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NO-FAULT COMPENSATION FOR UNAVOIDABLE INJURIES: EVALUATING THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION PROGRAM

Theodore H. Davis, Jr. & Catherine B. Bowman***

I. INTRODUCTION

In November of 1978, Mrs. Dean Kearl, on the advice of a physician, took her four-month-old daughter, Elizabeth, to a county clinic to be vaccinated for polio.[1] There, Elizabeth received a dose of an oral vaccine containing living, but weakened polio virus.[2] The vaccination took place after Mrs. Kearl had signed a consent form indicating her awareness that receipt of the vaccine could, in rare cases, lead to actual contraction of the disease.[3] Within four weeks this possibility became an unfortunate reality, as Elizabeth Kearl developed signs of paralysis later diagnosed as polio.[4]

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1. Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 818, 218 Cal. Rptr. 453, 456 (1985), *overruled by* Brown v. Superior Court of San Francisco, 44 Cal. App. 3d 1049, 1061, 245 Cal. Rptr. 412, 418, 751 P.2d 470, 477 (1988) (prescription drugs should not be measured by the comment k standard).

2. *Id.* at 819, 218 Cal. Rptr. at 456.

3. *Id.*

4. *Id.* at 820, 218 Cal. Rptr. at 456.

Seeking to recover damages for their daughter's injuries, the Kearls filed suit in California state court maintaining that the vaccine's manufacturer, Lederle Laboratories, had been negligent in its design and in its accompanying warnings.[5] Although the Kearls were successful at the trial level, the California Court of Appeals subsequently overturned their award, deeming the vaccine unavoidably dangerous and, therefore, exempt from strict products liability negligent design defect analysis.[6] Consequently, although the uncontested origin of Elizabeth Kearl's disease was the vaccine she had received, her parents were barred from recovering monetary damages on her behalf.[7]

As was the case with Elizabeth Kearl, Allen Whitledge also suffered adverse effects from receipt of a childhood vaccine.[8] On June 26, 1979, within several hours of receiving the third in a series of three Diphtheria, Pertussis and Tetanus inoculations,[9] Allen's head and body began to jerk in an uncontrollable manner. When he was taken to the local hospital three weeks later, after awakening his mother by emitting unusual sounds, the attending physician diagnosed him as suffering generalized seizures.[10] Further examination by a pediatric neurologist revealed that Allen was suffering from an encephalopathy and attendant diminution of intellectual capacity determined to have been caused by the third DPT inoculation.[11]

Like those of Elizabeth Kearl, Allen Whitledge's injuries were caused by the administration of a childhood vaccine which was required by state law.[12] In stark contrast to the Kearls' experience, however, Allen Whitledge's parents were successful in securing compensation for the projected reasonable unreimbursable expenses of caring for their son;[13] their suit resulted in an award of $ 976,341.97 allocated towards the purchase of an annuity capable of providing for Allen Whitledge throughout his anticipated life.[14]

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5. *Id.* at 820, 218 Cal. Rptr. at 456-57.

6. *Id.* at 836, 218 Cal. Rptr. at 468-69.

7. *See id.* at 828, 218 Cal. Rptr. at 463. Note that the result reached in *Kearl* is not necessarily reflective of that reached in all cases litigated prior to the implementation of the National Childhood Vaccine Injury Compensation Program. *See generally infra* notes 77-124 and accompanying text.

8. Whitledge v. Secretary of Dep't of Health & Human Servs., 19 Cl. Ct. 144, 146 (1990).

9. The inoculation is also referred to as DTP vaccine. *See generally infra* notes 55-76 and accompanying text.

10. *Whitledge*, 19 Cl. Ct. at 146-47.

11. *Id.*

12. *See generally infra* text accompanying notes 18-27.

13. *Whitledge*, 19 Cl. Ct. at 150.

14. *Id.*

The explanation for the disparate treatment accorded to the Kearls and the Whitledges lies in the passage of the National Childhood Vaccine Injury Act of 1986 (the Act).[15] This legislation was passed in response to concerns that traditional tort law had resulted in a shortage of manufacturers willing to produce vaccines and was an inadequate mechanism for compensating victims of the adverse consequences of these vaccines.[16] However, the Act is not intended merely as a reform of tort doctrine. Rather, it effects a limited abrogation of tort law principles in favor of a compensatory program funded by an excise tax applied to sales of covered vaccines.[17]

This article examines the efficacy of the National Childhood Vaccine Injury Compensation Program (the Program) as a means for compensating victims of injuries attributable to participation in mandatory childhood vaccination programs while protecting vaccine manufacturers from potentially crushing liability for unavoidably unsafe products. Part One of the article examines the perceived crisis in the area leading to the Program's establishment through passage of the Act. Part Two describes the procedures defined in the Act for securing reimbursement for vaccine-related injuries. Part Three establishes a framework for evaluating the operation of the Program from the perspectives of both victims of vaccine-related injuries and vaccine manufacturers. Part Three argues that the Program has achieved its goal of protecting the nation's vaccine supplies while providing compensation for the unavoidable injuries resulting from administration of vaccines within the Program's scope. Despite this apparent success, the article concludes that the particular nature of childhood vaccines and the mandatory state-run programs governing their administration renders it unlikely that the Program's structure may be successfully extended to cover injuries resulting from other drugs and medicines. Accordingly, the Program is best viewed as a starting point for discussions of possible future reform of the legal regime governing drug law, rather than a blueprint for similar schemes.

II. The Emergence of the Vaccine Liability Crisis

A. Background: The Vaccines

The constitutionality of state-mandated vaccination programs was established in 1905 by the United States Supreme Court's decision in

15. 42 U.S.C. §§ 300aa-1 to 33 (1986); *see also* The Vaccine Compensation Amendments of 1987, Pub. L. No. 100-203, 101 Stat. 1330 (1987) (providing for funding mechanism for National Childhood Vaccine Injury Act).

16. *See infra* text accompanying notes 125-133.

17. *See infra* text accompanying notes 134-154.

Jacobson v. Massachusetts.[18] The *Jacobson* Court rejected a fourteenth amendment challenge to Massachusetts' compulsory immunization statute, holding that the general welfare could not be subordinated to the convenience of a few.[19] In the Court's words: "Even liberty itself, the greatest of all rights, is not [an] unrestricted license to act according to one's own will. It is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others. It is then liberty regulated by law."[20]

Currently, all fifty states and the District of Columbia have laws mandating vaccination before a child is permitted to attend public school.[21] Generally, these vaccinations are required against the following diseases: polio, measles, mumps, rubella, diphtheria, tetanus, and pertussis;[22] a number of states, however, do not require pertussis vaccinations prior to a child's entry into public school.[23] All states other than Mississippi and West Virginia allow exemptions for religious reasons.[24] In addition, a number of states provide for exemptions where the child's parents object to vaccination for philosophical reasons.[25] Al-

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18. 197 U.S. 11 (1905).

19. *Id.* at 26.

20. *Id.* at 26-27.

21. SUBCOMMITTEE ON HEALTH AND THE ENV. OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 99TH CONG., 2D SESS., CHILDHOOD IMMUNIZATION 103-06 (Comm. Print 1986) [hereinafter CHILDHOOD IMMUNIZATION]. For an example of a typical state immunization statute, see OHIO REV. CODE ANN. § 3313.671 (Baldwin 1990) which states:

> (A) Except as otherwise provided in this division, no pupil . . . shall be permitted to remain in school for more than fourteen days unless he presents written evidence . . . that he has been immunized by a method of immunization approved by the department of health . . . against mumps, poliomyelitis, diphtheria, pertussis, tetanus, rubeola, and rubella or is in the process of being so immunized.
>
> . . . .
>
> (3) A pupil who presents a written statement of his parent or guardian in which the parent or guardian objects to the immunization for good cause, including religious convictions, is not required to be immunized.
>
> (4) A child whose physician certifies in writing that such immunization against any disease is medically contraindicated is not required to be immunized against that disease.

