ENTRUSTING FOXES WITH THE HEN HOUSE: HOW A BAD LAW PITS BIG PHARMA AND THE FEDERAL GOVERNMENT AGAINST VACCINE-INJURED CHILDREN

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INTRODUCTION

In 1796, Edward Jenner, a natural scientist, was investigating tales of dairy-maids becoming immune to small pox after being infected with cowpox.[1] He purposefully infected the son of his gardener, a nine-year-old, with the cowpox, and after the boy recovered he was immune to the smallpox.[2] Vaccination (from the Latin *vacca* for cow)[3] was rapidly promoted; Thomas Jefferson was an early champion during his tenure in the White House.[4] Today, vaccination is considered one of the most effective weapons against infectious diseases.[5] When a certain threshold of people are immune to a particular illness, the disease stops circulating and the population at large achieves a 'herd immunity' that protects everyone from the disease,[6]

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1. Stefan Riedel, *Edward Jenner and the History of Smallpox and Vaccination*, 18(1) BAYLOR U. MED. CTR. PROC. 21, 24 (2005).

2. *History of Smallpox*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/smallpox/history/history.html (last updated Aug. 30, 2016).

3. Riedel, *supra* note 1, at 24.

4. *Id.*

5. *See* Francis Andre et al., *Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide*, 86 BULL. WORLD HEALTH ORG. 140, 140–44 (2008) (discussing the importance and effectiveness of vaccination).

6. *See Vaccines Protect Your Community*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.vaccines.gov/basics/work/protection (last visited Oct. 19, 2019); Laura Helft & Emily Willingham, *What is Herd Immunity?*, PBS (Sept. 5, 2014), https://www.pbs.org/wgbh/nova/article/herd-immunity/.

especially people who are not immune;[7] governments worldwide strive to meet this public health goal of herd immunity through vaccination.[8] It is indisputable that vaccination has reduced the incidence of a number of diseases and improved general public health;[9] however, vaccinations are not without risk.[10]

On August 6, 1992, Scott Clements brought his healthy son, Andrew, for his third dose of the vaccine Diphtheria, Pertussis, Tetanus ("DPT").[11] Later that night, Scott heard rasping coming from the room and found that his son was not breathing.[12] The fire department arrived shortly thereafter and determined that Andrew was having convulsions, so they brought him to the hospital for treatment.[13] Andrew went on to have another seizure when he arrived at the hospital and another eighty-four seizures over the course of the next three years.[14] The eighty-fifth seizure lasted over four hours and put Andrew in a coma for four months.[15]

When Andrew emerged from his coma, he was mentally retarded and had lost, amongst other things, the ability to swallow.[16] Andrew's family applied to the Vaccine Injury Compensation Program ("VICP"),[17] a special court located in Washington D.C. designed to give families with vaccine-injured children fast and generous payments through a no-fault alternative to civil

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7. *See* Bruce Y. Lee, *2018 Surges in Measles in Europe and U.S. Show Importance of Herd Immunity*, FORBES (Nov. 24, 2018), https://www.forbes.com/sites/brucelee/2018/11/24/2018-surge-in-measles-in-europe-and-us-show-importance-of-herd-immunity/#4a44f1da6cdc.

8. *See* Susan Scutti, *How Countries Around the World Try to Encourage Vaccination*, CNN (Jan. 2, 2018), https://www.cnn.com/2017/06/06/health/vaccine-uptake-incentives/index.html.

9. Peter I. Folb et al., *A Global Perspective on Vaccine Safety and Public Health: The Global Advisory Committee on Vaccine Safety*, 94 AM. J. PUB. HEALTH 1926, 1926 (2004).

10. *See Vaccine Adverse Event Reporting System (VAERS)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html (last visited Oct. 19, 2019) (approximately 30,000 adverse reactions to vaccines are reported annually, with 10%-15% being considered serious); *see also* ROSS LAZARUS, HARVARD PILGRIM HEALTH CARE, INC., ELECTRONIC SUPPORT FOR PUBLIC HEALTH–VACCINE ADVERSE EVENT REPORTING SYSTEM (ESP:VAERS) 6 (2010), https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf ("fewer than 1% of vaccine adverse events are reported [to VAERS]").

11. Clements v. Sec'y of Dep't of Health & Human Servs., No. 95-484V, 1998 WL 481881, at *1 (Fed. Cl. July 30, 1998).

12. *Compensating Vaccine Injuries: Are Reforms Needed?*: *Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, and Hum. Res.*, 106th Cong. 18 (1999) [hereinafter *Compensating Vaccine Injuries*].

13. *Id.* at 19.

14. *Id.*

15. *Id.* at 19–20.

16. *Id.* at 20.

17. *Id.*

litigation.[18] Even though Andrew was expected to live until he was forty, requiring extensive care, the government only offered the Clements $350 thousand.[19] After Andrew's parents refused to accept the settlement, their claim was denied in a hearing in 1998 because Andrew's symptoms no longer met the criteria set forth by the Department of Health and Human Services ("HHS") for encephalopathy,[20] which had been revised in 1995 to exclude residual seizure disorders such as Andrew's.[21]

Andrew's tragic story reveals an unexpected and ugly cost for the advances the United States has achieved against infectious diseases through vaccination. Although rare, side effects for vaccines can include long-term disability and death.[22] Since vaccines are essentially mandatory with a few narrow exceptions,[23] almost every child living in the United States is vaccinated.[24] To protect public health and ensure continued high rates of vaccination, Congress enacted the National Childhood Vaccine Injury Act ("NCVIA") in 1986[25] when tort liability threatened to destabilize the vaccine market.[26] A portion of the NCVIA created the VICP, a special court designed program to provide a "swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation."[27] A close examination of Andrew's story will reveal that the NCVIA creates a series of deeply flawed incentives for the pharmaceutical companies and the federal

18. *See id.* at 9 (statement of NCVIA cosponsor Congressman Waxman) ("[W]e wanted to give parents confidence that if their child were to be injured by a vaccine, there would be predictable and generous compensation."); *see also* H.R. REP. NO. 99-908, at 7 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6348 (stating that one of the two goals of the legislation was to make compensation "fair, simple, and easy to administer.").

19. *Compensating Vaccine Injuries*, *supra* note 12, at 20–21.

20. *Id.* at 21; Clements v. Sec'y of Dep't of Health & Human Servs., No. 95-484V, 1998 WL 481881, at *15 (Fed. Cl. July 30, 1998).

21. *Clements*, 1998 WL 481881, at *1 n.2; *Compensating Vaccine Injuries*, *supra* note 12, at 21.

22. *See* HEALTH SERVS. & RES. ADMIN. (HRSA), NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT 5, (updated Mar. 1, 2019) (table of petitions filed, compensated, and dismissed by vaccine), https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-march-2019.pdf [hereinafter NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT].

23. *State Vaccination Requirements*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html (last updated Jan. 29, 2016).

24. *Immunization*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/fastats/immunize.htm (last updated May 3, 2017).

25. *See* 42 U.S.C. §§ 300aa-1–34 (2017); *see also* H.R. REP. NO. 99-908, at 3 (1986).

26. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1073 (2011).

27. *Vaccine Claims/Office of Special Masters*, U.S. CT. FED. CLAIMS, http://www.cofc.uscourts.gov/vaccine-program-readmore (last visited Sept. 17, 2019).

government that probably led to Andrew's injury and certainly denied his family the money necessary to care for him.

Part I of this Note will examine the origins of the NCVIA, the VICP that it created, and the incentives that it put in place. Part II will look at how these incentives have led to bad results over the past thirty years, and how that dubious legacy has fueled a backlash that ironically threatens the health goals of the law. To conclude, the bad incentives inherent in the NCVIA made Andrew's story tragic and inevitable, and those incentives will continue to wreak havoc on families until Congress makes a substantial change to the NCVIA.

Vaccination is controversial for a number of reasons. The most widely-known controversy began in the 1990s when Dr. Andrew Wakefield published a now-retracted study in a medical journal linking the Mumps, Measles, and Rubella ("MMR") vaccine to autism.[28] There have been a number of other concerns raised over the safety of vaccines,[29] including concerns that the small amount of aluminum or mercury in vaccines accumulate to dangerously high levels after repeated injections.[30] In addition, there are religious objections to certain vaccines derived from aborted fetal tissue.[31] This Note takes no position on religious or medical objections to vaccination, and relies exclusively on generally accepted legal and medical knowledge concerning vaccination and its health risks when examining the NCVIA.

