Bruesewitz v. Wyeth LLC: An Unsafe Presumption of Unavoidability?

I. INTRODUCTION

In the recent decision *Bruesewitz v. Wyeth LLC.*,[1] the Supreme Court eradicated a disease that threatened to injure innocent children throughout the country: vaccine manufacturer liability. By determining that the prescriptions of the National Childhood Vaccine Injury Act of 1986[2] [hereinafter Vaccine Act] preempt state court lawsuits, the Court has successfully immunized vaccine manufacturers from "all design-defect claims . . . brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects."[3] In doing so, the Court has defined the meaning of the term "unavoidable" as it relates to common vaccines. What the Court managed to avoid, however, was a serious discussion of the inequities built into the system designed to compensate the victims of unquestionably dangerous inoculations.

This note will explore how the ruling in *Bruesewitz* will disproportionately harm victims who have the misfortune of being injured by vaccines that serve a public purpose but cannot be

made to be completely safe. Part II of this note examines the legislative and judicial history behind the Vaccine Act, including the protections it is supposed to offer both manufacturers and the general public. Part III discusses the Supreme Court's evaluation of the unavoidability doctrine in *Bruesewitz*, focusing on the victim far more than the Court's opinion did. Part IV discusses the potentially harmful side effects the Court's decision will have on the general public. Finally, Part V explores how the *Bruesewitz* decision will serve to exacerbate existing flaws in the vaccine-related injury compensation system.

II. A BRIEF HISTORY OF VACCINE LITIGATION

Preventing the spread of communicable disease through vaccination was "'one of the greatest achievements' of public health in the 20th century."[4] Nevertheless, the significant public health benefits of large-scale immunization come with certain inherent risks. There is no such thing as a perfect or reaction-free vaccine, and inevitably a small percentage of children suffer serious reactions, sometimes even death.[5]

In the early 1980's, a significant increase in the number of lawsuits seeking damages from vaccine manufacturers threatened to destabilize the vaccine market.[6] Between 1980 and 1984, plaintiffs claiming injuries from vaccines sought $3.5

billion in damages.[7] Many of the claims arose from injuries thought to be related to the diphtheria, tetanus, and pertussis (DTP)[8] vaccines, particularly the pertussis component.[9] Facing huge financial exposure, inability to acquire liability insurance, and high litigation costs, manufacturers began to exit the market.[10] The withdrawal of vaccine manufacturers began to threaten the availability of vaccines to those in need. In 1984, vaccine shortages arose when the lone manufacturer left in the industry, Lederle Laboratories, had production problems.[11] By 1986, the vaccine stockpile had fallen below the Center for Disease Control's recommended reserve supply.[12]

At the same time, complaints began to emerge regarding the difficulty in obtaining compensation for legitimate vaccine-related injury claims in tort suits.[13] To address the concerns of innocent victims and equally innocent manufacturers, Congress created the National Vaccine Injury Compensation Program (VICP).[14] The two overriding concerns of Congress were "'the inadequacy--from both the perspective of vaccine-injured persons as well as vaccine manufacturers--of [a tort-based] approach to compensating those who have been damaged by a vaccine,' and 'the instability and unpredictability of the childhood vaccine market' due to vaccine manufacturers' fear of tort liability."[15]

To accomplish the incongruous goals of shielding

manufacturers from liability while adequately compensating victims, the VICP provides a no-fault compensation system that serves as an alternative to tort claims.[16] To receive compensation under the VICP, a petitioner is required to file a petition in "Vaccine Court," a part of the United States Court of Federal Claims.[17] A "Vaccine Injury Table" [hereinafter Vaccine Table] that lists the covered vaccines and any corresponding injuries known to be a result of the administration of those vaccines is used to separate claimants into two categories. Claimants who have suffered a Table injury within the appropriate timeframe are prima facie entitled to compensation.[18] Any claimants with injuries not listed on the Vaccine Table (or claimants whose injuries occur outside the times specified in the Table) must prove causation.[19] By establishing this system, Congress hoped to "ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines."[20]

However, it was not long before disputes arose regarding the VICP. Injured petitioners whose claims were not compensated in Vaccine Court sought relief in state and district courts by suing the manufacturers under defective design claims.[21] To determine whether state law design defect claims were preempted

by the Vaccine Act, the courts focused on the language in § 22(b) of the statute that read:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.[22]

