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IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ, *et al.*,

Petitioners,

v.

WYETH, INC., fka WYETH LABORATORIES, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF AMICUS CURIAE MARGUERITE WILLNER IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

Marguerite Willner is a recognized expert in federal vaccine policy. In 2004, at the recommendation of Senator John Warner, Ms. Willner was appointed by the Secretary of the Department of Health and Human Services (HHS) to the Advisory Commission on Childhood Vaccines (ACCV) to represent the public at large.[2] The ACCV was established by Congress to advise the Secretary on matters related to the implementation of the National Vaccine Injury Compensation Program. She was elected ACCV Vice-Chair in 2005 and completed her term in 2007.

During this period, Ms. Willner served as the ACCV liaison to and *ex officio* member of the National Vaccine Advisory Committee (NVAC), participating in the Subcommittee for Vaccine Safety and the NVAC Public Engagement Project. Ms. Willner has also been invited to present her views on expert panels at the 2005 and 2008 Federal Judicial Conferences as well as an expert panel convened last summer by the NVAC Vaccine Safety Working Group.

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus curiae, and her counsel, made a monetary contribution to its preparation or submission. Letters from the parties consenting to the filing of all amici briefs have been filed with the Clerk of the Court.

[2] Although some members are required to have vaccine-injured children, Ms. Willner does not.

This brief is submitted in support of Petitioners to describe the shortcomings of the existing vaccine safety infrastructure and to highlight the critical role that civil actions play in discovering if a vaccine is "unavoidably unsafe," compensating those who suffer avoidable injuries, and deterring those who would manufacture anything less than the safest vaccine feasible.

SUMMARY OF ARGUMENT

Although vaccines are a critical component of public health care, research on vaccine safety remains flawed and incomplete. This lack of information about vaccines' safety profile stems in part from the difficulties inherent in evaluating safety in large, diverse populations. Because vaccines are administered to healthy people and not for their therapeutic benefit, medical ethics require that they be extremely safe; however, clinical trials do not involve enough participants to determine whether a vaccine is likely to cause adverse events in a small number of patients. Thus, vaccines can only be fully evaluated once they are in general use. Even then, regulators may not be able to determine whether temporally-associated adverse events are caused by the vaccine.

In recognition of the uncertain state of medical research and the inherent justice of compensating vaccine-injured persons who have sacrificed their own health in service of the greater public benefit of widespread inoculation, in 1986 Congress passed the National Childhood Vaccine Injury Act ("NCVIA"). The NCVIA included many measures intended to encourage

vaccine research and the development of safer vaccines, and created a no-fault compensation system to quickly provide money damages to vaccine-injured persons. However, NCVIA was never intended to supplant incentives that state tort law provides to manufacturers to develop safer versions of their products. Most critically, the compensation system was not designed for determinations of causation, and, in fact, petitioners within the compensation system are denied access to basic discovery and other protections of the Federal Rules of Civil Procedure. Because of these limitations, Congress explicitly preserved state tort actions as one mechanism for ensuring continued improvement in vaccines.

The compensation system has not lived up to Congress's expectations. HHS, which administers the program, has wrought administrative changes that make it difficult for petitioners to recover for their injuries. Although in the early days of the program, the element of causation was usually presumed, HHS's changes have had shifted the burden of proving causation to the petitioners, who must do so without discovery or many reliable studies of vaccine safety. As a result, vaccine-injured patients are not being compensated for their injuries. These difficulties, coupled with the dearth of information about vaccine safety, render state tort actions a critical safety-valve in the regulatory system. Design defect claims in particular may provide the only incentive to manufacturers to utilize all means at their disposal to create the safest feasible product. Thus, to effectuate Congress's intent to ensure the development of safer vaccines, this Court should conclude that the NCVIA does not preclude design defect claims for products that could have been made safer.

ARGUMENT

I. RESEARCH ON VACCINE SAFETY IS INCOMPLETE

Vaccines are a ubiquitous aspect of American life. All 50 states require that children be vaccinated before entering school.[3] In 1999, 12 million vaccinations were delivered to children every year. *See* U.S. General Accounting Office, *Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily* 4 (1999) (hereinafter "GAO Report"). Vaccination is required for certain occupations, and many other adults also regularly receive vaccines. Institute of Medicine (IOM), *Priorities for a National Vaccine Plan* 53 (Dec. 2009) (hereinafter "*Priorities*"). For example, between two-thirds and three-quarters of the adult population 65 and older received the influenza vaccine in 2008. *See id.*

Over the years, the number of recommended vaccines has increased dramatically. In 1983, children under six received ten inoculations against seven diseases. In 2007, they received thirty-six inoculations against fifteen diseases. *See* Cynthia E.S. Staats & Joel M. Hamme, *The Greater Good: Rethinking Risks and Benefits of Childhood Vaccination Programs*, 3 J. Health & Life Sci. L. 164, 171 (2009). Additional doses are recommended for children aged 7-18 years old. *See* Centers for Disease Control (CDC), *2010 Child &*

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[3] Certain states grant exemptions for religious or philosophical objections, or for health reasons. *See* Institute of Medicine, *Priorities for a National Vaccine Plan* 51 n.2 (2009).

Adolescent Immunization Schedules, at http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm.

Though vaccines are undoubtedly a critical tool to protect populations from disease, "no vaccine is 100 percent effective or 100 percent safe." *Priorities*, *supra*, at 52. For example, the polio vaccine, introduced in the 1950s, caused paralysis in a small number of patients. *See id.* More recently, a vaccine to immunize children against rotavirus, an infection that targets the intestine, was found to cause intussusception, a type of intestinal collapse. *See id.* at 53. The vaccine had been tested in 27 clinical trials involving 10,000 patients before it was licensed in 1998, and no studies either before or immediately after licensure showed an association between the vaccine and intussusception. *See id.* at 55-56. However, as case reports of intussusception trickled in, the CDC ultimately recommended that the vaccine be suspended in 1999. *See id.* at 56. And, as described further below, the Diphtheria, Tetanus, and Pertussis vaccine (DTP)[4] has been associated severe injuries including seizures, brain inflammation, and death.