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28. Dr. Wakefield's paper was retracted by the publisher and denounced as fraud, and Dr. Wakefield lost his license to practice medicine. *See Retracted Autism Study an 'Elaborate Fraud,' British Journal Finds*, CNN (Jan. 5, 2011); *see also* T.S. Sathyanarayana Rao & Chittaranjan Andrade, *The MMR Vaccine and Autism: Sensation, Refutation, Retraction, and Fraud*, INDIAN J. PSYCHIATRY, Apr.–Jun. 2011, at 95. Dr. Andrew Wakefield has stood by his study. *See* Andrew Wakefield, *Dr. Andrew Wakefield Deals with Allegations*, VAXXED, http://vaxxedthemovie.com/dr-andrew-wakefield-deals-with-allegations/ (last visited Oct. 19, 2019); *see generally* Barry Belmont, *Anderson Cooper Interviews Andrew Wakefield*, YOUTUBE (Jan. 5, 2011), https://www.youtube.com/watch?v=l6kOxkPJfRM.

29. *See* Folb et al., *supra* note 9, at 1927–29 (discussion of some of the most prevalent concerns raised about vaccine safety).

30. *See id.* at 1929; *see also Thimerosal in Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html (last updated Oct. 27, 2015).

31. PONTIFICA ACADEMIA PRO VITA, MORAL REFLECTIONS ON VACCINES PREPARED FROM CELLS DERIVED FROM ABORTED HUMAN FOETUSES (2005), http://www.immunize.org/talking-about-vaccines/vaticandocument.htm.

PART I: THE NCVIA

A. *Born in Crisis*

Up until the 1980s, vaccination in the United States had broad public support.[32] The successful campaign against polio in the 1950s and the successful eradication of smallpox by 1980 were big wins for pharmaceutical companies, and public confidence in vaccines was high.[33] Between 1978 and 1981, there were only nine lawsuits filed against vaccine manufacturers for vaccine injuries.[34] Public confidence was shattered in 1982 when a documentary called "DPT Vaccine Roulette," produced by reporter Lea Thompson, aired locally in the Washington D.C. area on NBC affiliate WRC-TV and in excerpts on NBC's Today show.[35] The documentary won an Emmy nomination and drew national attention to the tendency of the Pertussis portion of the DPT vaccine to cause encephalopathy, a brain seizure disorder that can result in mental and physical retardation,[36] in a small number of patients.[37] Encephalopathy was, and remains today, a possible side effect of DPT.[38]

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32. *See Vaccine History: Developments by Year*, CHILD'S. HOSP. PHILA., https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year (last updated Mar. 7, 2019) (mentioning that Jonas Salk, the inventor of the polio vaccine, was hailed as a hero); *see also History of Smallpox*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/smallpox/history/history.html (last updated Aug. 30, 2016) (the worldwide eradication of smallpox is still considered the greatest achievement in public health).

33. *Vaccine History: Developments by Year*, *supra* note 32; *History of Smallpox*, *supra* note 32.

34. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1072 (2011).

35. Dona Hilts, *TV Report on Vaccine Stirs Bitter Controversy*, WASH. POST (Apr. 28, 1982), https://www.washingtonpost.com/archive/local/1982/04/28/tv-report-on-vaccine-stirs-bitter-controversy/80d1fc8a-1012-4732-a517-7976c86ab52d/?utm_term=.5ad0dfb35255; *see also* Elizabeth A. Breen, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 315 (1999); *see also* Vaccine News, *DPT Vaccine Roulette*, YOUTUBE (Feb. 25, 2016), https://www.youtube.com/watch?v=VDkeQKAnas8 (this clip contains a portion of the hour-long documentary).

36. *Encephalopathy Information Page*, NAT'L INST. NEUROLOGICAL DISORDERS & STROKE, https://www.ninds.nih.gov/Disorders/All-Disorders/Encephalopathy-Information-Page (last modified Mar. 27, 2019).

37. Breen, *supra* note 35, at 313; *see also Vaccine Information Statements*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html (last updated Apr. 5, 2019) (warning that there is a small chance the vaccines could cause a "severe allergic reaction, other serious injury, or death.").

38. *Compare* a warning label at issue in a vaccine case in 1988 before the NCVIA was implemented, *Hurley v. Lederle Laboratories*, 651 F. Supp. 993, 996 (E.D. Tex. 1986) ("[a]dverse reactions may be local and include pain . . . a transient shock-like episode, excessive screaming, somnolence, convulsions, *encephalopathy*, and thrombocytopenia"), *with* current package insert for INFANRIX, a DTaP vaccine produced by GlaxoSmithKline Biologicals, *Package Insert - INFANRIX*, FDA 1, 3, 12, https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf (last visited Oct. 19,

By 1986, more than 250 suits were filed for DPT related injuries,[39] causing some manufacturers to stop producing childhood vaccines, which created severe instability in the market.[40] One remaining manufacturer estimated that its liability was two hundred times larger than its annual vaccine sales.[41] This crisis in the vaccine market could have led to a severe shortage of DPT and Polio vaccines.[42]

At the peak of the crisis in 1986, Congress stepped in and passed the NCVIA.[43] It had two main goals: to adequately compensate children injured by vaccines, and to stabilize the vaccine market.[44] A substantial portion of the law was dedicated to creating the VICP,[45] which was intended to be a fast and generous alternative forum to the civil court system,[46] funded by a seventy-five cent excise tax on every vaccine dose administered.[47] The law effectively stabilized the market and brought a reduction to civil litigation,[48] but the incentives it put in place made it impossible for many of the families of injured children to quickly collect the compensation they needed.[49]

B. *Stability Through Effective Tort Immunity*

To stabilize the market, the drafters of the law included a number of provisions to keep the cases out of civil court and effectively provide vaccine manufacturers with tort immunity.[50] The most important provision is that all vaccine injury claims must be adjudicated through the VICP, under the jurisdiction of the United States Court of Federal Claims, before they can be

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2019) (listing encephalopathy as "a contraindication to administration of any pertussis-containing vaccine, including INFANRIX.").

39. Breen, *supra* note 35, at 319 n.84.

40. *Id.* at 315–16.

41. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1073 (2011).

42. Breen, *supra* note 35, at 315–16.

43. *See* 42 U.S.C. §§ 300aa-1–34 (2017); *see also* H.R. REP. NO. 99-908, at 3 (1986).

44. H.R. REP. NO. 99-908, at 7 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6348.

45. *Id.* at 12.

46. *Id.* at 13.

47. 26 U.S.C. § 4131(b)(1) (1997).

48. *See* Breen, *supra* note 35, at 319 n.84.

49. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-05-142, VACCINE INJURY COMPENSATION: MOST CLAIMS TOOK MULTIPLE YEARS AND MANY WERE SETTLED THROUGH NEGOTIATION 9–10 (2014) [hereinafter MOST CLAIMS TOOK MULTIPLE YEARS] (over half of claims took over five years); *see, e.g.*, *Compensating Vaccine Injuries*, *supra* note 12, at 22–26 (Ms. Clements's statement to Congress in 1999 about her son Andrew's ongoing claim from 1992).

50. *See* Breen, *supra* note 35, at 319 n.84.

brought in civil court under state law.[51] In 1855, Congress created the Court of Federal Claims in Washington, D.C.[52] and eventually gave it the authority to make final determinations in cases against the federal government without a jury.[53] It has since been granted jurisdiction over a myriad of claims, ranging from disputes over military pay to disputes concerning oyster grower insurance.[54] In the NCVIA, Congress gave the Court of Federal Claims jurisdiction over vaccine injury claims by requiring that injured persons bring his or her claims against the federal government, naming the Secretary of HHS as the respondent.[55] Vaccine manufacturers are not parties to litigation in the Court of Federal Claims;[56] injured persons can only bring a state-law claim against a vaccine manufacturer if their claim against the Secretary of HHS is dismissed or they refuse to accept a settlement in the Court of Federal Claims.[57]

The NCVIA contains certain provisions which severely limit the kinds of state-law claims that can be brought against vaccine manufacturers after an adjudication in the Court of Federal Claims.[58] The Supreme Court has held that the law effectively blocks actions based on products liability theory.[59] Products liability theory emerged as a way for plaintiffs to recover and hold manufacturers accountable for unsafe products.[60] The theory emerged as a response to the failures of traditional theories of warranty, privity of contract, and negligence to provide compensation in the face of complex modern manufacturing and distribution methods.[61] Products liability theory allows a

51. *See* 42 U.S.C. § 300aa-11(2)(A) (2017).

52. HEALTH RES. & SERVS. ADMIN., U.S. DEP'T HEALTH & HUMAN SERVS., WHAT YOU NEED TO KNOW ABOUT THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 4 (2016), https://www.hrsa.gov/sites/default/files/vaccinecompensation/resources/84521booklet.pdf.

