University of Arkansas at Little Rock Law Review

Volume 11 | Issue 4 Article 7

1988

Health Law—Vaccine Injuries—Federal Law Prescribes Procedures for Alternatives to Tort Actions for Vaccine-Related Injuries. The National Childhood Vaccine Injury Compensation Act of 1986. 43 U.S.C. §§ 300aa-1 to -34 (Supp. IV 1986).

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HEALTH LAW—VACCINE INJURIES—FEDERAL LAW PRESCRIBES PROCEDURES FOR ALTERNATIVES TO TORT ACTIONS FOR VACCINE-RELATED INJURIES. THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT OF 1986. 42 U.S.C. §§ 300aa-1 to -34 (Supp. IV 1986).

During the past two decades this country developed a national program of childhood immunizations.[1] This program's goal is to reduce the morbidity and mortality that accompanies many of the infectious childhood diseases.[2] While this program has been extremely successful in most respects, the mass immunization of a large percentage of our nation's children has also been responsible for a small, but significant, number of vaccine-related injuries and deaths.[3]

In the past, those suffering injuries as a result of adverse reactions to vaccines turned to the tort system for relief.[4] Plaintiffs often found this avenue very expensive in terms of both time and money, and in many instances, they were left without compensation.[5] In addition to the inequities suffered by those already injured, this litigation was responsible for a crisis that continues to threaten the national immunization program. Litigation expenses and increasing liability insurance premiums drove some manufacturers from the marketplace and forced those remaining to increase the price of vaccines substantially.[6]

In response to this crisis, Congress amended the Public Health Service Act by enacting the National Childhood Vaccine Injury Compensation Act of 1986 (Act).[7] Congress passed the Act without funding provisions in the closing days of the 99th Congress. An amendment to the Omnibus Budget Reconciliation Act provided ini-

1. STAFF OF HOUSE SUBCOMM. ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 99TH CONG., 2D SESS., REPORT ON CHILDHOOD IMMUNIZATIONS 43 (Comm. Print 1986) [hereinafter *Comm. Print*].

2. *Id.*

3. HOUSE COMMITTEE ON ENERGY AND COMMERCE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986, H.R. REP. NO. 99-908, 99th *Cong.*, 2d Sess. 4, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6345 [hereinafter *Legislative History*].

4. *Id.*

5. *Id.* at 6, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6347.

6. Smith, *National Childhood Vaccine Injury Compensation Act*, 82 PEDIATRICS 264, 266 (1988).

7. 42 U.S.C. § 300aa (Supp. IV 1986). The Act provides compensation for injuries related to the administration of vaccines against communicable *childhood* diseases, specifically, measles, mumps, rubella, diphtheria, pertussis, polio, and tetanus. *Id.* § 300aa-14.

tial funding for the programs established in the Act.[8] A trust fund established by the Act[9] and funded by excise taxes imposed on vaccine sales[10] will provide additional revenue.

The Act creates two new programs in response to concerns about a safe and sufficient supply of vaccines and the inequities found in tort litigation against manufacturers. The first of these programs (the National Vaccine Program) will assure the research and development of better and safer vaccines,[11] while the second (the National Childhood Vaccine Injury Compensation Program) provides a system of "no fault" compensation for persons suffering from vaccine-related injuries.[12] A third section of the Act sets forth specific rules for recording and reporting information pertaining to the administration of vaccines and any adverse reactions that may occur.[13]

The purpose of the National Vaccine Program is to coordinate and direct research on means to induce immunity and prevent adverse reactions.[14] This Program will oversee testing, licensing, production, and distribution of vaccines by various governmental and non-governmental agencies including the Centers for Disease Control (CDC) and the National Institutes of Health (NIH).[15]

The aim of the National Childhood Vaccine Injury Compensation Program (Compensation Program) is to provide a system for compensating those persons suffering vaccine-related injuries in a fair and expeditious manner, and alleviating the expense and long delays often encountered in the courts.[16] This goal is facilitated by the creation of a mandatory "no fault" system of compensation that discourages the use of the court system by requiring the vaccine-injured person to complete the compensation proceedings before suing.[17] The Compensation Program does not prohibit the use of the courts for

8. 26 U.S.C.A. § 4131 (West 1989).

9. 26 U.S.C.A. § 9510 (West Supp. 1989).

10. *Id.* § 9510(b). The taxes placed on the various vaccines are as follows: Diphtheria-Pertussis Tetanus (DPT), $4.65/dose, Measles-Mumps-Rubella (MMR), $4.44/dose, Oral Polio Vaccine (OPV), $0.29/dose, and Tetanus-Diphtheria (TD), $0.06/dose. *Id.* § 4131(b)(1).

11. 42 U.S.C. § 300aa-1 (Supp. IV 1986).

12. *Id.* § 300aa-10.

13. *Id.* § 300aa-25.

14. *Legislative History, supra* note 3, at 9, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6350. By conducting research to enhance knowledge about diseases, pathogens, and host responses, the development of safer vaccines should be possible.

15. *Id.* The Food and Drug Administration (FDA), the Department of Defense, and the Agency for International Development are also conducting research in the area of vaccine development.

16. *Id.* at 12, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6353.

17. *Id.*

compensation, but is intended to make litigation a last resort. As an added deterrent to litigation, the Act limits the theories under which a tort claim may be filed.[18] National Childhood Vaccine Injury Compensation Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (Supp. IV 1986).

There can be little doubt that our nation's initiatives in providing immunization programs for its children have been beneficial both socially and economically. Some of the common childhood diseases are quite contagious[19] and, in the past, these diseases have caused serious epidemics. Diseases that most of today's children will never acquire, killed or maimed many children only a few generations ago.[20]

Since Edward Jenner's pioneering work with smallpox in 1796, science has developed vaccines to prevent a wide variety of communicable diseases.[21] The federal government recognized the benefits of vaccine use and assumed a leadership role in establishing a national immunization program.[22] With federal support, state and local public health services in all fifty states established mandatory immunization programs for school children.[23]

The social benefits of the use of vaccines are most striking when viewed in terms of the number of lives saved each year. One report states that the "[u]se of vaccines against illness has prevented thousands of deaths each year . . . and has substantially reduced the morbidity resulting from disease."[24] For example, in 1941 measles caused 2,250 deaths in the United States, but in 1983, measles only caused two deaths.[25] The use of vaccines produced similar reductions

18. *Id.* at 25-26, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6366-67. This note will discuss the procedural aspects of the compensation program for the practicing attorney.