It is particularly critical to obtain accurate safety profiles for vaccines as compared to other drugs. Not only are they mandatory, but they are also not administered for the purpose of treating a specific ailment. Instead, vaccines are administered to healthy people who are, at most, only at *risk* of contracting a disease. As a result, vaccines must "have a low risk-to-benefit ratio when compared to therapeutic

[4] The DTP vaccine is also known as "DPT."

interventions." *Id.* at 53. The lower the risk of contracting the disease, the lower the acceptable risk level that may be posed by the vaccine. *Id.* at 52 (explaining how the risk-benefit calculation for the polio vaccine changed over time).

It is difficult to perform this necessary risk-benefit calculation because "anticipating, detecting, and quantifying the risks of rare adverse events [from vaccines] presents enormous challenges." *Id.* at 53. Most randomized clinical trials – the "gold standard" for pre-licensure applications, *id.* at 36 – do not have enough participants to detect rare adverse events, *id.* at 53. It is often only possible to detect rare adverse events *after* the vaccine is licensed and distributed to large populations, numbering in the millions. *Id.* Even then, identifying rare adverse events is no easy task. The NCVIA mandated the establishment of the Vaccine Adverse Event Reporting System (VAERS), whereby healthcare providers report to HHS adverse events following inoculation. *See* 42 U.S.C. § 300aa-25. But, like any passive reporting system, VAERS is flawed. It is estimated that only 10% of adverse events are reported. Staats & Hamme, *supra*, at 174.[5] Additionally, without information on the number of persons inoculated, or the

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[5] As an example, the IOM reports that with respect to the rotavirus vaccine, it was discovered that VAERS reporting of intussusception alone (without considering other, less serious, adverse events that may have occurred) only reached 47%. *Priorities*, *supra*, at 56. Among other problems, neither physicians nor patients may recognize an adverse event as associated with the vaccine if there is a delay between administration and the onset of symptoms.

number of persons expected to develop a particular condition without the vaccine, VAERS data is difficult to evaluate. *Priorities*, *supra*, at 57-58. Indeed, HHS has described VAERS data as "anecdotal" and will not rely on it for gauging the dangers posed by vaccines. *See National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table*, 60 Fed. Reg. 7678-01, 7685 (February 8, 1995).

More recent surveillance systems have been developed to detect adverse events associated with vaccines, but these also have weaknesses and/or are underutilized. For example, the Vaccine Safety Datalink (VSD), a joint project of the CDC, the FDA, university researchers, and several health plans, links the data from several health insurers. With its more complete records, it is more reliable and more easily analyzed than VAERS. However, the VSD covers only about 8.8 million people, which still may not be sufficient to detect exceedingly rare events. *Priorities*, *supra*, at 59.

Even with the VSD, critical gaps in our understanding remain. For example, there is no research on whether vulnerable populations, like the elderly or persons suffering from other conditions, have more adverse reactions to certain vaccines. There is no research on whether certain individuals are more susceptible to adverse events, or the effect of the common practice of concurrently administering several vaccines. *Id.* at 66. And a former head of the National Institutes of Health (NIH) points out that the current vaccination schedule – which recommends that all children receive the same dosages of vaccine at the same ages – has not been shown to be optimally safe.

See Bernadine Healy M.D., *A Call for Research on Vaccine Safety*, U.S. News & World Report, Feb. 1, 2009 at 25 (describing a study showing that a slight delay in administering DTP drastically reduced the risk of childhood asthma).

Attempts to accurately assess vaccine safety are hindered by the fact that the National Vaccine Program Office has not updated its National Vaccine Plan since 1994. *See Priorities*, *supra*, at 1. The Plan, required by the NCVIA, is intended to "establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines." 42 U.S.C. § 300aa-3. Even the 1994 Plan "had few measurable objectives and was largely a collection of short-term activities that were . . . scheduled to occur regardless of the National Vaccine Plan." *Priorities*, *supra*, at 139. Thus, functionally, a National Vaccine Plan has never been implemented as required by statute.

The weaknesses in the surveillance system for vaccine safety can be seen in the IOM's reports on specific vaccines. At the request of Congress, the CDC, and the NIH, the IOM has undertaken a series of studies to determine whether commonly-used vaccines are associated with certain serious diseases. *See, e.g.*, IOM, *Immunization Safety Review: Hepatitis B and Demyelinating Neurological Disorders* (Kathleen Stratton et al. eds., 2002); IOM, *Immunization Safety Review: Influenza Vaccines and Neurological Complications* (Kathleen Stratton et al. eds., 2004) (hereinafter "*Influenza Vaccines*"); IOM, *Adverse Effects of Pertussis and Rubella Vaccines* (Christopher

P. Howson et al. eds, 1991) (hereinafter "*Adverse Effects*"). Though the IOM occasionally accepts, or rejects, the hypothesis that a vaccine causes particular diseases, the IOM more commonly concludes that the evidence is insufficient to reach a conclusion either way and more research is required. Thus, the IOM's report on the influenza vaccine stated, "With a vaccine as widely used as influenza vaccine, the committee considers it important to pursue research and research-related activities aimed at ensuring that any risk of GBS [Guillain-Barré syndrome] or other neurological complications is minimized." *Influenza Vaccines*, *supra*, at 14. Dr. Healy similarly opines that "there is scant research on the way the complex networks of specialized white blood cells and immune chemicals behave in response to the currently licensed vaccines and their assorted nonvaccine components. . . . Studies showing that early childhood vaccination may promote chronic allergies, for example, beg for further research." Healy, *supra*; *see also* Committee on Government Reform, *The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices*, H.R. Rep. No. 106-977, at 5 (2000) ("[M]uch remains unknown about possible adverse events that may be associated with past and present vaccination practices"). In sum, vaccine research is "a field bereft of complete and direct proof of how vaccines affect the human body." *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

II. LEGISLATIVE RESPONSE TO CONCERNS ABOUT VACCINE SAFETY

Vaccines are also unique in that they are often administered not as a mechanism for protecting the individual, but as a mechanism for protecting the population as a whole. In *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), this Court held that the States may impose mandatory vaccination in the exercise of their police powers, recognizing that the goal of mass vaccination is not to protect the individual, but to protect the population from outbreaks. *See id.* at 27-28. As the Court put it, "in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand." *Id.* at 29. Today, this concept – known as "herd immunity," i.e., that widespread immunization "lessens the risk that the disease can be introduced and harm members of the community" – is still the main justification for compulsory vaccination. Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 Food & Drug L.J. 351, 359 (2001).