53. U.S. COURT OF FED. CLAIMS, HISTORY BROCHURE 2, 4, http://www.uscfc.uscourts.gov/sites/default/files/USCFC%20Court%20History%20Brochure_1.pdf. (last visited Mar. 14, 2019).

54. *Chief Judge Margaret M. Sweeney*, U.S. COURT OF FED. CLAIMS, http://www.cofc.uscourts.gov/node/3055 (last visited Oct. 19, 2019).

55. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1073 (2011); *see* 42 U.S.C. § 300aa-11(a).

56. *See* 42 U.S.C. § 300aa-11(a)(3).

57. 42 U.S.C. § 300aa-11(a)(2); 42 U.S.C. § 300aa-21 (2017).

58. *See* 42 U.S.C. § 300aa-22 (2017).

59. *Bruesewitz*, 131 S. Ct. at 1075 ("State-law design-defect claims are . . . preempted" when the defects are unavoidable.).

60. *See* Edward S. Digges Jr. & John G. Billmyre, *Product Liability in Maryland: Traditional and Emerging Theories of Recovery and Defense*, 16 U. BALT. L. REV. 1, 2–5 (1986) (discussing the emergence of products liability theory).

61. *See* Greenman v. Yuba Power Products, Inc., 377 P.2d 897, 900–01 (Cal. 1963) (The court runs through the defects in traditional tort liability as applied to manufacturers and then applies strict liability in tort for the first time "to insure that the costs of injuries resulting from defective products are borne by the

plaintiff to sue if a product has a manufacturing defect, a design defect, or an insufficient warning.[62]

The NCVIA specifically blocks any cause of action based on a products liability theory arising from a design defect or insufficient warning.[63] It does this by blocking a suit over the design of the vaccine "if the injury or death resulted from side effects that were unavoidable."[64] The Supreme Court held in *Bruesewitz* that this language leaves the design of vaccines to the experts and prevents second-guessing about the safety of vaccines.[65] The NCVIA also blocks any cases brought over an insufficient warning.[66] The law clarifies that if a warning label meets all the requirements set forth by the Food and Drug Administration ("FDA"), then the manufacturer cannot be sued for inadequately warning the consumer of the vaccine.[67] The manufacturer also does not need to give a warning directly to the person who is in danger of being injured.[68] Since vaccines have a package insert that is approved by the FDA and available on the FDA's website,[69] it is difficult to bring a products liability action based on an insufficient warning.[70] In practical terms, the inability to bring a case based on a design defect or insufficient warning completely deprives people injured by vaccines from bringing a case in civil court.[71]

C. *The VICP: An Alternative to Civil Litigation*

Each vaccine case brought in the VICP is heard before a Special Master.[72] A Special Master is appointed by the judges of the Court of Federal Claims

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manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves.").

62. Digges, *supra* note 60, at 11.

63. *See* 42 U.S.C. § 300aa-22(b).

64. *Id.* § 300aa-22(b)(1).

65. *See* Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1080 (2011).

66. 42 U.S.C. § 300aa-22(b–c).

67. *Id.* § 300aa-22(b)(2).

68. *Id.* § 300aa-22(c).

69. *See Vaccines Licensed for Use in the United States*, FDA, https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm (last visited Oct. 26, 2019).

70. *Bruesewitz*, 131 S. Ct. at 1074.

71. Breen, *supra* note 35, at 319 n.84 (citing statistics that show a precipitous drop in the number of state-law claims filed since the law was passed).

72. 42 U.S.C. § 300aa-12(a) (2017). Unlike federal judges, who are appointed by the President with the advice and consent of the Senate, Special Masters are appointed by a majority vote of the judges of the Court of Federal Claims. *Frequently Asked Questions*, U.S. CT. FED. CL., http://www.cofc.uscourts.gov/faqs (last visited Oct. 26, 2019). The Special Masters are unique because they are the finders of fact in

and serve for terms of four years, although there are no term limits.[73] The Special Master is to address the issues and issue a decision within 240 days,[74] although the law permits some delays under certain circumstances.[75] If the injured party disagrees with the Special Master, then that party may file an appeal with the Court of Federal Claims.[76] Appeals rarely succeed because the standard of review for the factual determinations by the Special Master is abuse of discretion, although questions of law are reviewed de novo.[77] Once there has been a final determination by the Court of Federal Claims, the family may either accept the decision or pursue a state-law claim in the conventional court system.[78]

Perhaps the most effective way that the VICP discourages families from pursuing a case in civil court after their case has been dismissed by a Special Master is to award legal costs to petitioners, even if they lose.[79] Although the VICP allows more informal methods of introducing evidence, allowing the Special Master to forego routine oral arguments or even cross examination,[80] a Government Accountability Office ("GAO") report found in a survey that many claimants are dissatisfied with the process, finding it difficult and even "traumatic."[81] Parents who lose their cases face a dilemma: they can accept the attorney's fees and shoulder the burden of caring for their child without compensation, or they can double down and pursue a state-law case against the manufacturer without the ability to sue under products liability theory. It is not surprising that suits in civil court declined from a peak of over 250 in

all vaccine cases, and their findings of fact are only overturned on appeal if they are arbitrary and capricious. Milik v. Sec'y of Health & Human Servs., 822 F.3d 1367, 1376 (Fed. Cir. 2016).

73. *Vaccine Claims/Office of Special Masters*, *supra* note 27; *see also* 42 U.S.C. § 300aa-12(c).

74. 42 U.S.C. § 300aa-12(d)(3)(A)(ii).

75. *Bruesewitz*, 131 S. Ct. at 1073 n.14.

76. 42 U.S.C. § 300aa-12(e).

77. Boatmon v. Sec'y of Health & Human Servs., 138 Fed. Cl. 566, 570–71 (Fed. Cl. 2018).

78. *Bruesewitz*, 131 S. Ct. at 1073.

79. 42 U.S.C. § 300aa-15(e)(1) (2019); *see also* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 1, 8–9 (as of March 1, 2019, the government had awarded over $81 million in attorney's fees for dismissed cases).

80. 42 U.S.C. § 300aa-12(d)(2).

81. *See* MOST CLAIMS TOOK MULTIPLE YEARS, *supra* note 49, 29–30 (discussing comments about the VICP gathered from petitioners and stakeholders); *see also Compensating Vaccine Injuries*, *supra* note 12, at 6–8 (written opening statement of Chairman Rep. John L. Mica) (discussing the concerns that the committee had about the implementation of the NCVIA ten years into its existence).

1986, to just four by 1997,[82] even though two-thirds of vaccine injury petitions are dismissed by the Special Masters.[83]

The mechanism the VICP uses to create a no-fault compensation scheme for some injuries is the Vaccine Injury Table.[84] If a person can show that he or she took a vaccine and experienced a symptom on the table within a specified timeframe, then it is presumed that the vaccine caused the injury.[85] HHS has an opportunity to rebut this presumption by a preponderance of the evidence.[86] If the injury is off-table or appears outside of the specified timeframe, then the petitioner must prove causation by a preponderance of the evidence.[87] The Secretary of HHS has the authority to modify the Vaccine Injury Table by removing or adding symptoms or changing time-frames during which symptoms must appear.[88]

82. Breen, *supra* note 35, at 319 n.84.

83. *See* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 1.

84. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1073 (2011); 42 U.S.C. § 300aa-11(c)(1) (2016).

85. 42 U.S.C. § 300aa-11(c)(1) (2016); HEALTH RES. & SERVS. ADMIN., *supra* note 52, at 9.

86. *See* 42 U.S.C. § 300aa-13(a)(1) (2016).

87. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I–II); 42 U.S.C. § 300aa-13(a)(1)(A).

88. 42 U.S.C. § 300aa-14(c) (2016).

To illustrate, here is a portion of the current Vaccine Injury Table, revision effective March 21, 2017:[89]

National Childhood Vaccine Injury Act: Vaccine Injury Table

This table, supplemented with definitions and other explanatory material, can be found on the National Vaccine Injury Compensation Program's website at www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis	≤4 hours
	B. Brachial Neuritis	2-28 days (not less than 2 days and not more than 28 days)
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e.g.*, DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis	≤4 hours
	B. Encephalopathy or encephalitis	≤72 hours
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
III. Vaccines containing measles, mumps, and rubella virus or any of its components (*e.g.*, MMR, MM, MMRV)	A. Anaphylaxis	≤4 hours
	B. Encephalopathy or encephalitis	5-15 days (not less than 5 days and not more than 15 days)
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
IV. Vaccines containing rubella virus (*e.g.*, MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days)
V. Vaccines containing measles virus (e.g., MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days)
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient: - Vaccine-strain virus identified - If strain determination is not done or if laboratory testing is inconclusive	 Not applicable ≤12 months
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio - in a non-immunodeficient recipient - in an immunodeficient recipient - in a vaccine associated community case	 ≤30 days ≤6 months Not applicable
	B. Vaccine-Strain Polio Viral Infection - in a non-immunodeficient recipient - in an immunodeficient recipient - in a vaccine associated community case	 ≤30 days ≤6 months Not applicable
VII. Vaccines containing polio inactivated virus (*e.g.*, IPV)	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour

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89. NAT'L CTR. FOR IMMUNIZATION & RESPIRATORY DISEASES, CTRS. FOR DISEASE CONTROL & PREVENTION, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES App. D-7 (Jennifer Hamborsky et al. eds., 13th ed. 2015), https://www.cdc.gov/vaccines/pubs/pinkbook/index.html [hereinafter EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES].