Manufacturers claimed that the language above clearly absolved them from any liability for the injurious side effects of unavoidably dangerous vaccines. Plaintiffs alleged that the meaning of "unavoidable" should be determined on a case-by-case basis, relying on a definition derived from comment *k* to Restatement (Second) of Torts §402A which describes strict liability exemptions for "unavoidably unsafe products."[23] Under comment *k*, the only "unavoidably unsafe" products are those that "in the present state of human knowledge, are quite incapable of being made safe for their ordinary and intended use."[24] Plaintiffs argued that vaccine manufacturers had an affirmative duty to produce the safest vaccines possible; if safer

alternatives could be produced, the side effects from the vaccines should not be considered unavoidable and should not be restricted by the Vaccine Act.

By 2009, different interpretations of § 300aa-22(b)(1) once again threatened to bring instability and unpredictability to the vaccine market. A number of courts ruled that the Vaccine Act preempted state courts from making ad hoc determinations of unavoidability.[25] However, the Georgia Supreme Court, in *American Home Products Corp. v. Ferrari*,[26] ruled that manufacturers were only immune from liability for defective design "if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe."[27] When *Bruesewitz v. Wyeth LLC* came before the Third Circuit,[28] the court disagreed with the Georgia Supreme Court's interpretation of § 300aa-22(b)(1), holding "the Vaccine Act preempts all design defect claims, including those based in negligence."[29] To clear up this discrepancy, both parties involved in *Bruesewitz* sought certiorari with the Supreme Court.[30]

III. THE DEFINITION OF "UNAVOIDABLE"

Bruesewitz involved the case of Hannah Bruesewitz, who received a DTP vaccination when she was five months old, consistent with the schedule recommended by the Center for Disease Control.[31] Within 24 hours of receiving the shot, a

"whole-cell" pertussis vaccine marketed under the name TRI-IMMUNOL,[32] Hannah began experiencing seizures.[33] Over the next month, Hannah would experience more than 100 seizures; eventually she was diagnosed with "residual seizure disorder" and developmental delay."[34]

In April 1995, Hannah's parents filed a petition in the Vaccine Court.[35] In December 2002, a Special Master denied the claim, although the Bruesewitzes were awarded $126,800 in attorney's fees and costs.[36] In October 2005, the Bruesewitzes filed a complaint in Pennsylvania state court alleging the defective design of the DTP vaccine Hannah received caused her injuries.[37] Wyeth removed the claims to federal court, where the District Court for the Eastern District of Pennsylvania granted Wyeth summary judgment, holding that § 300aa-22(b)(1) preempted those causes of action.[38] In March 2009, the Third Circuit affirmed the decision.[39] To settle the discrepancy between the Third Circuit's holding and the Georgia Supreme Court's holding in *Ferrari*,[40] the Supreme Court granted certiorari.[41]

The Bruesewitzes claimed that provisions of the Vaccine Act "required a case-specific threshold determination of whether a vaccine's design is unavoidably unsafe."[42] According to this theory, if a potentially safer design can be produced, the vaccine's side effects are not unavoidable. The Bruesewitzes

claimed that a different version of the pertussis vaccine – an "acellular" version that protects against pertussis without containing the "neurotoxic" "whole killed pertussis organisms" - existed at the time as a safer alternative to the TRI-IMMUNOL vaccine that Wyeth produced and Hannah received.[43] Under that theory, tort claims were not preempted by the Vaccine Act.

The majority disagreed with the petitioner's theory on unavoidability in a 6-2 decision. Justice Scalia wrote the opinion for the Court, which focused primarily on the linguistic construction and legislative history of § 300aa-22(b)(1). Justice Scalia found that the "even though" clause in § 300aa-22(b)(1)[44] outlined the measures a manufacturer must take in order for a side effect to be considered "unavoidable" under the statute.[45] Therefore, as long as an FDA-approved vaccine is properly labeled[46] and properly manufactured, the statute establishes unavoidability "*with respect to the particular design*" as a complete defense.[47]

Justice Sotomayor, joined by Justice Ginsburg, dissented. In her opinion, the "if" clause of § 300aa-22(b)(1)[48] indicates that some side effects stemming from a vaccine's design are avoidable.[49] Using this interpretation, manufacturers would have to prove that side effects from a particular vaccine's design were truly unavoidable before being granted immunity under the

Vaccine Act.[50] In her opinion, preempting claims without allowing juries to determine whether side effects were unavoidable "leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing their products."[51] However, juries may serve another role by determining that a vaccine's injurious side effects were unavoidable: determining that a plaintiff's injuries were the result of the vaccine's side effects.