22. CHILDHOOD IMMUNIZATION, *supra* note 21, at 1.

23. H. COULTER & B. FISHER, DPT: A SHOT IN THE DARK 346 (1985) (listing Arizona, Kentucky, Missouri, Montana, New York, Oregon, Pennsylvania, Rhode Island, and Washington as those states not requiring pertussis vaccinations).

24. *Id.*

25. ARIZ. REV. STAT. ANN. § 15-873A(1) (Supp. 1989) (exemptions due to personal beliefs); CAL. HEALTH & SAFETY CODE § 3385 (West 1990) (contrary to his/her beliefs); COL. REV. STAT. § 25-4-903(2)(a)-(b) (West 1990) (medical, religious or personal beliefs); DEL. CODE ANN. tit. 14, § 131(a)(5)-(6) (1990) (detrimental reaction or religious belief); IDAHO CODE § 39-4802(1)-(2) (1990) (endangerment to life, objections, religious or other grounds); IND. CODE § 10-4-1-16 (Supp. 1990) (spiritual means or prayer exception); LA. REV. STAT. ANN. § 17:170(D) (West Supp. 1991) (medical reasons or written dissent from parent or guardian); ME. REV. STAT. ANN. tit. 20-A, § 6351(2)(A)(i-iv) (1990) (medically threatening, already immune, sincere religious belief, moral, philosophical or other personal reason); MICH. COMP. LAWS ANN. §

though all states further provide for medical exemptions, the evidence suggests that the documentation required to secure such exemptions makes them difficult to obtain.[26] In any case, the effectiveness of these state laws in promoting vaccination has resulted in 57,000 American children being vaccinated per week.[27] Of these vaccinees, those receiving administrations of poliomyelitis and DPT vaccines are of most interest for the purposes of this commentary.

1. Poliomyelitis Vaccine

Poliomyelitis is a disease caused by an enterovirus that typically enters the body orally.[28] Once in the human body, the virus replicates in the intestinal tract and may eventually attack neurons in the brain and spinal column, resulting in neurological damage that can lead to paralysis.[29] Because eighty percent of a typical population with polio infections will already have acquired an immunity to the disease, only approximately one percent of infected individuals will develop classical clinical paralytic symptoms.[30] Of these cases, many will not result in paralysis at all, but will instead produce symptoms no more dangerous than those of a cold or mild stiffness of the neck.[31] Nevertheless, prior to the introduction of effective vaccines, the disease claimed as many as 57,879 victims in the United States annually, with 21,269 cases resulting in crippling paralysis.[32]

333.9215(2) (West 1980) (religious conviction or other objections); MINN. STAT. ANN. § 123.70(3)(d) (West Supp. 1991) (conscientiously held beliefs); MO. REV. STAT. § 167.181(3) (Supp. 1991); MONT. CODE ANN. § 20-5-405(1) (1989) (notarized affidavit that immunization is contrary to religious tenets and practices); NEB. REV. STAT. § 79.444.01 (1987) (immunization is necessary unless parent submits written statement stating objection); N.D. CENT. CODE § 23-07-17.1(6) (1978) (parent or guardian must be notified of right to refuse immunization); OHIO REV. CODE ANN. § 33.13.671(3) (Baldwin 1990) (religious convictions, medical reasons or other good cause shown); OKLA. STAT. ANN. tit. 70, § 1210.193 (West 1989) (parents, guardian or person with legal custody can claim medical, religious, or personal grounds for exemption); R.I. GEN. LAWS § 16-38-2 (1988) (immunization required unless parents sign a certificate stating reasons immunization contrary to beliefs or for medical reasons); UTAH CODE ANN. § 53A-11-302 (1988) (personal or religious belief); VT. STAT. ANN. tit. 18, § 1122(3) (1989) (religious beliefs or moral convictions); VA. CODE ANN. § 22.1-271.2 (Supp. 1990) (contrary to religious beliefs or detrimental to health); WASH. REV. CODE § 28A.31.106(3) (1979) (philosophical or personal reasons); WIS. STAT. § 140.05(16)(c) (Supp. 1990) (health, religion or personal conviction).

26. *See generally* H. COULTER & B. FISHER, *supra* note 23, at 346.

27. *Id.* at 402.

28. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1295 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

29. *Id.* at 1295-96.

30. *Id.* at 1296.

31. *See generally id.*; M. SCHAECHTER, G. MEDOFF & D. SCHLESSINGER, MECHANISMS OF MICROBIAL DISEASE 466 (1989); 3 SCHMIDT, ATTORNEY'S DICTIONARY OF MEDICINE P-249 (1975).

32. *Reyes*, 498 F.2d at 1269. The figures cited are from 1952.

Traditionally, American public health efforts to combat the polio virus have revolved around two vaccines developed in the 1950s. Early in the decade, Dr. Jonas Salk invented an injected vaccine that depends for its effectiveness on a sample of the virus grown in a tissue culture and then chemically "killed" to render it incapable of causing the disease.[33] Notwithstanding this lack of latency, however, the dead virus contained in the Salk vaccine continues to act as an antigen stimulating the production of antibodies capable of attacking any "wild" polio virus entering the body following vaccination.[34]

Despite remarkable utility in combatting the spread of polio, the Salk-type vaccine has a number of disadvantages. First, its administration through three injections[35] makes it a relatively unpopular remedy. Second, although providing the vaccinated individual with a systemic immunity to polio, the Salk vaccine does little to suppress the existence of the virus in the vaccinated individual's intestinal tract.[36] Thus, the vaccine fails to prevent the vaccinee from serving as a carrier of the disease and, therefore, does not contribute to the eradication of the wild virus.[37] Finally, and most importantly, the Salk vaccine fails to provide a lifetime immunity without the need for periodic booster shots.[38]

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33. Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 817, 218 Cal. Rptr. 453, 455 (1985), *overruled by* Brown v. Superior Court of San Francisco, 44 Cal. App. 2d 1049, 1061, 245 Cal. Rptr. 412, 418, 751 P.2d 470, 477 (1988) (citing Comment, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235, 237 (1976)).

34. *Id.* On the mechanics of vaccines in general, see Ezagui v. Dow Chem. Corp., 598 F.2d 727 (2d Cir. 1979):

> Vaccines confer protection against diseases by introducing antigens into the body which stimulate the production of immunizing antibodies. This process occurs when lymphocytes, cells contained in the lymph glands, absorb the antigens and produce an antitoxin against the particular disease. With some infectious diseases, such as diphtheria and tetanus, it has been possible to isolate the soluble toxin or poison excreted by these bacteria and to inactivate this toxin with formaldehyde, thereby converting the toxin into what is called a toxoid. This toxoid helps immunize the body against disease by stimulating the production of antibodies, but the toxoid will not cause disease because it has lost its poisonous qualities.

Id. at 731.

In the cases of polio and pertussis, unlike those of diphtheria and tetanus, researchers have to date been unable to develop toxoids capable of insuring the production of a safe vaccine. *See infra* notes 47-53, 67-76 and accompanying text.