But in service of this goal, individuals must not only sacrifice their liberty, but risk serious injury, as well. It was in recognition of the fact that some members of the public will, necessarily, sacrifice their health – and the health of their children – in service of the greater health of society, that Congress passed the NCVIA.

A. Concerns about DTP Lead to the Passage of the NCVIA

Pertussis, or whooping-cough, is a highly-contagious respiratory infection caused by the *Bordetella pertussis* bacteria. *See Adverse Effects*, *supra*, at 9. The disease causes a spasmodic cough and a high-pitched crowing, or "whoop," from which its name derives. *Id.* The earliest symptoms are similar to those of a minor cold, but over time, the coughing worsens, making it difficult for the patient to breathe and causing vomiting or choking spells and cyanosis. *See id.* at 10. The disease can also damage the central nervous system, resulting in acute encephalitis and cerebral hemorrhage. Long-term, pertussis can cause mental retardation or permanent neurological damage. *Id.* at 11.

Pertussis bacteria secrete a toxin with a variety of effects on the human body. *Id.* at 16. A pertussis vaccine exposes the body to the toxin antigens, thus stimulating the production of antibodies. In DTP, the antigens come from dead "whole-cell" pertussis cells. However, it is difficult to separate the antigens from the toxin, and traces of the toxin may remain, leading to serious side-effects such as vomiting and diarrhea, congestion, high-pitched screaming, collapse, seizures, spasms, loss of muscle control, brain inflammation, diabetes, and death. Scott, *supra*, at 353.

Pertussis vaccine was first created in the early 1900s, *Adverse Effects*, *supra*, at 17, and safety concerns have been raised about DTP since at least as early as the 1930s. Amy Fine, *Diptheria, Tetanus, and Acellular Pertussis Vaccine (DTaP): A Case Study*, Background

Paper Prepared for the Committee on the Evaluation of Vaccine Purchase Financing in the United States, Division of Healthcare Services, IOM at 2 (April 2003), *available at* http://www.iom.edu/~/media/Files/Activity%20Files/Disease/VaccineFinancing/FineBackgroundPaper.ashx. Nonetheless, DTP was one of the earliest combination vaccines licensed by the FDA,[6] and became a staple of pediatric care by the 1940s, where it remained in regular use for the next 50 years. *Id.*

In the 1970s, concerns about DTP's safety began to mount. In Japan and Britain, after widely-publicized cases of infant death following DTP administration, parents refused to immunize their children, resulting in pertussis outbreaks. *Id.* at 3. Japan responded by developing the acellular version of DTP, known as DTaP, which it licensed in 1981. *See* Fine, *supra*, at 7; *Adverse Effects*, *supra*, at 18. DTaP is safer than DTP because rather than using whole cells of the bacteria, it uses only portions of the bacteria and an inactivated form of the toxin. *See* Advisory Committee on Immunization Practices, *Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among Infants and Young Children Recommendations of the Advisory Committee on Immunization Practices* (1997), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00048610.htm.

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[6] Prior to the passage of the 1962 Kefauver-Harris Amendments to the Food, Drug, & Cosmetic Act, the FDA had much more limited ability to test for the safety of new drugs. *See* Katherine A. Helm, *Protecting the Public Health From Outside the Physician's Office*, 18 Fordman Intell. Prop. Media & Ent. L.J. 117, 129 (2007).

In the United States, concerns about DTP reached a tipping point in 1982, when NBC aired the television program "DPT: Vaccine Roulette," reporting on the adverse effects of the DTP vaccine. *See* Lainie Rutkow et al., *Balancing Consumer and Industry Interests in the Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 Penn St. L. Rev. 681, 688-89 (2007); Fine, *supra*, at 3. As a result, lawsuits against DTP manufacturers accelerated dramatically, and some manufacturers withdrew from DTP production entirely. Fine, *supra*, at 3. The publicity also resulted in the formation of a parents group known as Dissatisfied Parents Together, which is today known as the National Vaccine Information Center.

In response, Congress held a hearing regarding immunization and preventive medicine, at which the Director of the CDC testified that "a prospective study at UCLA on over 15,000 doses [of DTP] showed nine children with convulsions and nine with episodes of collapse, for a frequency of 1 in 1,750 immunizations for each complication." Rutkow, *supra*, at 689 (quoting *Immunization and Preventive Medicine: Hearing Before the Subcomm. on Investigations and General Oversight of the S. Comm. on Labor and Human Resources*, 97th Cong. 79, at 6 (1982) (testimony of William H. Foege)). By 1984, vaccine compensation bills had been introduced in both houses of Congress, precursors to the NCVIA. *Id.* at 691.

In passing the NCVIA, Congress navigated between parents, who wanted to preserve state tort actions as a mechanism for ensuring vaccine safety, and

manufacturers, backed by the Reagan administration, who sought indemnification from all liability. *Id.* at 693-96. The president of Dissatisfied Parents, for example, testified that only lawsuits can "reveal company negligence and force improvements." *Id.* at 695. Congressman Henry Waxman agreed, stating that Congress should not "assum[e] all the legal risks of immunization programs" and that "[t]his Government should not be in the business of guaranteeing profits to the drug industry." *Id.* at 696. Waxman also insisted that "the tort system [serves] as a constant incentive to regulators and manufacturers alike to keep the vaccine supply as safe as it can be." *Id.* at 698.

The final Act consisted of two parts. In keeping with the emphasis of ensuring safe vaccines, the Act established the National Vaccine Program, housed in HHS, "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C § 300aa-1. The Program empowered its Director to carry out a program of testing for the safety and efficacy of vaccines, and directed the creation of the National Vaccine Plan. *See id.* at §§ 300aa-2(a)(2); 300aa-3. The Program also created the NVAC to guide research priorities. *See id.* at § 300aa-5.

The second part of the act created the National Vaccine Injury Compensation Program (VICP), discussed in more detail below. As parents had requested, and as Congressman Waxman agreed, VICP was a streamlined compensation system that simultaneously preserved state tort remedies. *See id.* at §§ 300aa-10 to -17. This portion of the Act also

emphasized safety; Subpart C, titled "Assuring a Safer Childhood Vaccination Program in the United States," mandated the creation of VAERS, *id.* at § 300aa-25, and directed the Secretary to create a taskforce for the development of safer vaccines, *id.* at § 300aa-27.