IV. THE DEFINITION OF "SIDE EFFECTS"

The procedural step that is missing in the Court's logic is causality. A safer vaccine, acellular or not, would not have prevented Hannah Bruesewitz's residual seizure disorder or developmental delay. The Vaccine Court determined that Hannah's injuries were not caused by the DTP vaccine she received.[52] Therefore, no safer vaccine could have possibly prevented Hannah from suffering 125 seizures in the 16 days following her DTP inoculation.[53] In order for side effects to be unavoidable, they must first be determined to be side effects. If Hannah Bruesewitz's residual seizure disorder and developmental delay were vaccine-related injuries at all, she should have recovered damages in Vaccine Court, not the tort system.

Had the Bruesewitzes filed their petition with the Vaccine Court one month earlier, this case would most likely never had been in the civil system at all. Just one month before Hannah's parents sought compensation through the proper channels, the Secretary of the Department of Health and Human Services (DHHS)[hereinafter the Secretary] updated the Vaccine Table, removing residual seizure disorder and hypotonic-hyporesponsive episodes as compensable side effects of the pertussis vaccine,[54] shortening the timeframe for the onset of anaphylaxis,[55] and significantly narrowing the definition of encephalopathy (general brain damage).[56] If Hannah Bruesewitz's claim had been filed before the changes to the Vaccine Table, her injuries would have been on-Table injuries known to be associated with the pertussis vaccine[57] and she would have been compensated through the no-fault system as the VICP intended. Because 99.8% of petitioners compensated through the system accept their award,[58] there is a strong probability that if residual seizure disorder had been an on-Table no-fault injury on April 3, 1995 when the Bruesewitzes filed their petition,[59] the design defect claim against Wyeth would never have been filed.

Justice Scalia and Justice Sotomayor spent a lot of time discussing whether juries should be allowed to determine the definition of "unavoidable," but ignored the question of whether

juries should be allowed to determine causality.[60] Justice Breyer addressed the issue briefly in his concurrence: "A special master in the Act's compensation program determines whether someone has suffered an injury listed on the Injury Table and, if not, whether the vaccine nonetheless caused the injury. To allow a jury in effect to second-guess those determinations is to substitute less expert for more expert judgment."[61] Thus, determining what the harmful side effects of vaccines are is solely a matter between the Secretary and the special master. [62] By eliminating the ability of petitioners to seek redress outside the Vaccine Court, the Supreme Court has tacitly endorsed the Secretary's view that DTP vaccines do not cause residual seizure disorder.[63]

While it might be prudent to "leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries,"[64] the same does not necessarily hold true for judgments about vaccine side effects. Only 13% of petitioners bringing claims for injuries not listed on the Vaccine Table receive compensation.[65] These numbers are particularly troubling because the burden of proof in the Court of Appeals for the Federal Circuit is intended to be lower than that of civil courts "'to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect

the human body.'"[66] In addition, the VICP has recognized a dramatic shift in the ratio of on-Table claims compared to off-Table claims.[67] Before 1995, 74% of cases concerned on-Table injuries,[68] but by 1999, only 55% of cases involved on-Table injuries.[69] Currently, only one-third of petitioners receive compensation from the VICP for their injuries.[70]

The VICP was intended to be "'expeditious and fair' and to compensate recognized vaccine injuries 'without requiring the difficult individual determinations of causation of injury.'"[71] Nevertheless, the system has become slow,[72] contentious,[73] and unnecessarily frugal.[74] What is supposed to divert injured petitioners from litigation is "the relative certainty and generosity of the system's awards."[75] Instead, causation is determined almost exclusively by the Secretary (through the Vaccine Table),[76] who has reason to limit the number of claims linked to immunizations. In the VICP Strategic Plan, the Division of Vaccine Injury Compensation[77] outlined the reasons for narrowly interpreting links between vaccines and injuries: "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."[78]

V. CONCLUSION

Although Justice Scalia argues that it is mere "unsupported speculation that demand in the vaccine market is inelastic,"[79] a number of vaccines, including DTP, are practically mandatory for all children. Children are required to have up-to-date vaccinations for participation in school or day care.[80] The risks associated with widespread immunization are small but costly; the gains are great, but invisible.[81] If the risks cannot be eliminated, the manufacturers should not be held liable for the inevitable injurious side effects experienced by a tiny percentage of those "who have the grave misfortune to be injured by the very vaccines intended to keep them healthy."[82]