The money for this alternative forum to civil litigation comes from a seventy-five-cent tax on every dose of an administered vaccine.[90] For combination shots, like DPT for example, each component is treated separately for taxing purposes.[91] The amount of revenue the excise tax brings in is not trivial.[92] A quarter of the excise tax, or approximately nineteen cents a dose, goes directly into the federal budget.[93] Between 2006 and 2017, over 3.4 billion vaccine doses were administered, contributing approximately $637 million directly to the federal budget.[94] The other three quarters of the collected tax goes into the Vaccine Injury Trust Fund and is used to pay for compensation and administrative costs.[95] Even though the program has awarded approximately $4 billion in compensation and attorney's fees since its inception,[96] as of February 1, 2019, the fund held surplus assets of over $3.8 billion.[97] That means the tax has generated approximately over a $125 million surplus on average every year for the last thirty years.[98] These surplus assets are loaned to the Treasury to pay for other federal programs.[99]

In its 1999 report on the NCVIA, the GAO included a diagram designed to demonstrate what happened with the money that was collected from the excise tax.[100] Although the numbers on the chart have their limitations because they only represent the program for the ten-year period from 1989 to 1999, the chart provides a good visual aid for understanding how the tax money flows through the program and into the general federal budget.[101]

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90. *See* 26 U.S.C. § 4131 (2017).

91. *Id.* (For the purposes of this Note, a dose is counted the same way it is taxed, so one shot of DPT would be considered three doses. There is some controversy about counting doses in this fashion, *see infra* note 130.).

92. *See* U.S. GEN. ACCOUNTING OFF., GAO/HEHS-00-8, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 16 (1999).

93. *Id.* at 16 n.17.

94. *See* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 1 (divide the seventy-five-cent per dose tax by four and multiply by 3.4 billion to arrive at $637 million).

95. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 16.

96. NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 1.

97. *See* TREASURY DIRECT, VACCINE INJURY TRUST FUND FEBRUARY 2019 6 (Feb. 28, 2019), https://www.treasurydirect.gov/govt/reports/tfmp/vaccomp/vaccomp.htm.

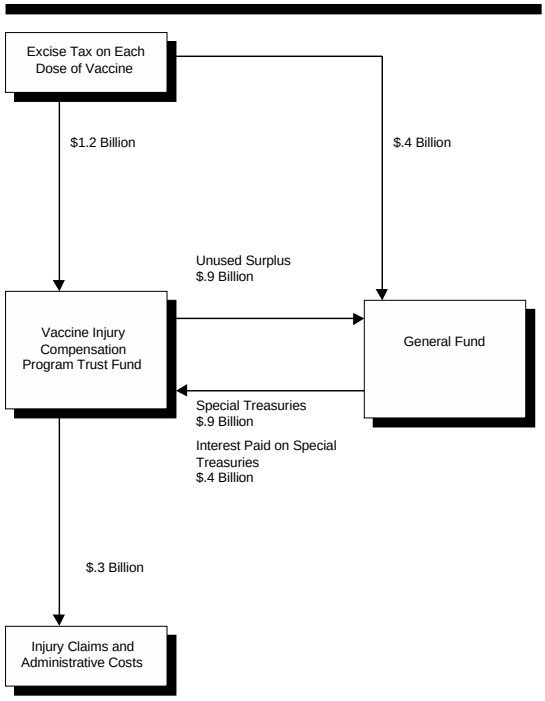
98. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 16–17 (divide the total surplus by the thirty-year life of the fund).

99. *Id.* at 16.

100. *Id.* at 17.

101. *Id.*

Figure 3: Money Flows Attributable to Vaccine Excise Taxes Collected From Fiscal Year 1989 Through Fiscal Year 1998



The NCVIA excited a number of people when it first came out.[102] Many hoped that the new law would both fairly compensate the injured and protect public health by ensuring a steady supply of vaccines.[103] Congress intended the NCVIA to benefit children generally by stabilizing a market in crisis,[104] and generously compensate individual children unfortunately injured.[105] The incentives woven into the fabric of the law succeeded in bringing stability to the market, but the law also encouraged pharmaceutical companies and the government to accomplish their goals at the expense of injured children.

102. *See generally* Mary Beth Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149 (1988) (discussing advantages of the VICP over traditional tort litigation).

103. H.R. REP. NO. 99-908, at 7 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6348.

104. *See id.*

105. *Compensating Vaccine Injuries*, *supra* note 12, at 9 (statement of Congressman Waxman, sponsor of NCVIA) ("[W]e wanted to give parents confidence that if their child were to be injured by a vaccine, there would be predictable and generous compensation.").

D. *The Problem of Moral Hazard*

Moral hazard is a term that arises out of the insurance industry and was originally used as a way of describing the temptation a business owner would have to burn down their place of business once the value of the insurance exceeded the value of the business as a going concern.[106] This term is now used more generally to describe the temptation that arises when the negative consequences of one person's actions are borne by another.[107] Moral hazard exists because "the more and better insurance that is provided against some contingency, the less incentive individuals have to avoid the insured event, because the less they bear the full consequences of their actions."[108] In the insurance paradigm, a multitude of individual policy-holders are tempted to be careless because their costs are borne by one deep pocket, the insurance company.[109]

In the context of the NCVIA, the paradigm has been turned on its head as the deep pocket, the pharmaceutical company, is tempted to be careless because its costs are borne by the children who take the vaccine, along with everyone who pays the excise tax. The law has worked as designed to keep cases out of civil court,[110] providing manufacturers with effective immunity from tort liability.[111] This immunity was designed to increase the potential profits of vaccines and encourage pharmaceutical companies to develop more vaccines and distribute them more widely, but immunity from liability also eliminates the pharmaceutical companies' incentives to improve current vaccines and to design and bring new vaccines to the market carefully.[112]

The most important bulwark against moral hazard is a relationship with the party bearing the cost.[113] A personal relationship can motivate a person to deal fairly with friends or co-workers when that same person will cheat on

106. *See* Tom Baker, *On the Genealogy of Moral Hazard*, 75 TEX. L. REV. 237, 250–51 (1996).

107. *Id.* at 272.

108. Joseph E. Stiglitz, *Risk, Incentives and Insurance: The Pure Theory of Moral Hazard*, 8 GENEVA PAPERS ON RISK & INS. 4, 6 (1983).

109. *See generally id.*; Baker, *supra* note 106.

110. H.R. REP. NO. 99-908, at 12 (1986), *as reprinted in* U.S.C.C.A.N. 6344, 6353; *see* Breen, *supra* note 35, at 319 n.84 (discussing the decline in suits brought against vaccine manufacturers after the passage of the NCVIA).

111. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1085 (2011) (Breyer, J., concurring).

112. *See id.* at 1101 (Sotomayor, J., dissenting) ("Manufacturers, given the lack of robust competition in the vaccine market, will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins.").

113. *See* Stiglitz, *supra* note 108, at 29.

their taxes or game a government program given the opportunity.[114] Pharmaceutical companies are not people; they are not capable of having the sort of relationships that serve as a bulwark against moral hazard. The primary purpose of any corporation is to benefit the shareholders by maximizing profits.[115]

E. *The Problem of Conflicting Government Interests*

Another problem with the NCVIA arises because the HHS has strong incentives to limit compensation.[116] HHS's goal is to achieve herd immunity by ensuring that as many children as possible are vaccinated,[117] and there is a concern that compensation of injured children undermines public confidence in vaccines and gives the impression that they are not safe.[118] Loss of public confidence in the safety of vaccines leads to lower vaccination rates and outbreaks of disease,[119] so HHS uses its power to limit compensation to protect public confidence.[120] Preventing compensation serves another goal, a

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114. *Id.*; *see, e.g.*, Jeremy Kohler, *Disability Pensions Allow Some Firefighters to Collect While Working Elsewhere*, ST. LOUIS POST-DISPATCH (Feb. 19, 2012), https://www.stltoday.com/news/local/metro/disability-pensions-allow-some-firefighters-to-collect-while-working-elsewhere/article_6b69107e-cf70-5d39-bfc0-2c8e6a10df04.html; Donovan Slack & Walter V. Robinson, *US Probes Firefighter Disability Abuse*, BOS. GLOBE (Apr. 17, 2008), http://archive.boston.com/news/local/articles/2008/04/17/us_probes_firefighter_disability_abuse/.

