University of the Pacific Law Review

Volume 53
Issue 4 *SYMPOSIUM—AALS: SOCIO-ECONOMIC PERSPECTIVES ON CONTRACT LAW*

Article 10

12-1-2022

Prophylactic Profit: The One-Sided Compromise

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University of the Pacific Law Review

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Volume 53 November 2022 Issue 4

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I. INTRODUCTION

In April 1992, Hannah Bruesewitz received a diphtheria, pertussis, and tetanus ("DPT") vaccine in accordance with Centers of Disease Control ("CDC") guidelines.[1] Within 24 hours of inoculation, Hannah experienced her first seizure and would suffer more than 100 seizures in the first month after her vaccination.[2] In 1995, Hannah's parents filed a complaint with the Vaccine Compensation Board.[3] Unfortunately, their claim came just months after Donna Shalala—

* Doctor of Chiropractic; J.D., University of the Pacific, McGeorge School of Law, conferred May 2022. This note is dedicated to the families who have had their lives forever changed because of an adverse vaccine reaction and to those who seek truth even when it is unpopular to do so.

1. *See* Valarie Blake, *The National Childhood Vaccine Injury Act and the Supreme Court's Interpretation*, 14 AM. MED. ASS'N J. ETHICS 31, 32 (2012) ("In 1992, newborn Hannah Bruesewitz received a diphtheria, pertussis, and tetanus (DPT) vaccine from her pediatrician, in accordance with the vaccine schedule set forth by the Centers for Disease Control at the time.").

2. *See* Bruesewitz v. Wyeth, 562 U.S. 223, 230 (2011) ("Within 24 hours of her April 1992 vaccination, Hannah started to experience seizures. She suffered over 100 seizures during the next month, and her doctors eventually diagnosed her with 'residual seizure disorder' and 'developmental delay.'").

3. *See* Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 AM. BAR ASS. 785, 787 (2011) ("In 1995, Hannah Bruesewitz's parents embarked on an unsuccessful fifteen-year odyssey through the courts. . . . [H]er parents litigated her case in every available forum, culminating in their recent loss in the U.S. Supreme Court.").

President Bill Clinton's Secretary of Health and Human Services—enacted rule changes that made it more difficult for claimants to receive compensation.[4]

These changes included removing residual seizure disorder—the same diagnosis Hannah received—from the list of compensable injuries.[5] Because Hannah's injury did not fit into the Vaccine Injury Table ("the Table"), she no longer benefited from the presumption that the vaccine caused her injury.[6] After the Special Master denied the Bruesewitzs' claim, the Bruesewitz family filed a design defect claim in state court against pharmaceutical manufacturer Wyeth—now known as Pfizer.[7] Subsequently, the vaccine manufacturer moved the case to federal court in hopes of settling the circuit split of whether vaccine manufacturers were immune to state design defect laws.[8] The *Bruesewitz* case reached the United States Supreme Court, which determined the National Childhood Vaccine Injury Act's ("the Act") provided vaccine manufacturers immunity from all design defect claims.[9] The Bruesewitz family never received compensation for Hannah's injuries, and she continues to suffer from residual seizure disorder as a young adult.[10]

Despite a growing anti-vaccination movement over the past decade, most public health experts view vaccines as western medicine's "crowning achievement."[11] In the early 1980s, parents of vaccine-injured children filed

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4. *Id.* at 99.

5. *See id.* ("Hannah had a strong claim of a residual seizure disorder under the prior table, but unfortunately for her family this Table injury had been eliminated."); *see also* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7682 (Feb. 8, 1995) (codified at 42 C.F.R. § 100.3 (2021)) ("[T]he intent of the [vaccine compensation program] was to compensate only those individuals whose injuries are vaccine-related. The proposed regulation is simply an attempt to come closer to realizing this goal than was possible with the language of the original Vaccine Injury Table.").

6. *See* Meyers, *supra* note 3, at 99 ("The special master ruled that Hannah had not proven that she either suffered an injury recognized by the Vaccine Injury Table in effect at the time she filed her case, or that her seizure disorder and related problems were caused in fact by the DTP vaccines she received.").

7. *See* Bruesewitz v. Wyeth, 562 U.S. 223, 231 (2011) ("The Bruesewitzes elected to reject the unfavorable judgement, and in October 2005 filed this lawsuit in Pennsylvania state court. Their complaint alleged . . . defective design of Lederle's DTP vaccine caused Hannah's disabilities, and that Lederle was subject to strict liability, and liability for negligent design, under Pennsylvania common law."); *see also Special Master*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/special_master (last visited Mar. 11, 2021) (on file with the *University of the Pacific Law Review*) (defining special master as an appointed on behalf of a court to perform special administrative duties, which may also include investigative duties).

8. *See* Meyers, *supra* note 3, at 787 ("After the Court of Federal Claims rejected Hannah's parents' petition for compensation, her parents filed a civil tort suit against the vaccine's manufacturer. The complaint was dismissed . . . by the District Court, which held that the Vaccine Act's preemption clause forbids a claim . . . based upon a design defect.").

9. *See Bruesewitz*, 562 U.S. at 243 ("[W]e hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects.").

10. *Supreme Court Rules Against Mt. Lebo Family's Vaccine Lawsuit*, CBS PITTSBURGH (Feb. 23, 2011, 12:24 AM), https://pittsburgh.cbslocal.com/2011/02/ 23/supreme-court-rules-against-mt-lebo-familys-vaccine-lawsuit/ (on file with the *University of the Pacific Law Review*).

11. *See* Timothy M. Todd, *The Tail That Wags the Dog: The Problem of Pre-Merit-Decision Interim Fees and Moral Hazard in the National Vaccine Injury Compensation Program*, 63 U. KAN. L. REV. 1, 4 (2014) ("Undoubtedly, vaccination against life-threatening and debilitating illnesses is one of the crowning achievements

hundreds of product liability lawsuits against vaccine manufacturers annually.[12] These lawsuits created an untenable business environment for some vaccine manufacturers, who demanded protection from civil liability to continue manufacturing and marketing vaccines.[13] Because Congress recognized vaccines as critical to public health, it passed the Act—a first-of-its-kind reform to the tort system.[14]

The Act's original objectives were twofold.[15] It limited vaccine manufacturers' tort liability and provided a faster, less adversarial process for parents of vaccine-injured children to receive compensation.[16] To achieve these ends, the Act established the Vaccine Injury Table, which listed injuries that—if suffered within the statutory period—provided compensation to claimants.[17] Claimants did not have to prove the vaccine was the cause-in-fact of their injuries if the timing of their symptoms fit into the Table.[18] By law, a Special Master needed to make a decision within 240 days of the petitioner's filing.[19]

Initially, the Act seemed to serve its intended dual purposes.[20] However, in 1995, Health and Human Services Secretary Donna Shalala significantly changed the Vaccine Injury Table through the rulemaking process.[21] Conflicting caselaw further contributed to the confusion.[22] Collectively, these executive changes diluted Congress's intent to provide an avenue for quick compensation to the

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in the history of public health.").

12. *See* Bruesewitz v. Wyeth, 562 U.S. 223, 227 (2011) ("[B]etween 1978 and 1981 only nine products-liability suits were filed against DTP manufacturers, by the mid-1980's the suits numbered more than 200 each year.").

13. *See id.* ("[Litigation] destabilized the DTP vaccine market, causing two of the three domestic manufacturers to withdraw; and the remaining manufacturer, Lederle Laboratories, estimated that its potential tort liability exceeded its annual sale by a factor of 200.").

14. *See* Meyers, *supra* note 3, at 799 ("The federal vaccine injury compensation law . . . was a pioneering example of no-fault federal tort reform legislation.").

15. Todd, *supra* note 11, at 7.

16. *See id.* ("The goals of the Act, according to its legislative history, are twofold: (1) to ensure adequate compensation for those injured by vaccines and (2) to promote stability in the vaccine market.").

17. *See id.* at 9–10 (2014) ("The Act has a 'vaccine table' that allows a 'finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.' Thus, petitioners can establish an entitlement to compensation by . . . proving that they suffered a specific injury on the vaccine table.").

18. *See* Meyers, *supra* note 3, at 789 ("The Vaccine Injury Table lists the specific injuries that the court recognizes as presumptively caused by a vaccine and the specified time limit for the occurrence of the onset of each listed injury.").

19. *Id.* at 796.

20. *See id.* at 789–90 ("When the Vaccine Program began, the overwhelming majority of cases that were litigated in the program involved the relatively simple question of whether the Table requirements had been satisfied.").

21. *See id.* at 790 ("The overwhelming majority of cases litigated in the program do not involve Table injuries. . . . There are a number of reasons for this, but the most important is that the Table was substantially modified and narrowed by the Secretary of HHS in 1995 through an administrative rulemaking proceeding.").

