as being unknown. *Id.*

In August 2009, doctors from the Centers for Disease Control ("CDC") and the FDA published their review of VAERS reports involving the Gardasil vaccine in the Journal of the American Medical Association (hereinafter "JAMA"). *See* Slade et al., *supra.* The JAMA article concluded that the rate of adverse effects following immunization with Gardasil were not greater than the background rates compared with other vaccines. *Id.* at 750. The study suggested, however, that there were disproportional reports of some reactions. *Id.* The authors additionally noted the limitations of a review of reports in the VAERS system due to the potential for underreporting. *Id.* at 756. Moreover, a majority of the reports came from the vaccine manufacturer, which the authors found did not include sufficient information to allow medical review. *Id.*

Thus, the primary published studies regarding adverse reactions to the Gardasil vaccine have simply been surveys of incidents reported in the VAERS database – a database that the study authors and others have noted is limited by potential underreporting and by incomplete reporting. *Id.* at 750. Notably, many of the VAERS reports that are incomplete were entered into VAERS by Merck. *Id.* at 756. In addition, Merck has failed to timely submit the large-scale study of Gardasil safety ordered by the FDA. *See* FDA Postmarket Requirements, *supra.*

D. Lacking medical literature and completed safety studies, Mrs. DeLoatch's vaccine proceeding has stalled.

What all this means for Mrs. DeLoatch is that there is virtually no medical literature on which to

rely in explaining the death of her daughter. Until additional studies are reported, Mrs. DeLoatch and her medical experts are stuck with little evidence but a strong suspicion that a healthy young woman died as a result of receiving the Gardasil vaccine – a suspicion that is bolstered by the proximity in time between Moshella's receipt of the vaccine and her death and the fact that no other causes of death or health problems were found by the medical examiner. Such suspicion is insufficient to support a finding of causation in either a vaccine compensation proceeding or a traditional tort action.

As of May 2010, the families of six young women, including Mrs. DeLoatch, have filed petitions for compensation in the Vaccine Program following the deaths of their daughters after receipt of the Gardasil vaccine. *See* Health Res. & Servs. Admin., U.S. Dep't of Health & Human Servs., *National Vaccine Injury Compensation Program – Statistics Reports: Claims Filed and Compensated or Dismissed by Vaccine* (May 5, 2010), *available at* http://www.hrsa.gov/vaccinecompensation/statistics_report.htm#claims_filed. An additional 48 petitions have been filed in the Vaccine Program for injuries associated with the Gardasil vaccine. *Id.* Many of these families will find themselves in the same awkward position as Mrs. DeLoatch. They will be hindered by the lack of medical evidence and literature. For these families, swift justice will become slow justice or no justice.

For Mrs. DeLoatch, the search for answers continues. Mrs. DeLoatch's counsel sent the medical records and the medical examiner's report to a respected pathologist for review. *See DeLoatch v. Sec'y of Health & Human Servs.*, slip op. at 2. On

initial review, Moshella's body revealed nothing of the cause of her death. The expert pathologist needed to look further and the question became – where? With no medical literature discussing the mechanisms by which Gardasil could cause an adverse vaccine reaction, where could the pathologist begin to look? Even the safety studies required by the FDA, which may have indicated the types of reactions found, have not been completed.

III. TO OBTAIN THE DISCOVERY HER PETITION REQUIRES, MRS. DELOATCH HAS NO OPTION BUT TO SEEK TORT RELIEF OUTSIDE THE VACCINE PROGRAM, AN OPTION THE THIRD CIRCUIT HAS HELD CONGRESS INTENDED TO DENY HER.