19. R. EDMOND, J. BRADLEY & N. GALBRAITH, INFECTION (1982).

20. For example, in the United States, diphtheria caused more than 15,000 deaths in 1921, measles caused 2,250 deaths in 1941, pertussis caused 2,500 deaths in 1942, and polio caused more than 3,000 deaths in 1952. Interview with Dennis A. Berry, Communicable Disease Section, Arkansas Department of Health (Feb. 9, 1989).

21. G. MANDELL, R. DOUGLAS & J. BENNETT, PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES 1690 (2d ed. 1979).

22. *Comm. Print, supra* note 1, at 43 & n.155. Some early public health legislation placed the supervision of maritime quarantine under the Secretary of the Treasury (1799), sought to prevent the introduction of communicable diseases into the United States (1878), and gave the Public Health Service responsibility for foreign and interstate quarantine (1893). *Id.*

23. *Id.* at 47. In order to ensure the immunization of all children, such programs require proof of vaccination as a condition to school entry and attendance. By the 1981-82 school year, 97 percent of the students entering U.S. schools had been immunized against measles and rubella, 96 percent against polio, diphtheria, tetanus, and pertussis, and 95 percent against mumps. *Id.*

24. *Id.* at 1.

25. *Id.*

in the mortality of other diseases and was responsible for the total eradication of smallpox.[26] In addition to the lives saved, there has also been a realization of economic benefits. It is estimated that immunizations saved "[b]illions of medical and health-related dollars."[27] Unfortunately, however, the immunization program has not been without its own expense which led to the creation of the Compensation Program.

Although the vaccines produced in the United States today are subjected to a wide range of clinical trials to assure their safety and efficacy, these trials are sometimes not sufficient to detect rarely occurring adverse reactions.[28] Consequently, when a vaccine is placed on the market and used in a mass immunization program, previously undetected adverse reactions may come to light.[29] These adverse reactions range from mild, local discomfort at the injection site, to more severe reactions such as febrile convulsions and death.[30] In addition to the adverse reactions that may be observed in the individual receiving the vaccine, certain vaccines (such as the Sabin oral polio vaccine) are capable of causing disease in susceptible persons who come in contact with the immunized individual.[31]

Adverse reactions are rare and usually unforeseeable. Consequently, physicians and public health officials agree that while immunization is not risk-free, the risks are outweighed by the benefits.[32] This risk-benefit analysis provides little consolation for those few individuals who suffer vaccine-related injuries—injuries for which they are not at fault and resulting from their efforts to comply with

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26. *Id.*

27. *Legislative History, supra* note 3, at 4, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6345.

28. *Adverse Events Following Immunization*, 34 MORBIDITY & MORTALITY WEEKLY REP. 43 (1985).

29. *Id.*

30. *Id.* Febrile convulsions are those that occur in patients (usually pediatric) with high fevers. STEDMAN'S MEDICAL DICTIONARY (Illustrated) 318 (24th ed. 1982).

31. J. CONTE & S. BARRIERE, MANUAL OF ANTIBIOTICS AND INFECTIOUS DISEASES 248 (6th ed. 1988). Persons who receive vaccines made with live viruses (for example polio or measles) may shed the virus in some body excretions, particularly urine, for several weeks. If hygiene is poor, the virus may be transmitted to a susceptible person.

32. *Legislative History, supra* note 3, at 6, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6347. *See also* OFFICE OF TECHNOLOGY ASSESSMENT REPORT: COMPENSATION FOR VACCINE-RELATED INJURIES 19 (1980) [hereinafter *OTA Report*]. One benefit of immunization programs is a phenomenon known as "herd immunity" wherein the immunization of a large percent of a population against a specific disease protects those persons not immunized by substantially reducing the likelihood of an individual's exposure to that disease. *OTA Report*, at 19.

mandatory immunization requirements.[33] In their search for compensation, individuals with vaccine-related injuries began turning to the tort system with suits against the manufacturers.[34]

The blame for vaccine-related injuries can scarcely be laid at the feet of the victim, but it is equally unfair to say that the blame lies with the manufacturer when the vaccine was produced in compliance with government regulations.[35] In an effort to provide some measure of relief for these injuries, the courts began to fashion remedies within the tort system.[36] Unfortunately, the use of the tort system created inequities because "the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered."[37] While court-ordered awards provided relief for some individuals with vaccine injuries, others with similar injuries have been left with nothing.[38]

Because vaccines are generally considered "unavoidably unsafe products,"[39] it is difficult for a plaintiff to prevail under traditional

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33. *Legislative History, supra* note 3, at 6, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6347.

34. *Id.* at 4, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6345. *See, e.g.*, Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977); Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968).

35. Krugman, *Immunization "dyspractice:" The need for "no fault" insurance*, 56 PEDIATRICS 159 (1975).

36. *See, e.g.*, Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977); Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968).

37. *Legislative History, supra* note 3, at 6-7, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6347-48.

38. *Id.* at 6, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6347. *See, e.g.*, Schindler v. Lederle Laboratories, 725 F.2d 1036 (6th Cir. 1983); Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985); Dunn v. Lederle Laboratories, 121 Mich. App. 73, 328 N.W.2d 576 (1983).

