Volume 111
Issue 3 *Dickinson Law Review - Volume 111, 2006-2007*

1-1-2007

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I. Introduction

Vaccines are widely hailed as one of the greatest medical and public health accomplishments of the twentieth century.[1] Every year, vaccines prevent untold numbers of people from contracting potentially fatal diseases.[2] Because vaccines are so effective and have such visibly positive results, it is easy to forget that they carry a modicum of risk. Some people who receive vaccinations, for reasons that are not entirely understood, experience reactions such as anaphylactic shock, seizures, and, occasionally, death.[3] These consequences raise the following

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1. Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900-1999: Impact of Vaccines Universally Recommended for Children*, 48 MORBIDITY & MORTALITY WKLY. REP. 243, 244 (1999).

2. *Id.* at 243.

3. Ctrs. for Disease Control & Prevention, *Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions: Recommendations of the Advisory Committee on Immunization Practices*, MORBIDITY & MORTALITY WKLY. REP. RR-12, Sept. 6, 1996, at 4-5.

question: When the government recommends that members of the public receive a vaccine and some people are subsequently injured by that vaccine, what role should the government play?

The United States first faced this question in 1976.[4] About sixty years earlier, in 1918, influenza swept the globe and left twenty million people dead.[5] In early 1976, a soldier at Fort Dix, New Jersey, died from a strain of influenza that was markedly similar to the 1918 virus.[6] Public health officials at the Centers for Disease Control and Prevention (CDC) feared that this was the beginning of a similar pandemic.[7] At their urging, the federal government initiated a swine flu immunization campaign with visible support from President Gerald Ford.[8]

Public health and government officials assumed "that the vaccine manufacturers would gladly produce[,] for a fee close to cost[,] the needed vaccine."[9] They did not anticipate that vaccine manufacturers and their insurers would not participate in such a massive campaign unless the government provided some form of liability protection to them.[10] Given these concerns and the rapidly approaching flu season, Congress quickly passed the National Swine Flu Immunization Program (Swine Flu Act).[11] President Ford signed the Act into law on August 12, 1976.[12] The Act transferred any liability on the part of the vaccine manufacturers and administrators to the United States government.[13] In other words, the United States became liable "for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program. . . ."[14]

Vaccinations began on October 1, 1976; ultimately, over forty-five million people were vaccinated.[15] But, several months into the campaign, only a few cases of the deadly influenza had emerged. On December 16, 1976, the government halted the campaign for two

4. Richard Krause, *The Swine Flu Episode and the Fog of Epidemics*, 12 EMERGING INFECTIOUS DISEASES 40, 41-42 (2006).

5. Press Release, Ctrs. for Disease Control & Prevention, Researchers Reconstruct 1918 Pandemic Influenza Virus; Effort Designed to Advance Preparedness (Oct. 5, 2005) (on file with authors).

6. Krause, *supra* note 4, at 41.

7. *Id.*

8. *Id.*

9. INST. OF MED., VACCINE SUPPLY AND INNOVATION 93 (1985) [hereinafter INST. OF MED., VACCINE SUPPLY AND INNOVATION].

10. *Id.*

11. *Id.* at 93-94.

12. National Swine Flu Immunization Program, Pub. L. No. 94-380, 90 Stat. 1113 (1976).

13. INST. OF MED., VACCINE SUPPLY AND INNOVATION, *supra* note 9, at 93 (quoting Pub. L. No. 94-380, § 2(k)(2)(A)).

14. *Id.*

15. Krause, *supra* note 4, at 41.

reasons: 1) a flu pandemic seemed unlikely, and 2) reports had emerged that one out of every 100,000 people who received the vaccine developed Guillain-Barré syndrome.[16] Guillain-Barré syndrome is a rare neurological disorder that can lead to paralysis.[17] Because the swine flu campaign was so widely publicized, and many cases of Guillain-Barré syndrome emerged, a flood of lawsuits appeared.[18] Due to the Swine Flu Act's liability provisions, the federal government was the defendant for each of those claims.[19] This resulted in the government devoting countless hours and millions of dollars to defending itself and, eventually, paying awards to Guillain-Barré victims.[20] It is widely accepted that the swine flu program was a disaster, resulting from hasty decisions by the CDC, presidential advisors, and a Congress that believed a deadly flu pandemic was imminent.[21]

Ten years later, the nation faced a shortage of childhood vaccines because manufacturers, who were exiting the market, lacked strong liability protections.[22] With the swine flu episode a not-so-distant memory, Congress fashioned a no-fault, ideally non-adversarial system to compensate the families of children who were injured after receiving a vaccination.[23] It took Congress over three years to pass the final legislation that created the National Vaccine Injury Compensation Program (VICP);[24] the program has remained in effect for nearly twenty years.[25] During the last few years, when the government has considered massive vaccine campaigns for seasonal influenza and smallpox, the

16. INST. OF MED., VACCINE SUPPLY AND INNOVATION, *supra* note 9, at 95.

17. Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 13 (2005).

18. INST. OF MED., VACCINE SUPPLY AND INNOVATION, *supra* note 9, at 95.

19. *Id.* at 95-111.

20. *Id.*

21. *See generally* RICHARD NEUSTADT & HARVEY FINEBERG, THE EPIDEMIC THAT NEVER WAS: POLICY MAKING AND THE SWINE FLU AFFAIR 17, 17-49 (1983) (detailing policy-making process that surrounded swine flu scare); Georgene Vairo, *Remedies for Victims of Terrorism*, 35 LOY. L.A. L. REV. 1265, 1293 (2002) ("[O]ne of the few times Congress involved itself in the personal injury realm was in the case of the Swine Flu disaster several decades ago when the federal government itself was one of the culpable targets."); Elyse Tanouve, *The Vaccine Business Gets a Shot in the Arm*, WALL ST. J., Feb. 25, 1988, at B1 ("A raft of lawsuits over adverse reactions to vaccines for 'swine flu' and other diseases followed."); Abigail Trafford, *It's Deja Flu All Over Again*, WASH. POST, Nov. 8, 2005, at F1 ("The disease turned out to be a phantom. There was no flu epidemic. Worse, the vaccine caused illness.").

22. *See infra* Part III.A.

23. *See infra* Part III.A-B.

24. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3756 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (2000)).

25. *Id.*

VICP has served as a model program for congressional members.[26] Congress's concerns about vaccine injury compensation and manufacturer and administrator liability are especially relevant today, as experts predict that the country, and the world, may soon face a deadly avian flu pandemic.[27]

With these issues in mind, it is useful to consider the forces that led to the creation of the VICP, and how the program has impacted subsequent vaccination campaigns in the United States. Part II of this article will explain the fundamental elements of the VICP. Part III will explore the program's genesis as well as the development of its funding mechanisms. Part IV will apply theoretical frameworks to the story told in Part III, to aid in understanding how Congress came to pass the VICP. Part V will evaluate criticisms that the VICP has faced during its first twenty years. Finally, Part VI will explore how the lessons learned from the VICP's creation can be applied to contemporary vaccine injury issues, such as the emerging threat of avian flu.

II. The National Vaccine Injury Compensation Program

A. Jurisdiction, Governance, and Funding

The VICP provides a no-fault compensation system that acts as an alternative to filing tort claims against vaccine manufacturers and administrators.[28] "No-fault" means that if certain predetermined conditions are met, a person will automatically receive an award from the VICP.[29] In other words, once a person qualifies to receive compensation from the VICP, there is no need to demonstrate fault on the part of the vaccine manufacturer or administrator.

The VICP is housed in the Division of Vaccine Injury Compensation, which is part of the Health Resources and Services Administration in the U.S. Department of Health and Human Services (DHHS).[30] Administration of the VICP rests primarily with the DHHS, but also involves the Court of Federal Claims (Claims Court) and the Department of Justice (DOJ).[31] The Advisory Commission on

26. *See infra* Part VI.A-B.

27. *See infra* Part VI.D.

28. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3756.

29. *See, e.g.*, William J. Gaine, *No-Fault Compensation Systems*, 326 BRIT. MED. J. 997, 998 (2003).

30. Health Res. & Servs. Admin., Fact Sheet: National Vaccine Injury Compensation Program, http://www.hhs.gov/nvpo/factsheets/fs_tableIV_doc1.htm (last visited August 4, 2006).

31. *Id.*

Childhood Vaccines, whose nine members are appointed by the DHHS Secretary, is charged, *inter alia*, with "advis[ing] the Secretary on the implementation of the [VICP]; . . . recommend[ing] changes in the [VICP]; [and] recommend[ing] to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the [VICP]."[32]

The Commission is composed of three health professionals who are not government employees.[33] At least two are pediatricians with expertise in the epidemiology and prevention of childhood diseases and adverse reactions associated with vaccines.[34] The next three members of the Commission are drawn from the general public, and at least two represent children who experienced a vaccine-related injury or death.[35] The final three members of the Commission are lawyers.[36] At least one specializes in representing families of children who experienced a vaccine-related injury or death and at least one represents a vaccine manufacturer.[37] Non-voting, ex officio Commission members include the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the CDC, and the Commissioner of the Food and Drug Administration (FDA).[38] The Commission holds no less than four public meetings a year.[39] During these meetings, the Commission receives briefings from those who contribute to the VICP's administration, such as representatives from the DHHS's Division of Vaccine Injury Compensation.[40] In addition, Commission members report on the progress of the Commission's working groups.[41]

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32. 42 U.S.C. § 300aa-19(f) (2006).

33. 42 U.S.C. § 300aa-19(a)(1)(A) (2006).

34. *Id.*

35. 42 U.S.C. § 300aa-19(a)(1)(B) (2006).

36. 42 U.S.C. § 300aa-19(a)(1)(C) (2006).

37. The current members of the Advisory Commission on Childhood Vaccines are: Don L. Wilbur, MD (Oklahoma City Clinic), Suzanne Hudson Vaughn, Robert P. Fuller, MD (Department of Traumatology & Emergency Medicine, University of Connecticut Health Center), Margaret Ann Barnett Stern, JD (Texas Children's Hospital), Loren G. Cooper, JD (US Legal Operations, Dispute Resolutions and Prevention, GlaxoSmithKline), Marguerite Evans Willner, Jaime G. Deville, MD (Department of Pediatrics Infectious Diseases, University of California-Los Angeles), William P. Glass, Jr., JD (Glass & Glass), and Robin Stavola. Health Res. & Servs. Admin., *Advisory Commission on Childhood Vaccines Roster*, http://www.hrsa.gov/vaccinecompensation/roster.htm (last visited Aug. 4, 2006).

38. 42 U.S.C. § 300aa-19(a)(2) (2006).

39. 42 U.S.C. § 300aa-19(c) (2006).

40. Health Res. & Servs. Admin., Minutes from the Advisory Commission on Childhood Vaccines Meeting, Dec. 12, 2005, http://www.hrsa.gov/vaccinecompensation/accvmin12-12-05.htm.

41. *E.g.*,

> [T]he Workgroup agreed on two overarching principles in the Guiding Principles. First, the [Vaccine Injury] Table should be scientifically and

The VICP is funded through two separate streams. For injuries related to vaccines that were administered before October 1, 1988, funding is drawn from federal tax dollars appropriated by Congress.[42] This stream accounts for $110 million a year.[43] For injuries related to vaccines that were administered on or after October 1, 1988, funding is provided by the Vaccine Injury Compensation Trust Fund.[44] The money in that fund comes from an excise tax, levied upon the consumer, of $0.75 on every dose of vaccine that is covered by the VICP.[45] In fiscal year 2005, the trust fund contained over $2.2 billion.[46] That year, the trust fund collected $196 million in revenue; $123 million was collected through the excise tax and $73 million was generated from interest.[47] In an average year, the VICP pays $50 to $75 million in awards.[48]

B. Procedures and Processes

A person can qualify to receive compensation from the VICP through one of three means: 1) the person shows that an injury listed on the VICP's Vaccine Injury Table occurred; 2) the person proves that a vaccine caused his or her condition; or 3) the person proves that a vaccine aggravated a previously existing condition.[49] The Vaccine Injury Table lists the vaccines covered by the VICP as well as compensable injuries and the timeframe following vaccination within which the injury must have occurred.[50] For example, a person would be eligible for VICP compensation if he or she received a measles, mumps, and rubella (MMR) vaccination and experienced anaphylactic shock zero to four hours later.

The Vaccine Injury Table can be amended by regulations promulgated by the DHHS Secretary.[51] The Secretary must request recommendations and comments from the Advisory Commission on

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> medically credible. Second, from a policy perspective, where there is credible scientific and medical evidence both to support and to reject a proposed change to the [Vaccine Injury] Table, the change should be made to the benefit of petitioners.

Id.

42. 42 U.S.C. § 300aa-15(i)-(j) (2006).
43. 42 U.S.C. § 300aa-15(j) (2006).
44. 42 U.S.C. § 300aa-15(i) (2006).
45. Nat'l Immunization Program, CDC Vaccine Price List, Oct. 31, 2006, http://www.cdc.gov/nip/vfc/cdc_vac_price_list.htm.
46. Health Res. & Servs. Admin., Minutes, *supra* note 40.
47. *Id.*
48. *Id.*
49. 42 U.S.C. § 300aa-11(c) (2006).
50. 42 U.S.C. § 300aa-14 (2006); *see* Appendix A: Vaccine Injury Table.
51. 42 U.S.C. § 300aa-14(c) (2006).

Childhood Vaccines for any proposed changes to the Table.[52] These changes can "add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death."[53] In addition, the Secretary must amend the Table to include any vaccine that the CDC recommends for "routine administration to children."[54]

Any person, child or adult, who believes that he or she was injured by a vaccine listed on the Vaccine Injury Table can apply to the VICP for compensation.[55] If the person in question died, then his or her estate or legal guardian can apply to the VICP.[56] A person can initiate contact with the VICP by filing a petition with the U.S. Court of Federal Claims.[57] The Claims Court's clerk will "immediately forward the filed petition to the chief special master for assignment to a special master."[58] Once he or she receives a petition, a special master will "issue a decision . . . with respect to whether compensation is to be provided under the Program and the amount of such compensation."[59] The person who filed the petition can then decide to accept the special master's award or appeal it to the Claims Court.[60] Once the Claims Court issues a decision, the petitioner can decide to accept the compensation, decline the compensation and leave the VICP to file a civil suit, or appeal the decision.[61] The Claims Court's decision can be appealed to the U.S. Court of Appeals for the Federal Circuit and, ultimately, to the U.S. Supreme Court.[62]

VICP awards are subject to a number of restrictions. Pain and suffering awards are limited to $250,000 and punitive damages are prohibited.[63] Awards can include compensation for medical expenses, loss of earning capacity, and reasonable attorney's fees.[64] In addition, if the person in question died, then the award is capped at $250,000 plus

52. 42 U.S.C. § 300aa-14(d) (2006).
53. 42 U.S.C. § 300aa-14(c)(3) (2006).
54. 42 U.S.C. § 300aa-14(e) (2006).
55. 42 U.S.C. § 300aa-11(b) (2006).
56. *Id.*
57. 42 U.S.C. § 300aa-11(a) (2006).
58. 42 U.S.C. § 300aa-11(a)(1) (2006). The Claims Court can appoint up to eight special masters for terms of four years. 42 U.S.C. § 300aa-12(d) (2006).
59. 42 U.S.C. § 300aa-12(d)(3)(A) (2006).
60. 42 U.S.C. § 300aa-12(e) (2006).
61. 42 U.S.C. §§ 300aa-12(e), 21 (2006).
62. 42 U.S.C. § 300aa-12(f) (2006).
63. 42 U.S.C. §§ 300aa-15(a)(4), 15(d) (2006).
64. 42 U.S.C. §§ 300aa-15(a), 15(e)(1)(A) (2006).

attorney's fees.[65] Since its inception, over 11,000 petitions have been filed with the VICP.[66] The average award is $824,463.[67]

A person can directly sue a vaccine administrator or manufacturer under the following conditions: 1) the person's petition was deemed non-compensable and dismissed by the VICP; 2) the person rejects the compensation granted by the VICP; or 3) the vaccine in question is not covered by the VICP.[68] If someone chooses to exit the VICP system and go to court, there are limitations on the available theories of tort liability. Liability against vaccine manufacturers is prohibited if the injury or death was "unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[69] Essentially, this means that the injured person can prevail only in certain types of situations, such as when the manufacturer conducted "insufficient testing, or produc[ed] [] a 'bad batch' of vaccine."[70]

III. Creation of the VICP

A. Establishment of the Program

In April 1982, the television network NBC aired a program entitled "DPT: Vaccine Roulette" that portrayed the harmful adverse effects experienced by some children following administration of the diphtheria, pertussis, and tetanus (DPT) vaccine.[71] These adverse reactions were largely attributed to the pertussis vaccine (the "P" in DPT). Several local radio stations picked up the story. On April 19, Kathi Williams, the mother of a child who suffered a severe reaction after receiving the DPT vaccine, called a radio station "to see if there was something being done by local parents."[72] The station took her name and number and said that,

65. 42 U.S.C. § 300aa-15(a)(2) (2006).