35. In contrast to most viruses, polio exists in only three strains—commonly referred to as Type I, Type II, and Type III, respectively—and only in humans, which makes possible the manufacture of relatively simple vaccines against its spread. *Reyes*, 498 F.2d at 1296. The approach taken by the Salk vaccine was to inoculate vaccinees against each strain via a separate injection. *Id.* at 1296. M. SCHAECHTER, G. MEDOFF & D. SCHLESSINGER, *supra* note 31, at 467-68.

36. *Reyes*, 489 F.2d at 1296.

37. *Id.*

38. *See generally* Boffey, *Salk Challenges Safety of Sabin's Live-Virus Vaccine*, 196 SCIENCE 35 (1977).

The experience of Finland, in its use of Salk-type vaccines, demonstrates this last point. In contrast to most countries, Finland (along with Sweden) until recently relied exclusively on Salk-

These disadvantages are not inherent in the use of the so-called "Sabin" vaccine, however.[39] Developed by Dr. Albert Sabin several years after the Salk vaccine, this vaccine, rather than relying on killed virus, contains living but "attenuated" or weakened virus.[40] Like that present in the Salk vaccine, the virus contained in the Sabin vaccine is generally incapable of causing the disease itself, but is strong enough to stimulate production of antibodies sufficient to repel infections of the wild virus.[41] Unlike the Salk vaccine, the Sabin formulation suppresses the wild virus from a vaccinated individual's intestinal tract, thus preventing vaccinees from serving as immunized carriers.[42] Also unlike the Salk vaccine, the Sabin vaccine is administered orally in a single dose,[43] thus facilitating the widespread vaccination of children. More importantly, however, the Sabin vaccine confers a lifetime immunity from polio without the need for booster shots.[44]

Largely as a result of these factors, American public health authorities have come to rely almost exclusively on the administration of the Sabin-type live vaccine in their mass immunization programs.[45]

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type vaccines in generally successful efforts to combat the spread of the virus. Franklin & Mais, *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CALIF. L. REV. 754, 768 n.55 (1977). In a period from late October 1984 to early January 1985, however, the country reported the discovery of five cases of polio. Of these, two previously had received five doses of the Salk vaccine. *See* Centers for Disease Control, *Polio Vaccines: Update*, 34 Morbidity & Mortality Weekly Rep., Jan. 11, 1985, at 5. In part because of this experience, Finnish authorities recently have abandoned exclusive reliance on the Salk vaccine. The disadvantages of the Salk vaccine are likely to have a disproportionate impact on the lower socio-economic groups at the greatest risk of contracting the disease from wild viruses. Comment, *supra* note 33, at 238.

39. Given that neither the Salk nor Sabin vaccines currently in use retain the exact formulation they contained when first introduced by their inventors, they are often referred to by their more generic names, "IPV" (for the Salk-type injected polio virus) and "OPV" (for the Sabin-type oral polio virus). *See, e.g.*, Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 817, 218 Cal. Rptr. 453, 455 (1985), *overruled by* Brown v. Superior Court of San Francisco, 44 Cal. App. 3d 1049, 1061, 245 Cal. Rptr. 412, 418, 751 P.2d 470, 477 (1988). For the purposes of this article, however, "Salk vaccine" refers to any vaccine relying on the injection of killed virus for its effectiveness, while "Sabin vaccine" refers to any vaccine which consists of an orally administered culture of a weakened virus.

40. Franklin & Mais, *supra* note 38, at 761 n.30.

41. *Id.*

42. *Id.* This feature of the Sabin vaccine has an additional beneficial effect. Because the Sabin vaccine produces a harmless infection lodging in the digestive system that interferes with a wild virus infection even before a vaccinee's production of antibodies, it is generally more effective than the Salk vaccine during actual outbreaks of polio. *Id.*

43. Unlike the Salk vaccine, *see supra* note 35, the Sabin vaccine may be administered in trivalent doses capable of immunizing vaccinees against all three strains of polio. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1296 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

44. On the characteristics of the Sabin vaccine, see generally Comment, *supra* note 33, at 238.

45. *See* Boffey, *supra* note 38, at 35.

Authorities concluded that the live-virus [Sabin] vaccine would be more acceptable to the

The success of these immunization programs has resulted in incidents of polio displaying clinical symptoms in the United States declining from a high of 57,879 cases in 1952 to an average of 12 cases per year from 1974 to 1983.[46] By early 1990, health care officials were even able to predict the wild virus' impending eradication in the Western Hemisphere.[47] Consequently, although the disease remains prevalent in the Eastern Hemisphere,[48] the chances of an unvaccinated individual acquiring polio in the United States from a wild virus are virtually nonexistent.[49]

Notwithstanding these advantages, public health authorities have come to recognize that live Sabin-type vaccines carry with them an inherent danger. Shortly after the widespread introduction of these vaccines, reports began to surface of incidents in which both individuals who were recently vaccinated with the Sabin vaccine and unvaccinated individuals who recently had contact with vaccinated individuals contracted polio.[50] In 1964, a report to the Surgeon General concluded

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public (because it is given orally on a sugar cube rather than by injection); would produce longer-lasting immunity; and would even immunize many people who had not bothered to get vaccinated but who came into contact with those who had and caught a generally harmless infection from them. They also felt that the live-virus vaccine would do a better job of eradicating the wild polio virus from the environment because the live-virus vaccine suppresses the wild virus from the intestinal tract, thereby interfering with the spread of polio through fecal matter and sewage, whereas the killed-virus does not.

Id.

Authorities favoring the Sabin vaccine over the Salk vaccine include, among others, the United States Public Health Advisory Committee on Immunization Practice, the Public Health Service Centers for Disease Control, the Committee on Infectious Diseases of the American Academy of Pediatrics, and the National Academy of Science. *Kearl*, 172 Cal. App. 3d at 818, 218 Cal. Rptr. at 455 (1985). Largely as a result of this support for the Sabin vaccine, the Salk vaccine has been used only sporadically in the United States and is currently not domestically produced. *Id.*

46. On the beneficial effects of childhood immunization programs in general in reducing infectious diseases, *see* CHILDHOOD IMMUNIZATION, *supra* note 21, at 5-15.

47. *See* Wash. Post, April 25, 1990, at A18, col. 1.

48. *Id.* In the Eastern Hemisphere, polio continues to produce more than 200,000 cases annually, mostly in Africa and Asia. About seventy percent of the world's population lives in countries where the disease is still prevalent. *Id.*

49. *Id.*

50. *See generally* J. PAUL, A HISTORY OF POLIOMYELITIS 465 (1971).

> Adverse Reactions: Paralytic disease following the ingestion of live [Sabin] vaccines has been, on rare occasion, reported in individuals receiving the vaccine, . . . and in persons who were in close contact with [recent] vaccinees. The vaccine viruses are shed in the vaccinee's stools for at least 6 to 8 weeks as well as via the pharyngeal route. Most reports of paralytic disease following the ingestion of the vaccine or contact with a recent vaccinee are based on epidemiological analysis and [a] temporal association between vaccination or contact and onset of symptoms. Most authorities believe that a causal relationship exists.