22. *See id.* at 802–03 ("[A] controversy emerged from a line of Federal Circuit cases that began with *Althen* in 2005, continued in *Walther* . . . in 2007, and included *Andreu* . . . in 2009. . . . However, a second line of cases, included *De Bazan* . . . in 2008 and *Moberly* . . . in 2010, takes a very different perspective.").

vaccine-injured.[23] Ultimately, Hannah's vaccine injury remains uncompensated because of these changes and the Supreme Court's flawed interpretation of the Act.[24]

The Act's title clearly illustrates Congress's original intent to protect children.[25] The Court's subsequent application and interpretation of the Act are demonstrably inconsistent with Congress's original intent since most compensation goes to vaccine-injured adults, not vaccine-injured children.[26] However, the Act's Vaccine Injury Table has evolved to cover more vaccinations like the seasonal influenza vaccine, which is responsible for the highest number of claims—filed mostly by vaccine-injured adults.[27] Congress must remedy the causation issues stemming from the 1995 rulemaking changes to protect vaccine-injured people and explicitly define the thirteen words in the Act the *Bruesewitz* Court excised.[28]

Part II of this Comment explores the passage of the Act, as well as analyzes the Act and the 1995 rule changes that fundamentally changed the vaccine compensation program.[29] Part III outlines the fundamental problem with current vaccination laws.[30] Part IV reviews potential ways to ensure the safest, most effective vaccine reaches the market through post-market research.[31]

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23. *See id.* 790 ("The cases are now substantially more difficult, complex, and time-consuming to litigate. The science is less clear, and the special masters have much more difficult and complex scientific disputes to resolve than they did for the relatively simpler Table injury claims.").

24. *See* Bruesewitz v. Wyeth, 562 U.S. 223, 243 (2011) ("[W]e hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects."); *see also* Jedediah Purdy, *Scalia's Contradictory Originalism*, NEW YORKER (Feb. 16, 2016), https://www.newyorker.com/news/news-desk/scalias-contradictory-originalism (on file with the *University of the Pacific Law Review*) (describing Justice Scalia's inconsistent application of textualism and his "theoretical ambition to separate judging from politics").

25. 42 U.S.C.A. § 300aa-22(b)(1) (West 2022).

26. *See* Meyers, *supra* note 3, at 795 ("In the Vaccine Compensation Program's early years, the overwhelming majority of the cases brought, and compensations awarded, involved injuries to children. This has changed dramatically, and in the past few years the majority of cases brought, and awards made, have involved adults.").

27. *See generally* 42 U.S.C.A. § 300aa-22(b)(1) (West 2022); *see Vaccine Injury Compensation Program Data and Statistics*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/vaccine-compensation/data/index.html (last visited Mar. 11, 2021) (on file with the *University of the Pacific Law Review*) (showing the seasonal influenza vaccine having the highest number of inoculations and the highest number of injury claims in the United States).

28. *See* Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 B.U. L. REV. 2153, 2222 (2017) (proposing five reforms to the Act: "(1) adjusting the requirements for adverse event reporting and post-market analysis of vaccine safety and efficacy, (2) predicating limited liability for vaccine manufacturers on compliance with post market analysis requirements, (3) exempting design defect claims from the preemption provision of the Vaccine Act in cases of negligent failure to utilize a safer alternative design, (4) restructuring the burden of proof for claims alleging off-table vaccine related injuries, and (5) mandating a minimum investment of Trust Fund proceeds for vaccine research and development").

29. *See infra* Part II.

30. *See infra* Part III.

31. *See infra* Part IV.

II. THE NATIONAL CHILDHOOD VACCINE INJURY ACT

Congress passed the Act in 1986 and subsequently funded the vaccine injury compensation program through legislation in 1988.[32] In the decade preceding the Act's passage, vaccine litigation increased sixfold.[33] These product liability claims resulted in tens of millions of dollars in litigation costs for vaccine manufacturers.[34] Some vaccine manufacturers calculated the litigation risk outweighed the financial rewards of the marketplace.[35] Section A outlines the litigation problem vaccine manufacturers faced before the Act.[36] Section B describes the Act.[37] Section C discusses the administrative rulemaking changes in 1995.[38] Section D analyzes the causation burden of off-table injury claimants.[39] Finally, Section E examines the Supreme Court's interpretation of the Act in *Bruesewitz*.[40]

A. The Issue: More Profits, More Injuries, More Lawsuits

Vaccine manufacturers faced a steady rise in products liability litigation in the 1970s and 1980s.[41] The cause of this increased litigation was simple: vaccine manufacturers did not adequately warn about the known dangers related to

32. *See* Meyers, *supra* note 3, at 792 ("The federal vaccine injury compensation law, which took effect in 1988, was a pioneering example of no-fault federal tort reform legislation.").

33. *See* Nina H. Compton & J. Douglas Compton, *DPT Vaccine Manufacturer Liability: Chipping Away at Strict Liability to Save the Product*, 20 N.M. L. REV. 531, 534 (1990) ("Vaccine manufacturers have been alarmed over the six-fold increase in lawsuits per year from approximately twenty-five in 1980 to approximately 150 in 1985."); *see also* James Hamblin, *Why the Government Pays Billions to People Who Claim Injury by Vaccines*, ATLANTIC (May 14, 2019), https://www.theatlantic.com/health/archive/2019/05/vaccine-safety-program/589354/ (on file with the *University of the Pacific Law Review*) ("One lawsuit in 1978 increased to 73 by 1984.").

34. James Hamblin, *Why the Government Pays Billions to People Who Claim Injury by Vaccines*, ATLANTIC (May 14, 2019), https://www.theatlantic.com/health/archive/2019/05/vaccine-safety-program/589354/ (on file with the *University of the Pacific Law Review*).

35. *See Diphtheria–Tetanus–Pertussis Vaccine Shortage*, CTRS. FOR DISEASE CONTROL AND PREVENTION: MORBIDITY AND MORTALITY WKLY. REP. (Dec. 14, 1984), https://www.cdc.gov/mmwr/preview/mmwrhtml/00000452.htm (on file with the *University of the Pacific Law Review*) ("[T]wo of the three U.S. commercial manufacturers (Wyeth and Connaught, Inc.) have stopped distribution of their products. . . . No new vaccine lots may be available until sometime in February 1985.").

36. *See infra* Section II.A.

37. *See infra* Section II.B.

38. *See infra* Section II.C.

39. *See infra* Section II.D.

40. *See infra* Section II.E.

41. James Hamblin, *Why the Government Pays Billions to People Who Claim Injury by Vaccines*, ATLANTIC (May 14, 2019), https://www.theatlantic.com/health/archive/2019/05/vaccine-safety-program/589354/ (on file with the *University of the Pacific Law Review*).

vaccines.[42] By the mid-1980s, vaccine-injury claims numbered 200 annually.[43] As a result of these lawsuits—mostly related to polio and DPT vaccinations—some pharmaceutical companies decided to stop manufacturing certain vaccines.[44] By December 1984, only one major vaccine manufacturer—Lederle—still produced the DPT vaccine, which threatened to seriously disrupt the manufacturing and distribution of the DPT vaccine in the United States.[45]

In 1985, a government-commissioned study recommended "a no-fault, national program to compensate individuals who suffer permanent adverse reaction to any of the seven mandated childhood vaccines."[46] The study's funding included grants from Lederle Laboratories and Merck Pharmaceuticals, highlighting a conflict of interest that persists to this day.[47]

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42. *See* Reyes v. Wyeth Lab'ys, 498 F.2d 1264, 1279 (5th Cir. 1974) (concluding vaccine manufactures have a duty to warn); *see also* Andrea Rock, *The Lethal Dangers of the Billion-Dollar Vaccine Business with Government Approval, Drug Companies Sell Vaccines that Can Leave Your Child Brain Damaged, Can Spread Polio from Your Baby to You—And Can Even Kill. Safer Stuff Is Available*, CNN MONEY (Dec. 1, 1996), https://money.cnn.com/magazines/moneymag/moneymag_archive/1996/12/01/218857/index.htm (on file with the *University of the Pacific Law Review*) ("For decades, American pharmaceutical companies have known how to produce the safer DPT vaccine but decided not to bring it to market because it would increase production costs and lower the drug's 50% or higher profit margins.").

43. *See* Bruesewitz v. Wyeth, 562 U.S. 223, 227 (2011) ("Whereas between 1978 and 1981, only nine products-liability suits were filed against DTP manufacturers, by the mid-1980's the suits numbered more than 200 each year."); *see also* Nina H. Compton & J. Douglas Compton, *DPT Vaccine Manufacturer Liability: Chipping Away at Strict Liability to Save the Product*, 20 N.M. L. REV. 531, 534 (1990) ("Vaccine manufacturers have been alarmed over the six-fold increase in lawsuits per year from approximately twenty-five in 1980 to approximately 150 in 1985.").