39. RESTATEMENT (SECOND) OF TORTS § 402A comment k. Comment k reads in part:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

strict liability theories. In *Davis v. Wyeth Laboratories, Inc.*,[40] the court found that the manufacturer's failure to warn recipients of potential adverse reaction was a basis for liability.[41] In *Davis*, a thirty-nine-year-old man contracted polio after being immunized with the Type III Sabin oral polio vaccine.[42] Although Wyeth took the precaution of adding a package insert warning of potential adverse effects in adults receiving the oral polio vaccine, the manufacturer made no other efforts to warn the public.[43] Mr. Davis received the vaccine at a mass immunization clinic from a pharmacist who failed to read the insert.[44] The court found that Wyeth had not taken proper precautions to assure that vaccine recipients were warned of the risks involved thus depriving them of the ability to make an informed decision about immunization.[45] The manufacturer's failure to directly warn vaccine recipients rendered the vaccine "unreasonably dangerous."[46]

Since *Davis*, courts have found manufacturers liable based on "failure to warn" in a variety of fact situations. Some of these cases expanded the manufacturer's duty to the consumer.[47] The Ninth Circuit[48] held in *Toner v. Lederle Laboratories, Div. of American Cyanamid Co.*, that while the manufacturer was not strictly liable for the plaintiff's paralysis, Lederle's failure to develop and market a safer vaccine constituted negligence. This holding was based on a finding that an alternative vaccine was available and Lederle had failed to produce evidence showing that the FDA would not have approved

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Id. (emphasis in original).

40. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968).

41. *Id.* at 130.

42. *Id.* at 122.

43. *Id.* at 125.

44. *Id.*

45. *Id.* at 130.

46. *Id.* The dissent in this case was based on the fact that the local Medical Society was in charge of the mass immunization program and was aware of the Surgeon General's report. The Medical Society decided to proceed with the program in spite of the warnings. Consequently it could not be held that, as a matter of law, the manufacturer had breached its duty to warn. *Id.* at 131-32 (Hamlin, J., dissenting).

47. *See* Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974) (failure to provide warning of risk or to provide medical judgment that treatment was necessary). *See also* Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977) (duty to take action to provide information to actual consumer). For a review of vaccine injury cases in favor of plaintiffs, *see* Comment, *Vaccine-Related Injuries: Alternatives to the Tort Compensation System*, 30 ST. LOUIS U.L.J. 919 (1986).

48. Toner v. Lederle Laboratories Div. of American Cyanamid Co., 831 F.2d 180 (9th Cir. 1987), *modifying* 828 F.2d 510 (9th Cir. 1987) (infant suffered paralysis after receiving Lederle's triple antigen vaccine used for immunization against diphtheria, pertussis and tetanus).

such a vaccine.[49] However, in *Johnson v. American Cyanamid Co.*,[50] the Kansas Supreme Court refused to expand the manufacturer's duty to warn and found that a manufacturer was not negligent because of its failure to provide warnings directly to vaccine recipients. In spite of the manufacturer's success in *American Cyanamid*, cases such as those noted above, coupled with increasing insurance costs, had a profound negative effect on vaccine manufacturers.[51]

A number of factors are responsible for this effect. First, vaccine sales account for a relatively small portion of a manufacturer's overall sales because of the limited market for vaccines.[52] Second, the cost of entry into the market is high, especially when compared to eventual revenues.[53] Third, "recent court cases have increased the risk of participating in the vaccine market."[54] Finally, liability insurance premiums for vaccine manufacturers increased while policy limits decreased.[55] The sum of these factors forced manufacturers to reconsider participation in the vaccine market and resulted in temporary shortages in vaccine supplies.[56]

Although the medical community stands in favor of this country's immunization programs, it also recognizes the problems and potential risks inherent in such programs. As early as 1975, an article published in *Pediatrics*[57] called for legislation to provide compensation for those suffering vaccine injuries. In his commentary, Dr. Richard Krugman of the University of Colorado noted the compensation legislation enacted in Europe and Asia.[58] He went on to say that because society as a whole benefits from mandatory immunization laws, "[s]ociety—not the manufacturer, the physician, or the pa-

49. Toner v. Lederle Laboratories, Div. of American Cyanamid Co., 828 F.2d 510, 514 (9th Cir. 1987).

50. 243 Kan. 291, 758 P.2d 206 (1988).

51. *Legislative History, supra* note 3, at 6, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6347. *See also* Plummer v. Lederle Laboratories, No. 81-2037 (S.D.N.Y. Oct. 1, 1984).

52. *Comm. Print, supra* note 1, at 72.

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id. See also Diphtheria-Tetanus-Pertussis Vaccine Shortage—United States*, 33 MORBIDITY & MORTALITY WEEKLY REP. 695 (1984). During the second half of 1984, two of the three manufacturers of DTP vaccine (Wyeth and Connaught) stopped distributing their product. A third manufacturer (Lederle) experienced problems with some lots of vaccine which prevented the release of the vaccine. In December of 1984, the CDC recommended modifications of DTP dosing schedules until supplies could be replenished. *Id.*

57. *See generally* Krugman, *supra* note 35.

58. *Id.* at 159-60. The author notes programs in Denmark, Germany and Japan designed to reimburse victims injured by vaccines administered under mandatory immunization laws.

tient—should support those who suffer the adverse consequences of our laws."[59]

The medical community was not alone in its concern. In 1977 the Department of Health, Education and Welfare began looking at all aspects of immunization.[60] While the studies ordered by HEW focused, in part, on the liability associated with immunizations, no formal recommendations were made at that time.[61] By 1980, however, the House of Representatives called for a study to "delineate the specific elements and principles necessary for inclusion in a legislative proposal for vaccine injury compensation."[62] During the next three years, the calls for legislation increased with groups such as the American Academy of Pediatrics and parents' organizations such as Dissatisfied Parents Together (DPT) speaking out in favor of a compensation program.[63]

In 1983 Senator Paula Hawkins introduced a proposal for compensation legislation to the Senate,[64] and in 1984, Congressman Waxman brought similar legislation before the House.[65] Although the provisions of these proposals were quite similar to those of the present Act, the earlier proposals made use of the compensation system optional rather than mandatory.[66] The 98th Congress adjourned without enacting a compensation program.[67] It is of note that the most serious vaccine shortages[68] occurred while Congress deliberated about the fate of the compensation legislation.[69]