Throughout the 1980s, in response to the growing crisis of public confidence and Congress's call for the development of safer vaccines, the NIH sponsored additional research on DTaP. Previously, though industry had developed a technique for making a safer "split-cell" vaccine, it was not marketed because of its costs. *See Graham by Graham v. Wyeth Labs.*, 906 F.2d 1399, 1403 (10th Cir. 1990). NIH now pressured industry to cooperate in DTaP development by making it clear that a switch to DTaP was "inevitable" and that data on DTaP "would be critical to licensure decisions." *Fine*, *supra*, at 7. The FDA finally licensed Wyeth's DTaP vaccine, Acel-Immune, in 1991 for use as the last two doses in a total series of five administered from infancy through early childhood. *See id.* at 8. Over the next eleven years, the FDA licensed additional DTaP vaccines, produced by different manufacturers, and in 1996 began approving previously-licensed vaccines to cover the first three doses in the series. *See id.* at 9, 15. Today, DTP is no longer used in the United States.

B. Creation of VICP

VICP was created to compensate "vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908 (1986) *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344 (hereinafter "House Report"); *see also id.* at 6353 ("The system is intended

to be expeditious and fair. It is also intended to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective.").

Under VICP, as amended,[7] vaccine-injured persons initially present their petitions to a special master in the Court of Federal Claims specifically employed to handle vaccine injury cases. *See* 42 U.S.C. § 300aa-12. The Secretary of HHS is the respondent. The special master hears evidence and makes a determination of entitlement to compensation, and, if relevant, a damages award. *Id.* at § 300aa-13. The NCVIA specifies the types of harms that may be compensated, and the maximum amount of damages. *See id.* at § 300aa-15(a). Awards are funded with an excise tax, paid by the consumer, imposed on every dose sold of every vaccine included in VICP. *See* 26 U.S.C. § 4131; CDC Vaccine Price List, *available at* http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm (listing current vaccine prices, including the portion attributable to the excise tax).[8]

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[7] Originally, VICP jurisdiction was placed in the federal district courts. The statute was amended in 1987 to transfer jurisdiction to the Court of Federal Claims out of concern that the original design ran afoul of Article III because plaintiffs could reject a judgment and seek state tort remedies. *See* H. Conf. Rep. 100-495, at 771 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1245, at 2313-1517.

[8] A "dose" refers to a dosage that prevents a particular disease; thus, a vaccine that prevents three diseases, such as the measles-mumps-rubella vaccine, counts as three doses. *See http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm.*

The monies are held in the Vaccine Injury Compensation Trust Fund ("Trust Fund"). *See* GAO Report, *supra*, at 7.

The Federal Rules of Civil Procedure do not apply to VICP proceedings. 42 U.S.C.A. § 300aa-12. Instead, special masters "provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions" with "flexible and informal standards of admissibility of evidence." *Id.* By statutory command, "[t]here may be no discovery in a proceeding on a petition other than the discovery required by the special master." *Id.*; *see also* Vaccine Rule of the Court of Federal Claims 7 ("There is no discovery as a matter of right. The informal and cooperative exchange of information is the ordinary and preferred practice.").

If the petitioner is unsatisfied with the special master's ruling, the petitioner may appeal to the Federal Circuit. *See* 42 U.S.C. § 300aa-12. Ultimately, if the petitioner is unsatisfied with the final judgment, he or she may reject it and bring an action in state court. *See id.* at §§ 300aa-21(a), 300aa-22. Congress anticipated that vaccine injury claims would be heard "within strict time limits, subject to similarly expeditious review." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) (citing §§ 300aa-12(d)(3)(A); 300aa-12(e)(2)).

The centerpiece of VICP is the Vaccine Injury Table. The Table, originally mandated in 42 U.S.C. § 300aa-14(a), lists vaccines covered by the program, their associated injuries, and expected onset times. The Table is accompanied by Qualifications and Aids to Interpretation (QAI) that further define the Table

injuries. *See id.* § 300aa-14(b). If the petitioner received a vaccine listed on the Table, and experienced a Table injury, causation is presumed, subject to a right of rebuttal by the Secretary. *See id.* at §§ 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(B). If the petitioner did not receive a Table injury, it is the petitioner's burden in the first instance to establish causation. *See id.* at § 300aa-11(c)(1)(C)(ii). "Thus, the content of the Table . . . is critical: it is only when a vaccinated child suffers a listed condition within applicable temporal parameters that compensation will be forthcoming without the time, expense, proof requirements, and uncertainty of full-blown litigation." *O'Connell v. Shalala*, 79 F.3d 170, 173 (1st Cir. 1996).[9]

Because Congress recognized that eventually "research on vaccine injury and vaccine safety" would provide "more definitive information about the incidence of vaccine injury," House Report, *supra*, at 6359, the Secretary may promulgate regulations that add to, or delete, the injuries listed on the Table, or alter the onset time periods. *See* 42 U.S.C. § 300aa-14(c)(3). Such revisions are made through ordinary notice and comment procedures. *Id.* § 300aa-14(c)(1).[10] To assist the

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[9] Vaccines not listed on the Table are not included in VICP; persons injured by those vaccines may bring ordinary tort actions. *See* 42 U.S.C. § 300aa-33 (defining "vaccine-related injury or death" to mean injuries associated with Table vaccines).

[10] In 1999, the Federal Circuit rejected a constitutional challenge to the Secretary's ability to make administrative changes to the statutory Table. *See Terran v. Sec'y of HHS*, 195 F.3d 1302 (Fed. Cir. 1999).

Secretary in this effort, Congress created the ACCV, composed of nine members appointed by the Secretary. *Id.* § 300aa-19. The members must include three non-governmental health care professionals with relevant experience, three members of the general public (at least two of whom have vaccine-injured children), and three attorneys (two of whom are experienced, respectively, in prosecuting and defending vaccine claims). *Id.* The ACCV advises the Secretary in the implementation of the National Vaccine Program, and recommends changes to the Table. *Id.* Any of the Secretary's proposed changes to the Table must first be reviewed by ACCV. *Id.* § 300aa-14(d).