66. Health Res. & Servs. Admin., *National Vaccine Injury Compensation Program Statistics Reports*, http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (last visited Aug. 4, 2006).

67. Health Res. & Servs. Admin, *Frequently Asked Questions: Award Amounts Under VICP*, http://www.hrsa.gov/vaccinecompensation/ (last visited Aug. 4, 2006).

68. Health Res. & Servs. Admin, *National Vaccine Injury Compensation Program Strategic Plan*, Apr. 2006, ftp://ftp.hrsa.gov/vaccinecompensation/strategic_Plan_20060411.pdf.

69. 42 U.S.C. § 300aa-22(b)(1) (2006).

70. John G. Culhane, *Tort, Compensation, and Two Kinds of Justice*, 55 RUTGERS L. REV. 1027, 1097-98 (2003).

71. *DPT: Vaccine Roulette* (NBC television broadcast Apr. 1982); INST. OF MED., ADVERSE EFFECTS OF PERTUSSIS AND RUBELLA VACCINES 323 (Christopher P. Howson et al., eds. 1991).

72. *Immunization and Preventive Medicine: Hearing Before the Subcomm. on Investigations and General Oversight of the S. Comm. on Labor and Human Resources*, 97th Cong. 79 (1982) [hereinafter *Hearing on Immunization and Preventive Medicine*]

if they received similar calls, they would put the callers in touch with her.[73] By the end of the day, the station had received calls from three other parents.[74] After speaking with these parents, Williams realized that they "were all hearing basically the same stories. Generally [they] found that most parents did not know the pertussis vaccine had severe side effects."[75] These parents decided to form a group to offer support and information to other concerned parents. They named the group Dissatisfied Parents Together.[76] The group's acronym, DPT, was a deliberate choice to clearly link the group to the DPT vaccine.[77]

About a month later, the Senate Labor and Human Resources Committee's Subcommittee on Investigations and General Oversight held a hearing about Immunization and Preventive Medicine.[78] Senator Paula Hawkins (R-FL), chairperson of the Subcommittee, invited multiple stakeholders to testify.[79] Kathi Williams and Marge Grant represented Dissatisfied Parents Together and detailed the post-vaccination reactions suffered by their children.[80] William H. Foege, Director of the CDC, expressed the agency's concerns about vaccine safety.[81] He explained that, while most children experience no reaction after receiving the DPT vaccine, "a prospective study at UCLA on over 15,000 doses [of the vaccine] showed nine children with convulsions and nine with episodes of collapse, for a frequency of 1 in 1,750 immunizations for each complication."[82] After acknowledging this complication rate, Foege urged the Subcommittee to recognize that the "DPT: Vaccine Roulette" program presented only one side of the vaccine safety issue. He explained that, while the program

> provided an excellent portrayal of the human suffering and pain which result from pertussis vaccine, . . . the documentary failed to clearly spell out the price of the disease. It did not show mental

(testimony of Kathi Williams, Dissatisfied Parents Together).

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*; *see National Childhood Vaccine-Injury Compensation Act: Hearing on S. 2117 Before the S. Comm. on Labor and Human Resources*, 98th Cong. 49 (1984) [hereinafter *Hearing on the National Childhood Vaccine-Injury Compensation Act*] (testimony of Jeffrey H. Schwartz, President, Dissatisfied Parents Together).

78. *See Hearing on Immunization and Preventive Medicine*, *supra* note 72.

79. *Id.*

80. *Id.* at 79 (testimony of Kathi Williams & Marge Grant, Dissatisfied Parents Together).

81. *Id.* at 6 (testimony of William H. Foege, Director, CDC).

82. *Id.*; *see* Christopher L. Cody et al., *Nature and Rates of Adverse Reactions Associated with DPT and DT Immunizations in Infants and Children*, 68 PEDIATRICS 650, 652-55 (1981).

> retardation caused by pertussis disease. It provided no feel for an outbreak of pertussis with children of a village whooping through the night. It provided no pictures of caskets of small children who are victims of a preventable disease.[83]

With this statement, Foege summarized one of the intrinsic dilemmas in vaccine policy brought out by the hearing: while the DPT vaccine was effective at preventing a devastating childhood disease, it would inevitably cause a small number of children to suffer permanent severe disabilities.[84]

By the start of the next Congress, Senator Hawkins was determined to craft a bill aimed at providing compensation to families of children who were injured by vaccines. Her interest in the issue was not surprising; as a survivor of child abuse,[85] she had developed a clear record as an advocate for children's issues.[86] As acting chairperson of the Senate Committee on Labor and Human Resources, Hawkins held another hearing on the pertussis component of the DPT vaccine on July 22, 1983.[87] By this time, Dissatisfied Parents Together had become more formalized and was run by a governing board.[88] When the group heard that Hawkins wanted to develop a vaccine compensation program, they used the hearing as an opportunity to suggest guidelines for the bill. Jeffrey Schwartz, the father of a child who died after receiving a vaccine and the new president of DPT, asked that any compensation program

> expressly acknowledge that pertussis vaccines can, and in some cases do, cause serious reactions, including seizures, brain damage, and even death. [And], the bill must not simply be an effort to sweep the DPT vaccine problem under the rug. . . . The bill should contain positive commitments and incentives to reduce the risk of reaction to

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83. *Hearing on Immunization and Preventive Medicine*, *supra* note 72, at 6-7 (testimony of William H. Foege, Director, CDC).

84. *Id.*

85. Nadine Brozan, *A Senator Recounts Her Own Experience as an Abused Child*, N.Y. TIMES, Apr. 27, 1984, at A1 ("[Hawkins] told a crowded hearing that she had been abused when she was a child by a 'neighbor, a man around the corner.'"); *see also* PAULA HAWKINS, CHILDREN AT RISK, MY FIGHT AGAINST CHILD ABUSE: A PERSONAL STORY AND A PUBLIC PLEA (1986).

86. *See, e.g.*, Phil Gailey, *For Senator Hawkins, A Debatable First Year*, N.Y. TIMES, Dec. 15, 1981, at B18 ("Her major legislative achievement is a proposal to give $500 million in tax breaks to working mothers who have to put their children in day care centers. She is also pushing legislation on the problem of missing children."); Ellen Hume, *Sen. Paula Hawkins Struggles in Reelection Bid to Overcome Challenge from Popular Governor*, WALL ST. J., Oct. 20, 1986, at 1 (naming Hawkins's priorities as "drugs and family violence").

87. *Task Force Report on Pertussis: Hearing Before the S. Comm. on Labor and Human Resources*, 98th Cong. (1983).

88. *Id.* at 50 (statement of Jeffrey H. Schwartz, President, Dissatisfied Parents Together).

> the current vaccine and promote development of safer vaccines.[89]

Schwartz's request anticipated the debate that would dominate negotiations to develop a vaccine compensation program: how could Congress create a program that would compensate the families of vaccine-injured children and simultaneously provide incentives for vaccine manufacturers to develop safer products?

By the middle of the 98th Congress, vaccine compensation bills had been introduced by Hawkins in the Senate and by Henry Waxman (D-CA) in the House of Representatives.[90] Waxman's concern appeared natural, given his interest in health and safety as well as his chairmanship of the House Subcommittee on Health and the Environment.[91] In addition, Waxman was skilled at constructively working with the pharmaceutical industry. He was in the midst of successfully brokering an agreement with drug manufacturers that would "foster the invention of new drugs and lower the price of older drugs coming off patent."[92]

On May 3, 1984, Hawkins held a hearing about her proposed compensation plan bill, S. 2117.[93] She opened the hearing by explaining that her intention was "not to frighten parents away from immunizing their children against childhood diseases, nor [was] it to assess any blame. My intent is simply to improve our Nation's immunization program so that it better achieves its original goal of safeguarding our children's health."[94] Senator Edward Kennedy (D-MA), who seconded Hawkins's sentiments, succinctly stated Congress's concerns:

> We must be able to get vaccines to children in the right time and place, at an acceptable cost and without creating exorbitant and unpredictable legal difficulties. We must be able to assure parents that when their children are the victims of an appropriate and rational national policy, a compassionate Government will assist them in their hour of need. We cannot tolerate a system which discourages immunization, increases the risks to the very children in need of

89. *Id.*

90. S. 2117, 98th Cong. (1984); H.R. 5810, 98th Cong. (1984).

91. *See, e.g.*, *Auto Rental Concerns Answer Safety Charges*, N.Y. TIMES, Dec. 8, 1983, at B11 ("At a news conference Tuesday, Representative Henry Waxman, Democrat of California, accused officials of the Federal Trade Commission of 'sitting on their hands' and blocking an investigation into complaints that the rental firms had poor records in complying with recall orders."); Editorial, *Cutting the Wrong Health Care*, N.Y. TIMES, Apr. 6, 1981, at A14 ("'If this [Medicaid] "cap" is adopted, millions will suffer and no "safety net" will catch them,' warns Representative Henry Waxman, the chairman of a House subcommittee on health.").

92. H.R. 3605, 98th Cong. (1984); Editorial, *How Much Haven for Drug Pioneers?*, N.Y. TIMES, June 25, 1984, at A14.

93. S. 2117, 98th Cong. (1984).

94. *Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77, at 1 (statement of Sen. Paula Hawkins).

> protection, and encourages litigation within a tort system which awards few handsomely and sends others equally aggrieved away penniless.[95]

The Committee then heard from representatives from all sides of the vaccine compensation debate, including the government, aggrieved families, pharmaceutical companies, and trade organizations.[96]

Edward M. Brandt, Jr., Assistant Secretary of DHHS, testified on behalf of the government. He explained that, although the bill had "a laudable goal," it also contained "major weaknesses which [made] it impossible for [DHHS] to support."[97] Because the bill contained a list of injuries or conditions that would be compensated, Brandt feared that the bill established "a strong presumption that vaccine[s] [are] responsible for essentially any adverse condition that happens after immunization unless there is incontrovertible evidence of other causation."[98] Next, Brandt explained that, based on calculations done by the Congressional Budget Office, the bill would cost the Federal Treasury nearly $5 billion in its first three years alone.[99] Finally, Brandt took on the bill's retroactivity provision. Because the bill would have allowed compensation for vaccine-related injuries that occurred before the proposed law took effect, Brandt felt that the public's confidence in immunizations would be even further undermined.[100]

Opposition to the bill continued when Alan R. Nelson, a member of the American Medical Association's (AMA) Board of Trustees, testified. Nelson's concerns were distinct from Brandt's. Nelson began by explaining that "[b]eneficial legislation should strike a fair balance between the desirable goal of compensating the victims of serious injuries and the need for vaccine-producing companies to operate in an environment with some measure of protection from the extremely high legal costs [that result from lawsuits by aggrieved families]."[101]

While the bill would have established a federal compensation

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95. *Id.* at 4 (statement of Sen. Edward Kennedy).

96. *See Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77.

97. *Id.* at 7 (testimony of Edward M. Brandt, Jr., Assistant Secretary, DHHS).

98. *Id.* at 7-8.

99. *Id.* at 8.

100. *Id.* Brandt's testimony was indicative of an administration that was reluctant to expand the role of the federal government. *See, e.g.*, Elizabeth Wehr, *Dying Children Prompt Legislation: National Health Policy Sought for Organ Transplant Surgery*, 1984 CONG. Q. 453 ("'Its objectives can be achieved without legislation,' according to Dr. Edward N. Brandt, Jr., assistant secretary for health at the Department of Health and Human Services. 'I just do not believe that direct government involvement in the procurement of organs will necessarily improve the system any further. . . .'").

101. *Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77, at 180 (testimony of Alan R. Nelson, Board of Trustees, AMA).

program for families of vaccine-injured children, it would have also preserved the option for these families to sue vaccine manufacturers and administrators in the traditional tort system.[102] Nelson believed that this would not provide "sufficient protection" against "the high expense of litigation that is driving [vaccine] manufacturers' costs up. . . ."[103] Nelson made clear that as long as "private tort remedy" remained an option, the AMA would not support the proposed compensation program.[104]

John E. Lyons, President of Merck Sharp & Dohme, a vaccine manufacturer, echoed Nelson's concerns. He likened the current torts system to "a lottery" and explained that "[i]f a compensation system promptly and fairly compensates all injured persons for their actual losses, there is no need to continue the tort system alternative."[105] He advocated for a no-fault compensation system that would be the exclusive remedy available to vaccine-injured children.[106] However, he did admit that the tort system could play a role in providing compensation. Lyons said that "when a manufacturer fails to produce a vaccine in accordance with Government standards or a health care provider fails to administer the vaccine in accordance with medical standards, the tort system should be open for an injured party to recover."[107] In other words, Lyons wanted to see a compensation program that eliminated the tort system option except in cases where a vaccine manufacturer had deviated from FDA guidelines.

Despite strong opposition from DHHS and vaccine manufacturers, some groups testified to express great support for the proposed program. Jeffrey Schwartz spoke on behalf of Dissatisfied Parents Together and voiced the group's support for the compensation program.[108] Martin H. Smith, President-elect of the American Academy of Pediatrics, explained that his group had commissioned its own estimate of the proposed program's costs, which came in at about one-fourth of the DHHS numbers.[109] He also reminded the Committee that "[t]he present day

102. S. 2117, 98th Cong. (1984).

103. *Id.*

104. *Id.*; *see* Philip M. Boffey, *Vaccine Liability Threatens Supplies*, N.Y. TIMES, June 26, 1984, at C1 ("The American Medical Association at its annual meeting last week approved a report calling for the Federal Government to assume responsibility for compensating the victims of mandatory childhood immunization programs, relieving the manufacturers of liability risk unless they are negligent.").

105. *Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77, at 277 (testimony of John E. Lyons, President, Merck Sharp & Dohme).

106. *Id.*

107. *Id.* at 278.

108. *Id.* at 49-51 (testimony of Jeffrey H. Schwartz, President, Dissatisfied Parents Together).

109. *Id.* at 147 (testimony of Martin H. Smith, President-elect, American Academy of

liability cost under the tort process is incorporated into the present-day cost of the vaccines. That cost involved in the vaccines could be reduced in proportion to the acceptance of a compensation system."[110] In his opinion, a well-run compensation program could actually lower the cost of vaccines, making them easier for parents to purchase and, in turn, bringing continued revenues to vaccine manufacturers.

After this hearing, the fate of Hawkins's bill remained unclear. Her bill had bipartisan support from the following three co-sponsors: Orrin Hatch (R-UT), Slade Gorton (R-WA), and Spark Matsunaga (D-HI).[111] Many Senators had told Hawkins that they were uncomfortable co-sponsoring her bill because it would still allow families to sue vaccine manufacturers directly. However, those Senators intimated that if that provision were removed, they would support the bill.[112]

A few months later, as many had predicted, the dire situation of vaccine manufacturers leaving the market began to emerge. On December 12, 1984, Connaught Laboratories, a U.S. pharmaceutical company, announced that it would no longer distribute the pertussis vaccine (a component of the DPT vaccine).[113] Six months earlier, Wyeth Laboratories, another U.S. pharmaceutical company, had announced that it would no longer distribute pertussis vaccine due to high litigation costs.[114] Similarly, Connaught chose to withdraw from the market "rather than pay sharply higher rates for liability insurance."[115] Both companies were responding to a series of lawsuits brought by parents who believed that their children had been injured by the pertussis vaccine.[116] This left only one pharmaceutical company in the nation that would manufacture and distribute the vaccine, a product which is given to virtually every child in the country.[117] Health experts predicted that this would exacerbate already existing shortages of some childhood

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Pediatrics).

110. *Id.*

111. *Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77, at 120 (statement of Sen. Paula Hawkins).

112. *Id.*

113. Stephen Engelberg, *Maker of Vaccine Quits the Market*, N.Y. TIMES, Dec. 12, 1984, at A21.

114. S. REP. NO. 99-483, at 3 (1986).

115. Engelberg, *Quits the Market*, *supra* note 113; Richard Levine, *Risk Forces Out Vaccine Maker*, N.Y. TIMES, Dec. 16, 1984, at A7 ("Connaught said it was quitting because of a sharp increase in the cost of insurance against lawsuits brought on behalf of children who suffer effects that can include brain damage and death.").