Physicians Desk Reference 1023 (40th ed. 1986) (footnote omitted); *cf.* Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1279 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974) (contraction of polio from administration of Sabin vaccine should properly be characterized as an allergic reaction

that these cases had indeed resulted from inoculation with the Sabin vaccine.[51]

The live Sabin-type vaccine, therefore, poses a significant health risk not associated with its Salk counterpart.[52] Although providing greater coverage in the aggregate than the Salk killed vaccine, the Sabin vaccine produces an actual case of polio every 11.5 million administered doses.[53] These odds narrow to one case in every 2.5 million doses when the number of victims contracting the disease through contact with recent vaccinees is taken into consideration.[54] It is this apparently inherent risk of infection associated with live Sabin-type vaccines that led to congressional inclusion of polio within the scope of the National Childhood Vaccine Injury Compensation Program.

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as "the risk appears to be distributed evenly among the substantial segment of the population that is not naturally immune to polio").

Dr. Sabin has disputed the conclusion that his vaccine has led to actual cases of polio. *See* SPECIAL ADVISORY COMM. ON POLIOMYELITIS, REPORT TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 5 (1964) (comments of Dr. Albert Sabin, M.D.) [hereinafter REPORT]. Most courts examining the issue, however, have accepted vaccinees' claims that their polio was caused by administration of the Sabin vaccine.

51. *See* REPORT, *supra* note 50, at 5.

> The Committee recognizes that it is not possible to prove that any individual case was caused by the vaccines and that no laboratory tests required can provide a definitive answer. Nevertheless, considering the epidemiological evidence developed with respect to the total group of compatible cases, the Committee believes that at least some of these cases were caused by the [Sabin] vaccine.

Id.

52. The general safety of the Salk vaccine holds only if it does not contain live virulent strains of the virus. *See supra* text accompanying notes 33-34. In the so-called "Cutter incident" of 1955, Cutter Laboratories, a manufacturer of the Salk vaccine, inadvertently made shipments containing some live virus. *See* Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 605, 6 Cal. Rptr. 320, 322 (1960). The unfortunate result was an outbreak of 207 vaccine-related cases of polio. *Id. See generally* J. PAUL, *supra* note 50, at 437-39; Johnson, *Once Again a Man With a Mission*, N.Y. Times, Nov. 25, 1990, (Magazine) at 57, 61.

The risk of such faulty preparation is, of course, hardly unique to the Salk vaccine. *See, e.g.*, Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), *aff'd in part and rev'd in part*, 500 F.2d 1059 (3d Cir. 1974) (holding U.S. government liable for releasing Sabin vaccine not conforming with required standards). For the purposes of this article's discussion of the respective merits of the Salk and Sabin vaccines, as well as of the DPT vaccine examined later in this article, each is presumed to be manufactured correctly in accordance with the federal regulations governing the area. *See generally* 21 C.F.R. §§ 630.10-.17 (1989).

53. Boffey, *supra* note 38, at 35.

54. *Id.* The chances of contracting polio vary with each strain of the virus that is contained in a given dose of vaccine. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 122-23 (9th Cir. 1968) (noting that the risk of Type III vaccine "is almost exclusively limited to adult populations"); REPORT, *supra* note 50, at 5 (estimating chances of contracting polio associated with vaccination with respective strains of polio).

2. The DPT Vaccine

The DPT vaccine addresses three diseases typically occurring in childhood—diphtheria, pertussis, and tetanus.[55] Unlike the virus present in the Sabin polio vaccine, the diphtheria and tetanus components of the DPT vaccine do not produce permanent injury as unavoidable side effects.[56] Consequently, it is the pertussis element that merits the most attention for the purposes of the National Childhood Vaccine Program.

Pertussis is caused by an exclusively human bacterium transmitted via coughed or sneezed droplets of sputum or mucous containing the organism.[57] Once inhaled, the bacterium causes a local infection in the respiratory tract with symptoms similar to those of a common cold.[58] Within several weeks, the effects of the disease spread throughout the entire body as the bacterium releases a highly toxic component that attacks different systems of the body causing more serious symptoms.[59]

It is at this second stage that victims begin to display characteristic symptoms such as severe coughing, vomiting, high fever, and occasional convulsions.[60] It is the cough that has given the disease its popularly known name of "whooping cough."

> [A]fter one to two weeks, the illness gets progressively worse. Thick mucous builds up in the lungs, triggering severe coughing spells as the children try to clear their clogged-up airways. Children can cough so long and hard that they literally cannot 'catch their breath;' their faces turn

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55. Because of its three elements, DPT vaccine is properly referred to as a triogen. During the late 1950s and the early 1960s, Parke-Davis & Company attempted to market a quadruple antigen vaccine consisting of diphtheria, pertussis, tetanus, and polio components under the trade name Quadrigen. This combination of vaccines, however, proved highly unstable, resulting in a frequency of adverse side effects beyond that normally regarded as typical. Although the vaccine was withdrawn in November 1969, successful tort suits against the company for breach of warranty and negligence continued throughout the following decade. *See, e.g.*, Ezagui v. Dow Chem. Corp., 598 F.2d 727 (2d Cir. 1979); Vincent v. Thompson, 79 Misc. 2d 1029, 361 N.Y.S.2d 282 (1974).

The theory of recovery employed by the plaintiffs in the above cases relied on faulty manufacturing of the vaccine in question, as was the case with litigation in the "Cutter Incident" and similar cases, *see supra* note 52. Consequently, these cases are distinguishable from the average case under the National Childhood Vaccine Injury Compensation Program.

56. *See Ezagui*, 598 F.2d at 731; Murphy, *Evaluation of the Pertussis Components of Diphtheria-Tetanus-Pertussis Vaccine*, 71 Pediatrics 200, 200 (1983).

Administration of the DPT vaccine in mandatory immunization programs in the United States has resulted in cases of diphtheria declining from 200,000 per year in 1921 to an average of three cases per year between 1980 and 1984 and cases of tetanus declining from 601 cases in 1948 to fewer than 95 cases in 1985. CHILDHOOD IMMUNIZATION, *supra* note 21, at 5-15.

57. H. COULTER & B. FISHER, *supra* note 23, at 21.

58. *Id.*

59. *Id.*

60. *Id.*

> blue when they are unable to get fresh oxygen into their system. As the coughing spell ends, children grasp for their next breath with a characteristic crowing sound, or whoop. These coughing spells can occur up to 40 times a day and can last two to three months.[61]

These severe coughing spells often leave their victims acutely undernourished and dehydrated with lungs and brains damaged from hemorrhaging, lack of oxygen, the direct effects of the pertussis toxin, or a combination of all three.[62] In its worst manifestations, the disease can produce permanent neurological disorders, including convulsions, paralysis, coma, blindness, deafness, seizures and varying degrees of mental retardation.[63]

Because there is no known antibiotic treatment for the disease, victims endured a long and risky convalescence.[64] Complications such as pneumonia, bronchitis, and severe middle-ear infections frequently made appearances in victims and exacted their own toll.[65] The disease's spread in the United States reached its peak in 1934, with 265,269 cases resulting in 7,518 deaths.[66]

Unlike the polio virus,[67] the bacterium responsible for pertussis has proven to be an extremely complex organism. To date, vaccine manufacturers have been unable to isolate the toxin that causes the disease's symptoms, therefore forcing them to produce vaccines based on whole pertussis bacteria.[68] Consequently, these live cells contain not only the toxin stimulating production of antibodies, but the symptom-producing toxin as well. As one researcher has explained:

> Reactions such as fever and neurological [damage from the vaccine] are reminiscent of symptoms of [natural] infection and suggest the possibility of common mechanisms for those physiologic conditions. Bordetella

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61. DISSATISFIED PARENTS TOGETHER, PERTUSSIS AND PERTUSSIS VACCINE: INFORMATION FOR PARENTS 1-2 (1985), *quoted in* Dark, *Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DTP Controversy?*, 19 U. TOL. L. REV. 799, 814 & n.89 (1988).