The proponents of compensation legislation again sought support for their proposals when the 99th Congress convened.[70] In a Committee hearing on proposed compensation legislation, Senator Dale Bumpers pointed out that while such a compensation program would be costly, "the cost of vaccines and, therefore, the cost of the immunization program itself will continue to increase alarmingly, perhaps en-

59. *Id.* at 159.
60. Smith, *supra* note 6, at 265.
61. *Id.*
62. *Id.*
63. *Id.* at 266.
64. S. 2117, 98th Cong., 1st Sess. (1983).
65. H.R. 5810, 98th Cong., 2d Sess. 130 CONG. REC. 15,484 (1984).
66. *National Childhood Vaccine Injury Compensation Act: Hearings on S. 2117 Before the Comm. on Labor and Human Resources*, 98th Cong., 2d Sess. 187 (1984) (statement of Alan R. Nelson, M.D., American Medical Association, Board of Trustees).
67. Smith, *supra* note 6, at 267.
68. *Id.*
69. *Id.*
70. *Id.* Senators Hawkins, Hatch, Bumpers, and Matsunaga, and Congressman Waxman were responsible for re-introducing vaccine compensation proposals to the Congress. *Id.*

dangering the program and our children's health if we don't address the problem of vaccine-related injuries."[71] His remarks mirrored the concerns expressed by Mrs. Bumpers in a house subcommittee hearing on the Federal Childhood Immunization Program,[72] and pointed out the relationship between the two programs.[73] Senator Bumpers noted the recent vaccine availability crisis and further noted that he was committed to seeing that families in this country never again face the devastation of childhood diseases.[74] This commitment he said, "means insisting on adequate funding for the vaccine program itself and also fair compensation to children who, through no one's fault, develop the statistically inevitable vaccine-related injuries."[75]

As the 99th Congress drew to a close, it became apparent to the Act's proponents that certain aspects of the legislation made passage unlikely.[76] The proposed legislation contained provisions for a surtax on vaccines to provide revenue for the compensation program.[77] Congressional rules[78] require Ways and Means Committee hearings on such provisions.[79] Late in 1986 it became obvious that a hearing would be impossible before the end of the session.[80] Supporters of the legislation agreed to the removal of the funding provisions to enable passage of the Act as part of an omnibus health package.[81] This package was the last item acted upon before Congress adjourned in 1986.[82]

The language of the Act "made the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation."[83] In an effort to protect the

71. *National Childhood Vaccine Injury Compensation Act of 1985: Hearings on S.827 Before the Comm. on Labor and Human Resources*, 99th Cong., 1st Sess. 7 (1985) (statement of Sen. Dale Bumpers) (hereinafter *Senate Hearing*).

72. *Federal Childhood Immunization Program: Hearings Before the Subcomm. on Health and the Environment of the Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 2 (1986) (statement of Betty Bumpers, Charleston, Arkansas).

73. *See Senate Hearing, supra* note 71, at 9.

74. *Id.*

75. *Id.*

76. Smith, *supra* note 6, at 267. At this point, the various proponents of the Act, although often at odds on specific provisions of the legislation, realized that their differences must be set aside and compromises made to allow passage of the Act. Telephone interview with Elizabeth Goss, Legislative Assistant for Sen. Dale Bumpers (Feb. 9, 1989).

77. Smith, *supra* note 6, at 267.

78. STAFF OF HOUSE COMM. ON WAYS AND MEANS, 99TH CONG., 1ST SESS. MANUAL OF RULES OF THE COMMITTEE ON WAYS AND MEANS FOR THE NINETY-NINTH CONGRESS 15 (Comm. Print 1985).

79. Smith, *supra* note 6, at 267.

80. *Id.*

81. *Id.*

82. *Id.*

83. HOUSE SUBCOMM. ON HEALTH AND THE ENVIRONMENT, OMNIBUS BUDGET REC-

needed provisions from veto, the Act's supporters introduced the funding provisions to the 100th Congress as an amendment to the Omnibus Budget Reconciliation Act of 1987.[84] In addition to funding provisions, this legislation also contained other amendments to the Act.[85] These changes dealt primarily with payment provisions and were made in an effort to assure the success of the program.[86] Another significant amendment protected vaccine administrators (pediatricians, immunization clinics, etc.) in much the same manner as manufacturers.[87] In December of 1987, President Reagan signed the Budget Reconciliation Act into law, and the National Childhood Vaccine Injury Compensation Act of 1986[88] became a reality.[89]

The purpose of the Act is to provide an expedient and fair system of compensation for those persons suffering adverse reactions as a result of the administration of vaccines.[90] The Act sets forth a Vaccine Injury Table which provides a list of the vaccines covered by the Act and the injuries for which compensation may be allowed.[91] Although this Act does not prohibit a party from seeking compensation through civil action, it discourages such action by requiring parties to first complete administrative compensation proceedings before pursuing those actions.[92] The Act also limits the theories upon which a civil tort action may be filed.[93]

The program charges attorneys to advise clients of the possibility of compensation under the program.[94] After the effective date of the Act,[95] most plaintiffs with vaccine-related injuries will be required to

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ONCILIATION ACT, H. REP. 391(I), 100th Cong., 1st Sess. 544, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS 2313-64 [hereinafter *Budget Act History*].

84. Smith, *supra* note 6, at 267.

85. *Budget Act History, supra* note 83, at 690, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS at 2313-64.

86. *Id.*

87. *Id.* at 699, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS at 2313-73.

88. 42 U.S.C. § 300aa-1-34 (Supp. IV 1986).

89. Smith, *supra* note 6, at 267.

90. *Legislative History, supra* note 3, at 3, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6344.

91. 42 U.S.C. § 300aa-14 (Supp. IV 1986).

92. *Legislative History, supra* note 3, at 3, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6344. *See also* 42 U.S.C. § 300aa-11 (Supp. IV 1986).

93. 42 U.S.C. § 300aa-22 (Supp. IV 1986). *See infra* text accompanying notes 155-61.

94. 42 U.S.C. § 300aa-10(b) (Supp. IV 1986).