115. Dodge v. Ford Motor Co., 170 N.W. 668, 684 (Mich. 1919). *But see* Harwell Wells, *The Purpose of a Corporation: A Brief History*, TEMP. 10-Q, Jan. 16, 2014.

116. There is a fear that compensation undermines public confidence in vaccines, *see* comment by the former medical director of the VICP, Geoffrey Evans *infra* note 118, and that lower public confidence will result in outbreaks of disease, *see* EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES *infra* note 119. Additionally, limiting compensation allows tax revenue brought in from the vaccine excise tax and originally slated for victim compensation to be reallocated to the federal general fund. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 18–19.

117. *See Vaccines Protect Your Community*, *supra* note 6.

118. Arthur Allen, *Shots in the Dark*, WASH. POST (Aug. 30, 1998), http://www.washingtonpost.com/wpsrv/national/longterm/sunmag/shots/shot2.htm (Geoffrey Evans, the medical director of the VICP in 1999 stated "I'm not going to say that awarding too many people will undermine vaccine safety, but I look on the Internet, and I see that our statistics are taken out of context."); *see, e.g.*, Dena Schmidt, *Vaccine Injury Payouts Exceed $4 Billion, Yet Most People Remain Uninformed About the Risks Linked to Vaccinations*, NATURALHEALTH365 (Dec. 1, 2018), https://www.naturalhealth365.com/vaccine-injury-2788.html (anti-vaccination site citing the total compensation awarded by the VICP in argument that vaccines are unsafe).

119. EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 89, at 48.

120. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 12–15 (indicating that HHS changed the vaccine table to reduce the number of petitioners who would receive compensation); MOST CLAIMS TOOK MULTIPLE YEARS, *supra* note 49, at 31 (indicating HHS has deliberately kept the program relatively unknown to reduce the number of petitioners who would receive compensation); *see also* Moxley *infra* note

financial one. Since the surplus $3.8 billion in the Vaccine Injury Trust Fund is loaned to the Treasury and used for other government programs,[121] if the HHS does not keep awards low, the government could face potential tax increases or spending cuts.[122]

HHS has the authority to change the rules governing the adjudication by unilaterally modifying the Vaccine Injury Table,[123] without any duty to do so in a transparent manner.[124] Modifying the Vaccine Injury Table changes who has the burden of either proving or disproving causation.[125] HHS has used this power, along with the power it has as the opposing party in the suit,[126] to pursue its goals through a process which many have considered adversarial,[127] despite the fact that as an executive government agency it should be helping to implement the desire of Congress to compensate injured people "quickly, easily, and with certainty and generosity."[128]

HHS frames vaccine injuries as extremely rare, with only one compensable claim for every million doses administered.[129] This statistic is misleading simply because the current vaccine schedule recommends over sixty doses per child.[130] But, it is also important to note that this impressive

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127 (former vaccine attorney criticizing HHS for denying the existence of vaccine injuries to protect their view of public health).

121. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 18–19.

122. *Id.*

123. *See* 42 U.S.C. § 300aa-14(c)(1) (2017); *see generally* O'Connell v. Shalala, 79 F.3d 170, 182 (1st Cir. 1996).

124. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 3.

125. *Id.* at 12.

126. *See* 42 U.S.C. § 300aa-12(b)(1).

127. *See* MOST CLAIMS TOOK MULTIPLE YEARS, *supra* note 49, at 29–30; U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 12–15; *see also* Robert Moxley, *The 'Vaccine Court' is Hazardous to Your Health*, AM. CONSERVATIVE (Mar. 30, 2017), https://www.theamericanconservative.com/articles/the-vaccine-court-is-hazardous-to-your-health/.

128. H.R. REP. NO. 99-908, at 3 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6344.

129. NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 1 (between 2006 and 2017, for every million doses that were administered, one person was compensated).

130. *See Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2019*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html (last visited Oct. 26, 2019) [hereinafter *Recommended Immunization Schedule*]. There is some debate as to what constitutes a dose because of the combination vaccines like MMR and DTaP. *Compare CDC Recommended Childhood Vaccine Schedule: 1983 vs 2017*, NAT'L VACCINE INFO. CTR., (last updated Jan. 2018), https://www.nvic.org/cmstemplates/nvic/pdf/downloads/1983-2017-vaccine-schedules.pdf (an infographic from an anti-vaccine website counting each antigen as a dose and comparing the current number of doses administered to the number of doses given in 1983, *with* Vincent Iannelli, *Do Kids Really Get 72 Doses of Vaccines?*, VAXOPEDIA (July 15, 2018), https://vaxopedia.org/2018/07/15/do-kids-really-get-72-doses-of-vaccines/ (pro-vaccine blogger arguing

ratio is a fragile one and would be dramatically adjusted with a relatively small increase in the number of people who are compensated.[131] This creates a temptation for HHS to dismiss as many claims as possible, even unfairly, to keep confidence high.

Since HHS is strongly motivated to maintain public confidence in vaccines[132] and maintain herd immunity,[133] the government has little incentive to publicly criticize the safety of vaccines. The NCVIA does require HHS to promote the development of safer vaccines and issue a report to Congress periodically;[134] however, in the thirty years since the NCVIA was passed, HHS has never issued a report to Congress as required by law.[135] Although there are groups that look at the safety of vaccines,[136] especially new ones,[137] HHS has not made examining the safety of existing vaccines a priority, and according to the President of the Institute of Medicine, there is a "paucity of strong conclusions about possible vaccine side effects."[138] Vaccines are beneficial to society in general, but they have a real cost to a small number of individuals; the inventive structure of the NCVIA motivates pharmaceutical companies and the government to push that cost onto the injured children and their families.

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that counting a combination shot as multiple doses is propaganda to scare parents). Since combination vaccines like DPT are taxed as multiple doses, *see* 26 U.S.C. § 4131 (2017), for the purposes of this Note each component of a combination shot is treated as a separate dose.

131. From 2006 to 2009, the average number of compensated claims was approximately 106 per year. This number has trended higher so that from 2015 to 2018 the average number of compensated claims per year was 606. *See* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 8–9. If this recent upward trend continues, then the ratio of compensable claims to doses administered could fall dramatically.

132. *See* EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 89, at 48.

133. *See Vaccines Protect Your Community*, *supra* note 6; Helft & Willingham, *supra* note 6.

134. 42 U.S.C. § 300aa-27 (2017).

135. HHS stipulated that it had never submitted a report in response to a FOIA request made by an anti-vax group called ICAN. *See* Press Release, ICAN, U.S. Dist. Judge Signs Order Granting Plaintiff, ICAN, and Counsel, Robert F. Kennedy, Jr., the Relief Sought in a Lawsuit Against the HHS (July 13, 2018), https://olis.leg.state.or.us/liz/2019R1/Downloads/CommitteeMeetingDocument/168629 (publishing stipulation filed in court accompanied by a press release).

136. *See* Dorit Rubinstein Reiss, *Anti-Vaccine ICAN Settles with HHS - What Does This Mean for Vaccines?*, SKEPTICAL RAPTOR (July 13, 2018), https://www.skepticalraptor.com/skepticalraptorblog.php/anti-vaccine-ican-settles-hhs-meaning/.

137. *See Making the Vaccine Decision: Addressing Common Concerns*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/parents/vaccine-decision/index.html (last visited Oct. 26, 2019).

138. Harvey Fineberg, *Vaccine Safety: Evidence and Belief*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/nvpo/national-vaccine-plan/annual-report-2013/goal-2/vaccine-safety-evidence-and-belief/index.html (last visited Oct. 26, 2019).

PART II: THE EFFECTS OF NCVIA

A. *Pharmaceutical Companies Make More Vaccines and More Profits*

The NCVIA ensures that producing vaccines continues to be a profitable business[139] for pharmaceutical companies as it removes the potential downside of tort liability. Here we can see, unsurprisingly, that the childhood vaccination schedule has doubled the number of diseases vaccinated against, and the number of doses has almost tripled.[140] Since every vaccine shot carries some risk, this expansion of the vaccine schedule has increased the risk of injury. The number of children compensated for vaccine injuries in the last ten years has gone up, from an average of ninety-two a year from 2000 to 2009, to an approximate average of 426 a year from 2010 to 2018.[141] This increase in the number of injured people has not dampened sales, as the top four vaccine manufacturers brought in over $25 billion in vaccine sales for 2017.[142] The top vaccine manufacturer, GlaxoSmithKline, which had approximately $7 billion in sales,[143] had an operating profit margin of over 31.9%, making £1.644 billion in 2017 (approximately $2.7 billion).[144]

Justice Sotomayor points out in her dissent to *Bruesewitz* that protecting vaccine manufacturers from liability will have an unintended consequence: these companies "will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins."[145] If past is prologue, then Justice Sotomayor's concerns are well founded. The increase in cases of encephalopathy related to the whole cell Pertussis found in DPT

139. Bourree Lam, *Vaccines Are Profitable, So What?*, ATLANTIC (Feb. 10, 2015), https://www.theatlantic.com/business/archive/2015/02/vaccines-are-profitable-so-what/385214/.