The only actor in possession of additional information that could provide Mrs. DeLoatch with the answers to the question of her daughter's death is Merck, the vaccine manufacturer. Merck is conducting the ongoing and overdue safety study of 44,000 young women vaccinated with Gardasil, as required by the FDA. *See* FDA Postmarket Requirements, *supra*. Merck is also the party in possession of the facts behind the majority of adverse reactions reported to the VAERS database. *See* Slade et al., *supra*, at 756. Reports that doctors from the CDC and the FDA found lacked sufficient information with which to conduct a medical review. *Id.* At this point, most of the data regarding adverse effects of the Gardasil vaccine is held by its manufacturer, which is, understandably, not keen on releasing such data.

A. Discovery is an important litigation tool that, on many occasions, has revealed problems with drugs that the drug manufacturers withheld from the public.

Traditionally, tort litigation has provided litigants and the public with important insights to a product's safety. "Today we have a much better understanding of the risks of asbestos, tobacco, ultra-absorbent tampons, and the Dalkon Shield, thanks to tort litigation brought against these companies." Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 Geo. L.J. 693, 711 (2007). Calling it the education effect of tort law, one commentator explained that pretrial discovery has frequently unearthed industry practices with respect to products like breast implants, Vioxx,[4] and antidepressants that "might otherwise never have seen the light of day." Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DePaul L. Rev. 293, 302 (2007).

In these cases, manufacturers resisted disclosing their internal documents that, through discovery, were uncovered and publicly exposed. *See* Wagner, *supra*, at 711. For example, in "the litigation brought against the manufacturers of Vioxx and Prozac, documents produced during discovery revealed additional information about the manufacturer's internal knowledge about product harms and led to increased public demand for more vigorous oversight of drug manufacturers." *Id.* at 712.[5]

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[4] Vioxx was developed by Merck. *See Merck & Co. v. Reynolds*, No. 08-905, 2010 WL 1655827, at *5 (U.S. Apr. 27, 2010).

[5] In an April 2008 article reported in the distinguished publication, the Journal of the American Medical Association, the

In drafting the Vaccine Act, Congress was aware of the benefit of discovery in tort litigation. At hearings on the Act, attorneys for vaccine-injured children testified as to how they had reviewed the records of the vaccine manufacturers through discovery in litigation. *See Hearings on H.R. 5810*, *supra*, at 217 (testimony of Boyd McDowell III).

Cognizant that litigation and discovery create incentives for greater vaccine safety, Congress created a compensation program that did not permit discovery as a matter of right *and* Congress considered whether to make such a program the injured's exclusive remedy. Knowing the importance of the tool of discovery to explaining how vaccine injuries occur, why would Congress intend to entirely take that tool away from injured children? The answer is it wouldn't.

When asked by Representative Henry A. Waxman why families needed to retain the option to litigate outside the program, Jeffrey Schwartz, co-founder of the National Vaccine Information Center and former counsel for the House of Representatives Health and Environment Subcommittee of the Energy and

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authors compared internal Merck documents regarding Vioxx with published studies of the drug's safety. *See* Bruce M. Psaty & Richard A. Kronmal, *Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment: A Case Study Based on Documents from Rofecoxib Litigation*, 299 J. Am. Med. Ass'n 1813, 1813-14 (2008). The authors concluded that Merck's internal data showed a significant increase in mortality while the published articles did not, a difference in reporting that the authors called "striking." *Id.* at 1813, 1816. The JAMA article noted that Merck's mortality analyses were "neither provided to the FDA nor made public in a timely fashion" and called for new approaches to the conduct, oversight, and reporting of industry sponsored drug trials. *Id.* at 1813, 1817.

Commerce Committee, the Subcommittee that drafted the Vaccine Act, replied, "Do you want to remove the mechanism to find the truth? These lawsuits are discovering things that ought to cause the Congress concern." *Hearings on H.R. 5810*, *supra*, at 115. The information revealed by discovery did cause Congress concern over the safety of vaccines, and it inspired Congress to keep the tort option available as a safety incentive. *See Hearing on S. 827*, pt. 1, *supra*, at 16-17 (statement of Sen. Robert T. Stafford).