Congress never intended that VICP would replace state tort law or its deterrent functions; instead, VICP was created in the hope that its simplicity and speed would lure some plaintiffs away from state tort litigation by choice, rather than legislative fiat. *See* House Report, *supra*, at 6354 ("The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation."). This goal rested on Congress's prediction that most vaccine petitions would concern on-Table injuries. *See id.* at 6353 (VICP is "intended to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury. . . ."). Professor Timothy Westmoreland, who served as Counsel to the Subcommittee on Health and the Environment in the House of Representatives at the time of the NCVIA's passage, characterized the Table as the "perceived giant

step" of VICP. In his view, provisions for off-Table injuries were merely an "afterthought" or a "safety-valve" in a system expected to be dominated by Table injuries. Seventeenth Judicial Conference of the United States Court of Federal Claims (2004) Tr. 25:25 to 26:25 (hereinafter "2004 Judicial Conference"), *available at* http://www.uscfc.uscourts.gov/sites/default/files/Judicial%20Conference%20transcript.pdf.

It is for this reason that Congress mandated restricted discovery and informal procedures during VICP proceedings: "Because the only issues relevant to the compensation proceeding are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages, there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues." House Report, *supra*, at 6357. Thus, when the Vaccine Court discovery rules were drafted in 1988 and 1989, they were "geared more towards the table cases" and were not designed to handle the burdens of off-Table cases. 2004 Judicial Conference, Chief Special Master Golkeiewicz of the Court of Federal Claims, Tr. 97:9-10.

III. VICP IN PRACTICE

Until 1995, 74% of vaccine cases concerned on-Table petitions. *See* GAO Report, *supra*, at 14. However, the tide shifted due to three changes to the operation of VICP.

First, in 1993, Congress amended the statute to require the Secretary to add to the Table all vaccines recommended by the CDC for routine administration

to children, thus including them in VICP. *See* Omnibus Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 646 (1993) § 13632; 42 U.S.C. § 300aa-14(e)(1)[11]; *see also* Vaccine Injury Table, ftp://ftp.hrsa.gov/vaccine compensation/vaccineinjurytable.pdf (listing "Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children" and identifying vaccines added pursuant to this provision). However, in making these additions, the Secretary did not associate any injuries with these vaccines. Thus, any person claiming to be injured by these vaccines necessarily must bring an off-Table petition, with the attendant burdens of proof. Eight vaccines are now on the table with no associated injuries.[12]

Additionally, in 1995 and 1997, the Secretary promulgated new regulations that removed many common injuries, and altered the QAI to narrow the definitions of others. As the GAO concluded,

> [M]ore claims were associated with the injuries removed from the table than were associated with the injuries that were added.

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[11] New vaccines may only be added to the Table under this category after Congress votes to impose the excise tax. *See* Pub. L. No. 103-66, Title XIII, Ch 2, Subch B, Part IV, § 13632(a)(3), 107 Stat. 646.

[12] One vaccine, Hepatitis B, was added with only a single associated injury – anaphylaxis – despite the "ongoing concern that rheumatoid arthritis and other autoimmune conditions have been triggered by the hepatitis B vaccine in those with genetic susceptibility." Healy, *supra*,

> Significantly, . . . about 45 percent (611) of the 1,368 claims awarded compensation under VICP were for injuries subsequently removed from the table. These claims accounted for about half of the $974 million awarded thus far under the program.

GAO Report, *supra*, at 14. By 1999, only 55% of petitions were on-Table. *See id.*; *see also* 2004 Judicial Conference Tr. 60:5 to 60:24 (Judge Abell, noting that since the Table alterations, the vast majority of cases are brought off-Table). The VICP Strategic Plan, prepared by the Division of Vaccine Injury Compensation within HHS ("DVIC"), confirms that one "critical issue" facing VICP includes the "dramatic shift in claims from nearly all alleging a Vaccine Injury Table condition to the majority now alleging a non-Table condition, which creates a more difficult burden for petitioners." DVIC, *National Vaccine Injury Compensation Program Strategic Plan*, at 1 (April 2006) (hereinafter "Strategic Plan"), *available at* ftp://ftp.hrsa.gov/vaccinecompensation/strategic_Plan_20060411.pdf. Chief Special Master Golkiewicz reported that as of 2001, he had "yet to adjudicate a case involving the interpretation of the amended Table; all litigated claims have been causation cases." *Stevens v. Sec'y of HHS*, No. 99-594V, 2001 WL 387418, at *8 (Fed. Cl. Mar. 30, 2001), *abrogated on other grounds by Althen*, 418 F.3d at 1274.

These alterations to the Table were ostensibly made, in part, in reliance on newer studies conducted by the IOM. As described above, Congress anticipated that the development of scientific understanding of vaccines would result in changes to the Table. *See* House Report,

supra, at 6359. Thus, the NCVIA directed the IOM to examine the medical evidence associating vaccines with particular injuries in order to assist HHS with Table revisions. *See* 42 U.S.C. § 300aa-1 note. These reviews were conducted in 1991 and 1994. *See* GAO Report, *supra*, at 13.

However, many of the administrative changes were at odds with the IOM's findings. For example, despite the IOM's finding of evidence of a causal relationship between tetanus and oral polio vaccines and Guillain-Barré syndrome, HHS did not add this injury to the table. GAO Report, *supra*, at 15. The GAO ultimately concluded that "establishing a clearly defined, transparent decisionmaking process [for Table revisions] is important to help advance the appearance of fairness. HHS has not produced such a methodology, and its actions do not always convey a sense of consistency." *Id.*[13]

Several of the 1995 Table revisions concerned the injuries associated with DTP. In particular, the revisions deleted "residual seizure disorder" and "hypotonic, hyporesponsive episodes" as compensable DTP injuries. *See* 60 Fed. Reg. at 7694-95. Moreover, after first proposing that encephalopathy be deleted as a compensable injury associated with DTP, the Secretary ultimately chose to significantly narrow the definition of encephalopathy in the QAI. *See O'Connell*, 79 F.3d at

[13] The IOM concluded that for seventy-five percent of the conditions studied, there was insufficient evidence to either accept or reject a causal connection, thus leaving the state of medical knowledge with respect to those vaccines largely unchanged from 1986, when the first Table was created by statute. *See* GAO Report, *supra*, at 13.