62. H. COULTER & B. FISHER, *supra* note 23, at 22.

63. *Id.*

64. *Id.*

> There is no effective antibiotic treatment for pertussis. Prolonged hospitalization is necessary in many cases to provide respiratory support and intravenous nutrition. Permanent lung disease, seizures, brain damage and death can result from whooping cough and its complications. Younger children, because of their smaller air passages, are more at risk for the problems produced by pertussis infection. The fatality rate is especially high in infants under six months of age.

Id.

65. *Id.* at 17.

66. CHILDHOOD IMMUNIZATION, *supra* note 21, at 5-15.

67. *See supra* note 35.

68. The first successful production of pertussis vaccine was in 1912 by Jules Bordet and Octave Gengou. H. COULTER & B. FISHER, *supra* note 23, at 23.

pertussis may produce a toxic substance which elicits the adverse reactions in disease and, similarly, these same toxic substances may be present to a limited extent in current whole sale vaccine and result in comparable effects.[69]

Whatever the precise mechanism, administration of the pertussis vaccine results in more adverse side effects than those associated with any other vaccine.[70] In their most benign form, these side effects consist of localized pain, redness, soreness, or swelling around the site of injection and are sometimes combined with a fever.[71] However, pertussis vaccination may, within hours of an injection, produce more serious symptoms, including vomiting and diarrhea, congestion, ear infections, high-pitched screaming, collapse, excessive sleepiness, seizure disorders, spasms, loss of muscle control, inflammation of the brain, blood disorders, diabetes and hypoglycemia, and death.[72]

Although government figures indicate that effective use of the pertussis vaccine in mandatory immunization programs has resulted in the reduction of whooping cough to 2,276 cases and 12 deaths in 1984,[73] critics of the vaccine have estimated that the number of children suffering permanent vaccine-related damage is as high as 11,666 cases annually.[74] Many of these victims require long-term medical and rehabilitative care available only at considerable expense.[75] As was the case with the Sabin-type live polio vaccine, parents with children allegedly suffering adverse side effects from the DPT vaccine increasingly filed suit against vaccine manufacturers immediately prior to the Program's establishment.[76]

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69. *Id.* at 22.

70. Ezagui v. Dow Chem. Corp., 598 F.2d 727, 731 (1979).

71. H. COULTER & B. FISHER, *supra* note 23, at 52-55; Mortimer, *Assessing Benefit-Risk Ratios*, 49 CLEV. CLINIC Q. 235, 236 (1982). The frequency of these side effects, however mild, makes vaccination even under the best of circumstances hardly an enjoyable experience. As one critic of the DPT vaccine has observed:

> If 3.5 million adults had to go out and get [the DPT] vaccine as a condition of getting a job, and 40% of them ended up with a fever of over 101 and 70% ended up with sore arms, we would sure have money spent on developing a better vaccine.

Brunell, *Editorial*, Am. Med. News, Jan. 18, 1985, at 4, col. 1.

72. *See generally* H. COULTER & B. FISHER, *supra* note 23, at 56-102; Mortimer, *supra* note 71, at 236.

73. CHILDHOOD IMMUNIZATION, *supra* note 21, at 5-15.

74. *See, e.g.*, H. COULTER & B. FISHER, *supra* note 23, at 375. This relatively expansive estimate includes in its count a number of infant deaths that, although officially attributed to Sudden Infant Death Syndrome (SIDS), were, the authors believe, caused by DPT vaccinations. This link, however, is not necessarily widely accepted within the scientific community as a whole. Accordingly, the actual numbers of annual DPT vaccine-related injuries may be lower.

75. *See, e.g.*, Clark v. Secretary of the Dep't of Health & Human Servs. 19 Cl. Ct. 113, 124-28 (1989) (present value of future medical and rehabilitative expenses of DPT vaccinee suffering severe injuries from administration of vaccine determined to be $2,772,855).

76. *Id.*

B. *Litigation Against Vaccine Manufacturers Prior to 1987*

1. The Common Law Framework

Prior to the effective operation of the Program in 1987, victims of vaccine-related injuries were forced to proceed against manufacturers in state common law tort suits. As a general rule, the resolution of these cases often revolved around the 1965 comment k to section 402A of the *Restatement (Second) of Torts*. Comment k designates vaccines as unavoidably unsafe products, whose benefits to the public generally outweigh any harm resulting from their use.[77] This passage indicates that where a manufacturer has properly prepared a vaccine and has given adequate warning as to its possible adverse side effects, liability will normally not attach for injuries resulting from its administration.[78]

Although litigation for vaccine-related injuries centered around comment k, the large number of jurisdictions in which such suits were brought produced varying interpretations of its text. Even where different jurisdictions adopted the same doctrinal approach, applications by different courts, in some cases, frequently led to opposing results on virtually identical sets of facts.[79] This section briefly examines the state of the common law with respect to vaccine-related injuries before 1987.

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77. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

78. *Id.* Section 402A subjects a seller or manufacturer of an "unreasonably dangerous" defective product to liability to the ultimate consumer for physical or property harm, even if the manufacturer exercised "all possible care in the preparation and sale of his product." RESTATEMENT (SECOND) OF TORTS § 402A (1965). Although lengthy, comment k to the section bears reprinting in full:

> *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 the 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 unavoidably 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 be sold, except by physicians or under the prescription of a physician. It is also true in particular of many new and experimental drugs, as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of these 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.

Id. § 402A comment k.

79. *Compare, e.g.*, Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977) *with* Johnson v. Amer-

a. The Duty to Warn Directly

Initial litigation following the adoption of the *Restatement* position established the principle that vaccine manufacturers had a duty to warn the vaccinee directly about the inherent risks posed by their products. In *Davis v. Wyeth Laboratories,*[80] the thirty-nine year-old plaintiff vaccinee had contracted polio after being injected with the defendant's Sabin vaccine at a mass immunization clinic.[81] At the time of the vaccination, it was well established that vaccinees in the plaintiff's age group were at higher risk of contracting the Type III polio strain through the Sabin vaccine.[82]

On appeal from a verdict for the defendant at the trial level, the Ninth Circuit's reversal of the judgment was heavily influenced by the defendant manufacturer's involvement in the vaccination program.[83] Although the immunization drive itself was administered by a state clinic, a Wyeth Laboratories representative had taken an active role in establishing the program and the manufacturer had expended considerable promotional funds encouraging the public to participate.[84] Given the defendant manufacturer's rather extensive involvement in the vaccine's administration, the court attributed to the defendant the knowledge that the vaccine ultimately would be distributed to recipients without individualized medical attention.[85]

As a result, the court found that the manufacturer had breached a duty to communicate adequate warnings of the vaccine's risk to poten-

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ican Cyanamid Co., 239 Kan. 279, 718 P.2d 1318 (1986).

80. 399 F.2d 121 (9th Cir. 1968).

81. *Id.* at 122.

82. In its examination of the Sabin vaccine, the Special Advisory Committee on Poliomyelitis Vaccine concluded that the risks for adults associated with use of the Type III polio vaccine were significantly greater than those for children. Accordingly, the Committee recommended that nonepidemic use of Type III vaccine be limited to children. REPORT, *supra* note 50, at 6. The Surgeon General reiterated this advice in a December 1962 report:

> It is . . . recommended: (1) that community plans for immunization be encouraged, using all three types [of polio vaccines]; and (2) that immunization be emphasized for children in whom the danger of naturally occurring poliomyelitis is greatest and who serve as the natural source of poliomyelitis infection in the community. Because the need for immunization diminishes with advancing age and because potential risks of vaccine are believed by some to exist in adults, especially above the age of 30, vaccination should be used for adults only with the full recognition of its very small risk.