B. Requiring the information that only the vaccine manufacturer possesses, Mrs. DeLoatch requested discovery from Merck, which discovery was denied pursuant to the restraints of the Vaccine Program.

Mrs. DeLoatch attempted to obtain Merck's records for use by her medical experts in the Vaccine Program. *See DeLoatch v. Sec'y of Health & Human Servs.*, slip op. at 1. While not the speediest approach, it was Mrs. DeLoatch's only choice and her only hope. Mrs. DeLoatch requested a subpoena seeking just two categories of documents from Merck regarding deaths related to the Gardasil vaccine.[6]

Merck objected to the subpoena and moved to quash it. *Id.* at 1-2. In its objection, Merck did not argue that the request was unduly burdensome but

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[6] Specifically, the subpoena requested:

1. Any reports of sudden death temporally related to Gardasil vaccination (please redact any patient identifying information).
2. Any papers, reports, or memoranda discussing a possible biological mechanism by which the Gardasil vaccine could cause or trigger sudden death.

DeLoatch v. Sec'y of Health & Human Servs., slip op. at 2 n.2.

instead argued that Mrs. DeLoatch had not satisfied the standard for discovery. *Id.* at 2.

In light of Merck's objection and the limited discovery permitted within the Vaccine Program, Mrs. DeLoatch faced an uphill battle in her quest for the documents that could explain how her daughter died. The Special Master ultimately agreed with Merck and quashed the subpoena. *Id.* at 9.

C. After quashing her subpoena to Merck, the Special Master suggested Mrs. DeLoatch leave the Vaccine Program and file suit against Merck.

Acknowledging Mrs. DeLoatch's dilemma in obtaining the information required for her claim, the Special Master outlined two potential consequences of his ruling. *See DeLoatch v. Sec'y of Health & Human Servs.*, slip op. at 8. First, the Special Master explained, Mrs. DeLoatch's experts "may require a relatively lengthy amount of time to develop a theory to explain how Gardasil can cause a person's death." *Id.* The Special Master, most graciously, indicated his willingness to grant Mrs. DeLoatch this time provided her experts were continuing to make progress in developing a theory. *Id.* Unfortunately for Mrs. DeLoatch, it is unlikely that literature on the adverse effects of Gardasil will be released in time to assist her case.

The second potential consequence set forth by the Special Master was that Mrs. DeLoatch may decide to leave the Vaccine Program and pursue an action against Merck in state or federal court. *Id.* In this scenario, the Special Master explained that Mrs. DeLoatch would be able to present a similar discovery request to Merck. *Id.* Thus, the Special Master stated, "Under this scenario, Merck's successful mo-

tion to quash the subpoena in this action may result in it being named as a defendant in a lawsuit over Gardasil. Merck is aware of this possibility." *Id.* at 9 (citing to oral argument on Merck's motion). Citing to the instant case of *Bruesewitz v. Wyeth*, the Special Master informed the parties that "Congress expressly left open the possibilities for some lawsuits against vaccine manufacturers." *Id.*

Thus, the Vaccine Court has informed Mrs. DeLoatch that in her case justice cannot be swift. For Mrs. DeLoatch, the type of evidence needed to satisfy even the streamlined standards of the Vaccine Program cannot be obtained within the discovery restrictions of the Vaccine Program. Ironically, Mrs. DeLoatch's case has been delayed, possibly derailed, by discovery restrictions that were designed to ensure the speedy resolution of vaccine injury compensation claims.

In this case, the Special Master advised the parties of Mrs. DeLoatch's right to opt out of the Vaccine Program and sue Merck under a traditional tort theory for the death of her healthy daughter after her receipt of the Gardasil vaccine. *Id.* at 8-9. A Special Master of the Vaccine Program, in essence, has informed Mrs. DeLoatch that the Vaccine Program may not be the appropriate forum for her. It may not be the best means by which to demonstrate the cause of her daughter's death. Mrs. DeLoatch has been told that the Vaccine Program can neither provide her with the discovery her case requires nor deliver the swift justice that Congress intended for the Program. Mrs. DeLoatch has been advised that she may be better off in state or federal court.