174-75. These changes were made despite the IOM's conclusion in 1991 that there existed a causal relationship between DTP and "acute encephalopathy and hypotonic, hyporesponse episodes," and the IOM's subsequent conclusion in 1994 that there existed a causal relationship between DTP and certain chronic nervous system dysfunctions. *Id.* at 174. As a result of the 1995 changes, the Table definition of encephalopathy is:

> more restrictive than that of the leading epidemiological study of pertussis vaccine injury, the British National Childhood Encephalopathy Study (NCES). Moreover, seizures have been removed from the Table, although that the pertussis vaccine can cause seizures is uncontested (and warned in the manufacturer's package insert), and although the NCES found a significant association between a severe seizure and DPT administration in the preceding three days (a finding that was endorsed by the Institute of Medicine).

"Compensating Vaccine Injuries: Are Reforms Needed?": Hearing Before the Subcomm. on Criminal Justice, Drug Policy and Human Res., Comm. on Gov't Reform (1999) (testimony of Marcel Kinsbourne, Pediatric Neurologist). Today, the Table associates DTP only with encephalopathy (using the narrowed definition) and anaphylaxis. *See* Vaccine Injury Table, *supra*.[14]

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[14] In this case, for example, Hannah Bruesewitz's injuries likely would have been considered on-Table but for the 1995 administrative revisions. *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 237 n.5 (3d Cir. 2009).

Without recourse to the Table, vaccine-injured patients do not receive the benefit of the bargain originally struck by VICP, whereby the "equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment." House Report, *supra*, at 6358. Petitioners report that VICP has become extremely adversarial, with veteran full-time litigators from the Justice Department fighting over "minutia like the future cost of diapers in a certain state." Scott, *supra*, at 362; *see also* GAO Report, *supra*, at 10 (HHS has "established an expert witness program" to challenge claims); Katherine E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 Geo. Wash. L. Rev. 426, 446-47 (2007).[15] The bars on discovery, coupled with the dearth of medical knowledge about vaccine safety, aggravates the plight of petitioners by making it even harder for them to prove that their injuries were caused by vaccines by a preponderance of evidence, as the NCVIA requires. 42 U.S.C. § 300aa-13(a)(1). As described above, evidence from VAERS is not accepted by the HHS. Moreover, petitioners are not granted access to the VSD. *See, e.g.*, *In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder*, 2007 WL 1983780 (Fed. Cl. May 25,

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[15] In the words of one special master, HHS's counsel was "abrasive, tenacious, obstreperous litigation tactics were inappropriate in a program that is intended to be less adversarial; and hindered greatly a fair, expeditious resolution of the case. In addition, counsel lacks simply tact and compassion. Quite frankly; the special master is embarrassed that respondent's counsel and respondent's life care planner represented the United States Government in this case." H.R. Rep. No. 106-977 at 13.

2007). Similarly, requests from petitioners to obtain discovery from manufacturers, who are not parties to VICP proceedings, are routinely denied. *See, e.g.*, Published Ruling Quashing Subpoena, *Deloatch v. Sec'y of HHS*, No. 1:09-vv-00171-UNJ (Fed. Cl. Apr. 27, 2010). As a result, "Even though the same vaccines and injuries are represented in the cases, clear answers have proven elusive to the numerous causation-in-fact issues presented over the twelve year history of the Program." *Stevens*, 2001 WL 387418, at *7.

Moreover, contrary to Congress's intent, VICP proceedings are anything but "expeditious," often taking years to resolve. *See* GAO Report, *supra*, at 20-21; Strategic Plan, *supra*, at 8; Scott, *supra*, at 358. Chief Special Master Golkiewicz agrees: "[L]itigating causation cases has proven the antithesis of Congress's desire for the Program. Instead of speed, certainty, and fairness, costly lengthy case presentations, inconsistent outcomes, and disparate treatment of similarly-situated litigants has resulted." *Stevens*, 2001 WL 387418, at *7.

The proof is in the pudding: with so many claims involving difficult-to-prove off-Table injuries, only one-third of petitioners receive VICP compensation. *See* Brief of the United States as Amicus Curiae, *Am. Home Prods. Corp. et al. v. Ferrari et al.*, No. 08-1120, at 4 (Jan. 29, 2010). Correspondingly, the Trust Fund has become engorged, holding over $3.2 billion as of April 30, 2010, as compared to $1.3 billion at the end of 1998. *Compare* ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0410.pdf *with* GAO Report, *supra*, at 16.[16] This

[16] The Fund has exceeded Congressional Budget Office projected growth rates. *See* H.R. Rep. No. 106-977, at 14.

figure far exceeds the amount expected to pay claims. *See* GAO Report, *supra*, at 18.[17]

HHS has demonstrated a marked reluctance to expand and update the injuries on the Table. For example, HHS rejected an ACCV recommendation in April 2005 to add to the Table certain injuries associated with the varicella and hepatitis A vaccines. *See* Letter to Secretary Michael O. Leavitt from Don L. Wilber, M.D., Chair of the ACCV (April 19, 2005).[18] Instead, HHS lists both vaccines on the Table without any associated injuries. *See* Vaccine Injury Table, *supra*.

HHS also refuses to use VAERS data as a basis for updating the Table. *See* 60 Fed. Reg. at 7685. The IOM reports that although vaccine cases could provide a valuable source of information regarding the association of vaccines with particular injuries, they are not used to formulate hypotheses for testing in the VSD. *See Priorities*, *supra*, at 65. Dr. Geoffrey Evans, Medical Director of DVIC, explains that HHS is more "reactive" than "proactive" in altering the Table:

> This is something that if HRSA [the HHS Health Resources and Services

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[17] The Strategic Plan concludes that the size of the fund is necessary and appropriate given the need for risk reserves. *See* Strategic Plan, *supra*, at 28. The GAO disagrees. *See* GAO Report, *supra*, at 18.

[18] The ACCV recommendations were based on a DVIC presentation at a March 2005 meeting regarding injuries associated with the varicella and hepatitis A vaccines. *See* ACCV Work Group Meeting Minutes, March 9, 2005.