Quoted in Davis, 399 F.2d at 124.

83. *See Davis,* 399 F.2d at 125.

84. *Id.* at 125, 131.

85. Indeed, the vaccine in this case was administered not by a physician or a physician's assistant, but by a pharmacist. *Id.* at 123, 131.

tial vaccinees.[86] Although the manufacturer had included a warning of the vaccine's potential side effects as an insert in the packaging material in which its vaccine had been shipped, it had failed to communicate the possible threat to the vaccinees themselves, either through its promotional materials or via the pharmacist administering the vaccination.[87] Indeed, the administering pharmacist himself had failed to read the package insert.[88] In light of these deficiencies, the court concluded:

> [T]he facts of this case imposed on the manufacturer a duty to warn the consumer (or make adequate provisions for his being warned) as to the risks involved, and that failure to meet this duty rendered the drug unfit in the sense that it thereby was rendered unreasonably dangerous. Strict liability, then, attached to its sale in absence of warning.[89]

Although the Ninth Circuit in *Davis* grounded its holding on the mass immunization setting presented by that case,[90] the Fifth Circuit, in 1977, expanded *Davis* to cover individual vaccinations given in physicians' offices. In *Givens v. Lederle*,[91] the plaintiff contracted polio

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86. In rejecting the manufacturer's contention that the unavoidably unsafe nature of its product relieved it of warning the plaintiff, the *Davis* court observed:

> There will, of course, be cases where the personal risk, although existent and known, is so trifling in comparison with the advantage to be gained as to be de minimis. Appellee so characterizes this case. It would approach the problem from a purely statistical point of view: less than one [case of polio] out [of] a million [vaccinations] is just not unreasonable. This approach we reject. When, in a particular case, the risk qualitatively (e.g., of death or major disability), as well as quantitatively, on balance with the end sought to be achieved, is such as to call for a true choice judgment, medical or personal, the warning must be given.

Id. at 129-30 (footnote omitted).

87. *Id.* at 125.

88. *Id.*

89. *Id.* at 130.

90. Other cases also have adopted this rationale in allowing recovery by plaintiffs in the context of mass immunization clinics. *See, e.g.*, Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974) (polio vaccine litigation); Graham v. Wyeth Laboratories, 666 F. Supp. 1483 (D. Kan. 1987) (DPT vaccine litigation); Wack v. Lederle Laboratories, 666 F. Supp. 123 (N.D. Ohio 1987) (DPT vaccine litigation); Stahlheber v. American Cyanamid Co., 451 S.W.2d 48 (Mo. 1970) (polio vaccine litigation); Cunningham v. Charles Pfizer & Co., 532 P.2d 1377 (Okla. 1974) (polio vaccine litigation).

Subsequent judicial applications of this approach have obviated the necessity for a jury instruction on whether the vaccine in question was the proximate cause of the plaintiff's injuries. For example, the *Reyes* court stated:

> Where a consumer, whose injury the [vaccine] manufacturer should have reasonably foreseen, is injured by a product sold without a required warning, a rebuttable presumption will arise that the consumer would have read any warning provided by the manufacturer, and acted so as to minimize the risks. In the absence of evidence rebutting the presumption, a jury finding that the defendant's product was the [cause-in-fact] of the plaintiff's injury would be sufficient to hold [it] liable.

Reyes, 498 F.2d at 1281. For criticism of this application, see Franklin & Mais, *supra* note 38, at 761.

91. 556 F.2d 1341 (5th Cir. 1977).

from her daughter who had recently been vaccinated with the Sabin vaccine, leaving the plaintiff confined to a wheelchair with total, permanent paralysis in the lower part of her body.[92] Despite the defendant manufacturer's inclusion of a package insert warning of the possibility of contracting polio from close contact with recent vaccinees,[93] the plaintiff's pediatrician had not communicated this information directly to her.[94]

Upholding the trial court's verdict for the plaintiff,[95] the *Givens* court found the factual situation of a vaccinee receiving a vaccine in a private individualized setting to be indistinguishable from the mass clinic setting found in *Davis* and its progeny.[96] Unlike the defendant in *Davis*, the defendant manufacturer had not engaged in a public relations campaign stressing the absolute safety of its vaccine. The manufacturer in *Givens* had done nothing beyond providing a simple package insert to bring the vaccine's inherent risks to the attention of potential vaccinees.[97] As was the case in the mass immunization setting, the court in *Givens* found that the vaccine manufacturer's failure to insure that its product would not be administered in the absence of a direct warning to the ultimate consumer constituted a negligent breach of duty.[98]

b. The Learned Intermediary Doctrine

Johnson v. American Cyanamid Co.[99] represented the second approach to dealing with vaccine-related injuries under comment k to section 402A of the *Restatement (Second) of Torts*.[100] There, the plaintiff contracted polio shortly after his daughter's vaccination with the Sabin

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92. *Id.* at 1343.

93. *Id.*

94. *Id.* at 1345.

95. The litigation in *Givens* actually took place in two stages. Following an initial verdict for the defendant in federal district court, the plaintiff's motion for a new trial was granted in light of the Fifth Circuit's intervening decision in Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974), which accepted the *Davis* court's rationale in allowing the imposition of liability for failure to warn the vaccinee directly in the mass immunization setting. *Givens*, 556 F.2d at 1343-44.

96. 556 F.2d at 1344.

97. *Id.* at 1345.

98. The court stated that:

> When a private doctor administers a drug by prescription, . . . it is defective as marketed only if the manufacturer does not warn the doctor about any hazard. There is solid evidence that the vaccine was administered here in a manner more like that at a small county health clinic, as in [*Davis* and] *Reyes*, than by prescription. . . . If so, then Lederle is responsible for taking steps to get the warning directly to the consumer.

Id.

99. 239 Kan. 279, 718 P.2d 1318 (1986).

100. *Id.* at 284, 718 P.2d at 1322.

vaccine, leaving him totally disabled.[101] In the trial court, the plaintiff presented evidence that the Salk vaccine represented a safer alternative to its Sabin counterpart.[102] A jury addressing the plaintiff's design defect and inadequate warning claims awarded him $2,000,000 actual damages and $8,000,000 punitive damages.[103]

On appeal, however, the Kansas Supreme Court rejected the trial court's admission of evidence concerning the relative safety and efficacy of the two vaccines.[104] Rather, it accepted the defendant's contention that, in light of comment k, there was, as a matter of law, no manufacturing or design defect in the vaccine at issue.[105] Consequently, the court held that the issue of liability turned on the adequacy of the manufacturer's warning.[106]

In contrast to the *Davis* and *Givens* courts, the *Johnson* court found that the defendant manufacturer had no duty to warn the plaintiff directly of the risk of actually contracting polio inherent in the use of the Sabin vaccine.[107] Although recognizing the general duty of a drug manufacturer to warn of possible adverse side effects of its products, the court found that this duty extended only to giving a warning to the physician administering the drug. The manufacturer in *Johnson* had included information that the court deemed as adequately advising the plaintiff's pediatrician of the attendant risks of the Sabin vaccine.[108] The *Johnson* court found, therefore, that "no submissible theory of liability" would support the imposition of damages against the manufacturer.[109] Thus, pursuant to the *Johnson* court's learned intermediary doctrine, adequate warnings supplied to a vaccine's administering physician served to protect the manufacturer from liability.[110]