44. *See* Vaccination Injury Compensation Program, THE HIST. OF VACCINES, https://www.historyofvaccines.org/content/articles/vaccine-injury-compensation-programs (last visited Jan. 9, 2021) (on file with the *University of the Pacific Law Review*) ("Through the 1970s and 1980s, the number of lawsuits brought against vaccine manufacturers increased dramatically, and manufacturers made large payouts to individuals and families claiming vaccine injury, particularly from the combined [DPT] immunization."); *see also Diphtheria–Tetanus–Pertussis Vaccine Shortage*, CTRS. FOR DISEASE CONTROL AND PREVENTION: MORBIDITY AND MORTALITY WKLY. REP. (Dec. 14, 1984), https://www.cdc.gov/mmwr/preview/mmwrhtml/00000452.htm (on file with the *University of the Pacific Law Review*) ("[T]wo of the three U.S. commercial manufacturers (Wyeth and Connaught, Inc.) have stopped distribution of their products. . . . No new vaccine lots may be available until sometime in February 1985.").

45. *See Diphtheria–Tetanus–Pertussis Vaccine Shortage*, CTRS. FOR DISEASE CONTROL AND PREVENTION: MORBIDITY AND MORTALITY WKLY. REP. (Dec. 14, 1984), https://www.cdc.gov/mmwr/preview/mmwrhtml/00000452.htm (on file with the *University of the Pacific Law Review*) ("[T]wo of the three U.S. commercial manufacturers (Wyeth and Connaught, Inc.) have stopped distribution of their products. . . . No new vaccine lots may be available until sometime in February 1985.").

46. NATIONAL RESEARCH COUNCIL, VACCINE SUPPLY AND INNOVATION 183 (1985).

47. *Id. at* ii (1985); *see also* Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999–2018*, 180 JAMA INTERNAL MED. 1, 693–95 (2020) ("Congress and the executive branch benefit from fully considering the interests of all parties in society, not just those who seek to improve their access to officials through campaign contributions and lobbying expenditures. In the health sector, several organizations, notably PhRMA, the American Medical Association, the American Hospital Association, and the Blue Cross Blue Shield Association, accounted for a disproportionate share of spending on lobbying over the study period. PhRMA and the American Medical Association have historically lobbied together against government interventions in drug markets.").

Eventually, Congress passed the Act, but President Ronald Reagan's administration opposed early versions of the bill.[48] The Department of Justice recommended President Reagan veto the Act because of the potential for the judiciary's inconsistent application of the Act; however, other cabinet officials disagreed.[49] Lobbyists for doctors and pharmaceutical companies held daily press conferences to build public pressure, and parent groups coordinated letter-writing campaigns addressed to the President.[50] On November 14, 1986. President Reagan relented to the public pressure despite "mixed feelings" over the Act's compensation mechanism.[51]

The President called the goal of compensating victims a "worthy purpose" but cautioned the potential for inconsistent application.[52] President Reagan—echoing his Justice Department's concerns—called the vaccine compensation program "unprecedented" and a "poor choice" for a "well-managed and effective program" because the judiciary would administer it.[53] Despite his reservations, President

48. Mike Robinson, *Reagan Under Pressure from Doctors, Drug Makers to Sign Vaccine Bill*, AP NEWS (Oct. 28, 1986), https://apnews.com/article/fdcc1171f2e916f6f616bb05802fa5cf (on file with the *University of the Pacific Law Review*).

49. *See* Statement by President Ronald Reagan Upon Signing S. 1744, 22 WEEKLY COMP. OF PRES. DOC. 1565 (Nov. 17, 1986) ("[U]nder this Title, there continues to be the opportunity for very substantial and inequitable differences in liability judgements awarded similarly situated plaintiffs."); *see also* Robert Pear, *Reagan Signs Bill on Drug Exports and Payment for Vaccine Injuries*, N.Y. TIMES (Nov. 15, 1986), https://www.nytimes.com/1986/11/15/us/reagan-signs-bill-on-drug-exports-and-payment-for-vaccine-injuries.html (on file with the *University of the Pacific Law Review*) ("The Justice Department had urged a veto of the bill because of its objections to the new system of compensating people injured by vaccines. But Vice President Bush, Commerce Secretary Malcolm Baldrige and Dr. Otis R. Bowen, Secretary of Health and Human Services, urged Mr. Reagan to sign it, as did James A. Baker 3d, Secretary of the Treasury.").

50. Mike Robinson, *Reagan Under Pressure from Doctors, Drug Makers to Sign Vaccine Bill*, AP NEWS (Oct. 28, 1986), https://apnews.com/article/fdcc1171f2e916f6f616bb05802fa5cf (on file with the *University of the Pacific Law Review*).

51. *See* Statement by President Ronald Reagan Upon Signing S. 1744, 22 WEEKLY COMP. OF PRES. DOC. 1565 (Nov. 17, 1986) ("I am today signing S. 1744, an omnibus health measure, with mixed feelings . . . I have serious reservations about the portion of the bill that would establish a Federal vaccine injury compensation program.").

52. *See id.* ("[U]nder this Title, there continues to be the opportunity for very substantial and inequitable differences in liability judgements awarded similarly situated plaintiffs."); *see also* Robert Pear, *Reagan Signs Bill on Drug Exports and Payment for Vaccine Injuries*, N.Y. TIMES (Nov. 15, 1986), https://www.nytimes.com/1986/11/15/us/reagan-signs-bill-on-drug-exports-and-payment-for-vaccine-injuries.html (on file with the *University of the Pacific Law Review*) ("The Justice Department had urged a veto of the bill because of its objections to the new system of compensating people injured by vaccines. But Vice President Bush, Commerce Secretary Malcolm Baldrige and Dr. Otis R. Bowen, Secretary of Health and Human Services, urged Mr. Reagan to sign it, as did James A. Baker 3d, Secretary of the Treasury."); Parasidis, *supra* note 28, at 2216–17 (describing the Act's compensation for [1] medical costs incurred from vaccine-injury; [2] medical costs for future costs related to vaccine-injury; [3] lost wages; [4] compensation for pain and suffering).

53. *See* Statement by President Ronald Reagan Upon Signing S. 1744, 22 WEEKLY COMP. OF PRES. DOC. 1565 (Nov. 17, 1986) ("Another serious deficiency of Title III is that it would create a program administered not by the Executive branch, but by the Federal judiciary. This is an unprecedented arrangement that represents a poor choice to ensure a well-managed and effective program.").

Reagan signed the Act because Congress did not appropriate funding for the vaccine compensation program.[54]

B. The Compromise: The Act and the Vaccine Injury Table

Congress passed the Act in response to the growing concern of both parents and vaccine manufacturers.[55] To balance the concerns of these opposing groups, Congress created the Vaccine Injury Table.[56] Congress intended the Vaccine Injury Table to ensure quick compensation for the vaccine-injured and legal protection from the expensive costs of traditional tort litigation for vaccine manufacturers.[57] The Vaccine Injury Table also mitigated the punitive damages vaccine manufacturers would pay out in civil litigation.[58] Congress's twin goals are only achieved when the majority of claims fall within the parameters of the Vaccine Injury Table.[59]

Initially, the Vaccine Injury Table contained a list of ten vaccinations, compensable injuries for those vaccines, and a timeframe for the onset of symptoms.[60] A claimant can use medical records to prove the timing of their vaccine injury, which relieves them of the burden of proving the vaccine was the cause-in-fact of their injury.[61] A claimant whose injury is not on the Vaccine Injury Table, or whose injury happens after the stated timeframe, has the burden of

54. *See id.* ("A major factor in my decision to approve S. 1744 despite the serious deficiencies in Title III is that the bill provides that the vaccine compensation program established in that Title will not be effective until a separate measure funding the program is enacted.").

55. Todd, *supra* note 11, at 7.

56. *See* Katherine E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426, 435 (2007) ("[T]he centerpiece of the Vaccine Injury Act was the creation of a no-fault recovery program for individuals injured by vaccines.").

57. *See* Meyers, *supra* note 3, at 798 ("The use of the Table is also essential to the expeditious and efficient processing of vaccine injury claims.").

58. Mike Robinson, *Reagan Under Pressure From Doctors, Drug Makers to Sign Vaccine Bill*, AP NEWS (Oct. 28, 1986), https://apnews.com/article/fdcc1171f2e916f6f616bb05802fa5cf (on file with the *University of the Pacific Law Review*) ("The [Table] was designed 'so that the evidence on the extent of the plaintiff's injury or on the actions of the defendant that allegedly justify punitive damages does not prejudice the findings as to causation and fault,' according to a fact sheet provided by the American Academy of Pediatrics.").

59. *See* Meyers, *supra* note 3, at 798 (explaining the shift away from table cases by showing 90% of claims filed between 1989 and 1992 fell into the table and from 2007 to 2010 "almost 90%" of claims were for injuries not listed on the table).

60. *See id. at* 796 ("The original Table adopted by Congress contained ten vaccines: measles, mumps, and rubella [commonly given together as an MMR shot]; diphtheria, tetanus, and pertussis [commonly given together as a DTP shot]; and the two polio vaccines [IPV and OPV].").