> Administration] had the extra resources it would have been nice if we did have timely reviews of the vaccine injury table all along. . . . But it is something that is not practical. There are not a lot of things that are done in government today that are proactive. They are more reactive and this would be one of the more important proactive things to do, but there is probably a whole long line of people with proactive things that they would like to see done for the program.

HHS, ACCV Conference (March 9, 2006), Tr. 103 (hereinafter "2006 ACCV Conference").

HHS's reluctance to update the Table with new injuries apparently stems, at least in part, from the fear that if vaccines are publicly linked with injuries on the Table, the negative association will dissuade people from seeking inoculation. A report issued by the House of Representatives' Committee on Governmental Reform notes that there is an inherent conflict in the dual roles of HHS in encouraging drug development and vaccination on the one hand, and administering VICP on the other. *See* H.R. Rep. No. 106-977, at 16. In the Strategic Plan, DVIC concludes, "Relaxed standards for assessing causation of vaccine-related injury could jeopardize the public's trust of, and reliance upon, vaccines. . . . The relaxed standard may lead to more claims being compensated; and therefore, the public may think that vaccines are not safe." *See* Strategic Plan,

supra, at 27.[19] Similarly, Dr. Evans, speaking at the Nineteenth Judicial Conference of the United States Court of Federal Claims in 2006 (hereinafter "2006 Judicial Conference"), *available at* http://www.uscfc.uscourts.gov/sites/default/files/061025.pdf stated:

> I want to at least put my public health hat on for a moment and address one of the ideas that was put forward, and that was that you could just simply add injuries to the vaccine injury table. . . . [T]here are statutory provisions tied to the table, such as the vaccine information statements[20] and the VAERS program . . . so that if we do add lots of different injuries to them, then it's going to have some public health consequences. This program doesn't really operate with the outside interest of what is going on in the public sector as much as one would think.

2006 Judicial Conference Tr. 111:15-112:3.[21] Notably, Congress heard this same objection from HHS when it considered the program – and, by enacting VICP,

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[19] *See also* Strategic Plan, *supra*, at 25 ("The very existence of the VICP communicates a mixed message that while vaccines are beneficial and safe, they may, in rare instances, cause injury or death.").

[20] Vaccine information statements, stating the risks and benefits of a vaccine, are required to be distributed to parents under the NCVIA. *See* 42 U.S.C. § 300aa-26.

[21] Though the transcript attributes the comment to an unidentified "male voice," Ms. Willner attended the conference and confirms that Dr. Evans was speaking.

apparently rejected it. *See* Rutkow, *supra*, at 692 (quoting the Assistant Secretary of HHS, testifying before a congressional committee in 1984, as objecting to the Table on the grounds that it created "a strong presumption that vaccine[s] [are] responsible for essentially any adverse condition that happens after immunization unless there is incontrovertible evidence of other causation").

As a result of this dual system – whereby new vaccines are added to the Table, but HHS does not add associated injuries – almost all persons suffering vaccine injuries must bring their claims through VICP,[22] and every injury is litigated in a full-blown adversarial proceeding without the protections of the Federal Rules of Civil Procedure. Chief Special Master Golkiewicz points out:

> The acuteness of the problem is seen with newly added vaccines, such as the hepatitis B vaccine which was added to the Program in August of 1997. These vaccines are being added without the benefit of a multi-injury Table. Thus, practice has shown that virtually all of the cases proceed as causation-in-fact disputes. In fact, all 267 pending hepatitis B cases are causation claims.

Stevens, 2001 WL 387418, at *8. As the IOM recently concluded, "[t]here have been delays in updating injuries

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[22] *See* Dr. Evans, 2006 ACCV Conference Tr. 51 ("[R]ight now we are covering 95 percent of vaccines distributed in this country. . . . So we are very close to covering all of the vaccines."); CDC Vaccine Price List, *supra* (listing prices for each vaccine, including the portion attributable to the VICP excise tax).

listed in the table and undertaking the necessary research to update the table. This has generated concern that there is a lack of government commitment to understanding the full extent of vaccine risks even as it pursues universal immunization as a public good." *Priorities*, *supra*, at 63. The system has thus diverged from Congress's original design: "[W]ithout such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner." House Report, *supra*, at 6358.

IV. THE IMPORTANCE OF STATE TORT REMEDIES

Within this context, the availability of state tort actions takes on critical significance. In creating VICP, Congress expressed a preference for offering vaccine-injured parents the "carrot" of quick compensation rather than the "stick" of preemption. *See* House Report, *supra*, at 6354 (recognizing that the benefits of VICP will "divert a significant number of potential plaintiffs from litigation"). VICP, with its no-fault structure, functions as an alternative to strict liability under state tort law. But Congress never intended either VICP or the NCVIA to replace state tort law with respect to substantive protections that states provide their citizens.

For example, the NCVIA could have, but did not, preempt failure-to-warn claims based on FDA-approved labeling. Instead, the NCVIA eliminated strict liability and imposed a higher burden of proof. *See* 42 U.S.C. § 300aa-22(b)(2). In this manner, Congress preserved the standards of conduct imposed by states while ensuring that vaccine manufacturers are protected

against excessive liability. Similarly, Congress did not eliminate claims based on a failure to properly prepare the vaccine, *see* 42 U.S.C. § 300aa-22(b)(1), despite heavy FDA regulation of manufacturing, *see* 21 C.F.R. § 312.23(a)(7); 21 C.F.R. Pts 210 & 211.

With respect to state law claims based on the failure to warn patients directly of the risks associated with vaccines, Congress legislatively adopted the learned-intermediary doctrine. 42 U.S.C. § 300aa-22(c); *see also Reyes v. Wyeth Labs*, 498 F.2d 1264, 1276 (5th Cir. 1974) (prior to the enactment of NCVIA, refusing to apply the learned intermediary doctrine to mass vaccination). At the same time, Congress required that all patients personally receive an information statement explaining the vaccine's risks and benefits. 42 U.S.C. § 300aa-26. Once again, though Congress eliminated a source of liability, it preserved the substantive protections of state law.