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101. *Id.*
102. *Id.*
103. *Id.* at 280, 718 P.2d at 1320.
104. *Id.* at 286-90, 718 P.2d at 1323-26.
105. *Id.*
106. *Id.* at 286, 718 P.2d at 1323-24.
107. *Id.* at 289-90, 718 P.2d at 1325.
108. *Id.* at 289-90, 718 P.2d at 1325-26.
109. *Id.* at 289-90, 718 P.2d at 1326.
110. The nature of the DPT vaccine as a prescription drug rather than a mass immunization device, as is the case with polio vaccines, has led some courts to conclude that the learned intermediary doctrine is particularly appropriate to the DPT context. In *Conafay v. Wyeth Laboratories*, Prod. Liab. Rep. (CCH) ¶ 10,487 (D.D.C. Mar. 19, 1985), *remanded*, 793 F.2d 350 (D.C. Cir. 1986) (declining to certify defendant class), the plaintiff had suffered significant neurological injuries following a DPT vaccination in his pediatrician's office. The court, however, dismissed the plaintiff's suit against the vaccine's manufacturer. Noting that the plaintiff's pediatrician had *prescribed* the administration of the vaccination in question, the court seized upon the distinction between prescription and mass immunization vaccines relied upon by the *Givens* court, to conclude that, in cases involving the former, the manufacturer's duty to warn of the possible adverse effects of its vaccine extended only to the prescribing physician. Prod. Liab. Rep. (CCH)

c. The Alternative Vaccine Approach

In 1987, the Supreme Court of Idaho adopted a third interpretation of comment k in *Toner v. Lederle Laboratories*.[111] There, the plaintiff developed a rare paralytic condition shortly after receiving the defendant manufacturer's DPT vaccine.[112] At trial in federal district court, a jury, applying Idaho law, rejected the plaintiff's strict liability and breach of warranty claims.[113] It did, however, find the defendant manufacturer negligent for failing to secure licensing from the Food & Drug Administration (FDA) for an alternative, safer design for delivering the components of the DPT vaccine.[114] Upon appeal by the manufacturer, the Ninth Circuit certified two questions of state law to the Idaho Supreme Court. First, did comment k apply to strict liability claims? Second, did comment k apply to negligence claims, and, if so, did the trial court's jury instructions sufficiently reflect this fact?[115]

After dismissing the first question as improvidently before it,[116] the Idaho Supreme Court examined the proper relationship between comment k and a negligence claim.[117] The court noted that, pursuant to comment k's literal terms, "where a product is deemed unavoidably unsafe," plaintiffs injured by that product are able to proceed against the manufacturer only under a negligence cause of action.[118] Adopting the Restatement's doctrinal framework, the court found that plaintiffs

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¶ 27,904. "Unlike the polio vaccine in [*Davis* and its progeny], the DTP vaccine [at issue] is a prescription drug not administered in a mass immunization setting, and there is always a physician intervening between the patient and the manufacturer." *Id.*

111. 112 Idaho 328, 732 P.2d 297 (1987).

112. *Id.*

113. *Id.* The plaintiff had originally filed suit in state court, but this action was removed to federal court on the basis of diversity jurisdiction. *Id.* at 330, 732 P.2d at 299.

114. *Id.* at 332-33, 732 P.2d 301-02. At trial, the plaintiff relied heavily on the existence of a DPT vaccine, Tri-Solgen, briefly manufactured by Eli Lilly, but withdrawn from the market in 1972. Although defendant Lederle Laboratories subsequently purchased the rights to Tri-Solgen, it made no efforts to secure FDA certification for the vaccine following the Bureau of Biologics' refusal to approve Tri-Solgen as "safe and effective." The plaintiff's argument contended that with proper research, Lederle Laboratories could have developed the Tri-Solgen formula into a vaccine capable of providing effective protection while at the same time causing five times fewer catastrophic reactions. *Id.* at 331-32, 331 n.2, 732 P.2d at 300-01, 300 n.2.

115. Toner v. Lederle Laboratories, 779 F.2d 1429, 1433 (9th Cir. 1986). The above description constitutes the Idaho Supreme Court's characterization of the certified questions. *Toner*, 112 Idaho at 334, 723 P.2d at 303.

116. The court held that, as the jury had found for the defendant on the plaintiff's strict liability theory (a finding that the plaintiff had not appealed), there was no need for it to address the defendant's contention on appeal that comment k barred all strict liability claims. *Id.* at 335, 732 P.2d at 304. Notwithstanding this conclusion, the court took the opportunity in dictum to summarize the state of the law with respect to comment k and strict liability claims. *Id.* at 334-40, 732 P.2d at 303-08.

117. *Id.* at 340-42, 732 P.2d at 309-11.

118. *Id.* at 340-41, 732 P.2d at 309-10.

claiming a breach of duty under a negligence analysis could recover on a showing that the product's risk was " 'of such magnitude as to outweigh what the law regards as the utility of the [product] or of the particular manner in which it [was manufactured].' "[119] Consequently, the court observed: "the determination under comment k that the design of a product is unavoidably unsafe and yet affords benefits outweighing its risks varies little from the determination under negligence law that the designing and marketing of the product was reasonably done."[120]

Applying this rule to the facts in *Toner,* the court examined the defendant manufacturer's claim that a jury instruction,[121] on the basis of which the jury had found the manufacturer had negligently failed to market the allegedly safer alternative vaccine, was fatally inconsistent with the principles of comment k.[122] Noting that the instruction had not required the defendant to anticipate, perhaps clairvoyantly, future safer vaccines, the court found that the defendant need only have demonstrated that it exercised ordinary reasonable care in the manufacture and marketing of its vaccine.[123] Accordingly, and in stark contrast to the holding in *Johnson,* the court held that the jury's consideration of potential alternative vaccines in a suit sounding in negligence was consistent with comment k.[124] Under *Toner,* therefore, litigation centered around potential alternative vaccines rather than either the sufficiency of the manufacturer's warning or the warning of the receiving physician.

2. The Perceived Crisis

As the preceding discussion suggests, the theory to be properly relied upon by courts in resolving plaintiffs' claims against drug manufac-

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119. *Id.* 340, 732 P.2d at 310 (*quoting* RESTATEMENT (SECOND) OF TORTS § 291 (1965)).

120. *Id.* at 342, 732 P.2d at 311.

121. The disputed instruction read as follows:

> INSTRUCTION NO. 27: A manufacturer of vaccines has the duty to exercise ordinary and reasonable care not to expose the potential customer to an unreasonable risk of harm from the use of its products. The failure to meet this standard of due care in light of all the attendant circumstances will constitute negligence and subject the manufacturer to liability for the resulting consequences. The fact that the consumer's injuries were proximately caused by the manufacturer's product does not in and of itself constitute a sufficient basis on which to predicate liability. When the cause of action sounds in negligence, a manufacturer's duty to additionally test and investigate the properties of its product is dependent upon the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge or discoveries.

Id. at 332, 732 P.2d at 301.

122. *Id.* at 332, 732 P.2d at 301-02. On the allegedly safer alternative formulation of the DPT vaccine, see *supra* note 114.

123. 112 Idaho at 342, 732 P.2d at 311-12.