Contrary to Justice Scalia's assertion that "vaccine manufacturers fund from their sales an informal, efficient compensation program for vaccine injuries,"[83] the VCIP is funded through an excise tax that consumers pay on every vaccine.[84] Yet, despite bearing the cost of funding the VICP[85] and bearing the cost of the dangers, the public is completely left out of the process of determining the validity of claims. Instead, claimants face an uphill battle in Vaccine Court attempting to prove that it was the vaccine that was defective, not the child.[86] It is true that given inconclusive medical evidence, juries might err on the side of providing parents with the

financial resources necessary to care for a disabled child, but "[s]ubstantial funds are available to pay awards under the Compensation Program, even if unexpected events place a significant demand on the Trust Fund."[87]

Congress created the VICP for two reasons: 1) to decrease tort liability for vaccine manufacturers and 2) to "compensate children who had been injured while serving the public good."[88] The late Senator Edward Kennedy summed up Congress's concerns when he stated, "We must be able to assure parents that when their children are the victims of an appropriate and rational national policy, a compassionate Government will assist them in their hour of need."[89] In *Bruesewitz*, the Supreme Court demonstrated a willingness to protect vaccine manufacturers in order to ensure a stable vaccine market, but did little to protect the victims of the unavoidable side effects of those vaccines. The Supreme Court's willingness to entertain the possibility that Hannah Bruesewitz's injuries were caused by unavoidable side effects of the DTP vaccine demonstrates the uncertainty that surrounds causality in vaccine-related injury claims. Until the inequities in the Vaccine Court are addressed, there will be stability in the vaccine market, but there will continue to be instability and uncertainty for parents of children unavoidably injured by vaccines.

[1] 562 U.S. ____ (2011).

[2] 42 U.S.C. § 300aa-1 *et seq.*

[3] Bruesewitz v. Wyeth, 562 U.S. ____, ____ (2011) (slip op. at 19).

[4] *Bruesewitz*, 562 U.S., at ____ (slip op., at 1). *See also* Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons From the Vaccine Act*, 44 AM. U. L. REV. 1853, 1854 (1995) ("During the twentieth century, America has developed a childhood immunization program that many praise as the most spectacular public health success in history.").

[5] Bruesewitz v. Wyeth, 561 F.3d 233, 247 (3d Cir. 2009).

[6] Cantor, *supra* note 4 at 1858.

[7] *Id.*

[8] Alternatively known as DPT.

[9] In particular, the pertussis vaccine has been considered "the most reactive of all the commonly used vaccines and has been one of the most concern in debates over adverse effects of vaccines." *Bruesewitz*, 561 F.3d at 250-51 (quoting Staff of H. Comm. On Energy & Commerce, 99th Cong., *Childhood Immunizations*, III (1986)).

[10] Lainie Rutkow et al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury*

Compensation Program and Its Influence During the Last Two Decades, 111 PENN ST. L. REV. 681, 694 (2007).

[11] *Bruesewitz*, 562 U.S., at ____ (slip op., at 2).

[12] Cantor, *supra* note 4 at 1859.

[13] *Bruesewitz*, 562 U.S., at ____ (slip op., at 2) ("Despite the large number of suits, there were many complaints that obtaining compensation for legitimate vaccine-related injuries was too costly and difficult.").

[14] The VICP was created as part of the NCVIA, 42 U.S.C. § 300aa–1 *et seq.*

[15] Br. for United States as Amicus Curiae Supporting Resp'ts. at 2, 562 U.S. ____ (No. 09-152) [hereinafter U.S. Amicus Br.] (quoting H.R. REP. NO. 908 (1986)).

[16] Rutkow, *supra* note 10 at 684.

[17] *Bruesewitz*, 561 F.3d at 235-36.

[18] *Bruesewitz*, 562 U.S., at ____ (slip op., at 4). For on-Table injuries, no showing of causation is necessary; the Secretary has the burden of disproving causation.

[19] *Id.*

[20] Rutkow, *supra* note 10 at 717 (quoting Health Res. & Servs. Admin, *National Vaccine Injury Compensation Program*, http://www.hrsa.gov/vaccinecompensation/)

[21] *See, e.g.,* Patten v. Lederle Laboratories, 655 F. Supp. 745 (D. Utah 1987); Blackmon v. American Home Products Corp., 328 F. Supp. 2d 659 (S.D. Tex. 2004); Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289 (E.D. Pa. 2004).