Read in this light, it is plain that when Congress preempted claims concerning "unavoidably unsafe" vaccines, it did not intend to eliminate state-imposed legal requirements without providing an effective replacement. Nothing in VICP, or in any federal regulation, requires that manufacturers develop the safest feasible design when manufacturing their products. At best, VICP is a substitute for design-defect claims where there is no safer alternative – i.e., compensation for patients who, as the necessary price of ensuring the public health, personally bear the burdens of compulsory vaccination. But Congress never intended that VICP would replace the important deterrent functions of state tort law in spurring

manufacturers to design safer products; indeed, due to the restricted discovery available in VICP proceedings, as well as the dearth of research regarding the adverse effects of vaccines and the difficulties in conducting such research, state tort actions remain a critical mechanism for realizing Congress's goal of "promot[ing] the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market." 42 U.S.C. § 300aa-27(a)(1).

It is indisputable that state damages litigation "may aid in the exposure of new dangers associated with" a product. *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 451 (2005). This is because "[t]he information-gathering tools lawyers have in litigation are, by any measure, more extensive than the FDA's." David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Effort to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461, 492 (2008). Plaintiffs frequently use the discovery process to uncover evidence that manufacturers are aware of risks unknown to regulatory authorities. *See id.* at 492-95; *see also* Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 309 (2007); Peter D. Jacobson & Kenneth E. Warner, *Litigation and Public Health Policy Making: The Case of Tobacco Control*, 24 J. Health Pol. Pol'y & L. 769, 788 (1999). In turn, these discoveries prompt government regulators to take action. *See* Kesselheim & Avorn, *supra*, at 310; Jacobson & Warner, *supra*, at 788-89.

Nor is it sufficient that federal agencies examine new vaccine applications and conduct post-market surveillance. Even for ordinary drugs, "pre-approval

testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies (for example, the elderly, ethnic minorities, and pregnant women)." Kessler & Vladeck, *supra*, at 471. After approval, "the FDA's information-gathering power is more limited. . . . [C]ompanies have no obligation to provide the FDA with the company's evaluations of the drug's performance in the market." *Id.* at 491-92.

The problem is particularly acute for vaccines because they are so widely distributed to people of varying ages or with greater or lesser health vulnerabilities. During the pre-licensure examination – when FDA scrutiny is at its zenith – there will not be a sufficiently large or diverse pool of patients to permit a full evaluation of the vaccine's safety profile. *Priorities*, *supra*, at 53. Only after the vaccine has been distributed to millions of people may safety problems become detectable to outside observers, and even then, the information available to regulators may be difficult to interpret.

Therefore, Congress's mandate for the development of safer vaccines will be critically hobbled if plaintiffs are not permitted to bring claims in state courts alleging that manufacturers could have designed safer products. With the abilities of government agencies so limited, and the scope of VICP determinations so narrow, state tort actions are indispensable mechanism of information-gathering in a field characterized by inherent difficulties in conducting research. Design defect claims in particular may provide the only incentive that

manufacturers have to utilize all means at their disposal to manufacture the safest feasible product. Given Congress's recognition of the importance of tort law, it is unreasonable to think that Congress directed the inclusion of virtually all vaccines on the Table, including the newest vaccines about which the least is known, without also intending to preserve the "constant incentive to regulators and manufacturers" of the state tort system to ensure that manufacturers continue to develop safer products. Rutkow, *supra*, at 698.[23]

In its *Ferrari* amicus brief, the United States argued that local juries may misunderstand the careful "cost/benefit calculus" that requires a trade-off of individual safety relative to the public good. U.S. Br. at 15. But nothing in Petitioners' argument displaces the role of federal regulators in conducting this cost/benefit analysis, because HHS has complete control over VICP. If HHS believes that the benefits of a drug are worth its costs to the public, it can list associated injuries on the Table and thereby "divert a significant number of potential plaintiffs from litigation as Congress intended. House Report, *supra*, at 6354.[24] But if HHS chooses to

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[23] That Congress did not see VICP as a substitute for the incentives provided through state tort law can be seen in the evolution of the excise tax. Originally, the tax was imposed on a risk-adjusted basis, with a higher tax for vaccines that caused the most injuries; in 1997, Congress amended the statute to provide a flat seventy-five cent tax on all doses. See GAO Report, *supra*, at 7 n.9. Thus, Congress made it clear that VICP is not part of the regulatory mechanism for incentivizing manufacturers to adopt safer vaccine designs.

[24] But for the 1995 table revisions, Petitioners in this case likely would have received VICP compensation and foregone a state lawsuit.

eliminate injuries from the Table and create virtually insurmountable barriers to petitioners proceeding through VICP, Congress has mandated that state tort law fill the gap. *See* House Report, *supra*, at 6358 (noting the "injustice" of eliminating state tort remedies without providing effective VICP compensation). Such an interpretation is supported by the NCVIA legislative history, where Congress recognized the importance that state tort law plays in spurring both manufacturers *and regulators* to create safer products. Rutkow, *supra*, at 698.

Moreover, as a practical matter, government agencies need access to the kind of information that only tort actions can provide to perform their own "cost/benefit calculus." And although the United States suggests that blanket protection from all design defect liability is necessary to shield fragile vaccine manufacturers from industry-destroying liabilities, U.S. Br. at 20, in fact, the IOM reports that today, vaccine manufacturing "appears increasingly promising for the industry, as demonstrated by the expansion of in the number of manufacturers, a promising pipeline of new vaccines, and a changing view of the profitability of vaccines." *Priorities*, *supra*, at 32.[25] Thus, the additional protections that the United States seeks to bestow are not necessary to preserve the field.[26]

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[25] Pfizer recently purchased Wyeth in part to enter the vaccine market by obtaining rights to Prevnar, Wyeth's children's pneumonia vaccine. *See, e.g.*, Pfizer 2008 Annual Review at 7, *available at* http://www.pfizer.com/investors/financial_reports/annual_reports/pfizer_wyeth.jsp.

[26] There is reason to doubt that relief from liability plays much of a role in manufacturing decisions today. For example, (Cont'd)

CONCLUSION

For the reasons stated above, the NCVIA should not be interpreted to preempt all design defect claims.

Respectfully submitted,

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(Cont'd)

in 2004, Congress voted to impose an excise tax on the influenza vaccine (thereby adding it to the Table) out of concern that fear of liability was driving manufacturers from the market. Such relief from liability did not increase influenza vaccine production. *See* Rutkow, *supra*, at 721-24.