61. *See id.* ("If petitioner makes this showing, the burden then shifts to the government to show, by a preponderance of evidence, that another cause . . . is the real source of the injury. . . . [T]he government cannot base its rebuttal on an idiopathic cause—a cause of unknown origin."); *see also* STUART M. SPEISER ET AL., 3 AMERICAN LAW OF TORTS § 11:6 ("The element of cause in fact, as required to support a finding of proximate cause in a negligence action, requires proof that (1) the negligent act or omission was a substantial factor in bringing about the harm at issue, and (2) absent the negligent act or omission, 'but for' the act or omission, the harm would not have occurred.").

proving the vaccination was the cause-in-fact of their injuries.[62] Claims that fall into the Vaccine Injury Table are simple and easy to litigate because the burden shifts to the government to show the vaccination did not cause the injury.[63]

C. The Changes: One-sided Rulemaking

In 1995, the Department of Health and Human Services officially amended the Vaccine Injury Table.[64] The agency had amended the Table in 1992 but officially postponed any changes when it became aware of a ten-year follow-up study that was not yet published.[65] The National Childhood Encephalopathy Study was of particular importance to the agency because it specifically analyzed "the relationship between vaccine administration and subsequent neurological damage" in children.[66] After analyzing the published study, the Advisory Commission on Childhood Vaccines ("the Advisory Committee") agreed that the Vaccine Injury Table needed "modification" but disagreed on the precise mechanism.[67] The Table required these "modification[s]" to remain "consistent with medical and scientific knowledge" on vaccine injuries.[68] The source of the Advisory Committee's disagreement was over which Vaccine Injury Table to use as a baseline for the changes: the original table in the statute or the amended—but unenacted—Vaccine Injury Table published in 1992.[69] Ultimately, the agency used the 1992 version of the Table as a baseline for the changes.[70]

The agency's two most problematic changes were removing several injuries—including residual seizure disorder—and narrowing the definition of

62. *See* Meyers, *supra* note 3, at 798 ("In vaccine cases where no Table injury claim can be made, the special masters have much more difficult and complex issues to decide. . . . These off-Table cases often involve complex medical questions about which there is likely to be no definitive consensus among experts.").

63. *See id.* ("[L]itigation in Table cases is relatively simple. The focus in these cases is first on whether the injury alleged is the injury specified in the Table. While there have been cases where medical experts disagreed . . . most of the time there will be no substantial dispute.").

64. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7678 (Feb. 8, 1995) (codified at 42 C.F.R. § 100.3 (2021)).

65. *Id.* at 7682.

66. *Id* .

67. *Id.* at 7678; *see generally* Federal Advisory Committee, *Advisory Commission on Childhood Vaccines*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/advisory-committees/vaccines/index.html (last visited Jan. 11, 2021) (on file with the *University of the Pacific Law Review*) (describing the function of the advisory committee as making recommendation to the Secretary of Health and Human services on the vaccine compensation program).

68. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7678 (Feb. 8, 1995) (codified at 42 C.F.R. § 100.3 (2022)).

69. *See id.* ("Some Commission members expressed the view that the starting point for revisions to the Table should be the original Table in the statue. The other commissioners agreed that the Secretary should further refine the Table, but that the starting point . . . should be the modified Table as published in . . . 1992.").

70. *See id.* ("After weighing all the varied opinions expressed at the June meeting, as well as the written comments received from two commission members, the Department has decided that a final rule which is a revised and redefined version of the proposed rule published in 1992 will reflect best the scientific evidence.").

encephalopathy to an "extremely difficult, if not impossible" standard.[71] The agency continually updates the Table with new vaccines, but the list of compensable injuries remains largely unchanged.[72] The addition of new vaccines to the Table—without commensurate changes to compensable injuries—has fundamentally restructured the original compensation process because plaintiffs must prove causation of off-table injuries.[73]

Commentators warned the Secretary of Health and Human Services about the detrimental effect of the rule changes.[74] Some commentators cautioned the regulation would increase costs of litigation, to which the Secretary responded, "the benefits of the proposed regulation outweigh the possibility of more protracted and complex hearings."[75] The rule changes completely shifted the compensation program and upended Congress's goal for a quick, less adversarial compensation process for victims of vaccine injury.[76]

D. The Application: The Judiciary's Confusing Causation Approach

After the 1995 rule changes, most vaccine-injury claims did not fit on the Vaccine Injury Table.[77] These off-Table injury claims created causation issues in "a field bereft of complete and direct proof of how vaccines affect the human body."[78] The Court of Appeals for the Federal Circuit—responsible for all Vaccine

71. *See* Meyers, *supra* note 3, at 800 (explaining "the redefining of the Table injury of encephalopathy from a broad, inclusive definition to a hyper-technical and narrow definition that is extremely difficult, if not impossible, to satisfy").

72. *See id.* ("[P]ractically all of the vaccines added to the Table in recent years have either no specified Table injuries, or else they have only the listed injury of an immediate anaphylactic shock reaction.").

73. *See id.* at 798 ("This has become a particular problem . . . because of the dramatic shift from the early years of the program . . . when more than 90% of the petitions filed asserted Table injuries, to the most recent years . . . when almost 90% of the petitions filed assert only non-Table injuries.").

74. *See* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7679–83 (Feb. 8, 1995) (codified at 42 C.F.R. § 100.3 (2021)) (describing a wide-range of critical comments including [1] changes to the table violate the separation of powers doctrine because only Congress can make changes to the Table; [2] the changes to the elements of proof of adjudication "exceeded" the agency's authority; [3] the new burden of proof on claimants was too high; [4] the regulation lacked the robust scientific proof Congress intended, ignored relevant data, and misunderstood certain findings; [5] the regulation increased the costs associated with litigation; [6] concerns advisors on the Immunization Practices Advisory Committee may have improper financial relationships with pharmaceutical companies).

75. *See id.* ("The revised [Vaccine Injury] Table merely affects the presumption of causation available to certain petitioners. Petitioners will, of course, continue to have the option of proving causation by a preponderance of evidence if they are unable to prove a Table injury.").

76. *See* Meyers, *supra* note 3, at 801 ("[T]he focus of vaccine case adjudication is now dramatically different. Ninety percent of vaccine cases are now causation-in-fact cases. The Table was intended to be a crucial innovation, a key to the quick, hospitable, and less adversarial Vaccine Act proceedings.").

77. *See id.* ("[T]he focus of vaccine case adjudication is now dramatically different. Ninety percent of vaccine cases are now causation-in-fact cases."); *see also* Nora Freeman Engstrom, *A Dose of Reality for Specialized Courts: Lessons from the VICP*, 163 U. PA. L. REV. 1631, 1703 (2015) ("Thus, the [Vaccine Injury] Table, which at enactment was viewed as the [vaccination compensation program]'s 'most important feature,' has . . . morphed into a 'meaningless thing.'").

78. Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005); Peter H. Meyers,

Compensation Board decision appeals—explained a causation test in *Althen v. Secretary of Health and Human Services*.[79] The three-part test required: "(1) a medical theory casually connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; (3) a showing of a proximate temporal relationship between vaccination and injury."[80] Even if claimants are successful in the difficult—if not impossible—endeavor of proving a vaccine caused their off-Table injury, there is no guarantee of compensation.[81] The government may still prove, by a preponderance of the evidence, that something unrelated to the vaccination caused the injury.[82]

The Court of Appeals for the Federal Circuit confused the parameters of the test in subsequent decisions.[83] In some cases, the courts resolved difficult causation issues in favor of injured petitioners.[84] In other cases, the Court treated the Act as "a waiver of sovereign immunity, calling for legal principles that require the courts strictly construe the Act against petitioners."[85] In these sovereign immunity cases, courts did not consider Congress's intent but focused on traditional tort principles to resolve causation issues.[86]

The Federal Judicial Center, the U.S. Government Accountability Office, and the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources reviewed the vaccine compensation program in the late 1990s.[87] These groups raised similar concerns about the adjudication process.[88] First, the proceedings were complex, which increased the duration of most cases over the 240-day statutory requirement.[89] Second, the adjudication process became extremely adversarial—mimicking traditional tort litigation.[90] Despite these findings,

Fixing the Flaws in the Federal Vaccine Injury Compensation Program, 63 AM. BAR ASS. 785, 797 n.58 (2011).

79. *See* Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1282 (Fed. Cir. 2005).

80. *Id.* at 1281–82; *see* Peter H. Meters, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 AM. BAR ASS. 785, 801 (2011) ("[T]he focus of vaccine case adjudication is now dramatically different. Ninety percent of vaccine cases are now causation-in-fact cases.").

81. Parasidis, *supra* note 28, at 2234.

82. *See id.* ("Even if a petitioner can meet this high burden, compensation is not available if the government can demonstrate, by a preponderance of the evidence, "that the injury was in fact caused by factors unrelated to the vaccine.").

83. *E.g.*, Andreu v. Sec'y of Health Hum. Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009); Peter H. Meters, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 AM. BAR ASS. 785, 803 (2011).