95. *Budget Act History, supra* note 83, at 696, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS at 2313-70. The original effective date of the compensation and tort reform provisions established by the Act was based on the date of enactment of an excise tax to fund the program. This excise tax became effective January 1, 1988. Other sections of the legislation require that a disability be of at least six months duration before a petition may be filed.

complete compensation program proceedings before filing a civil action.[96] However, depending upon the date of the injury, certain other plaintiffs may not be eligible for compensation under the program and may proceed directly to civil actions.[97] The class of proper petitioners includes, "any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table."[98] The Act also allows petitions by persons who contracted polio as a result of their exposure to another person who received a vaccine.[99]

Although the Act bars petitions by persons who have been awarded damages in prior civil suits,[100] persons who had such actions dismissed or damages denied are not precluded from filing a petition.[101] In addition, persons with civil suits pending on the effective date of the Act[102] have the option of withdrawing such suits and filing petitions under the Compensation Program.[103] However, if these actions are not withdrawn, the persons bringing the actions are barred

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The effective date of the compensation provision was October 1, 1988, thus allowing a nine month accumulation of excise taxes before the first compensation claims may be filed. *Id.*

96. 42 U.S.C. § 300aa-11(a)(2)(A) (Supp. IV 1986). This section provides:

> No person may bring a civil action for damages in an amount greater than $1000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such vaccine-related injury or death, unless—
>
> (i) a petition has been filed in accordance with § 300aa-16 . . .
>
> (ii) the United States Claims Court has issued a judgment under § 300aa-12 on such petition, and
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> (iii) such person elects under § 300aa-21(a) to file such an action.

Id.

97. *Legislative History, supra* note 3, at 22-23, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6363-64.

98. 42 U.S.C. § 300aa-11(b)(1)(A) (Supp. IV 1986).

99. *Id.* § 300aa-11(c)(1)(A) (petitions for compensation must demonstrate that the person who suffered the injury "received a vaccine . . . or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine.").

100. *Id.* § 300aa-11(a)(7).

101. *Id.* § 300aa-11(a)(4) (this section pertains to civil actions filed before the effective date of the legislation).

102. *Budget Act History, supra* note 83, at 696, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS at 2313-70 (October 1, 1988). *See supra* note 95.

103. 42 U.S.C. § 300aa-11(a)(5)(A) (Supp. IV 1986). Such civil actions must be withdrawn within two years of the effective date of the legislation or before judgment, whichever is first.

from filing a petition for compensation.[104]

The petition for compensation must contain specific materials set forth in the Act.[105] Put simply, the affidavit must show the elements required in a civil negligence action with the notable exception that there need be no allegation of negligence. The affidavit must include evidence that the petitioner:

> [R]eceived a vaccine listed in the Table or contracted polio from a recipient or [sic] oral polio vaccine;
>
> met certain citizenship or location restrictions;
>
> sustained or had significantly aggravated an injury listed in the Table;
>
> sustained or had aggravated the injury within the time periods specified in the Table;
>
> suffered residual effects for more than [six months] or died or incurred unreimbursable expenses of greater than $1,000; and
>
> has not previously collected an award or settlement for the injury.[106]

In addition to the affidavit, the petition must include the petitioner's medical records relating to the injury or identification of unavailable records[107] and documentation of any evaluations, assessments or other records that reasonably relate to the determination of the amount of compensation.[108]

Once completed, the petition must be filed in the United States Claims Court.[109] The Secretary of the Department of Health and Human Services (HHS) has been designated as the Administrator of the program, and service upon the Secretary, as respondent, initiates the proceedings.[110]

The United States Claims Court has jurisdiction over entitlement proceedings and the issuance and enforcement of any orders necessary to assure payment of compensation awards.[111] The court will appoint a special master to serve as an adjunct to the court.[112] In this capacity, the special master has the power to request evidence, information,

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104. *Id.* § 300aa-11(a)(5)(B).

105. *Id.* § 300aa-11(c).

106. *Legislative History, supra* note 3, at 15, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6356.

107. 42 U.S.C. § 300aa-11(c)(2) (Supp. IV 1986).

108. *Id.* § 300aa-11(c)(3).

109. *Id.* § 300aa-11(a)(1).

110. *Id.* §§ 300aa-10(a), -11(a), -12(b).

111. *Id.* § 300aa-12(a).

112. *Id.* § 300aa-12(c)(1).

and testimony relating to entitlement, and to conduct any necessary hearings.[113] The findings of the special master are then submitted to the court for further action.[114]

The court reviews the findings of the special master on its own motion or in response to objections from the petitioner or respondent.[115] If there are no objections from either party, the court may choose not to review the findings and may render a judgment based on an adoption of the findings.[116]

The petitioner must prove by a preponderance of the evidence that the person who suffered the injury "sustained, or had significantly aggravated, any illness, disability, injury, or condition . . . or died" as a result of the administration of a vaccine set forth in the Vaccine Injury Table.[117] The court must also find, by a preponderance of the evidence, that the injuries described in the petition were not caused by "factors unrelated to the administration of the vaccine described in the petition."[118] The court will base its decision to award compensation on any relevant medical and scientific evidence produced, including medical conclusions, judgments or reports "regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death."[119] Decisions of the court will be announced as soon as practicable, but in any event, such decisions must be rendered within one year of the filing of the petition.[120] If neither party appeals, the decisions of the claims court will be final.[121]

The Act establishes separate rules for compensation awards based on the date of the injury in relation to the effective date of the Compensation Program.[122] Awards for injuries sustained from vac-

113. *Id.* § 300aa-12(c)(2)(A-D).

114. *Id.* § 300aa-12(c)(2)(E). This section also provides:

> Information submitted to a special master in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express, written consent of the person who submitted the information. There may be no discovery in a proceeding on a petition other than the discovery required under this paragraph.

Id.

115. *Id.* § 300aa-12(d)(1).

116. *Id.* § 300aa-12(d)(2).

117. *Id.* § 300aa-13(a)(1)(A).

118. *Id.* § 300aa-13(a)(1)(B). *See also id.* § 300aa-13(a)(2).