140. *Compare Recommended Immunization Schedule*, *supra* note 130 (showing over sixty doses recommended), *with 1989 Childhood Immunization Schedule*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/schedules/images/schedule1989s.jpg (last visited Oct. 26, 2019).

141. NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 8–9. The Office of Special Masters has attributed this increase to injury claims from the flu vaccine, which was added to the injury table in the fiscal year of 2005. MOST CLAIMS TOOK MULTIPLE YEARS, *supra* note 49, at 25.

142. Eric Sagonowsky, *GlaxoSmithKline Tops Its Peers with $7.16B in 2017 Vaccine Sales*, FIERCEPHARMA (Feb. 13, 2018), https://www.fiercepharma.com/vaccines/glaxosmithkline-tops-its-peers-7-16b-2017-vaccine-sales.

143. *Id.*

144. GLAXOSMITHKLINE PLC, FILE NO. 1-15170, ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 (Form 20-F) 20 (Mar. 15, 2019), https://www.sec.gov/Archives/edgar/data/1131399/000119312518086062/d516109d20f.htm.

145. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1101 (2011) (Sotomayor, J., dissenting).

produced different reactions in other countries.[146] Where the United States created legislation to stabilize the market and compensate the injured,[147] Japan partially discontinued use of DPT in the 1970s until an acellular version of the Pertussis vaccine, with a far lower incidence rate of encephalopathy, became available in Japan in 1981.[148]

In the United States, an acellular version of the vaccine was not registered for widespread use until 1996.[149] Almost 4,000 claimants brought claims in the vaccine court for injuries relating to the whole cellular Pertussis vaccine in the eight years after the implementation of the VICP in 1988.[150] Fewer than 1,000 have brought claims in the last twenty-two years after the introduction of acellular Pertussis.[151] This means that the vast majority of the children injured by DPT from 1988 to 1996 would not have been seriously injured if they had been given the acellular version of the shot, which was already in use in Japan.[152] If the pharmaceutical companies had not been given effective immunity through the NCVIA, then the acellular version of DPT ("DTaP") probably would have been made available earlier and prevented many cases of encephalitis, including the one affecting Andrew Clements.[153]

The distortion of risk in the marketplace also affects which vaccines are brought to market.[154] A good example is the contrast in how chickenpox is treated in the United States, as opposed to its treatment in the United

146. *See* Tetsuo Nakayama, *Vaccine Chronicle in Japan*, 19 J. INFECTION & CHEMOTHERAPY 787, 793 (2013).

147. H.R. REP. NO. 99-908, at 7 (1986), *as reprinted in* U.S.C.C.A.N. 6344, 6348.

148. Nakayama, *supra* note 146, at 792–93; *see also* Allen, *supra* note 118.

149. MORBIDITY & MORTALITY WEEKLY REPORT, CTRS. FOR DISEASE CONTROL & PREVENTION, PERTUSSIS VACCINATION: USE OF ACELLULAR PERTUSSIS VACCINES AMONG INFANTS AND YOUNG CHILDREN, PUB. NO. 46(RR-7); 1-25 (Mar. 28, 1997), https://www.cdc.gov/mmwr/preview/mmwrhtml/00048610.htm.

150. *See* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 5.

151. *Id.*

152. Since there were no changes to Diphtheria or Tetanus, we can make a comparison of the likelihood of an injury complaint from the shot before and after the acellular version was introduced. Four thousand claims for injuries due to DPT were made over an eight-year period for an average of 500 a year. *See id.* Whereas approximately only twenty-five to thirty-two cases a year were brought for DTaP from the time it began to today (the number varies depending on whether or not complaints for larger combinations including DTaP are included). *See id.* This means that as many as 475 cases a year, or 95%, were attributable to whole cell pertussis.

153. *See, e.g.*, *Compensating Vaccine Injuries*, *supra* note 12, at 20–21.

154. *Compare Why Are Children in the UK Not Vaccinated Against Chickenpox? infra* note 155, (noting the absence of the chickenpox vaccine in the United Kingdom), *with Recommended Immunization Schedule*, *supra* note 130, *and* Goldman & King *infra* note 158 (discussing extensive use of vaccine in United States despite its negative effects).

Kingdom.[155] Chickenpox used to be contracted by almost every person in his or her childhood and rarely resulted in serious side effects.[156] The Varicella vaccine, designed to eliminate chickenpox, was licensed for use in 1995.[157] Administering the vaccine to children, however, has an unintended effect of increasing the likelihood that adults will contract shingles,[158] which is a far more serious illness.[159]

Apparently, encountering the chickenpox virus provides a natural boost to the immune system for people who contracted the illness as children, and this in turn prevents the virus from emerging from dormancy and causing shingles.[160] Widespread vaccinations prevent this natural boosting,[161] and arguably has led to a steady increase in the incidence of shingles so that one in three Americans currently experience this serious illness.[162] The Center for Disease Control ("CDC") does not acknowledge this connection,[163] but the National Health Service ("NHS") in the United Kingdom has found evidence of the connection compelling enough to keep the vaccine out of their schedule.[164]

One pharmaceutical company, Merck, made $774 million in 2018 selling *Varivax*, the vaccine that prevents the chickenpox from circulating.[165] The pharmaceutical giant, GlaxoSmithKline, has capitalized on the problem

155. *Compare Why Are Children in the UK Not Vaccinated Against Chickenpox?*, NHS (Sept. 20, 2016), https://www.nhs.uk/common-health-questions/childrens-health/why-are-children-in-the-uk-not-vaccinated-against-chickenpox/, *with Chickenpox Vaccination: What Everyone Should Know*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/vpd/varicella/public/index.html (last reviewed Aug. 7, 2019).

156. EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 89, at 359.

157. *Id.* at 353.

158. *Why Are Children in the UK Not Vaccinated Against Chickenpox?*, *supra* note 155; *see also* G.S. Goldman & P.G. King, *Review of the United States Universal Varicella Vaccination Program*, 31 VACCINE 1680, 1685–86 (2013).

159. *Shingles (Herpes Zoster Infection; HZ)*, HEALTH ENGINE (Dec. 27, 2003), https://www.myvmc.com/diseases/shingles-herpes-zoster-hz/.

160. *Why Are Children in the UK Not Vaccinated Against Chickenpox?*, *supra* note 155.

161. *Id.*

162. *Shingles (Herpes Zoster)*, CTRS. FOR DISEASE PREVENTION & CONTROL, https://www.cdc.gov/shingles/surveillance.html (last reviewed Aug. 14, 2019).

163. *See id.*

164. *Why Are Children in the UK Not Vaccinated Against Chickenpox?*, *supra* note 155.

165. MERCK & CO., INC. FILE NO. 1-6571, ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 (Form 10-K) 42 (Feb. 27, 2019), https://www.sec.gov/Archives/edgar/data/310158/000031015819000014/mrk1231201810k.htm.

created by the chickenpox vaccine by issuing a new vaccine for shingles which had a blockbuster year in 2018.[166]

The effective immunity given to vaccine manufacturers changes their behavior. It removes an important incentive to improve the safety of existing profitable vaccines and encourages the pharmaceutical companies to bring as many vaccines to market as possible. With an ample supply of lobbyists and over $283 million in campaign contributions by the pharmaceutical industry in 2018,[167] it is very likely that the vaccine schedule will continue to expand as new vaccines are developed.

B. *The Injured Go Without Compensation*

The HHS has two reasons to take an adversarial posture toward claimants: keeping payments low protects confidence in vaccines and valuable tax revenue.[168] There is a misconception that the money raised by the excise tax on vaccines sits in the fund and waits to be distributed as awards or administrative costs, and, therefore, a surplus in the fund should make pursuing a claim for that money easier because HHS has no financial reason to block compensation.[169] However, the surplus money in the fund is loaned to the Treasury department,[170] and when it leaves the vaccine injury fund and enters the general treasury fund it becomes fungible and effectively acts as tax revenue.[171] This means that awarding more compensation "would have implications for the overall federal budget, possibly requiring new or higher taxes elsewhere or a decrease in spending for other programs and activities."[172] The government's lawyers are not merely safeguarding a fund against weak or fraudulent claims, but zealously protecting a reliable revenue stream.