84. Capizzano v. Sec'y of Health Hum. Servs., 440 F.3d 1317, 1328 (Fed. Cir. 2006); Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1282 (Fed. Cir. 2005); Peter H. Meters, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 AM. BAR ASS. 785, 803 (2011).

85. Meyers, *supra* note 3, at 803.

86. *Id.*

87. *Id.* at 804.

88. *Id.*

89. *Id.*; *see also* Parasidis, *supra* note 28, at 2234 ("Even if a petitioner can meet this high burden, compensation is not available if the government can demonstrate, by a preponderance of the evidence, "that the injury was in fact caused by factors unrelated to the vaccine.").

90. Meyers, *supra* note 3, at 804.

Congress has still not acted to reinstitute its original intent of quick compensation adjudication for the vaccine-injured.[91]

Over the decades, both political parties acknowledge the need to reform the Vaccine Injury Table and the causation burden of claimants with off-Table injuries.[92] One possible solution is for Congress or the Secretary of Health and Human Services to expand the Table to include more injuries—much like the 1995 rule changes added new vaccinations to the Table.[93] Another solution proposed implementing a burden-shifting approach, which would relieve claimants with off-Table injuries of proving the vaccination caused their injury by a preponderance of the evidence.[94] Despite the obvious need to reform the Table and the unfair causation burden of off-Table vaccine-injury cases, Congress has yet to revisit the Act.[95]

E. The Interpretation: Deleting Words to Find Plain Meaning

Ultimately, Hannah Bruesewitz's case against the drug manufacturing company Wyeth reached the Supreme Court.[96] Before *Bruesewitz*, courts inconsistently interpreted whether the Act barred all design defect claims.[97] The Bruesewitz family wanted to hold Wyeth liable under Pennsylvania tort law.[98] Wyeth encouraged the Supreme Court to decide the issue in this case to resolve conflicting interpretations across the country.[99]

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91. *See id.* at 805 ("Problems with delays and the overly adversarial nature of the program have been exacerbated by the change in the Vaccine [Injury] Table and [causation issues in off-table injury cases].").

92. *See* Parasidis, *supra* note 28, at 2234–35 ("[B]etween 1999 and 2002, several congressional hearings examined the Vaccine Act, and Democrat and Republican lawmakers alike criticized the stringent legal bar for off table injuries and called for more lenient burdens for petitioners.").

93. Meyers, *supra* note 3, at 790.

94. *See* Parasidis, *supra* note 28, at 2236 ("Under this burden-shifting approach, the petitioner would have the initial burden of providing credible scientific evidence linking their injury with vaccination, but would not be required to prove causation by a preponderance of the evidence. If the petitioner provides credible evidence, the government would be responsible for demonstrating that the injury is not linked to the vaccine.").

95. Meyers, *supra* note 3, at 804.

96. Bruesewitz v. Wyeth, 562 U.S. 223 (2011).

97. *Compare* Am. Home Prod. Corp. v. Ferrari, 284 Ga. 384, 390 (2008) (holding the Act did not preempt all state design defect claims because Congress used conditional language mirroring comment k), *with* Bruesewitz v. Wyeth Inc., 561 F.3d 233, 246 (3rd Cir. 2009) ("We do not consider the Ferrari Court's reading to be compelling. First, while we recognize that the language is conditional, such a reading does not foreclose the preemption of some claims.").

98. *See Bruesewitz*, 562 U.S. at 231 ("The Bruesewitzes elected to reject the unfavorable judgement, and in October 2005 filed this lawsuit in Pennsylvania state court. Their complaint alleged . . . defective design of Lederle's DTP vaccine caused Hannah's disabilities, and that Lederle was subject to strict liability, and liability for negligent design, under Pennsylvania common law.").

99. Bruesewitz vs. Wyeth *Case Resolved*, THE HIST. OF VACCINES (Feb. 22, 2011), https://www.historyofvaccines.org/content/blog/bruesewitz-vs-wyeth-case-resolved (on file with the *University of the Pacific Law Review*).

The case presented a classic statutory interpretation question for the Court: whether the Act preempted state design defect law.[100] Justice Antonin Scalia penned the majority opinion and relied on textual tools to interpret the Act.[101] In doing so, the notorious strict textualist excised thirteen words from the statute: "the injury or death resulted from side effects that were unavoidable even though . . ."[102] He called the qualifying passage "unnecessary" to determine the meaning of the statute.[103] Justice Scalia reasoned, "[T]he rule against giving a portion of text an interpretation which renders it superfluous does not prescribe that a passage which could have been more terse does not mean what it says."[104] This analysis conflicts with the core tenets of textualism he pioneered.[105]

Justice Scalia's textual interpretation in *Bruesewitz* focused on the meaning of "unavoidable."[106] He highlighted the "even though" language to clarify the meaning of "unavoidable."[107] Justice Scalia reasoned the word "unavoidable" shows Congress intended to protect the "design of the vaccine" from "[s]tate-law design-defect claims."[108] Under this view, as long as pharmaceutical companies—like Wyeth—properly manufactured vaccines and provided adequate warnings of known side effects, then any other side effects were unavoidable.[109] According to Justice Scalia, the statute's plain meaning was vaccine manufacturers could not be held liable for other side effects.[110]

Justice Sonya Sotomayor's dissent—joined by Justice Ruth Bader Ginsburg—accused the majority of "impos[ing] its own bare policy preferences over the

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100. *Bruesewitz*, 562 U.S. at 226.

101. *See id.* at 231 ("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.").

102. *Id.* at 236.

103. *See id.* ("The intervening passage ['the injury or death resulted from side effects that were unavoidable even though'] is unnecessary. True enough.").

104. *Id.*

105. *See* Jonathon R. Siegel, *The Legacy of Justice Scalia and His Textualist Ideal*, 85 GEO. WASH. L. REV. 857, 866 (2017) ("[R]ejection of legislative history followed from an examination of first principles of statutory interpretation, and in particular from the textualist axiom that '[t]he text *is* the law, and it is the text that must be observed.'").

106. *See generally* Bruesewitz v. Wyeth, 562 U.S. 223, 233 (2011) (noting the different textualist approaches used to define "unavoidable"); RESTATEMENT (SECOND) OF TORTS, § 402A cmt. K (AM. LAW INST.1979).

107. *See Bruesewitz*, 562 U.S.at 231–32. ("The 'even though' clause clarifies the word that precedes it. It delineates the preventative measures that a vaccine manufacturer *must* have taken for a side effect to be considered 'unavoidable' under the statute. Provided that there was proper manufacture and warning, any remaining side effects, including those resulting from design defects are deemed to have been unavoidable. State-law design-defect claims are therefore pre-empted.").

108. *See id.* at 232 ("What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) *with respect to the particular design*. Which plainly implies that the design itself is not open to question.").

109. *Id.* at 231–32.

110. *Id.* at 232.

considered judgment of Congress."[111] The dissent treated the word "unavoidable" as a term of art and used the "if" clause to support its interpretation that unsuccessful claimants may bring certain design defect claims in state court.[112] Justice Sotomayor explained that the "even though" clause "requires the absence of manufacturing and labeling defects."[113] Conversely, she argued the conditional language of the statute, specifically the "if" clause, showed Congress did not intend to preempt all design defect claims.[114]

Justice Sotomayor compared the Act to a similar statute regarding vaccinations during a pandemic or epidemic.[115] She highlighted the difference in language between the two statutes to illustrate Congress's ability to use declarative language when it so desires.[116] For example, coronavirus vaccinations constitute a "covered countermeasure" and have a separate avenue for compensation outside of the Act.[117]

The dissent conceded that "complete preemption" would better stabilize the vaccine market, which was one of Congress's original goals.[118] However, Justice Sotomayor understood Congress's dual goals and the delicate balance it struck in the Act.[119] Citing the "general rule" in the Act, Justice Sotomayor reasoned that Congress intended state law apply in litigation relating to vaccine injuries or death.[120] In her view, this meant federal law did not preempt all design defect claims because Congress intended some vaccine-injured people to utilize

111. *See Bruesewitz*, 562 U.S. at 250 (Sotomayor, J., dissenting) ("[N]othing in the text, structure, or legislative history of the Vaccine Act remotely suggests that Congress intended such a result.").

112. *See id.* at 251–52 ("Given that the 'even though' clause requires the absence of manufacturing and labeling defects, the 'if' clause's reference to 'side effects that were unavoidable' must refer to side effects caused by something other than manufacturing and labeling defects.").

113. *See id.* ("Because § 22(b)(1) is invoked by vaccine manufacturers as a defense to tort liability, it follows that the 'even though' clause requires a vaccine manufacturer in each civil action to demonstrate that its vaccine is free form manufacturing and labeling defects to fall within the exemption of § 22(b)(1).").

114. *See id.* at 253 ("[W]hen Congress intends to pre-empt design defect claims categorically, it does so using categorical (*e.g.*, 'all') and/or declarative language (*e.g.*, 'shall'), rather than a conditional term ('if').").