116. Elizabeth Wehr, *Concern in Congress: Looming Vaccine Shortage Blamed on Threat of Lawsuits*, 1984 CONG. Q. 3146 [hereinafter Wehr, *Concern in Congress*] ("Vaccine reactions have provoked lawsuits whose costs, according to the drug firms, are intolerable.").

117. Engelberg, *Quits the Market*, *supra* note 113.

vaccines.[118]

The next day, December 13, 1984, the CDC asked physicians to delay giving DPT booster shots to older children.[119] This would, they hoped, ensure that enough DPT vaccine remained available to immunize infants. The CDC acted after Lederle Laboratories, the only remaining U.S. manufacturer and distributor of pertussis vaccine, produced two batches of the vaccine that did not meet the company's own standards.[120]

Members of Congress who had been following the exodus of American companies from the vaccine market recognized the crisis: parents of children who were injured by vaccines wanted to retain the right to sue vaccine manufacturers, yet vaccine manufacturers would rather exit the market than face multi-million dollar lawsuits.[121] In the House and Senate, respectively, Waxman's and Hawkins's bills, which proposed essentially the same compensation program, continued to spark heated testimony at congressional hearings. While the bills' proposed systems required parents to first explore the options provided by the compensation system, the door still remained open for parents to directly sue vaccine manufacturers.

At a hearing on Waxman's bill, H.R. 5810,[122] before the House Energy and Commerce Committee's Subcommittee on Health and the Environment on December 19, 1984, Jeffrey Schwartz, the President of Dissatisfied Parents Together, again expressed the need for this type of legislation.[123] He, along with other parents at the hearing, reminded the Subcommittee that, in their opinion, only lawsuits can "reveal company negligence and force improvements."[124] However, vaccine manufacturers, the AMA, and the Reagan administration all expressed reservations about the proposed legislation.[125] Their positions were the

118. *Id.*

119. Wehr, *Concern in Congress*, *supra* note 116, at 3146; Editorial, *The Whooping Cough Crisis Once Killed 7,000 American Children a Year and Infected 265,000 More. It May Again Become a Major Killer if the Problems Now Swirling Around the Vaccine are Not Speedily Resolved*, N.Y. TIMES, Dec. 21, 1984, at A34 ("The [pertussis] vaccine is in temporary shortage, forcing the Government to recommend that doctors delay booster shots.").

120. Wehr, *Concern in Congress*, *supra* note 116, at 3146.

121. *Id.*

122. H.R. 5810, 98th Cong. (1984).

123. *Vaccine Injury Compensation: Hearing on H.R. 5810 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 98th Cong. (1984) [hereinafter *Hearing on Vaccine Injury Compensation*] (testimony of Jeffrey H. Schwartz, President, Dissatisfied Parents Together).

124. *See* Wehr, *Concern in Congress*, *supra* note 116, at 3146; *see also* Peter D. Jacobson & Kenneth E. Warner, *Litigation and Public Health Policy Making: The Case of Tobacco Control*, 24 J. HEALTH POL. POL'Y & L. 769, 788 (1999) (discussing importance of discovery for revealing information during litigation).

125. Wehr, *Concern in Congress*, *supra* note 116, at 3146.

same as those stated at the hearings on Hawkins's bill seven months earlier; these groups felt that if the government was going to provide a compensation fund for children injured by vaccines, then vaccine manufacturers should be entirely indemnified, with the threat of litigation permanently removed.[126] Waxman later responded to these concerns, explaining that the current shortage of pertussis vaccine should not "'stampede' Congress into assuming all the legal risks of immunization programs."[127] He also warned that, while it might be possible for the government to relieve pharmaceutical companies of some liability, "[t]his Government should not be in the business of guaranteeing profits to the drug industry."[128]

The 98th Congress never reached resolution on the vaccine compensation program. However, in the next session of Congress, both Waxman and Hawkins reintroduced their vaccine compensation bills.[129] A few months later, on April 25, 1985, the CDC announced that the shortage of pertussis vaccine had been alleviated.[130] Connaught Laboratories had secured a new insurance arrangement, which allowed it to resume manufacturing and distributing the vaccine.[131] That same month, the Reagan administration announced that it hoped to put forth its own proposal for vaccine injury compensation.[132] The main feature of this plan would be the elimination of punitive damages for any vaccine-related claim and a cap of $100,000 on awards for pain and emotional distress.[133]

Although the vaccine shortage had been momentarily relieved, Congress continued to consider a vaccine compensation fund. The Senate Committee on Labor and Human Resources conducted two rounds of hearings on Hawkins's bill, S. 827.[134] The bill proposed a vaccine compensation system that was nearly identical to the one set forth during the 98th Congress.[135] The bill would apply to children who were injured after receiving one of the seven mandated childhood vaccines.[136] These vaccines would be listed on a Vaccine Injury Table, which would designate the adverse reactions that were covered and the

126. *Id.*
127. Stephen Engelberg, *Can Medicine Rely on the Rule of the Marketplace?*, N.Y. TIMES, Jan. 6, 1985, at A8.
128. *Id.*
129. S. 827, 99th Cong. (1985); H.R. 5546, 99th Cong. (1986).
130. *CDC Says Vaccine Shortage Easing*, 1985 CONG. Q. 865.
131. *Id.*
132. Robert Pear, *U.S. Plan to Curb Damage Claims Aims to Avert Vaccine Shortages*, N.Y. TIMES, Apr. 7, 1985, at A1.
133. *Id.*
134. S. 827, 99th Cong. (1985).
135. *Id.*
136. INST. OF MED., VACCINE SUPPLY AND INNOVATION, *supra* note 9, at 183.

timeframe in which they must have occurred. The proposed no-fault compensation program would have a non-exclusive option, meaning that families could elect either to sue vaccine manufacturers or accept money from the compensation program.[137] Manufacturers would receive a degree of protection in the tort system: they could not be sued merely for their failure to directly warn parents about adverse reactions.[138] In addition, the bill proposed a nine-member advisory commission to "advise the Secretary of Health and Human Services . . . on the implementation of that program; recommend changes in the Vaccine Injury Table; recommend ways to improve the safety, efficacy, and supply of vaccines; and recommend changes in surcharge and research priorities."[139] To finance the program, the bill proposed initially borrowing funds from general revenues and subsequently imposing an "annual surcharge on the manufacturer of each vaccine covered by the act."[140]

The first hearing on S. 827 began on July 18, 1985. Hawkins opened the hearing by suggesting a growing sense of collaboration:

> I am encouraged by the willingness of the vaccine manufacturers to speak openly and honestly about the problems and pressures facing them, as an industry; I'm encouraged by the parents that meet with us. I am encouraged by the pediatricians' willingness to review and to modify their original bill in order to address the concerns of other parties to this issue. I am very encouraged by the willingness of my Senate and House colleagues to address this now, before we are in another crisis situation. . . .[141]

Yet, by the second round of hearings on the bill, it became apparent that all stakeholders were standing firmly by their previously stated positions.[142] Hawkins could not find common ground between vaccine manufacturers and the parents of children injured by vaccines. In the Republican-controlled Senate, the bill was stalled.[143]

In the Democratic-controlled House, Waxman's bill, H.R. 5546,[144] was faring much better. Waxman refused to make the vaccine

137. *Special Report: Legislative Summary HEALTH*, 1985 CONG. Q. 2741; INST. OF MED., VACCINE SUPPLY AND INNOVATION, *supra* note 9, at 184.

138. INST. OF MED., VACCINE SUPPLY AND INNOVATION, *supra* note 9, at 184.

139. *Id.* at 183.

140. *Id.* at 185.

141. *National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S. 827 Before the S. Comm. on Labor and Human Resources*, 99th Cong. 6 (1985) (statement of Sen. Paula Hawkins).

142. *National Childhood Vaccine Injury Compensation Act of 1985, Part 2: Hearing on S. 827 Before the S. Comm. on Labor and Human Resources*, 99th Cong. (1985).

143. *Special Report: Legislative Summary HEALTH*, *supra* note 137, at 2742.

144. H.R. 5546, 99th Cong. (1986).

compensation program an exclusive option. He insisted that "the tort system [serves] as a constant incentive to regulators and manufacturers alike to keep the vaccine supply as safe as it can be."[145] His bill, which was very similar to Hawkins's, created "a mechanism whereby families of children who can demonstrate an injury as a result of an adverse vaccine reaction would be automatically entitled to compensation."[146] Awards for pain and suffering or death would be capped at $250,000.[147] Special masters, who would be appointed by U.S. district courts from across the country, would determine precise award amounts.[148] Once a special master had determined an award, a family would have ninety days "either to accept the award or file suit in state or federal court, with no limits placed on recovery for pain and suffering or injuries resulting in death."[149] However, families who chose the litigation route would forever forfeit their ability to receive compensation from the proposed federal program.[150] Like Hawkins's proposed system, the compensation program would be funded by "an excise tax on vaccine manufacturers."[151]

Throughout the summer of 1986, Waxman emphasized in hearings that his bill represented a compromise:

> I recognize that the bill I have introduced is probably not the first choice of most parties to this controversy. Manufacturers would undoubtedly prefer greater insulation from liability. Parents of injured children would certainly prefer larger compensation and fewer restrictions on court activity. The Reagan administration would, I am sure, prefer legislation that spends no money.[152]

Although Hawkins had adopted this same language of compromise, she had no luck crafting an arrangement that would receive bipartisan support in the Senate. As a result, Hawkins eliminated the compensation

145. *Vaccine Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 99th Cong. 2 (1986) [hereinafter *Hearing on Vaccine Injury Compensation 1986*] (statement of Rep. Henry Waxman).

146. Julie Rovner & Dave Kaplan, *Compensation Bill, Stockpile Measure: Vaccine Legislation Advances in House Committee, on Floor*, 1986 CONG. Q. 2243. The compensation would include "expenses for medical care, rehabilitation, special education, residential and custodial care, lost wages, and other 'reasonably necessary services.'" *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. *Id.*

151. Julie Rovner, *House Passes Vaccine-Injury Compensation Bill*, 1986 CONG. Q. 2626 [hereinafter Rovner, *House Passes Bill*].

152. *Hearing on Vaccine Injury Compensation 1986*, *supra* note 145, at 2 (statement of Rep. Henry Waxman).

fund provisions and instead refocused the bill on collecting data on adverse reactions to vaccines as well as encouraging research into safer vaccines.[153] On August 6, 1986, the Senate Labor and Human Resources Committee approved the revised version of Hawkins's bill.[154] About a month later, the House Energy and Commerce Committee approved Waxman's bill by a voice vote.[155]

But, the bill could not go before the full House until the Ways and Means Committee consented to the funding mechanism for the compensation scheme. Members of the Ways and Means Committee claimed that they did not have time to consider the excise tax option, and Committee Chairman Dan Rostenkowski (D-IL) voiced philosophical concerns about the bill.[156] "Every time you have a problem do you set up another trust fund?[,]" asked a Committee spokesperson.[157] Thus, the funding provisions were struck from the bill. While Waxman was disappointed with this, his aides expressed hope that passage of the revised bill "would prevent us from having to start back at square one in the next Congress."[158] On October 14, 1986, the House passed H.R. 5546, which included no provisions for funding the vaccine compensation program.[159]

Four days later, on October 18, the last day of the 99th Congress, Congress passed S. 1744,[160] an omnibus health package that included the unfunded vaccine compensation program.[161] The vaccine section of the bill "[d]irected the secretary of health and human services to create a National Vaccine Program and to appoint a director to coordinate federal research, licensing and distribution of vaccines."[162] In addition, the bill called for the creation of "a national advisory committee to help the program director ensure a continued supply of safe and effective vaccines and to establish research priorities for enhancing safety and efficacy."[163] And, the bill contained provisions for a vaccine compensation program drawn directly from Waxman's bill, H.R. 5564.[164] The National Vaccine Injury Compensation Program, a no-fault program, would provide compensation to the families of children who had

153. S. REP. NO. 99-483, at 3 (1986).
154. Julie Rovner, *House, Senate Panels Approve Vaccine Bills*, 1986 CONG. Q. 1828.
155. Rovner & Kaplan, *supra* note 146, at 2243; H.R. REP. NO. 99-908, at 35 (1986).
156. Rovner, *House Passes Bill*, *supra* note 151, at 2626.
157. *Id.*
158. *Id.*
159. *Id.*
160. S. 1744, 99th Cong. (1986).
161. *The 99th Congress: A Mixed Record of Success*, 1986 CONG. Q. 2662.
162. Julie Rovner, *Major Provisions of Nine-Part Omnibus Health Bill*, 1986 CONG. Q. 2952 [hereinafter Rovner, *Major Provisions*].
163. *Id.*
164. H.R. 5564, 99th Cong. (1986).

"suffer[ed] vaccine-related injuries or death as a result of receiving vaccines generally required by state law."[165] To begin the compensation process, a person would first have to "file a petition in U.S. district court for the district in which the injury or death occurred or in which they reside, and with HHS."[166] Next, the person would have to demonstrate that he or she had "received a vaccine covered by the bill, [and] that as a result of the vaccine the recipient was injured or had a previous injury aggravated, [or] that the injury's effects caused death. . . ."[167] A special master, appointed by the district court in which the petition was filed, would "determine whether a particular injury qualifie[d] for compensation and how much the award should be."[168] The award could include payment for medical expenses, lost earnings, pain and suffering, and attorneys' fees. However, "no punitive damages [would be] allowed."[169] Awards for pain and suffering or for death would be capped at $250,000.[170]

Once an award had been determined, a person would have ninety days either to accept the award or to reject the award and pursue litigation.[171] If the person chose to accept the award from the compensation program, he or she could not then sue a vaccine manufacturer.[172] If litigation was initiated, "vaccine manufacturers [would] not be held liable for damages for an injury resulting from an unavoidable side effect if the vaccine was properly prepared and was accompanied by proper directions and warnings."[173] The "directions and warnings" would correspond to FDA guidelines.[174] In addition, manufacturers would "not be held liable for punitive damages unless the plaintiff [could] show wrongful or illegal acts by the manufacturer that [were] related to the injury in question."[175]

The passage of S. 1744 resulted from a compromise negotiated between Waxman, chairman of the House Energy and Commerce Committee's Subcommittee on Health and the Environment, and Orrin Hatch, chairman of the Senate Labor and Human Resources Committee.[176] In addition, Representative Edward R. Madigan (R-IL),

165. Rovner, *Major Provisions*, *supra* note 162, at 2952.
166. *Id.*
167. *Id.*
168. *Id.*
169. *Id.*
170. *Id.*
171. Rovner, *Major Provisions*, *supra* note 162, at 2952.
172. *Id.*
173. *Id.*
174. *Id.*
175. *Id.*
176. Julie Rovner, *Omnibus Health Bill May Face Reagan Veto*, 1986 CONG. Q. 2712 [hereinafter Rovner, *Reagan Veto*].

the ranking member on the House's Subcommittee on Health and the Environment, and Senator Edward Kennedy, the ranking member on the Senate's Labor and Human Resources Committee, helped to craft the arrangement.[177] This bipartisan effort occurred because both Waxman and Hatch had major pieces of legislation that were in jeopardy of dying in committee. Waxman wanted to see the vaccine compensation program pass.[178] Hatch had also prioritized a bill that would allow "drugs not approved by the United States Government [to] be exported to any of 21 foreign countries if they were approved for use there."[179] The Senate had passed the bill, but Waxman had allowed it "to languish in subcommittee."[180] The Reagan administration's support for Hatch's bill was tremendous; Vice President George H.W. Bush, Commerce Secretary Malcolm Baldrige, and U.S. Trade Representative Clayton K. Yeutter all called for President Reagan to sign the bill.[181] C. Boyden Gray, counsel to Vice President Bush, reported that the vice president believed this portion of the bill "would help American companies remain competitive in international markets."[182]

However, Justice Department officials urged the President to veto any omnibus health bill that contained the vaccine compensation system. John R. Bolton, an Assistant Attorney General, summarized the administration's opposition to the system as follows: "[i]t would . . . create a [major] new compensation program for which 'no legitimate national need has been demonstrated.' . . . [I]t would lead to 'a dramatic increase' in the role of the Federal judiciary, which would rule on injury claims."[183] Bolton echoed concerns that had already been voiced by members of the House Judiciary Committee: the role of the courts remained unclear because "the bill [did] not explain how the special masters [would] be appointed or what standards they [would] use for their decisions."[184] In addition, during his testimony Bolton explained

177. *Id.*

178. Rovner, *Reagan Veto*, *supra* note 176, at 2712; Robert Pear, *President's Aides Divide on Signing of a Health Bill*, N.Y. TIMES, Oct. 28, 1986, at A1 ("Representative Henry A. Waxman, Democrat of California, said, 'I cannot see why President Reagan would not sign this excellent bill, which guarantees supply of vaccine and compensation of children who are injured by vaccines.'").