119. *Id.* § 300aa-13(b)(1)(A).

120. *Id.* § 300aa-12(d)(3). *See also id.* § 300aa-21(b). If the claims court fails to act within one year of the petition date, the petitioner may withdraw the petition and file a civil action.

121. *Id.* § 300aa-12(e).

122. *Budget Act History, supra* note 83, at 693, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS at 2313-67. Awards for vaccine-related deaths are set at $250,000 regardless of the date of death.

cines administered after October 1, 1988, may include compensation for actual unreimbursable[123] expenses incurred before and after the judgment date,[124] actual and anticipated loss of earnings,[125] and actual and projected pain and suffering.[126] Compensation awards for injuries sustained from vaccines administered *prior* to October 1, 1988,[127] are similar in most respects, but do not allow awards for unreimbursable expenses incurred *before* the date of judgment.[128] The Act specifically prohibits compensation in the form of punitive or exemplary damages[129] or awards based on factors other than the health, education, and welfare of the injured individual.[130]

After the court renders a final decision, the petitioner must decide whether to accept the court's decision or file a civil action[131] and, in either case, must file an election in writing with the court no later than ninety days after the entry of the court's judgment.[132] Compensation awards will not be paid until the petitioner makes an election to accept the compensation and waives the right to file a civil action.[133] If the petitioner elects to accept the payment, compensation will be paid from the date of judgment.[134] A similar written election must be filed if the court does not award compensation and the petitioner

123. 42 U.S.C. § 300aa-15(g) (Supp. IV 1986). This section makes it clear that the program is not primarily liable for vaccine injuries, and that awards will not cover expenses covered by other insurance or compensation programs.

124. *Id.* § 300aa-15(a)(1)(A). *See also Budget Act History, supra* note 83, at 693, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS at 2313-67, which states that awards will be made in one lump sum payment based on the net present value of the award. The bill places a cap of 150 on the number of awards that may be paid in any year.

125. 42 U.S.C. § 300aa-15(a)(3) (Supp. IV 1986).

126. *Id.* § 300aa-15(a)(4). Compensation under this section is limited to $250,000.

127. *Budget Act History, supra* note 83, at 696, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS 2313-70.

128. 42 U.S.C. § 300aa-15(b) (Supp. IV 1986).

129. *Id.* § 300aa-15(d)(1).

130. *Id.* § 300aa-15(d)(2). *See also Legislative History, supra* note 3, at 20, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6361. The drafters recognized the special or unusual health care and educational needs of vaccine-injured children and provided a broad description of compensable care. Compensation will be awarded for needs ranging from special nutrition to clothing for incontinence to physical protection. *Id.*

131. 42 U.S.C. § 300aa-21(a) (Supp. IV 1986).

132. *Id.* If the person does not file the required petition within the prescribed period, that person will be deemed to have accepted the judgment of the court and will be barred from later civil action. *Id.*

133. *Id.* § 300aa-15(f)(1).

134. *Id.* § 300aa-15(f)(2). Congressional appropriations will be used for payment of awards for injuries incurred before the effective date of the Act. Payment of awards for injuries incurred after the effective date will be provided through the Vaccine Injury Compensation Trust Fund.

wishes to proceed with a civil action.[135]

The Act sets forth a table for use in determining a petitioner's standing to file for compensation.[136] The table provides a list of vaccines covered by the Act and specific injuries attributable to such vaccines.[137] Petitioners may only seek compensation under the program

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135. *Id.* § 300aa-21(a)(2).

136. *Id.* § 300aa-14.

137. *Id.* For purposes of compensation, time periods in which the first symptoms or manifestations of illnesses occur after vaccine administration are specified in the table.

VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s). Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (c)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not Applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus toxoid.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	C. Residual seizure disorder in accordance with subsection (c)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not Applicable

if the injuries suffered are associated with vaccines listed in the table.[138] A related provision allows the Secretary of Health and Human Services to promulgate changes in the table pertaining to the kinds of injuries covered or the time period for onset of symptoms,[139] but the power to add new vaccines to the table lies with Congress.[140]

In addition to the standing restrictions of the Vaccine Injury Table, there are also time limitations on petitions for compensation. These limitations are based on the date of injury and its relation to the effective date of the program.[141] Using these dates, the Act divides potential petitioners into three groups:

> 1) [T]hose who were injured by a vaccine more than eight years before enactment of the legislation; 2) those who were injured by a vaccine that was administered before the enactment of the legislation but less than eight years ago; and 3) those who are injured by a vaccine that is administered after the enactment of the legislation.[142]

Persons who suffered vaccine-related injuries more than eight years before the effective date of the Act (group 1) are not eligible for com-

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III. Polio Vaccines (other than Inactivated Polio Vaccine).
  A. Paralytic polio
    —in a non-immunodeficient recipient ... 30 days
    —in an immunodeficient recipient ..... 6 months
    —in a vaccine-associated community case ..... Not Applicable
  B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed ..... Not Applicable

IV. Inactivated Polio Vaccine
  A. Anaphylaxis or anaphylactic shock ..... 24 hours
  B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed ..... Not Applicable

Id. This section also includes interpretive aids for using the table. *Id.*

138. *Id.*

139. 42 U.S.C. § 300aa-14(c).

140. *Id.* § 300aa-14(e).

141. *Id.* § 300aa-16.

142. *Legislative History, supra* note 3, at 22, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6363-64.

pensation under the Program[143] and must seek compensation through civil actions.