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166. *See* GLAXOSMITHKLINE PLC, REPORT OF FOREIGN ISSUER PURSUANT TO RULE 13A-16 OR 15D-16 OF THE SECURITIES EXCHANGE ACT OF 1934 (FORM 6-K), (Feb. 6, 2019), https://www.sec.gov/Archives/edgar/data/1131399/000165495419001110/a2711pfr.htm (reporting sales of *Shingrix* of £784 million, approximately $1.04 billion).

167. Ctr. for Responsive Politics, *Pharmaceutical/Health Products*, OPENSECRETS, https://www.opensecrets.org/lobby/indusclient.php?id=H04 (last visited Oct. 30, 2019).

168. *See* Allen, *supra* note 118.

169. *Compensating Vaccine Injuries*, *supra* note 12, at 44 (Rep. Burton remarking that the purpose of the fund was to create a non-adversarial process) ("[The] adversarial relationship that has been created should not be happening, because that was not the purpose of the fund.").

170. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 18.

171. *Id.* at 18–19.

172. *Id.* at 3.

The second goal is to maintain high public confidence in the safety and efficacy of vaccines,[173] because vaccination rates are needed to maintain herd immunity.[174] High payouts from the vaccine injury fund fuel doubts about the safety of vaccines,[175] and so it is in the interests of the HHS to reduce payouts. In a 2014 report, the GAO highlighted criticism that HHS has faced for keeping the VICP relatively unknown,[176] and the report included concerns that public unawareness of the program has caused injured people to lose their legitimate claims because they miss their deadline to file.[177] This failure to notify the public comes from a fear that people who are educated about the program will jump to the conclusion that vaccines are dangerous and stop vaccinating.[178]

The most controversial method that HHS has used to reduce the number of compensable injuries is to narrow the definition of what is a compensable injury.[179] The NCVIA grants HHS the power to alter the Vaccine Injury Table.[180] Altering the table is a powerful tool because if someone's symptoms do not fit the table, he or she must prove, through a preponderance of the evidence, that the vaccine was the cause-in-fact of the injury.[181] Proving causation in vaccine cases is "elusive."[182] It is not enough to show an absence of some other cause,[183] or that the injury occurred shortly after the vaccination.[184] Causation requires that "epidemiological evidence and the particular vaccinee's clinical picture substantiate that conclusion."[185] Out of

173. National Vaccine Advisory Committee, *Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory Committee*, 130 PUB. HEALTH REPS. 573, 576 (2015).

174. *See* Helft & Willingham, *supra* note 6.

175. *See* Allen, *supra* note 118.

176. *See* MOST CLAIMS TOOK MULTIPLE YEARS, *supra* note 49, at 31.

177. *Id.* at 32.

178. Anders Kelto, *Vaccine Court Aims to Protect Patients and Vaccines*, NPR (Jun. 2, 2015), https://www.npr.org/sections/health-shots/2015/06/02/411243242/vaccine-court-aims-to-protect-patients-and-vaccines.

179. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 15.

180. 42 U.S.C. § 300aa-14(c)(1) (2017).

181. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(2016); 42 U.S.C. § 300aa-13(a)(1)(2016); Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1074 (2011).

182. Allen, *supra* note 118.

183. *See* Clements v. Sec'y of Dep't of Health & Human Servs., No. 95-484V, 1998 WL 481881, at *11 (Fed. Cl. July 30, 1998) (quoting Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1149 (Fed Cir. 1992)).

184. *Id.* (citing Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983)).

185. *Id.*

all of the cases where an injured person receives compensation, HHS only concedes that the vaccine medically caused the injury in 30% of cases.[186]

The original Vaccine Injury Table included encephalopathy as one of the compensable injuries that could result from a vaccine for Pertussis, Measles, Mumps, Rubella, or Tetanus,[187] and furthermore defined encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain."[188] In 1995, HHS tightened the requirements for encephalopathy so that a seizure had to result in a change in consciousness that endured longer than twenty-four hours.[189] HHS also specifically eliminated residual seizure disorder from the Vaccine Injury Table, which had accounted for over $450 million, approximately half of the money awarded through the program at that time.[190] HHS made these changes after the Institute of Medicine reviewed medical literature in 1991 and 1994 to determine which conditions were caused by vaccination.[191] A GAO report in 1999 pointed out that HHS did not apply the findings of the Institute of Medicine consistently.[192] HHS added some, but not all, of the injures that the Institute of Medicine determined were caused by vaccines.[193] HHS also removed residual seizure disorder because the Institute of Medicine "found the evidence inadequate to accept or reject a causal relation between vaccines and residual seizure disorder," but it did not remove every injury that received this designation from the Institute of Medicine.[194]

Andrew Clements, whose first seizure started fifteen hours after he received the DPT vaccine, and who had approximately eighty more seizures over the next three years before an acute seizure crippled him, had his claim dismissed because he could not provide sufficient proof that the DPT vaccine was the cause of his seizure disorder.[195] The Special Master informed Andrew's mother that under the previous definition Andrew would have

186. NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 1.

187. 42 U.S.C. § 300aa-14(a) (1988).

188. 42 U.S.C. § 300aa-14(b)(3)(A).

189. *Compare* the Vaccine Injury Table issued with the original legislation, 42 U.S.C. § 300aa-14, *with* the current *Vaccine Injury Table*, HRSA 4–5 (Mar. 21, 2017), https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf.; *see also* Allen, *supra* note 118.

190. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 14.

191. *Id.* at 12–13.

192. *Id.* at 15–16.

193. *Id.*

194. *Id.*

195. Clements v. Sec'y of Dep't of Health & Human Servs., No. 95-484V, 1998 WL 481881, at *1, 3, 15 (Fed. Cl. July 30, 1998).

received compensation,[196] but because Andrew's family filed after the rule change on March 10, 1995, they had the burden of proving the vaccine caused the injury.[197] Despite the fact that HHS is a party in all vaccine cases, the First Circuit of the United States Court of Appeals held that it has the unilateral power to redefine what is considered a vaccine injury by altering the Vaccine Injury Table.[198] HHS continued to reduce the number of compensable injuries to such an extent that a GAO report found that between 2009 and 2014, 98% of new claims were off-table.[199]

Another way HHS reduces compensable injuries is to exhaust the resources of the claimants by dragging out the process for years, despite the fact that the NCVIA was designed to finish the process within 240 days.[200] In a GAO report issued in 2014, over half of the cases which had been brought in the preceding ten years had taken over five years to adjudicate.[201] Considering that the VICP was intended to be an expeditious alternative to the civil tort system,[202] it is ironic that a vaccine case will often take longer than the average medical malpractice suit.[203] In litigation, having more resources gives a party a significant edge,[204] and the difference in resources between the parents of injured children and HHS is stark.

HHS's goal has been to limit the number of people it compensates, and the results speak for themselves because two-thirds of claimants have been dismissed.[205] In the 1999 GAO report, only thirty-five percent of on-table claims received compensation, even though causation was presumed.[206] Off-table injures were compensated at a rate of 13%.[207] And, for those few cases

196. *Compensating Vaccine Injuries*, *supra* note 12, at 21.

197. *Clements*, 1998 WL 481881, at *1 n.2.

198. O'Connell v. Shalala, 79 F.3d 170, 181–82 (1st Cir. 1996).

199. *See* MOST CLAIMS TOOK MULTIPLE YEARS, *supra* note 49, at 20.

200. 42 U.S.C. § 300aa-12(d)(3)(A)(ii) (2017).

201. *See* MOST CLAIMS TOOK MULTIPLE YEARS, *supra* note 49, at i.

202. H.R. REP. NO. 99-908, at 3, 13 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6344, 6353.

203. Martindale-Nolo Research, *How Long Does a Medical Malpractice Case Take?*, LAWYERS.COM, https://www.lawyers.com/legal-info/medical-malpractice/average-compensation-and-duration/medical-malpractice-how-long-will-my-case-take.html (last visited Sept. 16, 2019).

204. Albert Yoon, *The Importance of Litigant Wealth*, 59 DEPAUL L. REV. 649, 652 (2010).

205. *See* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 1.

206. *See* U.S. GEN. ACCOUNTING OFF., *supra* note 92, at 12.