179. S. 1848, 99th Cong. (1986); Pear, *President's Aides*, *supra* note 178. "The countries include[d] Austria, Britain, Canada, France, Italy, Japan, and West Germany." *Id.*; *see also* Phil Gailey, *Legislators Head Home After Final Flurry of Bills*, N.Y. TIMES, Oct. 20, 1986, at B12.

180. Rovner, *Reagan Veto*, *supra* note 176, at 2712.

181. Pear, *President's Aides*, *supra* note 178; Robert Pear, *Reagan Signs Bill on Drug Exports and Payment for Vaccine Injuries*, N.Y. TIMES, Nov. 15, 1986, at 1.

182. Pear, *President's Aides*, *supra* note 178.

183. *Id.*

184. Rovner, *Major Provisions*, *supra* note 162, at 2952. However, members of the

that "'the Administration strongly opposes the imposition of any new tax' such as the excise tax envisioned in the bill."[185] Vice President Bush had called Waxman earlier in the month to urge him to support the drug export legislation.[186] At the time, that legislation was separate from the vaccine compensation system.

Waxman and Hatch wanted to ensure the omnibus bill's passage, so they included several smaller, but influential pieces of proposed legislation along with the drug export and vaccine compensation bills.[187] First, they added a bill that would repeal the "authorization for the federal health planning program,"[188] which they knew the administration would support. The program "sought to slow rising health care costs by requiring states to set up approval systems before hospitals could add new beds or make major equipment purchases."[189] The administration had sought to repeal the program since 1981.[190] Also, Waxman and Hatch knew that Senator Howard M. Metzenbaum (D-OH) strongly opposed Hatch's drug export bill.[191] To appease him, they included a bill that Metzenbaum had co-sponsored that would "expand research into Alzheimer's disease and efforts to help victims and their families."[192]

Due to the vaccine compensation program, Reagan repeatedly threatened to veto S. 1744 both before and after Congress passed the legislation.[193] However, he ultimately signed the bill on November 14, 1986.[194] He took action primarily to legalize the drug export provisions and expressed "serious reservations" about the vaccine compensation program, particularly in terms of its anticipated funding mechanism.[195]

Judiciary Committee had suggested that "there [might] be an effort to enact clarifying legislation [about the special masters] in early 1987." *Id.*

185. Pear, *President's Aides*, *supra* note 178.

186. *Id.*

187. Rovner, *Reagan Veto*, *supra* note 176, at 2712.

188. *Id.*

189. *Id.*

190. *Id.*

191. Julie Rovner, *Senate Loosens Restraints on Drug Exports*, 1986 CONG. Q. 1105 ("Approval of the bill, charged Metzenbaum, is tantamount to 'opening the door to the dumping of potentially unsafe and ineffective drugs on the Third World.'").

192. Rovner, *Reagan Veto*, *supra* note 176, at 2712.

193. *See, e.g.*, *id.* ("Although an administration official said no decision has been made on whether to veto the package, the White House objects to the vaccine provision. . . ."); Pear, *U.S. Plan to Curb Damage*, *supra* note 132 ("Administration officials said they considered and decided against proposals to create a federally sponsored vaccine compensation fund. . . .").

194. Rovner, *Reagan Veto*, *supra* note 176, at 2712.

195. Pear, *Reagan Signs Bill*, *supra* note 181.

B. *Funding of the Program*

Early in the 100th Congress, on March 5, 1987, the House Ways and Means Committee's Subcommittee on Select Revenue Measures held a hearing to determine how the vaccine compensation program would be funded.[196] Waxman opened the hearing by reminding the Subcommittee that the program represented a compromise between "conservatives, liberals, consumer advocates, and pharmaceutical lobbyists."[197] He made one request of the Subcommittee:

> Whatever form of financing this committee arrives at, one criterion must be met. The funding mechanism for the compensation program must be reliable. We are, through this act, asking some families with injured children to waive their rights to sue forever. We cannot expect these people to give up fundamental rights if they cannot depend on the compensation payments. And if they do not give up these rights, the national vaccine injury compensation program will not work as it is designed to do. The results of such a failure would be a continuation of the courtroom lottery for compensation and a genuine threat of vaccine shortages and disease epidemics.[198]

The Committee then heard testimony from the Department of the Treasury, pharmaceutical manufacturers, and trade organizations.

Dennis E. Ross, the Treasury's Tax Legislative Counsel, detailed the administration's objections to the law. He explained that, because the tort system remained an option, "many injured persons with potentially large claims, particularly for pain and suffering, would still resort to the tort system."[199] As stated during the 99th Congress, the administration believed that this would leave vaccine manufacturers facing the same type of "financial ruin" that they currently feared.[200] And, Ross expressed concerns about the costs of administering a federal compensation program.[201] Finally, he suggested that any public funding stream would present sustainability issues. He explained that funding the compensation program through an excise tax was

> perhaps the least attractive alternative. In the first place creation of a new excise tax and a related trust fund would entail substantial

196. *Funding of the Childhood Vaccine Program: Hearing Before the Subcomm. on Select Revenue Measures of the H. Comm. on Ways and Means*, 100th Cong. (1987) [hereinafter *Hearing on the Funding of the Childhood Vaccine Program*].

197. *Id.* at 10 (statement of Rep. Henry Waxman).

198. *Id.* at 11.

199. *Id.* at 18 (testimony of Dennis E. Ross, Tax Legislative Counsel, Dep't of the Treasury).

200. *Id.*

201. *Id.*

> administrative costs. More importantly, however, . . . funding the Vaccine Act's compensation program through an excise tax would create a substantial risk. The program would either operate at a deficit or be unable to compensate many injured persons. Since excise tax rates could be adjusted by Congress, maintenance of an adequate funding level would depend on reasonably accurate predictions of the numbers and amounts of claims.[202]

Ross stated similar concerns about appropriations as a funding source: because appropriations could be "reduced or eliminated as part of the annual budget process, . . . injured persons may have little incentive to accept awards under the compensation program. . . ."[203]

Douglas MacMaster, President of Merck Sharp & Dohme, urged the Subcommittee and others testifying at the hearing to "set aside" the issue of manufacturer liability.[204] Instead, he suggested that "all parties work toward a fiscally and financially sound funding mechanism so this worthwhile program can begin."[205] He seconded the Treasury's concern that the program be funded with a stable revenue source, and expressed similar worries about the unpredictable nature of appropriations.[206] However, he questioned Ross's claim that an excise tax could not work. Instead, he reported that, after considering the issue for several years, Merck had concluded that "a trust fund financed through the imposition of a surcharge or an excise tax on pediatric vaccines could be made fiscally sound."[207]

When Committee members worried that an excise tax would draw a presidential veto, Waxman admonished them:

> There is always a threat of veto. . . . There was a threat of veto of this bill but the President did sign it. In addition, there are ways of packaging proposals so that the President would find it unattractive to veto it. I can't believe that when you have a compensation system for children that are hurt from vaccines that when it came down to it, he would veto it.[208]

Waxman spoke with confidence to a Democratic-controlled House.[209]

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202. *Hearing on the Funding of the Childhood Vaccine Program*, *supra* note 196, at 19; *see* Spencer Rich, *Administration Attacks Vaccine Law; '86 Act Calls for 'No-Fault' Compensation to Injured Children*, WASH. POST, Mar. 6, 1987, at A6.

203. *Hearing on the Funding of the Childhood Vaccine Program*, *supra* note 197, at 20; *see* Rich, *supra* note 202.

204. *Hearing on the Funding of the Childhood Vaccine Program*, *supra* note 197, at 88 (testimony of Douglas MacMaster, President, Merck Sharp & Dohme).

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.* at 15 (statement of Rep. Henry Waxman).

209. Haynes Johnson, *The Power Conflict in Iran-Contra Affair; Reagan Policies,*

And, ultimately, his prediction would be proven correct.

On July 13, 1987, the House Ways and Means Subcommittee on Select Revenue Measures revisited how to fund the vaccine compensation program.[210] After a two-hour, closed-door meeting, the subcommittee decided to defer to the full committee.[211] However, the subcommittee did agree to "use general revenues to create a trust fund to compensate 3,500 children injured or killed by vaccines prior to enactment of [the vaccine compensation program]."[212] Staffers estimated that this fund would cost "a total of $315 million, with $54 million necessary for fiscal 1988."[213] The subcommittee was reluctant to tackle a financing plan for future injuries or deaths because "cost estimates [were] still uncertain."[214] For example, an estimate by the Congressional Budget Office would have placed a tax of $8.04 on each dose of DPT vaccine.[215] But, "there [was] general agreement that an excise tax over $5 per dose would be counterproductive because it would result in fewer children getting vaccinated."[216] Committee staffers spent the rest of the summer trying to create a system that would yield an excise tax of less than $5 per vaccine dose.

Over the next few months, lawmakers struggled to develop a way to fund the vaccine compensation system that would ensure that children continued to be vaccinated, appropriately compensate the families of children who were injured by vaccines, and hopefully avoid a presidential veto. In mid-October 1987, Waxman presented a new framework for funding the program to the House Energy and Commerce Committee.[217] He suggested providing separate sources of funding for

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Congress Undergo Trial, WASH. POST, May 31, 1987, at A4 ("Not since the Vietnam war has there been so serious a debate about the respective constitutional roles and responsibilities of the legislative and executive branches of governments."); Waxman's attitude toward a presidential veto may have been influenced by Reagan's weakened reputation in the wake of the Iran-Contra scandal. *E.g.*, Haynes Johnson, *Unsettling Portrait of Reagan Presidency; Hearings Tell a Story of Contempt*, WASH. POST, June 14, 1987, at A16.

210. Julie Rovner, *'No-Fault' System Waiting in Wings: Still No Agreement on Funding for Vaccine Compensation Plan*, 1987 CONG. Q. 1594 [hereinafter Rovner, *Waiting in Wings*].

211. *Id.*

212. *Id.*

213. *Id.*

214. *Id.*

215. *Id.*; Julie Rovner, *Cost-Paring Move May Not Avert Veto: Vaccine Compensation Plan Cut Back by Two House Panels*, 1987 CONG. Q. 2516 [hereinafter Rovner, *Cost-Paring Move*].

216. Rovner, *Waiting in Wings*, *supra* note 211, at 1594.

217. The House Energy and Commerce Committee "maintains principal responsibility for legislative oversight relating to telecommunications, consumer protection, food and drug safety, public health, air quality and environmental health, the supply and delivery of energy, and interstate and foreign commerce in general." The

cases that arose before and after the October 1, 1988 implementation of the VICP. Children who were injured by vaccines administered before that date would be eligible to receive "compensation for all medical expenses and up to $30,000 in miscellaneous costs, and would be paid from appropriations. . . ."[218] Appropriations would be $80 million a year for the next four years.[219] For children who were injured by vaccines administered on or after October 1, 1988, compensation would be paid out of a trust fund financed by an excise tax on certain vaccines.[220] In addition, the system would be limited to paying an average of 150 claims over a twelve-month period.[221] If this number were exceeded, "the secretary of Health and Human Services would be required to notify Congress and shut down the program to new applications. . . ."[222] These changes garnered approval from the Energy and Commerce Committee on October 14, 1987. Waxman regretted scaling back the program, but he knew that if changes were not made, "'it would make a nullity of last year's bill, and no one would benefit.'"[223]

The next day, October 15, 1987, the House Ways and Means Committee approved Waxman's revised funding scheme.[224] However, the committee only authorized the new excise taxes for four years. The following excise taxes were agreed upon: $4.56/dose for DPT; $4.44/dose for MMR; $0.29/dose for polio.[225]

About a week later, the funding provisions for the vaccine compensation program were added to the already enormous omnibus budget reconciliation bill, "where [they might] be less vulnerable to veto."[226] H.R. 3545 contained an additional provision that might have made the bill more appealing to the administration. The bill altered the jurisdictional structure of the 1986 vaccine compensation program.

Committee on Energy & Commerce, *About the Committee*, http://energycommerce.house.gov/aboutCommittee.htm (last visited July 19, 2006).

218. Rovner, *Cost-Paring Move*, *supra* note 215, at 2516. Miscellaneous costs would include attorneys' fees, lost earnings, and pain and suffering. *Major Provisions of the Fiscal 1988 Reconciliation Bill*, 1988 CONG. Q. 73.

219. Rovner, *Cost-Paring Move*, *supra* note 215, at 2516.

220. *Id.*

221. *Id.*

222. *Id.*

223. *Id.*

224. *Id.* Miscellaneous costs would include attorneys' fees, lost earnings, and pain and suffering. *Major Provisions of the Fiscal 1988 Reconciliation Bill*, *supra* note 218, at 73-85. The House Ways and Means Committee's jurisdiction includes federal revenue measures, the bonded debt of the United States, national social security programs, and trade and tariff legislation. H.R. REP. NO. 108-810, at 122-25 (2005).

225. Rovner, *Cost-Paring Move*, *supra* note 215, at 2516.

226. Spencer Rich, *Far-Reaching Medical Programs in the Works; Congressional Committees Prepare AIDS Funding, No-Fault Child-Vaccine Plan*, WASH. POST, Oct. 21, 1987, at A21.

Originally, claims had to be filed with the U.S. District Court in the region in which the injured person lived or in the region where the injury occurred.[227] The administration had complained that this could put a tremendous strain on the judicial system.[228] H.R. 3545 moved jurisdiction to the U.S. Court of Federal Claims.[229] This meant that claims could no longer be filed with district courts across the country; the Claims Court would serve as a centralized repository that would decrease the burden on local systems.

By the time the omnibus bill reached the Senate, it had gone "through so many incarnations that even some of its sponsors had difficulty keeping up."[230] This worked to the advantage of the vaccine compensation program's funding provisions. Because the Senate, with its new Democratic majority, had so many other issues to discuss regarding the omnibus bill,[231] and the funding provisions had been a last-minute addition, they received virtually no direct attention from the Senate.[232] On October 27, 1987, the Senate sent the final version of the bill to the House. A week later, the House cleared the bill, S. 1158,[233] and sent it to the President. In late December, facing a solidly Democratic Congress, Reagan signed the bill, funding the VICP.[234]

IV. Application of Theoretical Frameworks to the Creation of the VICP

In an effort to understand the policy processes at work during the creation of the VICP, two prominent models of policy formation will be considered. The first is John Kingdon's model of agenda setting, in which governmental handling of an issue depends on the interaction of three "process streams."[235] As Kingdon explains:

> The three major process streams in the federal government are (1) problem recognition, (2) the formation and refining of policy proposals, and (3) politics. First, various problems come to capture the attention of people in and around government. . . . Second, there

227. Rovner, *Major Provisions*, *supra* note 162, at 2952.

228. Pear, *President's Aides*, *supra* note 178.

229. Julie Rovner, *Nursing Homes, Vaccine Injuries, Rural Health: Reconciliation Bill Includes Several Key Health Changes*, 1988 CONG. Q. 72 [hereinafter Rovner, *Nursing Homes*]; H.R. CONF. REP. NO. 100-495, at 771-72 (1987).

230. Julie Rovner, *Research, Manpower and Vaccine Reauthorizations: Omnibus Health-Programs Bill Cleared for President Reagan*, 1987 CONG. Q. 2744.

231. *See, e.g.*, *Senate Votes to Reauthorize Health Programs*, 1987 CONG. Q. 1692.

232. H.R. CONF. REP. NO. 100-495, at 771-73.

233. S. 1158, 100th Cong. (1987).

234. *Major Provisions of The Fiscal 1988 Reconciliation Bill*, *supra* note 218, at 73; Rovner, *Nursing Homes*, *supra* note 229, at 72.

235. JOHN W. KINGDON, AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES 86-89 (2d ed. 2003).

> is a policy community of specialists—bureaucrats, people in the planning and evaluation and in the budget offices, Hill staffers, academics, interest groups, researchers—which concentrates on generating proposals. . . . Third, the political stream is composed of things like swings of national mood, vagaries of public opinion, election results, changes of administration, shifts in partisan or ideological distributions in Congress, and interest group pressure campaigns.[236]

Kingdon argues that these processes or streams act upon each other and, when acting in concert, they can provide the basis for substantial policy change.[237] The power of the Kingdon model, particularly as it aids in understanding the creation of the VICP, is that it provides a theoretical basis for explaining both the substance and timing of significant policy change. At the same time, the model accounts for the extreme difficulty that advocates for such policy change often face.