[22] 42 U.S.C. § 300aa-22(b)(1).

[23] Br. for Pet'rs. 29.

[24] *Id.* at 29-30.

[25] *See Blackmon*, 328 F. Supp. 2d at 665 ("Individual challenges to the design of FDA-approved vaccines would undermine the FDA's authority to set standards for childhood vaccines."); Sykes, 484 F. Supp. 2d at 302 ("A case-by-case determination of whether a vaccine was unreasonably unsafe would defeat the protection the Act was intended to provide vaccine manufacturers.").

[26] 668 S.E.2d 236 (Ga. 2008).

[27] *Id.* at 242.

[28] 561 F.3d 233 (3d Cir. 2009).

[29] *Id.* at 248.

[30] Pet. for Writ of Cert., *Bruesewitz*, 562 U.S. ____ (No. 09-152); Br. in Resp. to Pet. for Writ of Cert., *Bruesewitz*, 562 U.S. ____ (No. 09-152).

[31] *Bruesewitz*, 562 U.S., at ____ (slip op., at 5).

[32] *Bruesewitz,* 561 F.3d at 236.

[33] *Bruesewitz*, 562 U.S., at ____ (slip op., at 6).

[34] *Id.*

[35] *Bruesewitz*, 561 F.3d at 237.

[36] *Bruesewitz*, 562 U.S., at ____ (slip op., at 6).

[37] *Id.*

[38] *Id.*

[39] *Bruesewitz*, 561 F.3d 233 (3d Cir. 2009).

[40] 668 S.E.2d 236 (Ga. 2008).

[41] 559 U.S. ____ (2010).

[42] Br. for Pet'rs. 35.

[43] *Id.* at 3.

[44] 42 U.S.C. § 300aa-22(b)(1) ("even though the vaccine was properly prepared and was accompanied by proper directions and warnings.").

[45] *Bruesewitz*, 562 U.S., at ____ (slip op., at 7).

[46] The Vaccine Act creates a general presumption that a vaccine is properly labeled if the manufacturer shows that it complied with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*) and 42 U.S.C. § 262, which concerns licensing requirements. 42 U.S.C. § 300aa-22(b)(2).

[47] *Bruesewitz*, 562 U.S., at ____ (slip op., at 7) (emphasis in original).

[48] 42 U.S.C. § 300aa-22(b)(1) ("if the injury or death resulted from side effects that were unavoidable").

[49] *Bruesewitz*, 562 U.S., at ____ (Sotomayor, J., dissenting) (slip op. at 3).

[50] *Id.* at 5.

[51] *Id.* at 1. *See also* Wyeth v. Levine, 129 S. Ct. 1187, 1202 (2009) ("In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation.").

[52] Br. for Pet'rs. 21.

[53] *Id.* at 20.

[54] Br. for Marguerite Willner as Amicus Curiae Supporting Pet'rs. at 23, *Bruesewitz*, 562 U.S. ____ (No. 09-152) [hereinafter Willner Amicus Br.].

[55] U.S. Amicus Br. at 30.

[56] Willner Amicus Br. at 23.

[57] The fact that the pertussis vaccine can cause seizures is "uncontested" and even warned about in the manufacturer's label. Willner Amicus Br. at 24 (internal citations omitted).

[58] U.S. Amicus Br. at 28.

[59] Br. for Pets. 21.

[60] A jury could determine that a plaintiff's injuries were caused by the vaccine, but the manufacturer was not liable for damages due to an inability to produce a safer vaccine.

[61] *Bruesewitz*, 562 U.S., at ____ (Breyer, J., concurring) (slip op. at 5).

[62] The Vaccine Court is not entirely consistent in determinations of causation between seizures and the DTP vaccine. *See Andreu ex. rel. Andreu v. Secretary of HHS*, 569 F.3d 1367, 1374-75 (Fed. Cir. 2009) (reversing special master's finding that parents failed to show causal relationship between whole-cell pertussis vaccine and son's seizures). Br. for Pet'rs. 21-22.