For injuries or death associated with vaccines administered less than eight years before the effective date, petitions must be filed no later than twenty-four months after the effective date.[144] Petitions for injuries associated with vaccines administered after the effective date must be filed no later than thirty-six months after the onset of the injury's symptoms.[145] For deaths related to vaccines administered after the effective date of the Program, petitions must be filed no later than twenty-four months after the date of death or forty-eight months after the onset of symptoms from which death resulted.[146]

A petitioner's right to file a civil suit after completing the compensation proceedings is also protected under the Act.[147] State statutes of limitations on civil actions for vaccine injuries will be stayed during the pendency of the compensation proceedings.[148] Such a stay begins on the date the petition is filed and ends on the date final judgment is entered on the petition.[149]

As noted above, petitioner retains the right to file a civil suit after hearing the finding of the claims court. If the petitioner elects not to accept compensation, the petitioner may file a civil action in a state court.[150] State law will apply in most civil actions, but the Act will supercede state law and protect manufacturers from some liability for vaccines administered after October 1, 1988.[151]

Manufacturers may be relieved of liability for damages in actions based on the unavoidable adverse side effects of a vaccine.[152] If the manufacturer shows that it complied "in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act," there is a presumption that all proper directions and warnings accompanied the vaccine.[153] This provision incorporates the principle of comment k of Section 402A of the Restatement of Torts (Second) into

143. *Id.*
144. 42 U.S.C. § 300aa-16(a)(1) (Supp. IV 1986).
145. *Id.* § 300aa-16(a)(2).
146. *Id.* § 300aa-16(a)(3).
147. *Id.* § 300aa-16.
148. *Id.* § 300aa-16(c). *See also* § 300aa-16(b). The Act also makes provisions for revisions of the Vaccine Injury Table and allows persons who become eligible for compensation because of such revisions to file petitions within two years of the effective date of the revision. *Id.*
149. *Id.* § 300aa-16(c).
150. *Id.* § 300aa-21(a).
151. *Id.* § 300aa-22(a).
152. *Id.* § 300aa-22(b)(1).
153. *Id.* § 300aa-22(b)(2).

the Act.[154] The drafters intended to shield manufacturers from liability for unavoidable adverse reactions.[155]

To overcome this presumption, the plaintiff must show that the manufacturer engaged in fraud or misrepresentation, intentional and wrongful withholding of information, or other criminal or illegal activity with respect to the safety of the vaccine.[156] The plaintiff may also overcome the presumption "by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with [FDA regulations]."[157]

The Act also protects manufacturers from liability based on failure to provide direct warnings to vaccine recipients.[158] If the plaintiff alleges that the injury or death occurred solely as a result of the manufacturer's failure to provide the vaccine recipient with direct warnings of the potential dangers associated with vaccine administration, the manufacturer may not be held liable.[159] This provision is based on the rationale that vaccine administrators should bear some of the responsibility for providing such warnings.[160] It should be noted that vaccine administrators also receive some measure of protection under the Act in an amendment added "[to] remove any possibility for a person to pursue a compensation claim while also pursuing a tort claim against an administrator . . . [or] pursuing a tort claim after accepting a compensation claim."[161]

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154. *Legislative History, supra* note 3, at 25, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6366.

155. *Id.* at 26, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6367.

> [E]ven if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtably will find it difficult to rule in favor of the "innocent" manufacturer if the equally "innocent" child has to bear the risk of loss with no other possibility of recompense.

Id.

156. 42 U.S.C. § 300aa-23(d)(2) (Supp. IV 1986).

157. *Id.* § 300aa-22(b)(2)(B).

158. *Id.* § 300aa-22(c). Civil actions for injuries incurred before October 1, 1988, will continue to be governed by appropriate state law. *Id.*

159. *Id.*

160. *Legislative History, supra* note 3, at 27, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6368.

> If the manufacturer provides an adequate warning and adequate directions to an intermediary such as a doctor, nurse or pharmacist who can be expected to know about the product and its risks, and who is responsible for informing the ultimate recipient of a vaccine . . . , the manufacturer should not be held liable for any failure to warn or provide directions directly to a person . . . who is injured from the vaccine.

Id.

161. *Budget Act History, supra* note 83, at 699, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS 2313-73.

Civil actions based on other theories are not prohibited by the Act, and state law may not prohibit any actions allowed by the Act.[162] Any permissible civil action will be tried in three stages to determine liability, general damages, and, if sought, punitive damages.[163] Findings of the claims court or special master are not admissible in any stage of a later civil action.[164]

The Act also provides for citizen's actions against the Secretary for failure to perform acts or duties under the Act,[165] and for judicial review of regulations under the Act.[166] The Act also sets forth specific definitions to be used in the course of compensation proceedings.[167]

The Act's major influence on the practicing attorney arises from the restrictions it places on when and how a civil action may be filed. The attorney and client may not always be able to chart their own course of action because the requirements of the Act must be followed. A person who consults an attorney for the purpose of filing a civil action against a manufacturer or administrator must be advised of the Act's requirements and the limits on their actions.[168]

The use of the administrative proceeding will relieve the attorney of some of the burdens of a civil action. Although the attorney must collect and compile evidentiary material similar to that which would be required in a civil action,[169] he will be relieved of the burden of pleading and proving fault on the part of the manufacturer or administrator. This should make the attorney's job much easier, because in

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162. 42 U.S.C. § 300aa-22(e) (Supp. IV 1986).

163. *Id.* § 300aa-23(a)-(d). *See also Legislative History, supra* note 3, at 27, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6369. The issue of liability must be determined before any consideration is given to the issue of damages. The drafters urge courts to use diligence in their efforts to keep such deliberations free of irrelevant and prejudicial factors. If the court finds the defendant is liable, it must then consider the issue of general damages. Here, as in the consideration of punitive damages, the drafters intended to prevent the introduction of evidence of the manufacturers' financial position. If the court finds evidence of "particularly reprehensible, conscious behavior" on the part of the manufacturer, punitive damages may be considered and awarded. *Id.*

164. 42 U.S.C. § 300aa-23(e) (Supp. IV 1986). *See also Legislative History, supra* note 3, at 29, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6370. "Compensation standards, evidence, and proceedings are sufficiently different from civil proceedings in tort that the findings made in compensation are not likely to be based on the more rigorous requirements of a tort proceeding and might confuse such civil actions." *Id.*

165. 42 U.S.C. § 300aa-31(a) (Supp. IV 1986).

166. *Id.* § 300aa-32. Review of administrative proceedings will be by a United States court of appeals. *Id.*

167. *Id.* § 300aa-33.