Fundamental aspects of another well-known model, disjointed incrementalism,[238] also apply to selected events in the creation of the VICP. This model helps explain certain aspects of governmental decision-making and subsequent public policy. Disjointed incrementalism is grounded upon the notion that policy does not emerge from rational-comprehensive analysis and decision-making.[239] Rather, policy results from the constant interplay between myriad interested individuals and groups. Additionally, inherent in the model's explanation of policy development, the levels and branches of government, with their institutionally-defined checks and balances, all act in accordance with their own interests, needs, and limitations.[240] This fractionalized process takes place within the reality of both time constraints and limited information. The resulting policy decisions are typically incremental, departing only marginally from current policy.[241] It follows from this model that significant change, while rarely occurring under any circumstance, is almost always the result of many successive incremental changes; these incremental changes are likely not connected by any well-defined longer term goals and objectives.[242]

There are two objectives connected to the juxtaposition of these conceptual models: 1) to develop a clear understanding of the processes

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236. *Id.* at 87.
237. *Id.* at 90-164.
238. MICHAEL T. HAYES, INCREMENTALISM AND PUBLIC POLICY 13-25 (1992).
239. *See id.* at 13-16; CHARLES E. LINDBLOM & EDWARD J. WOODHOUSE, THE POLICY MAKING PROCESS (3d ed. 1992).
240. *See* HAYES, *supra* note 238, at 13-25.
241. *Id.* at 17.
242. *Id.* at 20.

involved in the passage of the VICP with identification of key pivotal points, and 2) to demonstrate how two apparently competing models of the policy-making process—the Kingdon framework and disjointed incrementalism—can actually complement each other in explaining the outcomes of complex situations and events.

A. The Build-up to a Focusing Event

In 1982, the television documentary "DPT: Vaccine Roulette" brought public attention to the problem posed by the potential adverse medical effects of certain vaccines.[243] This documentary led to the creation of Dissatisfied Parents Together.[244] Most importantly for the evolution of the VICP, this unifying group afforded a focal point to aggrieved parents which, in turn, contributed to an increase in the number of lawsuits filed by the families of children who suffered adverse effects from vaccines.[245]

Perhaps the most severe consequence of the substantial increase in litigation involved the near total elimination of available liability insurance for vaccine manufacturers.[246] Whatever insurance remained was available at greatly increased rates and with substantially increased deductibles. In short, manufacturing childhood vaccines was rapidly losing its financial viability for pharmaceutical companies. From this arose the situation in which a single domestic source, Lederle Laboratories, remained as a manufacturer of DPT vaccine.[247] Further, the continued participation of Lederle was also problematic. The company experienced great difficulty in obtaining insurance coverage and was concerned as well with the impact of continued participation upon its bottom line.[248]

As examined from the perspective of the Kingdon model, two interrelated events followed. First, the problem definition underwent an important transformation. Specifically, the problem went from one concerning the essentially unnoticed impact of a small number of parents suing large and powerful pharmaceutical companies to a problem where, due to the exit of manufacturers, America's children might well be denied life-saving vaccinations. As a result of this transformation, the issue of ensuring an adequate supply of safe childhood vaccines made its

243. *See supra* Part III.A; Elizabeth A. Breen, Note, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 315 (1999).

244. *See supra* Part III.A.

245. Breen, *supra* note 243, at 315-16.

246. Greenberger, *supra* note 17, at 13-14.

247. Stephen Engelberg, *Official Explains Gaffe on Vaccine Shortage*, N.Y. TIMES, Dec. 19, 1984, at A21.

248. *See id.*

way onto the national policy agenda. It became part of the group of problems and subjects the federal government and those connected to it considered important enough to warrant study and potential action. In other words, due to what Kingdon terms a "focusing event," the issue of vaccine manufacturing and supply became a part of the problem stream.[249] A complex pivotal event is involved here: the focusing event necessary to place the issue of manufacturer liability within the problem stream first necessitated a transformation of the problem into one concerning the safety of the nation's children.

It appears that this policy agenda issue was most likely confined to children for several reasons. The social construction of the vaccine injury problem was most effective with an emphasis on children.[250] This provided a relatively safe political format for those legislators who supported the proposed system. Additionally, young children receive an inordinate share of vaccines and concomitantly suffer the majority of adverse reactions, so it made sense to focus on them.[251] Lastly, and following from this, throughout the course of the VICP legislation's development and implementation, the official accounting of vaccine-related injuries, the Vaccine Injury Table, contained only childhood vaccines.[252] This made it difficult to forecast the cost of adult vaccine reactions.

Disjointed incrementalism offers a complementary explanation of these same events. Disjointed incrementalism, while not requiring focusing events, allows for them as a vehicle to get issues onto the national agenda.[253] According to the Lindblom model, such problems become defined in fundamentally remedial terms. This model parameter is consistent with the circumstances of the VICP. A specific problem existed, namely an unstable supply of childhood vaccine due to manufacturers exiting the market.[254] Further, the focus was clearly upon finding a solution that would remediate this specific problem. At this

249. KINGDON, *supra* note 236, at 94-100.

250. *See* Anne Schneider & Helen Ingram, *Social Construction of Target Populations: Implications for Politics and Policy*, 87 AM. POL. SCI. REV. 334, 336-37 (1993).

251. *Cf.* Dru Stevenson, *Libertarian Paternalism: The Cocaine Vaccine as a Test Case for the Sunstein/Thaler Model*, 3 RUTGERS J. L. & URB. POL'Y 4, n.170 (2005).

> A child born today will receive five doses of DPT, four doses of polio vaccine, two doses of measles, mumps, and rubella, three injections of hepatitis B, one shot of varicella (chicken pox), four doses of haemophilus influenzae b (Hib), four injections of a pneumococcal conjugate vaccine, and, depending on where the child lives, perhaps one shot of hepatitis A.

Id.

252. *See supra* Part III.

253. HAYES, *supra* note 238, at 31-32.

254. *See supra* Part III.A.

point in the analysis, the incremental model and the Kingdon model provide complementary explanations of the initial events that led to the VICP: both models incorporate an explanatory focusing event and propose to deal with the problem in a way intended to result in the same outcome.

B. Coalescing of Interests

In 1984, Representative Henry Waxman and Senator Paula Hawkins introduced legislation in their respective chambers to create a federal vaccine injury compensation fund.[255] Beyond the introduction of similar bills, no evidence in the VICP's legislative history suggests that these two legislators viewed themselves as working together to get the program passed.

As resolution of the childhood vaccine problem attained formal status in proposed federal legislation, a coalescing of opposed sides developed. The issue was not one of disagreement on the need to protect the health of children—on that there is always agreement.[256] Nor was the issue one of providing some relief for the vaccine manufacturers; it was abundantly clear that they were exiting the market, thereby endangering the supply of vaccine.[257]

Rather, the points of interest group contention were generally distinguished as those attributed to the parents of vaccine-injured children (with support from the American Academy of Pediatrics),[258] the manufacturers,[259] and the AMA.[260] The parents required assurances that any legislation would still allow them to obtain financial relief commensurate with the harm done to their children.[261] The manufacturers were intent upon receiving adequate tort relief so that they could obtain affordable and sufficient liability insurance to ensure

255. *See id.*

256. *E.g.*, *Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77, at 4 (statement of Sen. Edward Kennedy) ("We cannot tolerate a system which discourages immunization, [and] increases the risks to the very children in need of protection. . . ."); *id.* at 7 (testimony of Edward M. Brandt, Jr., Assistant Secretary, DHHS) (explaining that the bill in question had a "laudable goal").

257. *See supra* Part III.A.

258. *E.g.*, *Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77, at 49-51 (testimony of Jeffrey H. Schwartz, President, Dissatisfied Parents Together) (expressing support for the bill); *id.* at 147 (testimony of Martin H. Smith, President-elect, American Academy of Pediatrics).

259. *E.g.*, *id.* at 277 (testimony of John E. Lyons, President, Merck Sharp & Dohme) (expressing reservations about the bill).

260. *Id.* at 180 (testimony of Alan R. Nelson, Board of Trustees, AMA) (expressing concerns about the bill).

261. *See supra* Part III.A.

solvency and a reasonable return in the form of profits.[262] The AMA expressed interest in ensuring a stable vaccine supply but was primarily concerned with limiting the liability of its members, who served as vaccine administrators.[263]

From inside the federal government, many Republicans, as well as President Reagan and key administrative representatives, opposed any legislation that would increase taxes and impact the tort system through federal government intervention.[264] Among the administration group were senior Justice Department officials.[265] Also, as previously discussed, DHHS Secretary Otis Bowen, through the testimony of Assistant Secretary Edward M. Brandt, Jr., expressed strong opposition to the plan.[266]

In contrast, it appears that many within Congress, the majority being Democrats, saw the issue in traditional Democratic terms. This perspective includes the appropriateness, indeed requirement, for federal intervention when the public good is at stake, the legitimacy of taxation for the broader public good, and the necessity to insure critical social welfare programs such as child immunizations.[267] In accordance with this reasoning, this group likely saw the proposed legislation as a way of solving a critical social welfare problem and as a vehicle for furthering federal intervention through specific forms of tort restriction.

As defined by Kingdon, the issue that divided those crafting policy options, within Congress and the Reagan administration, was compensation for the families of children who suffered adverse immunization reactions.[268] This broad issue was, in turn, divided into two policy options. First, the no-fault compensation option could be the exclusive remedy except in cases where the manufacturer deviated from FDA guidelines. This option was represented principally by the AMA and the pharmaceutical manufacturers.[269] The second entailed inclusion of a compensation system in conjunction with continued availability of the tort system. The primary advocates for this policy option were the parents of vaccine-injured children and the American Academy of Pediatrics.[270]

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262. *Id.*
263. *Id.*
264. *See, e.g., Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77, at 7-8 (testimony of Edward M. Brandt, Jr., Assistant Secretary, DHHS).
265. *See* Pear, *President's Aides*, *supra* note 178.
266. *Hearing on the National Childhood Vaccine-Injury Compensation Act*, *supra* note 77, at 7-8 (testimony of Edward M. Brandt, Jr., Assistant Secretary, DHHS).
267. *E.g., id.* at 4 (statement of Sen. Edward Kennedy).
268. *See supra* Part III.
269. *Id.*
270. *Id.*

On December 19, 1984, hearings in the House Energy and Commerce Subcommittee commenced.[271] The timing was causally linked with a notable event and the current national mood. First, the hearings were conducted just after news broke that all but one of the DPT vaccine manufacturers had exited the market.[272] Second, as is consistent with the workings of the political stream in Kingdon's policy model, the "national mood" toward this issue was evolving. For example, an article in the *New York Times* addressed the issue of the diminishing vaccine supply and, of greatest importance, the impact of the thinning supply upon children.[273]

The process of securing the program's approval extended from December 1984 until December 1987, when the legislation, which included funding provisions for the VICP, was finally signed by President Reagan.[274] Throughout this legislative process, stakeholders accepted that a significant problem existed and, further, that the federal government had some role to play in resolving this problem.[275] The points of contention were fairly constant and involved both the pragmatic concern of funding with the attendant question of who should pay and how.

C. *The Role of Policy Entrepreneurs*

Kingdon defines a "policy entrepreneur" as someone who is willing "to invest their resources—time, energy, reputation, and sometimes money—in the hope of a future return."[276] In the case of the VICP, both Waxman and Hawkins played the role of policy entrepreneurs. They advocated for a compensation system from the beginning and returned to it throughout the legislative process.[277]

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271. *See generally Hearing on Vaccine Injury Compensation*, *supra* note 123.

272. Wehr, *Concern in Congress*, *supra* note 116, at 3146.

273. Specifically, the article stated the following:

> Connaught's withdrawal means that each vaccine for childhood diseases, those used to prevent polio, measles, mumps, rubella, diphtheria, tetanus and whooping cough, is now produced by a single manufacturer. The development is likely to stimulate a drive by parents' groups and the drug companies to set up a Federally sponsored system of compensation for children harmed by vaccines.

Engelberg, *Quits the Market*, *supra* note 113.

274. *Major Provisions of the Fiscal 1988 Reconciliation Bill*, *supra* note 218, at 73; Rovner, *Nursing Homes*, *supra* note 229, at 72.

275. *See supra* Part III.

276. KINGDON, *supra* note 236, at 122.

277. *See supra* Part III; *cf.* Thomas R. Oliver & Pamela Paul-Shaheen, *Translating Ideas into Actions: Entrepreneurial Leadership in State Health Care Reforms*, 22 J. HEALTH POL. POL'Y & L. 721, 764 (1997).

> In almost all situations, entrepreneurs must sell a prototype of their innovation

What motivated Representative Waxman and Senator Hawkins? As politicians, it is reasonable to assume that they each saw the issue of securing life-saving vaccines for children as furthering their own policy agendas regarding the role of government and child welfare.[278] Hawkins had established a record of being involved in children's issues and was a vocal advocate about children's issues including child abuse.[279] She was also a victim of such abuse and wrote a book about her experiences in 1986.[280] Waxman was developing a record that showed interest in a variety of health and safety issues.[281]

It is possible, even likely, that either or both of them saw their advocacy as furthering their respective reelections. Hawkins was facing a very tough reelection race in Florida during this time,[282] which she ultimately lost. Waxman continues to serve in the House of Representatives.

D. The "Softening Up" Process

"Softening up," another process described by Kingdon, can be applied to the three years associated with the passage of the VICP legislation. Softening up occurs to "insure that the relevant public is ready for a certain type of proposal when its time does come."[283] As policy entrepreneurs, both Waxman and Hawkins pushed for intervention into the tort process. As is characteristic of entrepreneurs, they never abandoned that focus.[284] Over time, members of Congress and those connected to them became accepting of, or at least tolerated, the concept. This is suggested by the VICP's ultimate passage. As this process

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> not only to interested investors but to a broader coalition of policy makers, organized interests, and various segments of the public. They must be prepared to demonstrate the superiority of their product to the status quo and other legitimate alternatives.

Id.

278. *Cf.* Oliver & Paul-Shaheen, *supra* note 277, at 748-49 (discussing the role of policy entrepreneur in a problem-driven opportunity).

279. *See supra* Part III.

280. *See generally* HAWKINS, *supra* note 85.

281. *See, e.g.*, *Auto Rental Concerns Answer Safety Charges*, *supra* note 91 ("At a news conference Tuesday, Representative Henry Waxman, Democrat of California, accused officials of the Federal Trade Commission of 'sitting on their hands' and blocking an investigation into complaints that the rental firms had poor records in complying with recall orders."); Editorial, *supra* note 91 ("'If this [Medicaid] "cap" is adopted, millions will suffer and no "safety net" will catch them,' warns Representative Henry Waxman, the chairman of a House subcommittee on health.").

282. *Florida Governor Opens Senate Bid*, N.Y. TIMES, Jan. 29, 1986, at D20 ("The Governor, a Democrat, is seeking the seat held by Paula Hawkins, a Republican who has said she will seek re-election in November.").

283. KINGDON, *supra* note 236, at 128.

284. *See supra* Part III.

evolved, competing interests managed to bargain and compromise on key provisions. For example, vaccine manufacturers and the AMA preferred total indemnification while parents, as represented by Dissatisfied Parents Together, insisted on retaining their unencumbered right to sue.[285] The successfully bargained compromise allowed limited, but prompt no-fault compensation and access to the courts during a ninety-day decision window in which the parents could accept or reject the settlement offer.[286]

E. Consensus Building

Over time, bargaining and compromise, the work of the entrepreneurs, as well as other factors such as the national mood and the definition of the problem as caring for our children, created a consensus for this legislation.[287] As the process continued, opposition from the Reagan administration remained as the principal obstacle. This objection took the form of resistance to government taxation, sponsorship of indemnification, and a strong ideological objection to federal involvement in the nation's tort system.[288] At one point, the administration attempted to derail the compensation plan by introducing legislation that would have substantially altered the Waxman and Hawkins bills.[289]

Why, then, did President Reagan ultimately sign the legislation? On November 15, 1986, he agreed to legislation that included the vaccine compensation system.[290] However, the legislation established the VICP without a mechanism to fund the program. It can be inferred that it remained his hope to effectively block implementation in this fashion. Also, even given the lack of funding, he likely only signed the unfunded compensation system bill because Congress placed the legislation within an omnibus health bill that also contained other legislation he very much favored.[291] This legislation, which Waxman had strategically bundled with the VICP, involved the ability of pharmaceutical manufacturers to sell domestically unapproved drugs to certain foreign countries.[292]

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285. *Id.*
286. *E.g.*, Rovner & Kaplan, *supra* note 146, at 2243.
287. KINGDON, *supra* note 236, at 159-62.
288. *See supra* Part III.
289. Pear, *U.S. Plan to Curb Damage*, *supra* note 1332.
290. Pear, *Reagan Signs Bill*, *supra* note 181.
291. *Id.*
292. *Id. See generally* Oliver & Paul-Shaheen, *supra* note 277, at 768-72 (discussing strategies of policy entrepreneurs, such as taking advantage of institutional procedures like bundling legislation to advance their proposals).