207. *Id.*

where compensation was given, only 30% received the satisfaction of having HHS concede that the vaccine caused the injury.[208]

C. *The Loss of Public Trust and Recent Outbreaks of the Measles*

A third effect of the law is a growing mistrust of vaccines and vaccine manufacturers in the public.[209] As Justice Scalia wrote in his opinion in *Bruesewitz*, vaccine manufacturers have been "victims of their own success" as the reduced incidence or even virtual elimination of certain diseases and increased quality of medical care have made parents less fearful of illnesses, and more fearful of possible side effects of vaccines.[210] Since children are required to get vaccinated to attend most schools, childhood vaccines are effectively mandatory for nearly all Americans.[211] Vaccination rates in the United States are high;[212] however, people are objecting to vaccines in record numbers.[213]

Dropping use of vaccines in the West has contributed to Measles outbreaks in Europe.[214] It has also resulted in a rash of outbreaks in the United States, usually in communities where vaccination rates are low.[215] The reemergence of Measles in the United States was a big story in the news during 2018 and 2019, creating something close to panic.[216] Some people have made the

208. *See* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 1.

209. *See* Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1072 (2011).

210. *Id.*

211. *State Vaccination Requirements*, *supra* note 23.

212. *Immunization*, *supra* note 24.

213. *See* Maggie Fox, *Vaccine Rates Are Up, But So Are Refusals*, NBC NEWS (Jan. 18, 2018), https://www.nbcnews.com/health/health-news/vaccine-rates-are-so-are-refusals-n838811.

214. Helen Stokes-Lampard, *Anti-Vaxxers Are Still Spreading False Claims as People Die of Measles*, GUARDIAN (Aug. 21, 2018), https://www.theguardian.com/commentisfree/2018/aug/21/anti-vaxxers-measles-mmr-vaccine-gp-online; Jason Beaubien, *Measles Cases Rise Globally with Spikes in the Middle East, Europe and the Americas*, NPR (Dec. 3, 2018), https://www.npr.org/2018/12/03/673022649/measles-cases-rise-globally-with-spikes-in-the-middle-east-europe-and-the-americ.

215. *Measles (Rubeola)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/measles/cases-outbreaks.html (last visited Mar. 15, 2019) (372 cases have been reported for 2018, the second highest since 2010).

216. *See, e.g.*, *Editorial: The Anti-Vaxx Movement Is a Worldwide Pandemic*, L.A. TIMES (Feb. 6, 2019), https://www.latimes.com/opinion/editorials/la-ed-global-vaccine-hesitancy-20190206-story.html; Alexia Lardieri, *New York Yeshivas Face Fines, Restrictions Amid Measles Outbreak*, U.S. NEWS & WORLD REP. (Dec. 14, 2018), https://www.usnews.com/news/health-news/articles/2018-12-14/new-york-yeshivas-face-fines-amid-measles-outbreak-for-not-iding-unvaccinated-students.

argument that no one should have the freedom to refuse vaccination.[217] This is paired with claims that vaccines are completely safe and effective.[218] However, no vaccine is completely effective,[219] and every vaccine carries some risk.[220] At least 30,000 people a year self-report some sort of negative reaction to a vaccine,[221] and around 10 to 15% of these cases are considered serious.[222] It is likely that the number of adverse reactions is higher because the Vaccine Adverse Event Reporting System relies on self-reporting.[223]

The government promotes vaccines with a heavy hand, and that in itself prompts mistrust.[224] For many people who know someone who has experienced an adverse reaction to a vaccine, or have experienced an adverse reaction themselves, the social stigma against talking about the real risks posed by vaccines and coercive government measures will likely reinforce doubts instead of dispelling them.[225]

CONCLUSION

The NCVIA has succeeded in ensuring that there are no vaccine shortages, but it has failed to provide an adequate remedy for the injured, many of them children. There was an alternative to the NCVIA proposed in 1985 during the vaccine crisis.[226] H.R. 1780 was introduced in 1985 by Congressman Edward

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217. Isha Ann Emhoff et al., *Is There a Moral Right to a Nonmedical Vaccine Exemption?*, 42 AM. J. L. & MED. 598 (2016) (arguing that the only exemptions for vaccinations should be medical); *see also* Claire McCarthy, *Why We Need To Make It Harder For Parents To Refuse Vaccination*, HARVARD HEALTH BLOG (Sept. 6, 2016), htpp://www.health.harvard.edu/blog/why-we-need-to-make-it-harder-for-parents-to-refuse-vaccines-2016090610258.

218. *Vaccine Safety*, U.S. DEP'T OF HEALTH & HUM. SERV., https://www.vaccines.gov/ basics/ safety/ index.html (last reviewed Dec. 2017); *The Science Is Clear: Vaccines Are Safe, Effective, and Do Not Cause Autism*, JOHN HOPKINS U. (Jan. 11, 2017), https://hub.jhu.edu/2017/01/11/vaccines-autism-public-health-expert/.

219. *See Global Vaccine Safety: Six Common Misconceptions About Immunization*, WORLD HEALTH ORG., https://www.who.int/vaccine_safety/initiative/detection/immunization_misconceptions/en/index2.html (last visited Sept. 16, 2019) ("Most routine childhood vaccinations are effective for 85% to 95% of recipients.").

220. *See Vaccine Adverse Event Reporting System (VAERS)*, *supra* note 10.

221. *Id.*

222. *Id.* (describing 85-90% of reports as mild, with the remaining being serious).

223. *See* LAZARUS, *supra* note 10, at 6.

224. Beaubien, *supra* note 214.

225. *See* David Ropeik, *The Backlash Against Anti-Vaxxers Is Going Too Far*, BIGTHINK (Mar. 12, 2015), https://bigthink.com/risk-reason-and-reality/the-backlash-against-anti-vaxxers-is-going-too-far.

226. H.R. REP. NO. 99-908, at 78 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6382.

Madigan, from Illinois' 15th congressional district,[227] and had bipartisan support from forty-five cosponsors.[228] That bill would have allowed injured people to sue the manufacturers in a no-fault compensation scheme that capped damages at $1 million, so that the manufacturers could have predicted their costs and purchased insurance.[229] Although this bill certainly would have deprived many families of adequate compensation, as many injured children require a life of expensive care,[230] at least the government would have remained an independent third party and the pharmaceutical companies would make more money when their products hurt fewer people.

The author of this Note would offer yet a different solution, returning these cases to state court where they would be decided by juries. The jury trial, preserved in the Seventh Amendment to the Constitution,[231] puts the decision in the hands of people who are truly disinterested in the case.[232] Vaccines that generate so much litigation that they cease to be profitable would quickly be replaced by safer alternatives, as DPT was replaced by DTaP in Japan in just six years.[233] Justice Sotomayor's insight in *Bruesewitz* that the current scheme removes the incentive of manufacturers to improve the safety of current vaccines[234] gets to the heart of the matter. Vaccine manufacturers should not have immunity from tort liability, especially when they make profits in the billions[235] while their consumers suffer hundreds of millions of dollars-worth of injuries.[236]

As it stands today, the NCVIA creates a set of incentives that encourages vaccine manufacturers to be careless and HHS to deny a full remedy to many people injured by vaccines. Congress will need to substantially rewrite the law if it wishes to accomplish its goal, stated at the beginning, that

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227. Overview of *H.R. 1780 (99th): National Childhood Vaccine-Injury Compensation Act of 1985*, GOVTRACK, https://www.govtrack.us/congress/bills/99/hr1780 (last visited Sept. 16, 2019).

228. Details for *H.R. 1780 (99th): National Childhood Vaccine-Injury Compensation Act of 1985*, GOVTRACK, https://www.govtrack.us/congress/bills/99/hr1780/details (last visited Sept. 16, 2019).

229. *See* H.R. REP. NO. 99-908, at 78.

230. *See, e.g.*, *Compensating Vaccine Injuries*, *supra* note 12, at 19–21.

231. U.S. CONST. amend. VII.

232. Only 20,428 claims have been filed in the VICP from its creation on October 1, 1988, through March 1, 2019. *See* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 5. It is unlikely that returning these cases to the traditional tort system would inundate the courts.

233. Nakayama, *supra* note 146, at 792–93.

234. Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1101 (2011) (Sotomayor, J., dissenting).

235. *See* Eric Sagonowsky, *The Top 5 Vaccine Companies by 2017 Revenue*, FIERCEPHARMA (Aug. 1, 2018), https://www.fiercepharma.com/special-report/top-5-vaccine-companies-by-2017-revenue.

236. *See* NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT, *supra* note 22, at 8–9.

compensation for injuries ought to be "fair, simple, and easy to administer."[237] The story of Andrew Clements, shared by many other Americans, demonstrates how short the NCVIA has fallen. Hopefully, Congress will correct its mistake before it finds itself in a public health crisis of its own making.

237. H.R. REP. NO. 99-908, at 7 (1986), *as reprinted in* 1986 U.S.C.C.A.N 6344, 6348.