115. *See id.* ("For example, in a related context, Congress has authorized the Secretary of Health and Human Services to designate a vaccine designed to prevent a pandemic or epidemic as a 'covered countermeasure.'").

116. *See id.* ("Congress provided that subject to certain exceptions, 'a covered person *shall* be immune from suit and liability under Federal and State law with respect to *all* claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by any individual of a covered countermeasure,' [emphasis added], including specifically claims relating to 'the design' if the countermeasure.").

117. *See Countermeasures Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/cicp (last visited Mar. 11, 2021) ("A countermeasure is a vaccination, medication, device, or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic or security threat.").

118. *See Bruesewitz*, 562 U.S.at 271 (Sotomayor, J., dissenting) ("The importance of the States' traditional regulatory role is only underscored by the unique features of the vaccine market, in which there are 'only one or two manufacturers for a majority of the vaccines listed in the routine childhood immunization schedule.'").

119. *See id.* at 272 ("In enacting the Vaccine Act, Congress established a carefully wrought federal scheme that balances the competing interests of vaccine-injured persons and vaccine manufacturers. As the legislative history indicates, the Act addressed 'two overriding concerns.'").

120. *See id.* at 273 ("Congress specifically chose *not* to pre-empt state tort claims categorically.").

traditional litigation tools like civil discovery.[121] She suggested that claimants may not prove certain causal links until they get access to civil discovery.[122] Ultimately, the dissent accused the majority of creating a "regulatory vacuum" where "no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing" vaccines.[123]

III. THE PURSUIT OF PROFIT AT THE EXPENSE OF PUBLIC HEALTH

Favorable regulations toward the pharmaceutical industry—like the Act—promote the industry's profit margins and its ability to lobby elected officials to further increase its influence.[124] Evidence suggests Wyeth knowingly and flagrantly placed a less safe DPT vaccine on the market to increase its bottom line.[125] Japan administered a safer version of the DPT vaccination as early as 1981.[126] Yet, as of 1996, 90% of vaccinations in the United States were the more dangerous 'whole cell' version of the vaccine, which caused injuries to many American children.[127] Section A discusses anecdotal experiences with the vaccine compensation program.[128] Section B illustrates improper financial relationships between vaccine manufacturers and regulators.[129] Section C briefly discusses the excise tax that funds the vaccine compensation program.[130]

121. *See id. at* 273–74 ("That decision reflects Congress' recognition that court actions are essential because they provide injured persons with significant procedural tools—including, most importantly, civil discovery—that are not available in administrative proceedings under the compensation program. . . . Congress thus clearly believed there was still an important function to be played by state tort law.").

122. *See id.* at 274 n.25 ("As an initial matter, the Special Masters in the autism cases have thus far uniformly rejected the alleged causal link between vaccines and autism. To be sure, those rulings do not necessarily mean that no such causal link exists, or that claimants will not ultimately be able to prove such a link in a state tort action, particularly with the added tool of civil discovery.").

123. *See id.* at 250 ("Until today, that duty was enforceable through a traditional state-law tort action for defective design."); *see also supra* text accompanying note 28.

124. *See* Patrick Smith & Sarah Tincher, *Big Spenders: The Players, the Firms in 2020 Lobbying*, LAW.COM (Sept. 30, 2020), https://www.law.com/nationallawjournal/2020/09/30/lobbying-2020-the-players-the-money-and-the-firms/ (on file with the *University of the Pacific Law Review*) (showing the pharmaceutical industry increased lobbying efforts by 20.3% from 2012 to 2020).

125. *See* Rock, *supra* note 42 ("According to a 1977 Wyeth document, scientists analyzed the Lilly formula and found that the purification process would yield 80% less of the component that fights pertussis than the whole-cell formula, which would result in 'a very large increase in the cost of manufacture.'").

126. *See id.* ("The Japanese use an acellular vaccine, extracting only the portion of the pertussis bug that will trigger the body's immune response to protect against the diseases. They remove or neutralize poisons that are byproducts of the bacteria, including endotoxin(s).").

127. *Id.*

128. *See infra* Section III.A.

129. *See infra* Section III.B.

130. *See infra* Section III.C.

A. Personalizing the Problem: The Death of Nathan Silvermintz

Hannah Bruesewitz was not the only child with a serious adverse reaction to the DPT vaccine.[131] Miriam Silvermintz had a similar experience when she took her son Nathan for his third DPT vaccination.[132] At the appointment, the pediatrician remarked Nathan was "growing beautifully."[133]

However, just hours after receiving the DPT vaccine, Nathan experienced severe pain and suffered a serious seizure.[134] He died less than an hour later.[135] According to Mrs. Silvermintz, Nathan's pediatrician initially said the child probably experienced an adverse reaction to the DPT vaccine.[136] After Nathan's death, the pediatrician denied the DPT vaccine caused his death.[137] Congenital heart defect was the official cause of Nathan's death; however, like many parents of vaccine-injured children, Mrs. Silvermintz was not satisfied with her doctor's answers.[138] She later learned nine other children died shortly after Nathan from the same DPT vaccine.[139] Federal regulations do not require vaccine manufacturers to produce the safest, most effective vaccine possible, even though that is a stated purpose of the Act.[140]

Mrs. Silvermintz received compensation through the Act because Nathan's death came before the 1995 rule changes.[141] She summarized the frustration parents of vaccine-injured children faced, even before the 1995 rule changes:

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131. *See generally* Rock, *supra* note 42 (describing the experiences of vaccine-injured children and their parents).

132. *See id.* ("Miriam Silvermintz of Fair Law, N.J. took her seven-month-old son Nathan to the pediatrician for his third series of vaccinations on Feb. 8, 1991.").

133. *Id.*

134. *See id.* ("Nathan collapsed, his eyes rolling back in his head, as he suffered a severe seizure.").

135. *Id.*

136. *Id.*

137. *See id.* (quoting Miriam Silvermintz) ("But when Nathan died, the doctor did an about-face and said it had nothing to do with the vaccine.").

138. *Id.*

139. *See id.* ("[B]ecause of lax federal recall regulations, Nathan appears to be the first of nine children who died shortly after getting a shot from the same DPT lot."); *see also* Parasidis, *supra* note 28, at 2222 ("The Vaccine Act contains a mandate for creating safer childhood vaccines. The HHS Secretary must 'promote the development of childhood vaccines that result in fewer and less serious adverse reactions.'").

140. 42 U.S.C.A § 300aa-27(a) (West 2022); Andrea Rock, *The Lethal Dangers of the Billion-Dollar Vaccine Business with Government Approval, Drug Companies Sell Vaccines that Can Leave Your Child Brain Damaged, Can Spread Polio from Your Baby to You—And Can Even Kill. Safer Stuff Is Available*, CNN MONEY (Dec. 1, 1996), https://money.cnn.com/magazines/moneymag/moneymag_archive/1996/12/01/218857/index.htm (on file with the *University of the Pacific Law Review*).

141. *See* Rock, *supra* note 42 ("In 1994, the U.S. Court of Federal Claims awarded damages to the Silvermintzes under the National Childhood Vaccine Injury Act of 1986."); *See generally Silvermintz, et al. v. HHS*, PLAIN SITE, https://www.plainsite.org/dockets/7ovmvsjt/united-states-court-of-federal-claims/silvermintz-et-al-v-hhs/ (last visited Apr. 25, 2021) (on file with the *University of the Pacific Law Review*) (showing no opinion was published in Mrs. Silvermintz's case).

> It was bad enough suspecting that Nathan's death was caused by a vaccine, but still I had believed it was one of those one-in-a-million things. When I learned that his death was followed within three weeks by another in New Jersey and then another in Illinois and another in Pennsylvania and five more after that while this batch of vaccine stayed on the market for an entire year. It broke my heart. I feel betrayed by the drug companies who make vaccines and by the doctors and government agencies I'd always trusted to protect us.[142]

The Act requires the Secretary to provide public notice of all vaccine-related injury claims.[143] When the Secretary published notice of Mrs. Silvermintz's claim, her name appeared alongside 199 other petitioners.[144] This represents a small percentage of actual vaccine-injuries because many may not file for compensation at all.[145]

B. Pharmaceutical Lobbying Influence in Research and Rulemaking

Large Pharmaceutical Companies ("Big Pharma") have special interest ties to policymakers and members of the advisory committee, who are supposed to provide the vaccine compensation board with unbiased scientific opinions.[146] Those connections erode the advisory committee's effectiveness as well as public trust.[147] An example of this detrimental influence is James Cherry, a pertussis expert and professor of pediatrics at the University of California at Los Angeles.[148]

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142. Rock, *supra* note 42.

143. 42 U.S.C.A §§ 300aa-27(b)–(c) (West 2021); National Vaccine Injury Compensation Program; List of Petitions Received, 61 Fed. Reg. 145 (July 26, 1996).