F. A Policy Window

Ultimately, legislation funding the VICP was signed by President Reagan in December 1987.[293] What factors led to this? First, as was the case in the original authorizing legislation, the VICP funding provisions were part of an omnibus package.[294] Second, and of great importance, was the opening of a new policy window. As discussed earlier, according to the Kingdon model, the problem and policy streams had been aligned for some time. Then, the political stream came into line and with it a policy window emerged as a result of the 1986 mid-term congressional elections. The Republicans lost a total of eight seats, including five in the House and three in the Senate.[295] The loss of three seats in the Senate was sufficient to return power to the Democrats.[296]

In short, the VICP bill milled about in the policy agenda for several years. This, in part, was a consequence of continued bipartisan interest in both houses.[297] However, it appears that this bipartisanship did not exist sufficiently in the Senate to allow passage of the compensation program with attendant funding. The Democrats strongly favored this bill, in accordance with typical party principles involving the proper role of government as intervener, the acceptance of taxation for the common good, and the centrality of social welfare issues. Once the Senate was controlled by the Democratic Party, the bill's passage became more likely. Further, this substantial power swing, and the impact resulting from the Iran-Contra affair, left Reagan in a position of severely diminished power and influence to oppose the VICP in Congress or pose a credible veto threat.[298]

As argued above, the adoption of a fundamentally new and different policy can be explained through the Kingdon model. How can this explanation be enhanced by a consideration of disjointed incrementalism? Disjointed incrementalism suggests that policy outcomes are the result of the interaction of numerous and varied policy actors all viewing the problem and its solutions differently from the perspective of divergent values.[299] As a result, the final policy is simply

293. *Major Provisions of the Fiscal 1988 Reconciliation Bill*, *supra* note 218, at 73; Rovner, *Nursing Homes*, *supra* note 229, at 72.

294. H.R. CONF. REP. NO. 100-495, at 771-73 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1245.

295. Albert R. Hunt, *Democrats Win, Sans an Agenda, No Help in '88*, WALL ST. J., Nov. 6, 1986, at 1.

296. *Id.*

297. *See supra* Part III.A-B.

298. *E.g.*, George Lardner, Jr., *Reagan Administration's Ethics are Under Siege; Nofziger Faces Trial; Iran Indictments Ahead*, WASH. POST, Dec. 17, 1987, at A29.

299. HAYES, *supra* note 238, at 17-19.

the product of all of those competing interests that happen to be engaged in the issue at a given point in time.

Relative to the VICP, then, the history clearly shows some measure of the final policy developing in this fashion. The competing interests of the parents, the physicians, the manufacturers, the policy entrepreneurs, the remaining concerned members of Congress in both houses, and the administration all had their moments and impacted the final product.[300] The initial bills proposed by Hawkins and Waxman underwent numerous adjustments, including the development of multiple potential funding schemes, as the partisan bargaining process unfolded.

G. Reconciling the Models

In summary, both the Kingdon model and disjointed incrementalism have certain factors in common that, taken together, can enhance a policy analysis.[301] They both allow for the central role played by the multitude of actors and interests that impact the policy process. They both accept, either tacitly or expressly, the limits of rationality and how these limits profoundly impact policy. While the Kingdon model attempts to explain policy innovation that may represent a substantial departure from the status quo in both substance and scale, the Lindblom model of disjointed incrementalism can in fact help explain policies and programs that establish a new role for government yet do not require large-scale institutional change or economic resources.

V. Criticisms of the VICP During Its First Twenty Years

According to the DHHS, "[Congress] established the VICP to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines."[302] In addition to this goal, however, the VICP was established to provide compensation "quickly, easily, with certainty and generosity."[303] While the VICP program has experienced moderate success in distributing funds to individuals who have been injured by a vaccine, the program has been criticized for failing to live up to some of the standards set by Congress when the program was enacted. A report from the U.S. Government

300. *See supra* Part III.

301. *See supra* Part IV.

302. Health Res. & Servs. Admin, *National Vaccine Injury Compensation Program*, http://www.hrsa.gov/vaccinecompensation/ (last visited Jan. 21, 2007).

303. Robin J. Strongin & Eileen Salinsky, *Who Will Pay for the Adverse Events Resulting from Smallpox Vaccination? Liability and Compensation Issues*, Nat'l Health Policy Forum Issue Brief, Mar. 12, 2003, at 14, *available at* http://www.nhpf.org/pdfs_ib/IB788_Smallpox_3-12-03.pdf.

Accountability Office found that "the process has not been as quick or as easy as expected."[304] And, public health law experts have concurred that the "VICP in its current state has become adversarial, burdensome on claimants, and time-consuming."[305] These criticisms can be broken down into two categories: 1) slow process times for claims and 2) ambiguity in changes to the Vaccine Injury Table.

A. Time to Process and Award Claims

Although the VICP has succeeded in reducing the number of lawsuits brought under the tort system,[306] critics claim that the program is operating at a much slower pace than promised.[307] Most VICP claims take more than a year to process, with only fourteen percent of claims settled in a year or less.[308] Most claims are not settled within two years of filing.[309] This can be attributed to the increased volume of claims as the program progressed.[310] In addition,

> in 1990, HHS and DOJ began to increasingly scrutinize claims of vaccine injury as funding to fully implement their legislated authority under the program became available. DOJ established a cadre of attorneys . . . to represent HHS in hearings, and HHS established an expert witness program to help assess whether alleged vaccine injuries such as seizure disorders may have been present from birth or were due to other causes.[311]

As a result of the government's increasing expertise at running the VICP, "petitioners were requested to provide supplementary medical records or other information."[312] Because gathering medical records and related

304. U.S. GOV'T. ACCT. OFF., VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 2 (Dec. 1999), *available at* http://www.gao.gov/new.items/he00008.pdf [hereinafter U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION].

305. Lawrence O. Gostin, *Medical Countermeasures for Pandemic Influenza: Ethics and the Law*, 295 JAMA 554, 555 (2006).

306. Breen, *supra* note 243, at 319–20.

307. *Id.*; U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 7.

308. Breen, *supra* note 243, at 319–20; U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 7.

309. Breen, *supra* note 243, at 319–20; U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 7; *cf.* Jaclyn Shoshana Levine, Note, *The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology?*, 4 B.U. J. SCI. & TECH. L. 9, 47 (1998) ("[A]djudication delays today would not serve any noble or useful purpose—they would only highlight administrative weakness.").

310. U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 9.

311. *Id.* at 10.

312. *Id.* at 11; *cf.* Susan G. Clark, *The National Childhood Vaccine Injury Act, The National Childhood Injury Compensation Program*, 94 EDUC. L. REP. 671, 677 (1994) ("Absent any medical records or opinion, no causal connection will be found.").

information may involve consulting multiple hospitals and physicians, most petitioners took more than a year to produce these materials.[313] In fact, the VICP's chief special master has reported that "while the court could process claims more quickly, delays are granted primarily to benefit petitioners who need more time to gather information, have medical tests performed, or identify costs related to an injured child's developmental needs."[314] Therefore, both the government and those asking for compensation have contributed to the claim processing times. DHHS, DOJ, and the Court of Federal Claims have taken steps to reduce waiting times and speed up claim processing, such as producing a guide to aid petitioners and attorneys to navigate the VICP.[315]

B. The Vaccine Injury Table

Variations on the VICP's Vaccine Injury Table have been widely used in other compensation programs, such as the Smallpox Vaccine Injury Compensation Plan.[316] Since the VICP's inception, DHHS has made several major changes to the Vaccine Injury Table. For example, in 1995, some injuries, such as chronic arthritis following administration of vaccines containing rubella, were added to the Table.[317] In addition, the definition of encephalopathy was clarified.[318] And, in 1997, three new vaccines were added to the table: hepatitis B, Hemophilus influenzae type b, and varicella.[319] At the same time, DHHS has deleted some injuries from the Table. For example, in 1995, DHHS removed "residual seizure disorder" following the administration of DPT or MMR vaccines from the Table.[320]

The rationale behind these changes is always published in the *Federal Register*, but sometimes it is difficult to follow. In 1994 the Institute of Medicine found "evidence of a causal relationship between the tetanus and oral polio vaccines and Guillain-Barré syndrome, but HHS did not add this condition to the injury table."[321] At the same time,

313. U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 11.

314. *Id.*; *cf.* Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 65 (1999) ("These [time] delays compare favorably with the [time] delays encountered in civil vaccine litigation.").

315. U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 11.

316. *See infra* Part VI.B.

317. Vaccine Injury Table, 42 C.F.R. § 100.3 (1995).

318. *Id.*

319. Vaccine Injury Table, 42 C.F.R. § 100.3 (1997).

320. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678 (Feb. 8, 1995) (to be codified at 42 C.F.R. pt. 100).

321. U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 15; INST. OF MED., ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES (Kathleen R.

the Institute of Medicine concluded that "[t]he evidence is inadequate to accept or reject a causal relation between measles or mumps vaccine and encephalitis or encephalopathy."[322] Yet, DHHS chose to keep encephalopathy on the Table.[323] DHHS explained the thoughts behind these decisions in the *Federal Register*, stating that "decisions not to add injuries, such as Guillain-Barré syndrome, or to remove injuries, such as residual seizure disorder, were based to some extent on the level of risk in compensating an inordinate number of non-vaccine-related cases for the extremely rare vaccine-related case."[324] The U.S. Government Accountability Office has expressed concern with this approach because DHHS does not define its "assumptions about the number of potential claims and thresholds for deciding the reasonable level of financial risk for compensating non-vaccine-related injuries. . . ."[325]

An additional concern about changes to the Table surfaces among petitioners whose injury was removed from the Table. When an injury is not listed on the Table but is believed to have resulted from a vaccine covered by the VICP, a petitioner bears the burden of proving that the vaccine caused the injury in question.[326] In other words, the no-fault benefit conferred by the Table is lost. About twenty-eight percent of the petitions that the VICP receives concern these types of "off-Table" injuries, where the petitioner bears the burden of proof.[327] On average, only thirteen percent of these petitioners receive compensation.[328] Yet, those who suffer injuries listed on the Table have compensation rates "nearly three times higher."[329] The difference can be attributed to the mechanics of a no-fault system, where the petitioner does not assume the burden of proof. As these statistics indicate, when the burden of proof is imposed, it becomes quite difficult for a petitioner to definitively prove that a vaccine caused the injury or death in question. This disparity highlights the need for DHHS to seriously consider the ramifications for petitioners before making alterations to the Vaccine Injury Table.

The Advisory Commission on Childhood Vaccines has begun to address this issue by developing guidelines to aid in the process of

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Stratton et al. eds., 1994) [hereinafter INST. OF MED., ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES].

322. INST. OF MED., ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES, *supra* note 321, at 130.

323. U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 15.

324. *Id.*

325. *Id.* 15-16.

326. 42 U.S.C. § 300aa-11(c) (2006).

327. U.S. GOV. ACCT. OFF., VACCINE INJURY COMPENSATION, *supra* note 304, at 12.

328. *Id.*

329. *Id.*

revising the Table.[330] In addition, the 108th and 109th Congresses considered bills that would have increased available compensation, including compensation for family counseling, and required DHHS to conduct a campaign to publicize the availability of the VICP. However, both bills died in the House Energy and Commerce Committee's Subcommittee on Health.[331]

VI. Influence of the VICP on Subsequent Vaccine Programs

Despite the above criticisms, the VICP has been treated as a model for subsequent vaccine compensation programs in the United States. This can be attributed to several factors, including the program's longevity and the fact that it has generally received bipartisan support in Congress.[332] As new biological threats emerge, either due to terrorism or to the natural transmission of disease, members of Congress continue to look to the VICP as a successful example of how to provide liability protections to vaccine manufacturers and administrators and to compensate those who suffer adverse effects from a vaccination.

A. Influenza

Influenza or flu, a contagious respiratory illness, affects five to twenty percent of the American population each year, resulting in 36,000 deaths and 200,000 hospitalizations.[333] Although vaccination appears to be an effective solution to reduce morbidity and mortality from the flu, there are many barriers to the flu vaccine's production, distribution, and effectiveness.[334]

According to the CDC, multiple strains (and different variants within each strain) of the influenza virus circulate each year.[335] For

330. *See supra* Part II.A.

331. H.R. 1297, 109th Cong. (2005); H.R. 1349, 108th Cong. (2003).

332. *See supra* Part III.

333. Ctrs. for Disease Control & Prevention, Fact Sheet: Key Facts About Influenza and the Influenza Vaccine, Sept. 28, 2005, *available at* http://www.cdc.gov/flu/pdf/keyfacts.pdf.

334. *See, e.g.*, Deborah Franklin, *The Give and Take of Flu Shots: Mostly Give*, N.Y. TIMES, Feb. 21, 2006, at F5 ("Flu strains are constantly undergoing mutation, and the effectiveness of the vaccine varies from year to year. . . ."); Michael S. Rosenwald, *Flu Crisis Sparks Fresh Look at Vaccine Production*, WASH. POST, Nov. 27, 2004, at A1 ("With a crisis sparked by the flu-shot shortage, federal health officials are eager for new, more flexible technologies that could produce vaccine faster and more cheaply, enticing companies to enter a market that others have largely abandoned because of poor profits."); *cf.* Betsy McKay & Marilyn Chase, *U.S. Works to Improve Flu-Vaccine Production*, WALL ST. J., May 5, 2005, at D5 ("'The current system of producing and distributing influenza vaccine is broken, both technically and financially . . . [w]e need to develop a new way to bring the private sector to the table with flu vaccine.'").

335. Ctrs. for Disease Control & Prevention, Influenza (Flu): Questions & Answers:

example, influenza A (H3N2) was the dominant strain during the 2003-04 and 2004-05 flu seasons, but influenza A (H1) and B viruses were also present in 2004-05.[336] Consequently, the influenza vaccine must change every year to effectively prevent the disease. This is no simple task: predicting which strain will move across the globe months ahead of time requires international flu surveillance and even stronger international public health systems.[337]

In addition to predicting the "right" influenza strain, other serious complications arise once a strain has been identified for vaccine production. Because the flu vaccine is only viable for one season, production of too many doses often leads to the destruction of excess vaccine.[338] This can be costly to manufacturers who have invested significant resources into vaccine development.[339] The actual production of these vaccines is also highly sensitive and can be subject to serious safety concerns.[340] In October 2004, these issues came to a head when Chiron, a biotechnology company, announced that it would not be able to provide flu vaccines for the United States due to production safety concerns.[341] As a result, vaccine shortfalls occurred across the country, leaving many Americans without access to flu vaccinations.[342]

In addition to vaccine shortages and the difficulty of anticipating the correct flu strain, vaccine injury liability concerns have affected the influenza vaccine production market. Lack of a formalized compensation plan for individuals injured or killed by the influenza vaccine contributed to the reluctance of manufacturers to produce the

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The Disease, Nov. 8, 2006, *available at* http://www.cdc.gov/flu/about/qa/disease.htm.

336. *Id.*

337. Ctrs. for Disease Control & Prevention, Fact Sheet: Overview of Influenza Surveillance in the United States, June 26, 2006, *available at* http://www.cdc.gov/flu/weekly/pdf/flu-surveillance-overview.pdf.

338. Editorial, *An Influenza Vaccine Debacle*, N.Y. TIMES, Oct. 20, 2004, at A26 ("The main problem is that influenza vaccine needs to be reformulated every year, and companies suffer huge losses if they overestimate the amount that will be needed because they end up having to destroy millions of doses.").

339. *Id.*

340. Rosenwald, *supra* note 334 ("Cell culture vaccines may hold safety advantages. Unlike those produced in chicken eggs, some cell culture vaccines are not processed with chemicals that can cause rare side effects, and people with egg allergies won't have dangerous reactions to them.").

341. Sarah Lueck & Pui-Wing Tam, *FDA Concurs that Chiron Flu Vaccine is Unusable*, WALL ST. J., Oct. 18, 2004, at A2 ("Federal health officials said none of Chiron Corp.'s flu vaccine is safe for use, after their inspection of the biotechnology company's plant in Liverpool, England, uncovered manufacturing defects and bacterial contamination.").