168. *Id.* § 300aa-11(a)(2)(A).

169. *Id.* § 300aa-11(c).

the majority of cases, vaccine injuries are unavoidable and unforeseeable.[170] In addition, use of the Compensation Program will, in many cases, reduce the time an attorney must spend in pursuing a remedy for the client since a judgment must be rendered within a year of the filing of a petition.[171]

If, after the completion of compensation proceedings, the client elects not to accept the court's award and chooses to pursue a civil action, the attorney is limited in the theories of liability that may be used. Actions based on strict product liability and the "failure to warn" premise used in *Davis* and *Givens* are now prohibited by the Act.[172] The legislation's goal is not to make the practice of law easier or more difficult, but to address the needs of the person suffering a vaccine-related injury. The legislators intended to provide relief for such a person by creating an "appealing alternative to the tort system"[173] that allows petitioners to be "compensated because they suffered harm from the vaccine . . . not because they demonstrated wrongdoing on the part of the manufacturer."[174]

The Act will also affect the attorney's potential fee. The Congressional Budget Office (CBO) predicted that attorney and litigation expenses will be lower[175] under the Compensation Program than in civil actions. CBO's estimates will very likely be a factor in the determination of "reasonable attorneys' fees"[176] to be included in compensation awards.

The Act's impact on manufacturers is more difficult to predict because persons suffering vaccine-related injuries are not compelled to accept the judgment of the claims court. One of the early stumbling blocks was the insistence by some of the Act's proponents that any compensation program be the exclusive remedy.[177] These proponents[178] argued that manufacturers would not realize any relief from

170. Krugman, *supra* note 35.

171. *Legislative History, supra* note 3, at 17, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6358.

172. *Id.* at 27, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6368.

173. *Id.* at 26, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6367.

174. *Id.*

175. *Budget Act History, supra* note 83, at 695, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS at 2313-69. CBO estimates that attorney fees and other legal costs will be about $50,000 per case.

176. 42 U.S.C. § 300aa-15(e) (Supp. IV 1986). The provisions of this section allow the court to include attorney's fees and other costs in the amount of the award. *Id.*

177. Telephone interview with Elizabeth Goss, Legislative Assistant for Sen. Dale Bumpers (Feb. 9, 1989).

178. *Id.* Proponents favoring administrative proceedings as an exclusive remedy include the American Medical Association and manufacturers such as Lederle.

the burdens of litigation if persons with vaccine-related injuries could still seek relief in the courts. While this argument has some merit, it is weakened by the tort reforms included in the Act. Although litigation is an option, the two most successful theories of liability are no longer available. Although one cannot realistically presume that all injured persons will accept the compensation offered, it seems reasonable to assume that the awards granted will be acceptable to a substantial number of potential plaintiffs. The judiciary will be cognizant of the availability of compensation under the Act, and while it is by no means certain what effect this knowledge will have upon awards in civil actions, it is at least conceivable that it may foster smaller awards.

Because compensation is not available for persons injured more than eight years before the effective date of the Act, manufacturers will still face potential liability for these injuries.[179] However, time and state statutes of limitations will act to reduce this burden.

The excise tax imposed on vaccines may at first glance appear to place another burden on the manufacturers. However, manufacturers increased the price of vaccines substantially in anticipation of the taxes.[180] In reality, the monetary burden created by the excise tax will be borne by state and local health departments in the form of increased charges by manufacturers.[181]

In addition to the monetary burdens, the Act will burden state and local immunization programs in other ways. Under the Act, the consent forms that must be signed by parents before a child may be immunized are extremely long and complicated.[182] Assuring that the parents' consent is truly "informed" will require increased time and effort on the part of public health officials. This will be especially true in areas where adult illiteracy is a problem.

Two questions not answered by a careful reading of the Act and its legislative history involve the Vaccine Injury Table and the vaccines covered by the compensation system. At present the table includes vaccines against only seven childhood diseases.[183] While the

179. *Legislative History, supra* note 3, at 22, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6363.

180. Telephone interview with Charles Beets, Director, Immunizations Program, Arkansas Department of Health (Feb. 15, 1989).

181. *Id.*

182. *Id.* For example, the consent form used by the Arkansas Department of Health is now nine pages in length instead of the original two pages.

183. *See* 42 U.S.C. § 300aa-14 (Supp. IV 1986) (measles, mumps, rubella, diphtheria, pertussis, polio, and tetanus).

Act makes provisions for needed additions to the Table, such additions may be made only by congressional action.[184] Although there is some indication in the legislative history of the Act that certain additions would be favored,[185] there is no way of knowing when or if such changes will be forthcoming.

It is also not certain if expansions of the table will include vaccines more commonly administered to adults. The swine flu vaccine disaster[186] is a clear illustration that the risk of an adverse reaction is not limited to the vaccines routinely administered to children.[187] At present, it is not clear whether "adult" vaccines will be added to the table, but the discovery of an AIDS vaccine would almost certainly bring this question to the forefront. The ramifications of adding "adult" vaccines to the table could be staggering because the number of potential recipients would be great.

The National Childhood Vaccine Injury Compensation Act does not answer all the questions and concerns associated with vaccine injuries, but it is a step in the right direction. The nation as a whole benefits from its immunization programs, and a no fault compensation system appears to be the most logical way of assuring the continued success of such programs.

Victoria Bennett

184. 42 U.S.C. § 300aa-14(e).

185. *Legislative History, supra* note 3, at 20, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6361. The drafters are particularly interested in the addition of *Haemophilus influenzae* and Hepatitis B vaccines to the Vaccine Injury Table. *Id.*

186. Smith, *supra* note 6, at 265. In 1976, in anticipation of a swine flu epidemic, the Public Health Department sponsored a mass immunization program for that disease. Although clinical trials of the vaccine revealed no adverse reactions, the administration of several million doses resulted in a number of cases of Guillain-Barré syndrome. This syndrome causes a rapidly progressing muscular weakness which can lead to life-threatening respiratory paralysis. *Id.*

187. *Id.*