144. National Vaccine Injury Compensation Program; List of Petitions Received, 61 Fed. Reg. 145 (July 26, 1996).

145. *See generally* Parasidis, *supra* note 28 at 2153 (showing lack of public awareness for reporting adverse vaccine reactions).

146. Rock, *supra* note 42.; *Big Pharma*, MERRIAM-WEBSTER DICTIONARY, https://www.merriam-webster.com/dictionary/Big%20Pharma (last visited Mar. 11, 2022) (defining big pharma as "large pharmaceutical companies considered especially as a politically influential group."); *see also* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7680 (Feb. 8, 1995) (codified at 42 C.F.R. § 100.3 (2021)) ("One commenter [wrote] regarding concerns that members of the [Advisory Committee] who have advised pharmaceutical companies, or conducted research funded by such companies have a conflict of interest which precludes their serving on the [Advisory Committee]. The Department has determined that this comment is irrelevant as far as modification of the Table is concerned.").

147. Rock, *supra* note 42; *Big Pharma*, MERRIAM-WEBSTER DICTIONARY, https://www.merriam-webster.com/dictionary/Big%20Pharma (last visited Mar. 11, 2021) (defining big pharma as "large pharmaceutical companies considered especially as a politically influential group"); *see also supra* text accompanying note147.

148. Rock, *supra* note 42; *see James D. Cherry, MD*, UCLA HEALTH, https://www.uclahealth.org/james-cherry (last visited Jan. 11, 2021) ("Dr. Cherry has published 302 research papers, 108 editorials and commentaries and 282 book chapters. He is the senior editor of Feigin and Cherry's Textbook Pediatric Infectious Disease."); *Pertussis (Whooping Cough)*, CTRS. FOR DISEASE CONTROL, https://www.cdc.gov/pertussis/index.html (last visited Mar. 11, 2021) (on file with the *University of the Pacific Law Review*) (defining pertussis as contagious respiratory disease that causes coughing and difficulty breathing).

Professor Cherry was a leader on advisory committees responsible for recommending vaccine policy.[149] He also served as a paid expert witness for Lederle—which manufactured the more dangerous whole-cell DPT vaccine—in at least fifteen different lawsuits for DPT-related injuries.[150]

In 1979, Professor Cherry lectured on the potential dangers of the whole-cell pertussis vaccine, which included death.[151] However, after receiving over $500,000 in gifts from Lederle, Professor James called severe neurological reactions to the DPT vaccine "a myth."[152] By 1990, there was ample evidence to show the acellular version of the DPT vaccine was more effective and safer than Lederle's whole-cell manufacturing method.[153] That method would cost Lederle substantially more to manufacture.[154] Mark Geier, a vaccine researcher for the National Institutes of Health, put it succinctly: "Drug companies have paid a lot of money to people like James Cherry to put forth [the] image" that the whole cell DPT vaccine is safe.[155] Clear conflicts like that of Professor Cherry persist to this day; yet, Professor Cherry still researches pertussis and partners with the California Department of Public Health on research.[156]

Despite publicly inspiring confidence in vaccine safety and effectiveness, vaccine manufacturers privately continue to advocate for stronger protections against strict liability.[157] Vaccine manufacturers and their advocates—like Professor Cherry—argue vaccines are unavoidably unsafe and therefore require protections from products liability lawsuits to provide an important public

149. Rock, *supra* note 42; *see James D. Cherry, MD*, UCLA HEALTH, https://www.uclahealth.org/james-cherry (last visited Jan. 11, 2021) (on file with the *University of the Pacific Law Review*) (describing Dr. Cherry's experience serving as a visiting worker at the Medical Research Council).

150. Rock, *supra* note 42.

151. *See id.* (quoting James Cherry) ("All physicians are aware that pertussis vaccine occasionally produces severe reactions and that these may be associated with permanent sequelae [complications caused by the vaccine] or even death.").

152. *See id.* ("From 1980 through 1988, Cherry got $400,000 in unrestricted grants that he termed 'gifts' from Lederle. From 1988 through 1993, he was given $146,000 by Lederle for pertussis research, and from 1986 through 1992, UCLA received $654,418 from Lederle for pertussis research.").

153. *Id.*

154. *Id.*

155. *Id.*

156. *See James D. Cherry, MD*, UCLA HEALTH, https://people.healthsciences.ucla.edu/institution/personnel?personnel_id=7994 (last visited June 17, 2022) (on file with the *University of the Pacific Law Review*) ("Over the last 10 years [Dr. Cherry] and collaborators at the California Department of Public Health and California pediatrics infectious diseases physicians have been studying severe pertussis in young infants.").

157. MacKenzie Sigalos, *You Can't Sue Pfizer or Moderna if You Have Severe Covid Vaccine Side Effects, The Government Likely Won't Compensate You for Damages Either*, CNBC (Dec. 23, 2020, 12:32 AM), https://www.cnbc.com/2020/12/16/covid-vaccine-side-effects-compensation-lawsuit.html (on file with the *University of the Pacific Law Review*); Ludwig Burger & Pushkala Aripaka, *AstraZeneca to be Exempt From Coronavirus Vaccine Liability Claims in Most Countries*, REUTERS (July 30, 2020, 6:19 AM), https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability/astrazeneca-to-be-exempt-from-coronavirus-vaccine-liability-claims-in-most-countries-idUSKCN24V2EN (on file with the *University of the Pacific Law Review*).

benefit.[158] These groups argue for civil protection from emotional juries who may assess punitive damages that threaten the profitability and viability of manufacturing vaccines.[159] Still, most modern legal scholars recognize the need to reform the Act and ensure vaccine manufacturers are adequately researching and bringing to market the best vaccines.[160]

C. Funding the Program with Public Money

Another criticism of the Act is the excise tax levied on each vaccine dose, which funds the compensation program.[161] The current excise tax is seventy-five cents per dose.[162] The problem is not the cost of the tax, but that taxpayers bear the burden without any assurance that the vaccines they receive are the safest and most effective possible.[163]

President Reagan nearly vetoed the Act because of the excise tax.[164] He chose to sign the legislation, hoping Congress would address his concerns in subsequent funding legislation before the vaccine compensation program became fully operable.[165] Congress never addressed those concerns.[166]

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158. *See* Nina H. Compton & J. Douglas Compton, *DPT Vaccine Manufacturer Liability: Chipping Away at Strict Liability to Save the Product*, 20 N.M. L. REV. 531, 534 (1990) ("[V]accine manufacturers often defend against strict liability claims by arguing that (1) their vaccines are unavoidably unsafe products which are socially useful but associated with a small degree of risk, and (2) their vaccines were properly marketed for distribution with adequate warning. The defendant manufacturer must establish that the benefits of the product outweigh the inherent risks to obtain the unavoidably unsafe product classification and comment k protection from strict liability.").

159. *See* Bruesewitz v. Wyeth, 562 U.S. 223, 247–48 (2011) (Breyer, S., concurring) ("To allow a jury in effect to second-guess those determinations is to substitute less expert for more expert judgement."); *see also* Nina H. Compton & J. Douglas Compton, *DPT Vaccine Manufacturer Liability: Chipping Away at Strict Liability to Save the Product*, 20 N.M. L. REV. 531, 534 (1990) ("The defendant manufacturer must establish that the benefits of the product outweigh the inherent risks to obtain the unavoidably unsafe product classification and comment k protection from strict liability.").

160. *See supra* text accompanying note 28.

161. *See* Rock, *supra* note 42 ("[T]he damages awarded are not paid by drug companies; they are paid by you—in the form of a user tax tacked onto the price of each vaccination. The tax totals $33 for a child fully immunized.").

162. *About the National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/vaccine-compensation/about/index.html (last visited Jan. 10, 2021) (on file with the *University of the Pacific Law Review*).

163. Rock, *supra* note 42; Timothy M. Todd, *The Tail That Wags the Dog: The Problem of Pre-Merit-Decision Interim Fees and Moral Hazard in the National Vaccine Injury Compensation Program*, 63 U. KAN. L. REV. 1, 1 (2014).

164. Statement by President Ronald Reagan Upon Signing S. 1744, 22 WEEKLY COMP. OF PRES. DOC. 1565 (Nov. 17, 1986).

165. *See id.* ("A major factor in my decision to approve [the Act] despite the serious deficiencies in Title III is that the bill provides that the vaccine compensation program established . . . will not be effective until a separate measure funding the program is enacted. This provision offers the opportunity to ensure that any funding measure enacted by the next Congress to implement [the vaccine compensation program] will not call for any part of the cost to be borne by the Federal taxpayer.").

166. 42 U.S.C.A §§ 300aa-27(b)–(c) (West 2022); *see* Parasidis, *supra* note 28, at 2222.