342. SARAH A. LISTER & ERIN D. WILLIAMS, INFLUENZA VACCINE SHORTAGES AND IMPLICATIONS 1-2 (2004), *available at* http://digital.library.unt.edu/govdocs/crs//data/2004/upl-meta-crs-6128/RL32655_2004Oct29.pdf

vaccine.[343] In the latter half of 2004, Congress considered adding the flu vaccine to the list of vaccines covered by the VICP.[344] This would mean that any person who received an enumerated injury due to the flu vaccine within a time period specified by the Vaccine Injury Table fell under the purview of the VICP. To receive compensation, an injured person would first file a petition with the VICP, through the Court of Federal Claims.[345] The subsequent processes for moving a flu vaccine claim through the system would be the same as those described above for childhood vaccine-related injuries.[346]

During hearings on the proposed legislation, members of Congress suggested that concerns about litigation costs had driven flu vaccine manufacturers from the market: "[W]hy have we gone from just three or four [flu vaccine] manufacturers down to just one? Perhaps the manufacturers just decided 'I'm going to throw up my hands. I'm not going to deal with this. I don't want the litigation. It's too much hassle,'" said Representative Cliff Sterns (R-FL).[347] Indeed, Congress responded to these types of liability concerns in late 2004, when it passed legislation that added the flu vaccine to vaccines covered by the VICP.[348] President Bush signed the law on October 22, 2004.[349]

And yet, as of February 2006, only four companies were producing the influenza vaccine worldwide, with only two conducting operations in the United States.[350] This current lack of manufacturer participation in the flu vaccine market suggests that liability concerns were not as crucial to manufacturers as the American public and Congress supposed. A recent survey of judicial opinions found "only ten reported cases [of flu vaccine-related litigation] in the last 20 years."[351] While reported cases, which are those that resulted in either a jury verdict or a judicial opinion, represent only a fraction of total claims, they do offer "a sense of how [flu-vaccine] cases are faring in court."[352] Nearly all of the reported

343. *See Flu Vaccine Shortage Builds as Election Issue*, WALL ST. J., Oct. 19, 2004, at B4 ("Liability concerns . . . are to blame for a shortage of flu shots this year, Vice President Dick Cheney said during a campaign stop at a West Virginia restaurant.").

344. H.R. 4520, 108th Cong. (2004).

345. 42 U.S.C. § 300aa-12(a) (2006).

346. *See supra* Part II.B.

347. *The Flu Vaccine: Hearing Before the Subcomms. on Health and Oversight and Investigations of the House Comm. on Energy and Commerce*, 108th Cong. 2 (2004) (statement of Rep. Cliff Sterns).

348. American Jobs Creation Act of 2004, Pub. L. No. 108-357, § 890, 118 Stat. 1418, 1644 (codified as amended at 26 U.S.C. § 4132(a)(1)(N) (2004)).

349. *Bills Signed*, 2004 CONG. Q. 2567.

350. Gostin, *supra* note 305, at 554.

351. Michelle M. Mello & Troyen A. Brennan, *Legal Concerns and the Influenza Vaccine Shortage*, 294 JAMA 1817, 1819 (2005).

352. *Id.*

cases "settled for . . . [small] amounts or were resolved by the courts on summary judgment."[353] This track record and the addition of the flu vaccine to the VICP should have alleviated most liability concerns for flu vaccine manufacturers. Therefore, the current small number of flu vaccine manufacturers implies that other issues, such as the difficulty of determining which strain of the flu will appear each year, outweigh liability concerns for these companies.

B. Smallpox

Although smallpox was officially eradicated worldwide in 1980, it is still a feared and highly infectious disease.[354] In the aftermath of the September 11, 2001 attacks, and the anthrax attack on the U.S. Capitol one month later, smallpox fears resurfaced.[355] Reports that rogue nations had illegally obtained stockpiles of smallpox appeared in the media.[356] In response to these fears and recommendations from the CDC's Advisory Committee on Immunization Practices,[357] President George W. Bush announced his plan for a smallpox vaccination program on December 13, 2002, and signed the program into law on April 30, 2003.[358] The program called for the vaccination of health care workers, emergency response personnel, and military personnel who would be the first responders for the general population in the case of an intentional release of smallpox.[359]

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353. *Id.*

354. Zack S. Moore et al., *Smallpox*, 367 LANCET 425, 425 (2006).

355. *E.g.*, Terence Chea, *Investing in National Security; Local Labs' Vaccines, Other Products Have New Relevance*, WASH. POST, Dec. 20, 2001, at T5; Brad Smith, *Health Experts Weigh Bioterrorism Threats*, TAMPA TRIB., Dec. 12, 2001, at 1 ("With anthrax scares down sharply, public health officials say smallpox—not anthrax—is bioterrorism's deadliest potential threat.").

356. Judith Miller & Sheryl Gay Stolberg, *A Nation Challenged: The Strategy; Sept. 11 Attacks Led to Push for More Smallpox Vaccine*, N.Y. TIMES, Oct. 22, 2001, at 1 ("Although smallpox was eradicated as a disease in the 1970's, American intelligence had suspected for years that Iraq and North Korea, and possibly other rogue nations, had maintained clandestine stocks of the deadly smallpox virus."); John Fialka et al., *Are We Prepared for the Unthinkable?—Officials Fear U.S. Ill-equipped To Cope With Biological or Chemical Terrorism*, WALL ST. J., Sept. 18, 2001, at B1 ("The gravest fear is that . . . terrorist kingpins might acquire weapons from a rogue state such as Iraq, Libya or Sudan, all of which have pursued the development of chemical, biological and nuclear weapons [.]").

357. *Vaccinia (Smallpox) Vaccine: Recommendation of the Advisory Committee on Immunization Practices (ACIP), 2001*, MORBIDITY AND MORTALITY WKLY. REP. No. RR-10, June 22, 2001, at 17-21.

358. Smallpox Emergency Personnel Protection Act of 2003, Pub. L. No. 108-20, 117 Stat. 638 (codified as amended at 42 U.S.C. §§ 201-202 (2006)); *Bush Will Offer Public Vaccine for Smallpox*, ST. PETERSBURG TIMES, Dec. 12, 2002, at A10.

359. Smallpox Emergency Personnel Protection Act of 2003, Pub. L. No. 108-20, 117 Stat. 638; *Remembering Smallpox: Lessons Learned from the State Experience*, Ass'n of

Despite initial strong public support,[360] cracks soon appeared in the plan. As of June 2003, the Department of Defense had vaccinated 350,000 military personnel and only 37,487 civilians against smallpox.[361] The White House had anticipated that more than 500,000 civilians would voluntarily agree to be vaccinated.[362]

Several theories exist as to why vaccination rates were so low. The first theory involves practical limitations to the CDC's highly ambitious vaccination plan. In early 2003, the CDC anticipated that 500,000 health care workers would be vaccinated within the first thirty days of the smallpox vaccination program.[363] However, many state and local jurisdictions did not receive the smallpox vaccine on time.[364] In addition, technical issues, such as database system incompatibility, led to fewer health care workers receiving vaccinations.[365]

Other theories concern fears about the smallpox vaccine's side effects. The smallpox vaccine carries significant health risks. Because the vaccine is composed of living vaccinia virus,[366] it poses unique threats to those who receive it.[367] One thousand out of every 1,000,000 persons who receive the vaccine will experience serious health effects such as toxic/allergic reactions.[368] More seriously, the CDC anticipated that one to two of every 1,000,000 persons vaccinated would die as a result of the vaccine.[369]

According to the U.S. Government Accountability Office, lack of adequate compensation for injuries incurred via vaccination was ranked highly as a reason for low civilian participation in the vaccination program.[370] These concerns were echoed by several organizations,

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State & Territorial Health Officials Issue Brief, Oct. 2004, at 1-2, *available at* http://www.astho.org/pubs/SmallpoxLessonsLearned20.pdf?PHPSESSID=bafb6ad.

360. *See, e.g.*, Anita Manning, *U.S. Readies Offensive Against Smallpox Threat*, USA TODAY, July 31, 2002, at D8 ("With more than 350,000 truckers [that the Teamsters] . . . represent, we would certainly support having our members vaccinated[.]").

361. SUSAN THAUL, SMALLPOX VACCINE INJURY COMPENSATION 1-2 (2003), *available at* http://biotech.law.lsu.edu/blaw/bt/smallpox/Congress/RL31960.pdf.

362. *Id.*

363. U.S. GOV. ACCT. OFF., SMALLPOX VACCINATION: IMPLEMENTATION OF NATIONAL PROGRAM FACES CHALLENGES 1 (Apr. 2003), *available at* http://www.gao.gov/new.items/d03578.pdf [hereinafter U.S. GOV. ACCT. OFF., SMALLPOX VACCINATION].

364. *Id.* at 4.

365. *Id.*

366. *Who Will Pay for the Adverse Events Resulting from Smallpox Vaccination?*, *supra* note 303, at 3.

367. *Id.*

368. Ctrs. for Disease Control & Prevention, Smallpox Fact Sheet, Mar. 31, 2003, at 2, *available at* http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/vaccine-overview.pdf.

369. *Id.*

370. U.S. GOV. ACCT. OFF., SMALLPOX VACCINATION, *supra* note 363, at 4-5.

including the Association of State and Territorial Health Officials and the National Association of City and County Health Officials, both of which described a need for a compensation plan that would protect civilians who participated in the smallpox vaccination program.[371] Specifically, several stakeholders including state officials, public health officers, the American College of Emergency Physicians, and health care worker unions suggested a federally funded, no-fault compensation system modeled, in part, on the VICP.[372]

In response to these concerns, Congress took steps in the first few months of 2003 to enact legislation that would compensate individuals who were injured or killed after receiving a smallpox vaccination.[373] Congress looked to existing compensation programs, such as the VICP, to help craft a smallpox vaccine injury compensation plan.[374] As a result, two major proposals were drafted. H.R. 865,[375] the Smallpox Vaccine Compensation and Safety Act of 2003, was introduced by Representative Henry Waxman on February 13, 2003, and drew heavily on Waxman's previous work with the National Vaccine Injury Compensation Program. Waxman's plan, like the VICP, suggested that special masters, appointed by the Court of Federal Claims, would hear each vaccine injury claim.[376] Available compensation would include lost wages, medical expenses, and a one-time $250,000 payment for non-economic damages.[377] In addition, if a person died due to the smallpox vaccine, an $850,000 death benefit would be paid.[378] The bill mandated and authorized the appropriations that would pay for the compensation program.[379]

Unfortunately, elements of the VICP did not easily translate to smallpox vaccine injury compensation. For example, the National Health Policy Forum anticipated that funding issues would likely arise because Waxman's plan for smallpox injuries would include lost wages whereas childhood vaccine injury-related compensation lacked reimbursement for missed work.[380] Furthermore, while part of the VICP

371. *Who Will Pay for the Adverse Events Resulting from Smallpox Vaccination?*, *supra* note 303, at 8-9.

372. *Id.* at 11.

373. *E.g.*, Kate Schuler, *First Responders' Apprehension Slows Progress With Smallpox Vaccination Plan*, 2003 CONG. Q. 705 [hereinafter Schuler, *First Responders*]; Kate Schuler, *Smallpox Compensation Fund Gets Through Senate Committee After Surprise Rejection in House*, 2003 CONG. Q. 828 [hereinafter Schuler, *Smallpox Compensation*].

374. THAUL, *supra* note 361, at 5.

375. H.R. 865, 108th Cong. (2003).

376. *Id.* § 4(a).

377. THAUL, *supra* note 361, at 10.

378. H.R. 865, 108th Cong. § 4(a) (2003).

379. *Id.*; THAUL, *supra* note 361, at 10.

380. *Who Will Pay for the Adverse Events Resulting from Smallpox Vaccination?*,

funding scheme is paid by an excise tax on the vaccines themselves, this tax would not be possible with smallpox vaccines as the vaccine would be purchased by the federal government rather than by individuals.[381] These concerns contributed to the bill's failure. It died in the House Education and Workforce Committee's Subcommittee on Workforce Protections.

The administration-favored proposal,[382] S. 719,[383] the Smallpox Emergency Personnel Protection Act, was submitted by Senator Judd Gregg (R-NH) on March 26, 2003. The plan assigned administrative responsibility for the compensation program to the Secretary of Health and Human Services and did not provide for judicial review of any procedures developed by the Secretary.[384] Similar to the VICP, the bill required the Secretary to develop a vaccine injury table with timeframes for specific injuries that could occur after a smallpox vaccination.[385] Gregg's plan was less financially generous than Waxman's. Available compensation was divided into three categories: medical benefits, lost employment income, and death or permanent disability. The medical benefit included "medical items and services as reasonable and necessary" to treat a vaccine-injured person.[386] Lost employment income would be compensated at two-thirds for a person with no dependents and at seventy-five percent for a person with dependents. The total compensation for lost employment income could not exceed $50,000.[387] Compensation for death or permanent disability would be paid in a one-time lump sum of $262,100, minus payments made for lost employment income.[388]

The bill squeaked through the Senate's Committee on Health, Education, Labor, and Pensions with an 11-10 vote.[389] Democrats voiced strong opposition to the bill and wanted "higher funding levels for injured workers."[390] Despite these concerns, Democrats and Republicans were anxious to pass a smallpox compensation bill because the issue had become "the biggest prize in the race to show support for emergency workers and preparedness programs."[391] This sentiment led to the

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supra note 303, at 12.

381. *Id.*

382. Schuler, *Smallpox Compensation*, *supra* note 373, at 828 (referring to bill as "Bush's vaccination program").

383. S. 719, 108th Cong. (2003).

384. *Id.* § 2.

385. *Id.*

386. *Id.*

387. *Id.*

388. *Id.*

389. Schuler, *Smallpox Compensation*, *supra* note 373, at 828.

390. *Id.*

391. *Id.*

introduction of H.R. 1770,[392] a compromise bill, by Representative Richard Burr (R-NC) on April 11, 2003. The bill specified that the Secretary of Health and Human Services would "establish procedures" for carrying out the smallpox vaccination compensation program.[393] Judicial review of these procedures was prohibited.[394] To be eligible for compensation, an individual would have to suffer an enumerated injury within a prescribed period of time, as indicated on the smallpox vaccine injury table.[395] Available compensation would include the following: 1) medical benefits, including "medical items and services as reasonable and necessary to treat a covered injury of an eligible individual, including the services, appliances, and supplies prescribed or recommended by a qualified physician . . .";[396] 2) lost employment income compensated at two-thirds for those with no dependents and at seventy-five percent for those with dependents;[397] and 3) for those who died after receiving a smallpox vaccination, a death benefit of $262,100.[398] The total compensation in this category would not exceed $50,000 for any one year.[399] While any payment for lost income would be subtracted from the death benefit, any payment or reimbursement for medical care would be made in addition to the death benefit.[400]

This slightly more generous compensation program was signed into law by President Bush on April 30, 2003.[401] However, despite the passage of the law and the appropriation of $42 million to provide compensation,[402] vaccination rates for civilian first responders did not show any real signs of improvement in the following months.[403] This can be attributed to several lingering issues. First, as the administration shifted its focus to the war in Iraq, it "did not [continue to] convey a sense of urgency about the possibility of a smallpox outbreak. . . . [As a

392. H.R. 1770, 108th Cong. (2003).
393. *Id.* § 2.
394. *Id.*
395. *Id.*
396. *Id.*
397. *Id.*
398. H.R. 1770, 108th Cong. (2003); THAUL, *supra* note 361, at 12.
399. H.R. 1770, 108th Cong. § 2 (2003).
400. THAUL, *supra* note 361, at 12-13.
401. *Id.* at 11; Smallpox Emergency Personnel Protection Act of 2003, Pub. L. No. 108-20, 117 Stat. 638 (2003).
402. Health Res. & Servs. Admin., Fact Sheet: Smallpox Vaccine Injury Compensation Program, http://www.hrsa.gov/smallpoxinjury/fact.htm (last visited Aug. 4, 2006).
403. *E.g.*, Christian Davenport, *Fears About Smallpox Shots May Put Public at Risk*, WASH. POST, Sept. 12, 2004, at C1 ("'There was really very little interest on the part of first-responder groups to receive the vaccine,' said Lisa Kaplowitz, the Virginia Department of Health's deputy commissioner for emergency preparedness and response. 'It wasn't zero, but really very little interest.'").

result,] the medical community did not take on board the real possibility of a smallpox outbreak."[404] Thus, the efforts of people responsible for vaccinating first responders slowly dissipated. In addition, potential vaccinees remained concerned about the vaccine's possible side effects.[405] In fact, as of October 31, 2005, only 39,608 civilians had received the smallpox vaccine.[406]

C. *Project Bioshield*

After the anthrax attacks of 2001, many in government and industry recognized that the United States lacked effective medical countermeasures for a variety of biological threats, such as botulinum toxin and plague.[407] In addition, experts concurred that the country had not developed sufficient stockpiles for known threats, such as anthrax.[408] As a result, in early 2003, Senator Judd Gregg introduced Project Bioshield,[409] which tried to address some of these issues. The bill contained provisions to encourage pharmaceutical companies to develop new drugs and vaccines to combat biological threats.[410] The legislation

404. Editorial, *Smallpox Fiasco*, WASH. POST, July 14, 2003, at A20.

405. *E.g.*, Davenport, *supra* note 403 ("Officials said people are reluctant to volunteer to be vaccinated because of risks associated with the vaccine, which has been linked to several cases of a potentially fatal heart inflammation.").