Most importantly, Mrs. DeLoatch has been informed by the Vaccine Court that leaving the Vaccine

Program and filing suit against Merck is an option available to her. *Id.* The Vaccine Court has expressly acknowledged that Congress left open the possibility of suits against vaccine manufacturers. *Id.* The Vaccine Court has informed Mrs. DeLoatch that she may need to sue Merck to demonstrate how the Gardasil vaccine contributed to her daughter's death. *Id.*

D. The practical effect of the Third Circuit's opinion in the instant case is to deny justice to petitioners in the Vaccine Program whose cases cannot be fully litigated given the restrictions built into the Program.

Of course, Mrs. DeLoatch may feel this is an option available to her, and the Vaccine Court itself may believe this is an option available to Mrs. DeLoatch, but there can be little doubt that, should Mrs. DeLoatch opt out of the Vaccine Program and file suit, Merck would immediately seek to dismiss Mrs. DeLoatch's action based upon the Third Circuit's opinion in the instant case.[7] Once again raising the battle cry that the Vaccine Act was intended to protect vaccine manufacturers from litigation, Merck would likely argue that Mrs. DeLoatch has no right to obtain discovery or even to proceed against Merck in federal or state court, as suggested by the Special Master.[8] Should the vaccine manufacturer prevail in

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[7] In stating her tort claim, Mrs. DeLoatch would plead that her daughter's death was caused by the defective design of the Gardasil vaccine. She would show that Moshella's death could have been avoided through a safer design.

[8] Vaccine manufacturers may argue that the Vaccine Act still permits manufacturing defect claims and failure to warn claims even in light of the Third Circuit's interpretation of the Act as preempting design defect claims. However, in practice, manufacturers rely on precedents that all but subsume manufactur-

this argument, the consequences for Mrs. DeLoatch would be tragic. For Mrs. DeLoatch, there would be no justice.[9]

The Vaccine Act was designed to provide swift and simple justice. However, to achieve this justice, the Vaccine Program could not be administered in the same manner as traditional tort litigation. Restrictions on discovery, evidence, and motion practices were employed to speed up the process. Congress and those persons who contributed to the drafting of the Act, through years of Congressional hearings and effort, realized that the restrictions needed to supply swift and simple justice would not mete out justice in all situations. The Vaccine Act was not envisioned as providing a one size fits all form of resolution. Given the limits of the Act, the Vaccine Program cannot provide satisfactory relief for every family of a vaccine-injured child. Mrs. DeLoatch's case provides a concrete example of this principle.

Time and time again, as the Vaccine Act was debated, vaccine manufacturers demanded that the Vaccine Program be the exclusive remedy available to the vaccine injured. *See Hearings on H.R. 5810, supra*, at 230 (statement of Robert Johnson, Presi-

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ing defect claims and failure to warn claims into design defect claims. *See Cronin v. J.B.E. Olson Corp.*, 501 P.2d 1153, 1163 (Cal. 1972) ("[A] distinction between manufacture and design defects is not tenable. ... We wish to avoid providing such a battleground for clever counsel.").

[9] This Court has rejected the application of an analysis that would render a "humane legislative plan" a "delusive remedy." *Urie v. Thompson*, 337 U.S. 163, 168-70 (1949). In *Urie*, this Court found that such an analysis could "only serve to thwart the congressional purpose." *Id.* Similarly, it cannot be justly supposed that Congress intended the Vaccine Act to be a delusive promise of a remedy for petitioners like Mrs. DeLoatch.