IV. VACCINE SAFETY AND EFFICACY

The Act's most problematic oversight is that it does not require vaccine manufacturers to retain and review data on adverse vaccine reactions.[167] This is contrary to the Act's expressed directive to manufacture safer vaccinations for children.[168] Regulators at the Food and Drug Administration—not vaccine manufacturers—monitor adverse vaccine reactions using a "passive system" called the Vaccine Adverse Event Reporting System ("VAERS").[169]

In response to growing concern over vaccine safety, the CDC and FDA established the VAERS.[170] The system relies on self-reporting of symptoms and "is not designed to determine if a vaccine caused a health problem."[171] Instead, the VAERS identifies "unusual or unexpected patterns" that may indicate an underlying vaccine safety issue.[172] The CDC and FDA monitor the system to evaluate any unusual reporting activity or safety concerns.[173]

The VAERS is flawed for several reasons.[174] Some public health experts complain its "greatest limitation" is the "inability to determine whether a vaccine actually caused the reported adverse event."[175] This inability is compounded because the system relies on voluntary reporting of adverse reactions and much of the public—including one in four primary care physicians—is unaware of this program.[176] This confluence of factors results in inaccurate and nonexistent data on adverse events and vaccine safety.[177]

Without accurate information after vaccinations, it is impossible to determine whether a vaccine is safe or effective.[178] Accurate reporting information requires

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167. *See* Parasidis, *supra* note 28, at 2224 ("[T]he Vaccine Act does not mandate that vaccine manufacturers collect or analyze safety and efficacy data from patients in which their vaccines administered. Rather, the bulk of this work is left to regulators.").

168. 42 U.S.C.A §§ 300aa-27(b)–(c) (West 2022); *2* U.S.C.A §§ 300aa-2(a)(5) (West 2022); *see* Parasidis, *supra* note 28, at 2222 ("The Vaccine Act contains a mandate for creating safer childhood vaccines. The HHS Secretary must 'promote the development of childhood vaccines that result in fewer and less serious adverse reactions.'").

169. Parasidis, *supra* note 28, at 2224.

170. *About VAERS*, HEALTH AND HUM. SERVS., https://vaers.hhs.gov/about.html (last visited Mar. 11, 2021) (on file with the *University of the Pacific Law Review*).

171. *Id.*

172. *Id.*

173. *Id.*

174. *See generally* Parasidis, *supra* note 28, at 2153 (describing the flaws in reporting and accurate data collection).

175. 42 U.S.C.A § 300aa-22(b)(1) (West 2021); Parasidis, *supra* note 28, at 2224 (describing the flaws in reporting and accurate data collection).

176. *See* Parasidis, *supra* note 28, at 2222–23 ("According to a study by CDC officials. . . . 63.1% of pediatric healthcare providers indicated that they were very unlikely to report a minor vaccine-related adverse event, and 3.6% indicated that they were unlikely to report a serious symptom known to be an adverse event.").

177. *See id. at* 2225 ("The current, passive system results in significant underreporting of adverse events and may lead to spurious associations between vaccines and injuries. Furthermore, it is difficult to draw conclusions about risks of individual vaccines because many children receive multiple vaccinations at one time.").

178. *See id. at* 2226 ("[E]ven when adverse events are reported, the FDA is unable to determine which

vaccine manufacturers to actively gather data on vaccine injuries in exchange for products liability protections.[179] Such a requirement would not be burdensome due to technological advancements like electronic health records.[180] Whatever Big Pharma's financial burden may be in creating and monitoring an effective vaccine injury reporting system is substantially outweighed by the benefits of tort protection Big Pharma now enjoys.[181] A robust and active review system for vaccinations will ensure the public receives the safest and most effective vaccination.[182] Such a review system also reduces the public's reliance on experts, which are often on Big Pharma's payroll.[183]

V. CONCLUSION

Most of the Act's critics recognize the immense public health benefits of vaccination.[184] The Act's problem is that it achieves only one of Congress's twin goals.[185] It protects vaccine manufacturers from tort liability.[186] However, it does not provide for a quick, less adversarial avenue of compensation for vaccine-related injuries.[187] Major oversights in the Act—like the lack of mandatory data collection of adverse vaccine reactions and the causation burden of off-Table injuries—allow vaccine manufacturers to place profits ahead of people.[188]

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vaccine is associated with the adverse event, let alone whether a given vaccine may be causally related to the adverse event.").

179. *See id. at* 2228 ("A twenty-first century post-market framework must leverage recent and emerging advancements in health information technology, and should place a legal burden of diligent post-market analysis on vaccine manufacturers.").

180. *See id.* at 2227 ("Insofar as the Vaccine market is strong, the costs of a manufacturer-led active post-market analysis system are unlikely to have a substantial financial impact on manufacturers.").

181. *See supra* text accompanying note 180.

182. *See supra* text accompanying note 28.

183. *Id.* at 2227; *see* Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999–2018*, 180 JAMA INTERNAL MED. 1, 693–95 (2020) ("Congress and the executive branch benefit from fully considering the interests of all parties in society, not just those who seek to improve their access to officials through campaign contributions and lobbying expenditures. In the health sector, several organizations, notably PhRMA, the American Medical Association, the American Hospital Association, and the Blue Cross Blue Shield Association, accounted for a disproportionate share of spending on lobbying over the study period. PhRMA and the American Medical Association have historically lobbied together against government interventions in drug markets.").

184. *See* Rock, *supra* note 42 ("No one is suggesting that your kid skip their shots. However, shouldn't children receive the safest vaccine that can be made? And shouldn't your doctors always alert you to the danger signs—before and after immunization—that you should watch for to prevent tragedy?").

185. *See* Meyers, *supra* note 3, at 788 ("[T]he objectives of parents' groups and other advocates for children and adults who have suffered serious injuries after receiving vaccines have not been satisfied.").

186. *See* Bruesewitz v. Wyeth, 562 U.S. 223, 243 (2011) ("[W]e hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects.").

187. *See supra* text accompanying note 185.

188. *See* Rock, *supra* note 42 ("Manufactures put profits ahead of vaccine safety—with impunity.").

Part of the problem is the financial influence of Big Pharma over regulators.[189] Advocacy groups for the vaccine-injured have substantially less resources to engage in the political process and change the Act.[190] Despite bipartisan agreement that Congress needs to revise certain aspects of the Act, Congress has made no serious effort to revise the legislation.[191]

Perhaps the best example demonstrating the Act no longer aligns with congressional intent is the number of off-Table vaccine injuries.[192] Initially, over 90% of claims under the Act were table injuries; however, since the 1995 rule changes the vast majority of claims are off-Table injuries.[193] Off-Table claims are problematic because they often lead to the same type of adversarial and prolonged litigation Congress intended the Act to avoid.[194] These cases clog up the court system and are contrary to Congress's original intent for the Act.[195] Making matters worse, off-Table injury claims are more difficult to prove due to the weak data collection systems for adverse reactions.[196]

The need to revise the Act began with the 1995 rule changes, but since 2011 the need has amplified, as the haphazard *Bruesewitz* decision exemplifies.[197] Congress must define the thirteen words that the Supreme Court excised from the Act in *Bruesewitz.*[198] Furthermore, Congress must clearly explain whether it sees value in certain design defect claims that give injured claimants access to tools like civil discovery.[199] Without doing so, Congress risks jeopardizing the health of ″

189. *See* Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999– 2018*, 180 JAMA INTERNAL MED. 1, 1 (2020) ("[P]harmaceutical and health product industry spent $4.7 billion, an average of 233 million per year, on lobbying the US federal government; $414 million on contributions to presidential and congressional electoral candidates, national party committees, and outside spending groups; and $877 million on contribution to state candidates and committees.").

190. *See generally* Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999–2018*, 180 JAMA INTERNAL MED. 1, 1 (2020) (showing the disproportionate influence Big Pharma lobbyists have over the legislative process).

191. Parasidis, *supra* note 28 at 2234–35.

192. Meyers, *supra* note 3, at 801 ("The Table was intended [by Congress] to be a crucial innovation, a key to quick, hospitable, and less adversarial proceedings. [The Table] is now central to only a small minority of cases.").

193. *See id.* at 790 n.19, 798, 801 (explaining 90% of claims are off-table injuries and are essentially cause-in-fact cases).

194. *See id.* at 790 ("The cases are now substantially more difficult, complex, and time-consuming to litigate. The science is less clear, and the special masters have more difficult and complex scientific disputes to resolve than they did for the relatively simpler Table injury claims.").

195. *See* Parasidis, *supra* note 28, at 2234 ("[A]s of April 2016, off-table injuries accounted for more than ninety-eight percent of the average caseload of a special master.").

196. *See id.* at 2235 ("If the CDC, FDA, and IOM acknowledge that the data often are insufficient to make meaningful conclusions about vaccine-related adverse events, how can injured parties be expected to meet the high legal standard for compensation?").

197. Bruesewitz v. Wyeth, 562 U.S. 223, 271 (2011); *see supra* text accompanying note 28.

198. *Bruesewitz* , 562 U.S. at 273.

199. *Id.*

future generations by promoting confusing and time-consuming adjudication to protect the profits of vaccine manufacturers.[200]

200. *Id.*