406. Ctrs. for Disease Control & Prevention, *Smallpox Vaccination Program Status by State*, http://www.cdc.gov/od/oc/media/pressrel/smallpox/spvaccin.htm (last visited Jan. 21, 2007); *cf.* MURRAY EDELMAN, THE SYMBOLIC USES OF POLITICS (2d ed. 1985) (explaining importance of symbolism to policy development).

407. Editorial, *Smallpox and Beyond*, WALL ST. J., Dec. 13, 2002, at A15 ("The terrorist goal is to kill, using whatever is available—anthrax, the plague, botulinum toxin, tularemia, ebola, Lassa fever, Yellow fever, Rift Valley fever, brucela. The U.S. lacks effective vaccines and therapies for many of these."); Denise Grady, *Bioterror Agents Join List of 'Emerging' Ills*, N.Y. TIMES, Apr. 2, 2002, at F1 ("Now, anthrax and other potential bioterror agents—smallpox, plague, tularemia, botulism, Q fever and the Ebola and Marburg viruses—have been added to the ranks of emerging infectious disease [by the CDC].").

408. Reed Abelson & Robert Pear, *A Nation Challenged: The Medical Stockpile; Concerns About How Quickly the U.S. Can Deliver Drugs*, N.Y. TIMES, Oct. 30, 2001, at B8 ("For all the government's talk about a stockpile of antibiotics and other medical supplies that can be delivered anywhere in the nation in 12 hours, it is not at all clear that federal officials can actually get drugs or medical supplies to millions of Americans that quickly."); Guy Gugliotta, *No Decision on Anthrax Vaccine Program; Pentagon Weighs Military, Civilian Needs Against Limited Supply, Says It's 'Close' to Resolving Issue*, WASH. POST, May 20, 2002, at A2 ("[Defense] Department sources say limitations on vaccine supplies and production capacity will make it impossible to start all 2.4 million of the nation's military personnel at once on the cumbersome six-dose course of injections required for full immunization.").

409. S. 15, 108th Cong. (2003).

410. FRANK GOTTRON, PROJECT BIOSHIELD, CONG. RES. SERVICE REP., at 2 (2005), *available at* www.fas.org/sgp/crs/terror/RS21507.pdf.; *For the Record*, WASH. POST, July 22, 2004, at T24 ("[Project Bioshield] streamlines contracting rules and provides

"provides expedited procedures for bioterrorism-related procurement, hiring, and awarding of research grants, making it easier for the Department of Health and Human Services (HHS) to quickly commit substantial funds to countermeasure projects."[411] A companion bill, H.R. 2122,[412] was introduced by Representative Billy Tauzin (R-LA) on May 15, 2003.

During hearings on the proposed legislation, representatives of pharmaceutical companies repeatedly mentioned the need for protection from liability should their countermeasures cause an adverse reaction in a recipient. As Frank Rapoport, an attorney representing Aventis Pasteur explained,

> The issue of potential liability for any entity that provides, or performs research and development related to, Biodefense countermeasures absolutely must be addressed in order to stimulate private sector interest in entering into agreements for such countermeasures. Our experience was that the absence of liability protection was a major obstacle in the recent procurement by NIH for development of the next-generation Anthrax vaccine and continues to be a major hurdle for our company.[413]

Legislators appeared less concerned about liability protections. During debates about the bill, liability issues were rarely mentioned. And, the bill's accompanying House Report "encourage[ed] the Secretaries [of HHS and the Department of Homeland Security] to indicate in any call for proposals the potential availability of indemnification or liability protections under other laws."[414] However, the "other laws" provide indemnification against lawsuits by those who are adversely affected by a countermeasure only after the Secretary of the Department of Homeland Security makes a declaration that there is an "actual or potential bioterrorist incident or other actual or potential public health emergency."[415] Because this type of provision does "not apply to harm

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financial incentives to encourage companies to develop pharmaceuticals and other countermeasures that have no broad commercial application.").

411. GOTTRON, *supra* note 410, at 2.

412. H.R. 2122, 108th Cong. (2003).

413. *Project BioShield: Contracting for the Health and Security of the American Public: Hearing Before the H. Comm. on Gov. Reform*, 108th Cong. 74-75 (2003) (testimony of Frank Rapoport, Attorney on behalf of Aventis Pasteur); *see also Furthering Public Health Security: Project BioShield: Hearing Before the House Comm. on Energy and Commerce*, 108th Cong. 56 (2003) ("[T]he Government must assure private sector partners that they will not be exposed to a risk of litigation out of proportion to the rewards for success.").

414. H.R. REP. NO. 108-147 (2003).

415. Homeland Security Act of 2002, Pub. L. No. 107-296, § 304(c), 116 Stat. 2135, 2166 (2002) (codified as amended at 6 U.S.C. § 101 (2002)).

caused when no act of terrorism has occurred, [] it may not cover products, such as vaccines . . ., deployed when an attack is only suspected or threatened."[416]

Project Bioshield was signed into law on July 21, 2004,[417] and members of Congress implied that they would eventually revisit the issue of manufacturer indemnification.[418] However, the current Congress has taken few definitive steps in this direction.[419] Consequently, it should perhaps not be surprising that many vaccine manufacturers have stayed out of the novel vaccine production market. Although Project Bioshield allocated $5.6 billion for contracts with drug manufacturers, DHHS has signed only four contracts to date, totaling approximately $1 billion.[420]

In addition to lack of manufacturer liability protections, the Project Bioshield legislation offers no compensation package to those who are injured after receiving a vaccination or other countermeasure. This omission can be attributed to the fact that the smallpox vaccine compensation program was being developed at the same time that legislators were debating the Project Bioshield bill.[421] After witnessing how controversial the smallpox vaccine compensation program was, legislators shied away from introducing that type of program with Project Bioshield.[422] Instead, priority was placed on passing the Project Bioshield program so that the government could begin contracting with drug companies who were willing to develop countermeasures.[423] To date, Congress has not passed legislation that would create a compensation program for those injured by Project Bioshield vaccines or countermeasures.

D. Avian Flu

Vaccine compensation concerns arose again in 2005-06 as avian flu

416. GOTTRON, *supra* note 410, at 5.

417. Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004) (codified as amended at 42 U.S.C. § 201 (2004)).

418. Rebecca Adams, *Bioterrorism Bill Advances with Hybrid Funding Plan*, 2003 CONG. Q. 1190 ("Tauzin said that he would have 'loved to put liability protections in [the Project Bioshield bill],' but that such a controversial move could doom the bill. He predicted that Congress will revisit the issue at a later date.").

419. In April 2005, Senator Joseph Lieberman (D-CT) introduced S. 975, which would have added some liability protections for manufacturers who receive Project Bioshield contracts. S. 975, 109th Cong. (2005). However, this bill has received little attention and appears to have died in the Senate Committee on Health, Education, Labor, and Pensions.

420. Rebecca Adams, *Project Bioshield: A Second Look*, 2006 CONG. Q. 234.

421. Schuler, *First Responders*, *supra* note 373, at 705.

422. *2003 Legislative Summary: Project Bioshield*, 2003 CONG. Q. 3122.

423. Schuler, *First Responders*, *supra* note 373, at 705.

(H5N1) rapidly spread across the globe.[424] Avian flu occurs primarily in birds, but it is the first known influenza strain that is able to cross the species barrier and infect and kill humans.[425] In fact, scientists have drawn similarities between H5N1 and the flu of 1918 that killed approximately two percent of the world's population.[426] While there have not been any reported cases of avian flu in the United States, according to the World Health Organization, 205 cases and 113 deaths had been reported worldwide as of April 27, 2006.[427] As H5N1 makes its way around the world, efforts are underway at the CDC and other government agencies to prepare the United States for the eventual arrival of what is now known as the pandemic flu.[428]

On November 1, 2005, President Bush unveiled a National Strategy for Pandemic Influenza.[429] The plan listed the following goals: "1) stopping, slowing or otherwise limiting the spread of a pandemic to the United States; 2) limiting the domestic spread of a pandemic, and mitigating disease, suffering and death; and 3) sustaining infrastructure and mitigating impact to the economy and the functioning of society."[430] The plan includes provisions to "purchase stockpiles of vaccines and antiviral drugs, and accelerate the development of new vaccine technologies. . . ."[431] However, in its current form, the plan contains no compensation provisions for those who are injured by a pandemic flu vaccine nor does it offer liability protection to pandemic flu vaccine

424. *E.g.*, Susan Levine, *D.C. Plans Summit on Pandemic Response; Meeting April 28 is Part of Effort to Coordinate Business, School, Religious Groups*, WASH. POST, Mar. 21, 2006, at B4.

> With the spread of avian flu across the globe, and the threat posed should the deadly H5N1 strain mutate to allow human-to-human transmission, the federal government is urging states, cities and even neighborhoods to ready themselves for the extended and extensive disruption a pandemic could cause in every aspect of daily life.

Id.

425. Ctrs. for Disease Control & Prevention, Key Facts About Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus, Feb. 7, 2006, *available at* http://www.cdc.gov/flu/avian/gen-info/facts.htm.

426. SARAH A. LISTER, PANDEMIC INFLUENZA: DOMESTIC PREPAREDNESS EFFORTS, CONG. RES. SERVICE REP., at 1 (2005), *available at* www.fas.org/sgp/crs homesec/RL33145.pdf.

427. World Health Org., *Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO* (Apr. 27, 2006), *available at* http://www.who.int/csr/disease/avian_influenza/country/cases_table_2006_04_27/en/index.html.

428. *E.g.*, Betsy McKay, *CDC Proposes Traveler Database to Help Fight Infectious Diseases*, WALL. ST. J., Nov. 23, 2005, at D4 ("The [CDC] proposed requiring airlines and cruise lines to hand over names, home addresses and other information about passengers and crew to help public-health officials track down people who might have been exposed to infectious diseases such as avian flu.").

429. LISTER, *supra* note 426, at 13.

430. *Id.*

431. *Id.*

manufacturers.[432]

Although Congress added the influenza vaccine to the VICP in 2004,[433] this does not mean that a pandemic flu vaccine is covered as well. The VICP covers trivalent flu vaccine, which is "the annual vaccine that contains three strains."[434] A pandemic flu vaccine would be monovalent, or singled-strained, which would not fall under the VICP.[435] Although influenza vaccines carry a low risk of adverse side effects,[436] a plan that does not contain compensation provisions for those injured by the vaccine could deter first responders and the general public from being vaccinated. In addition, manufacturers may be reluctant to enter the market if they fear costly lawsuits from those who experience a vaccine's adverse effects.

As a result of these concerns, the 109th Congress is considering several bills that would address liability and compensation concerns. For example, on December 16, 2005, Representative Nita M. Lowey (D-NY) introduced the Pandemic and Seasonal Influenza Act of 2005.[437] In the event that the United States government declares a state of flu pandemic, the bill would establish a compensation system for those injured by the pandemic flu vaccine.[438] It would be modeled on the VICP, including a Vaccine Injury Table. However, payments for compensation would be drawn exclusively from appropriations and not from an excise tax. In addition, the bill would protect pandemic flu vaccine manufacturers and administrators by requiring people to pursue compensation through the VICP-modeled program first.[439] The bill has fifty-one co-sponsors and, in early May 2006, was referred to the House Education and Workforce Committee's Subcommittee on 21st Century Competitiveness. Partisan disagreement about this type of program concerns the extent of liability protection for manufacturers and the amount of compensation available for vaccine-injured persons.[440] However, because there is generally bipartisan agreement that manufacturer liability and victim compensation provisions are necessary for a successful pandemic flu program,[441] it is likely that this type of proposed legislation will eventually pass.

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432. *Id.* at 27-29.
433. *See supra* Part VI.A.
434. LISTER, *supra* note 426, at 28.
435. *Id.*
436. John J. Treanor et al., *Safety and Immunogenicity of an Inactivated Subvirion Influenza A (H5N1) Vaccine*, 354 NEW ENG. J. MED. 1343, 1343-51 (2006).
437. H.R. 4603, 109th Cong. (2005).
438. *Id.* § 101.
439. *See id.*
440. Kate Schuler, *2005 Legislative Summary: Pandemic Flu Preparedness*, 2006 CONG. Q. 43.
441. *Id.*

VII. Conclusion

As the preceding examples illustrate, vaccine manufacturer liability protections and victim compensation remain controversial and timely issues. With this understanding, it is helpful to revisit the story of how Congress created the United States' longest-running and most successful vaccine compensation program, the VICP. With the swine flu episode only a decade behind them, it took members of Congress over three years to create and pass the VICP legislation. As the application of theoretical frameworks demonstrated, this passage can be attributed to numerous factors, including 1) a problem definition that concerned the need to protect American children from preventable diseases; 2) a coalescing of bipartisan interests around this idea; 3) the work of policy entrepreneurs Paula Hawkins and Henry Waxman; 4) the softening up process that had prepared stakeholders and members of Congress for this type of legislation; 5) the strategic packaging of the VICP in omnibus legislation that included initiatives desired by the Reagan administration; and 6) the opening of a new policy window to establish a long-term funding stream for the VICP when the Democrats regained control of the Senate and President Reagan's veto threat had significantly weakened.

Given emerging biological threats, such as smallpox and avian flu, it is virtually inevitable that Congress will create vaccine injury compensation programs in the near future. In anticipation of these events, lawmakers can draw on the experiences of past Congresses that have considered vaccine compensation programs. As the recent examples of influenza, smallpox, Project Bioshield, and avian flu have shown, vaccine manufacturers will not automatically invest in combating a new disease. Without sufficient liability protections, they are apt to avoid the market entirely. At the same time, first responders and other likely vaccinees will shun new vaccinations if no plan exists to compensate them should they be injured by the vaccines. And, even if a plan exists, it must offer compensation that vaccinees will perceive as appropriate to the risks posed by the vaccine. These lessons and the story of the VICP will help stakeholders and lawmakers to craft future immunization programs that will successfully protect the public's health, stabilize the market for vaccine development and distribution, and provide compensation to those who are injured by a government-recommended vaccine.

Appendix A
National Childhood Vaccine Injury Act
Vaccine Injury Table[a]

Vaccine	Adverse Event	Time Interval
I. Tetanus toxoid-containing vaccines (e.g., DTaP, Tdap, DTP-Hib, DT, Td, TT)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Brachial neuritis	2-28 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, Tdap, DTP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Encephalopathy (or encephalitis)	0-72 hours
	C. Any acute complication or sequela (including death) of above events	Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Encephalopathy (or encephalitis)	5-15 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days
	B Any acute complication or sequela (including death) of above event	Not applicable

V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A Thrombocytopenic purpura	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	0-6 months Not applicable
	C Any acute complication or sequela (including death) of above events	
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio	
	-- in a non-immunodeficient recipient	0-30 days
	-- in an immunodeficient recipient	0-6 months Not applicable
	-- in a vaccine assoc. community case	0-30 days
	B. Vaccine-strain polio viral infection	0-6 months Not applicable
	-- in a non-immunodeficient recipient	Not applicable
	-- in an immunodeficient recipient	
	-- in a vaccine assoc. community case	
	C. Any acute complication or sequela	
	(including death) of above events	

VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A Anaphylaxis or anaphylactic shock	0-4 hours
	B. Any acute complication or sequela (including death) of above event	Not applicable
VIII. Hepatitis B antigen-containing vaccines	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Any acute complication or sequela (including death) of above event	Not applicable
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Vaccines containing live, oral, rhesus-based rotavirus	A. Intussusception	0-30 days
	B. Any acute complication or sequela (including death) of above event	Not applicable
XIII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIV. Any new vaccine recommended by the Centers for Disease Control and		

Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage[b]	

[a]Effective date: July 1, 2005

[b]As of December 1, 2004, hepatitis A vaccines have been added to the Vaccine Injury Table (Table) under this Category. As of July 1, 2005, *trivalent* influenza vaccines have been added to the Table under this Category. Trivalent influenza vaccines are given annually during the flu season either by needle and syringe or in a nasal spray. All influenza vaccines routinely administered in the U.S. are trivalent vaccines covered under this Category. See *News* on the VICP website for more information (www.hrsa.gov/osp/vicp).

Source: 42 C.F.R. § 100.3 (2006); Health Servs. & Res. Admin., *National Childhood Vaccine Injury Act Vaccine Injury Table*, http://www.hrsa.gov/vaccinecompensation/table.htm.