[63] *See* Theodore Ruger, *Preemption of Vaccine Injury Lawsuits Upheld*, REGBLOG (Apr. 5, 2011), http://www.law.upenn.edu/blogs/regblog/2011/04/us-supreme-court-rules-in-favor-of-preemption-forvaccine-injury-lawsuits.html (*Bruesewitz* offers an "exemplar of a broad array of Justices effectively endorsing the consensus position of the public health and scientific establishments.").

[64] *Bruesewitz*, 562 U.S., at ____ (slip op., at 15).

[65] Rutkow, *supra* note 10 at 720. In addition, petitioners found to have suffered on-Table injuries receive compensation rates "'nearly three times higher.'" *Id.* (quoting U.S. Gov. Acct. Off., Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily 12 (Dec. 1999), *available at* http://www.gao.gov/new.items/he00008.pdf).

[66] Mary Holland et al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of*

Vaccine-Induced Brain Injury, 28 PACE ENVTL. L. REV. 480, 489 (Winter 2011) (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005)).

[67] Willner Amicus Br. at 22.

[68] *Id.* at 20.

[69] *Id.* at 22.

[70] *Id.* at 26.

[71] Holland, *supra* note 66 at 485 (quoting H.R. REP. NO. 99-908, at 12.).

[72] Petitions in the Vaccine Court typically take two to three years to resolve. U.S. Amicus Br. at 26. In the case of Hannah Bruesewitz, her original claim was filed in April of 1995, but the final judgment from the Vaccine Court was not handed down until December of 2002. *Bruesewitz*, 561 F.3d at 237.

[73] *See* Willner Amicus Br. at 25 ("Petitioners report that VICP has become extremely adversarial."). Even successful claimants have complained that government attorneys were "disrespectful and combative," resolution of claims was "a war," and the court "spends far too much time looking for ways NOT to compensate families." Holland, *supra* note 66 at 526.

[74] Because only one-third of petitioners receive VICP compensation, the Trust Fund has grown to more than $3.2 billion, as compared to $1.3 billion at the end of 1998.

Willner at 26. In 2005, the Trust Fund had more than $2.2 billion. That year, the fund collected $196 million in revenue; on average, the VICP pays out between $50 to $75 million in awards annually. Rutkow, *supra* note 10 at 686.

[75] Holland, *supra* note 66 at 485.

[76] *See Blackmon*, 328 F. Supp. 2d at 665 ("The Vaccine Act delegates questions of vaccine safety to the Secretary of Health and Human Services.").

[77] The VICP is housed in the Division of Vaccine Injury Compensation (DVIC), a division of the Health Resources and Services Administration in the Department of Health and Human Services (DHHS). Rutkow, *supra* note 10 at 684.

[78] Willner Amicus Br. at 28.

[79] *Bruesewitz*, 562 U.S., at ____, n.64 (slip op., at 15, n. 64).

[80] Br. for GlaxoSmithKline, et al. as Amicus Curiae Supporting Resp'ts. at 16, *Bruesewitz*, 562 U.S. ____ (No. 09-152).

[81] *See Id.* at 12 ("The irony is that vaccines' great success in eliminating preventable diseases has reduced the perceived threat of those diseases and led to undervaluation of vaccines generally.").

[82] Holland, *supra* note 66 at 481.

[83] *Bruesewitz*, 562 U.S., at ____ (slip op., at 15).

[84] *See Bruesewitz*, 562 U.S., at ____ (Sotomayor, J., dissenting) (slip op. at 24, n.22) ("The majority's suggestion that 'vaccine manufacturers fund from their sales' the compensation program is misleading. Although the manufacturers nominally pay the tax, the amount of the tax is specifically included in the vaccine price charged to purchasers." (internal citations omitted)).

[85] The excise tax for every vaccine covered by the VICP is $0.75. Cantor, *supra* note 4 at 686.

[86] Not all legitimate injuries from the side effects of vaccines are borne by the person vaccinated. Lenita Schafer received a $750,000 award from the Vaccine Court after contracting polio from her daughter's vaccine. Schafer v. American Cyanamid Co., 20 F.3d 1, 3 (1st Cir. 1994).

[87] U.S. Amicus Br. at 28.

[88] Holland, *supra* note 66 at 484.

[89] Rutkow, *supra* note 10 at 691 (quoting *National Childhood Vaccine-Injury Compensation Act: Hearing on S. 2117 Before the S. Comm. On Labor & Human Resources*, 98th Cong. 4 (1984)) (statement of Sen. Edward Kennedy).