dent, Lederle Laboratories); *Hearing on S. 827*, pt. 1, *supra*, at 240-41, 265, 274-75 (statements of Robert Johnson, President, Lederle Laboratories, and David Williams, Vice President and General Manager, Connaught Laboratories). Time and time again, parents and members of Congress alike insisted that the alternative of a traditional tort suit remain available for the families of the injured. *See Hearings on H.R. 5810*, *supra*, at 115-16 (statement of Jeffrey H. Schwartz); *Hearing on S. 827*, pt. 1, *supra*, at 392 (statements of Jeffrey H. Schwartz and Barbara Loe Fisher); *Hearing on S. 827 Before the S. Comm. on Labor & Human Res.*, pt. 2, 99th Cong. 1-2 (1986) (opening statement of Sen. Robert T. Stafford). During those debates, the vaccine manufacturers insisted that allowing families the right to choose between the compensation program and an action sounding in tort would result in no relief for vaccine manufacturers. *See Hearing on S. 827*, pt. 1, *supra*, at 250, 274-75 (statements of Robert Johnson, President, Lederle Laboratories, and David Williams, Vice President and General Manager, Connaught Laboratories); *Hearing on H.R. 1780, H.R. 4777, and H.R. 5184*, *supra*, at 217 (questioning by Rep. Henry A. Waxman). Despite testimony from parent groups to the contrary, manufacturers insisted that parents would not choose the Vaccine Program and, instead, manufacturers would be beset with vaccine suits. *Id.*

In briefing before this Court, the vaccine manufacturer has again raised the specter of state and federal courts being flooded with vaccine cases. *See* Brief in Response to Petition for a Writ of Certiorari at 2, 17-18, 22, *Bruesewitz v. Wyeth, Inc.*, No. 09-152 (U.S. filed Oct. 7, 2009). This scare tactic did not prove to be true in the 1980s, nor would it be true today. The

amicus curiae on this brief, the Petitioners Bar, has, through its members, been representing petitioners in the Vaccine Program since the Program's inception. As a group, these *amici* can recall less than 12 instances, including the present case, in which a petitioner with a claim in the Vaccine Program has opted out of the Program and then pursued a state or federal court claim against a vaccine manufacturer. While these *amici* have always understood the Vaccine Act and Congress's intent to permit petitioners to opt out of the Program to pursue design defect claims against manufacturers, they have witnessed their clients and other petitioners actually opt out only a handful of times.

Via the vaccine manufacturer's interpretation of the Vaccine Act, petitioners such as Mrs. DeLoatch are simply out of luck. It is their contention that the Act was designed to protect them from entanglement within the Vaccine Program even where such entanglement is not burdensome. They further contend that the Act was designed to protect them from entanglement in suits outside of the Program. Such contentions ignore the intent of the creators of the Program.[10] Cognizant of the limits in the compensation program it established, did Congress intend for families like Mrs. DeLoatch and her daughter, Moshella, to be left without a route to justice?

It is for the children and for petitioners such as Mrs. DeLoatch who have lost their children that

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[10] The sponsors of the Vaccine Act did not intend to prevent claimants like Mrs. DeLoatch from having their day in court. According to Representative Henry A. Waxman, "If an injury is the result of a bad vaccine or *one inadequately researched* or warned of, then the courts could still make awards." 132 Cong. Rec. H9943-02 (daily ed. Oct. 14, 1986) (emphasis supplied).

Congress created the Vaccine Program. It is for petitioners such as Mrs. DeLoatch and the other five families of young women who died shortly after receiving the Gardasil vaccine, as well as other families that may not receive a full resolution in the Vaccine Program, that Congress chose *not* to make the Vaccine Program the exclusive remedy available for families of the vaccine-injured. There is a purpose for the statutory language that permits a petitioner to leave the Program and file suit against a manufacturer. That purpose is to provide justice for *all* families of vaccine-injured children.

If this Court closes the courthouse doors to petitioners like Mrs. DeLoatch, they will not receive the swift justice promised by Congress. They will not receive the slower justice of a tort claim, also promised by Congress. These petitioners, families of the vaccine-injured, will be denied justice.

CONCLUSION

For the foregoing reasons, the judgment below should be reversed.

Respectfully submitted,

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