124. *Id.*

turers for vaccine-related injuries was a subject of considerable judicial debate prior to 1987. The result of this confusion was that plaintiffs' attempts to recover compensation for vaccine-related injuries were uncertain endeavors at best. As the House Committee on Energy and Commerce characterized plaintiffs' chances of recovery in 1986:

> [F]or the relatively few who are injured by vaccines — through no fault of their own — the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered. Currently, vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with the vaccine manufacturer. Over time, neither approach has proven satisfactory. Lawsuits and settlement negotiations can take months and even years to complete. Transactions costs—including attorneys' fees and court payments—are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met.[125]

This uncertainty did not, however, dissuade victims of vaccine-related injuries from increasingly filing suit against vaccine manufacturers in the early 1980s. Although plaintiffs filed only twenty-four actions in 1980, by 1985 this figure had risen to an estimated 144 new cases

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125. H.R. REP. NO. 908, 99th Cong., 2d Sess. 6 (1986), *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6347.

On plaintiffs' perils under traditional state tort law regimes in general, see J. O'CONNELL & B. KELLY, THE BLAME GAME 126-27 (1986).

> The [tort system], as legal academics since the 1930s have pointed out, is a nightmare, despite its intuitive appeal. The result . . . is a system in which many deserving victims are not paid anything because they cannot prove that someone or something was at fault, even though in fact that may have been the case, and many others are paid a small fraction of their loss because they can't afford the years of delay until the matter is settled. These injured persons, with mounting medical expenses and wage losses, are often pressured into settling their cases with a tremendous discount against the delay that a jury trial would entail. The settlement process itself is so cumbersome that [plaintiffs] usually are paid only years after the event. . . . [F]or tort claims, seriously injured people wait in angst and uncertainty for years to find out if they will be paid, what they will be paid, and when they will be paid. And when paid, because of all the uncertainty involved—which calls for very skillful expertise on the part of counsel and others—the injured party will be forced to turn over a third or a half, or even 60 percent of what he is awarded for litigation expenses and counsel fees.

annually.[126] These actions requested damages from manufacturers in excess of $3.5 billion.[127] In addition to damages sought by plaintiffs, by 1984 manufacturers faced unreimbursed litigation defense costs in excess of $9.8 million annually.[128]

The result of this litigation was a rapid exodus of drug manufacturers from the vaccine market. At the time of the Act's passage, only two firms, Lederle and Connaught Laboratories, continued to produce polio vaccines commercially.[129] Moreover, although at one time eight manufacturers produced the DPT vaccine,[130] by 1986 only Lederle and Connaught, together with the Massachusetts and Michigan state health departments, were still engaged in production.[131] With vaccine stockpiles well below the Center for Disease Control's recommended six-month supply levels, Congress found that "the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases."[132] It was this legal and political climate in 1986 that led to congressional efforts which sought a more efficacious method of reimbursing victims of vaccine-related injuries, while at the same time preserving vaccine supplies.[133]

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126. *See* CHILDHOOD IMMUNIZATION, *supra* note 21, at 86.

Number of Vaccine Injury Lawsuits Filed by Year, 1980-85

YEAR	NUMBER OF SUITS
1980	24
1981	29
1982	39
1983	70
1984	101
1985	144
1985 (est.)	144
63-month total	299

127. *Id.*

128. *Id.* at 87.

129. *Id.* at 67.

130. Lunzer, *Scared Shotless*, Forbes, Nov. 18, 1985, at 256.

131. CHILDHOOD IMMUNIZATION, *supra* note 21, at 68-69.

132. H. REP. NO. 908, *supra* note 125, at 7, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS at 6348.

133. Although this article's focus is on the no-fault compensatory mechanism effected by Subtitle 2 of the Act, the Program, Subtitle 1 of the Act represented a significant departure from previous United States policy in that it established within the Department of Health and Human Services a National Vaccine Program. 42 U.S.C. § 300aa-1 (1988). This program is intended to coordinate all federal agencies involved in vaccine-related matters, including research and development, safety and efficacy testing of vaccines, and the production, distribution and use of vaccines. *Id.* § 300aa-2(a).

III. THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION PROGRAM: PROCEDURES AND FIRST YEAR OF OPERATION

A. Procedures

As established by the Act, the Program attempts to provide a no-fault mechanism for compensating victims of vaccine-related injuries. Rather than facing the varying legal and evidentiary common law barriers in place at the time of the Act's passage, claimants under the Program need not address the issues of product defectiveness or the adequacy of manufacturers' warnings.[134] Instead, they must show only that their injury is related to the receipt of a covered vaccine.[135]

Petitions for compensation under the Program are filed with the United States Claims Court,[136] which then assigns the petition to a Special Master.[137] The Special Master examines the petition to see if it demonstrates, by a preponderance of the evidence, that the person on whose behalf the petition is filed: (1) sustained, or significantly aggravated, any illness, disability, or injury as a result of being vaccinated, or, in the case of a polio vaccine, contracted polio directly or indirectly from another person who received an oral polio vaccine; (2) has either (a) died; or (b) suffered residual effects from the illness, disability, or injury for more than six months after the administration of the vaccine resulting in unreimbursable expenses in an amount greater than $1,000; and (3) has not previously collected an award or settlement of a civil action for such injury or death.[138]

In making this determination, the Special Master refers to the "Vaccine Injury Table" set forth in 42 U.S.C. §300aa-14. This table contains prescribed time limits between administration of the vaccine and onset of symptoms,[139] and offers limited definitions for eligible in-

134. National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-22(b)-(c) (1986) (requires proof of failure to warn).

135. The covered vaccines are specified at *id.* § 300aa-14.

136. *Id.* §§ 300aa-11(a)(1), 300aa-12.

137. *Id.* § 300aa-12(b), (c).

138. *Id.* § 300aa-11(c).

139. The Vaccine Injury Table's treatment of adverse effects resulting from receipt of the DPT vaccine is illustrative.

juries.[140] If the petition demonstrates these requirements, the government, should it choose to contest the petition, then bears the burden of proof of establishing that the injury was due to factors unrelated to the vaccine's administration.[141]

Once the Special Master has determined that the victim's injuries stem from the administration of the vaccine in question, the Act establishes differing levels of victim compensation, depending on the severity of their injuries, and whether they were injured before or after the Program's effective date.[142] Where adverse effects from a vaccination following the effective date of the Program have proven fatal to the victim, the Act establishes an automatic award of $250,000.[143] The Program is more generous where the plaintiff has merely been injured by the vaccine, however, providing compensation for virtually all the victim's past and future economic losses.[144] The losses include past and future costs incurred for "diagnosis, medical, or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emo-

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I. DTP; P[ertussis]; DTP/Polio Combination; or any vaccine containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigens

Illness, disability, injury, or condition covered:	Time Period for first sympton . . . 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 [. . .]	3 days

Id. § 300aa-14(a).

140. *See, e.g., id.* § 300aa-14(b)(1) (defining "shock-collapse" for purposes of program eligibility).

141. Guidelines include:

> (2) For purposes of [the Act], the term "factors unrelated to the administration of the vaccine" —
>
> (A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition and
>
> (B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia) or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

Id. § 300aa-13(a)(2).

142. *Id.* § 300aa-15.

143. *Id.* § 300aa-15(a)(2).

144. *Id.* § 300aa-15(a).

tional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary."[145] In addition, claimants injured after the Program's effective date are entitled to compensation for actual and anticipated loss of earnings,[146] and may also receive an award of no more than $250,000 for actual and projected pain and suffering and emotional distress.[147]

The Program places some restrictions on the compensation available to claimants injured prior to the Program's effective date.[148] Although petitioners on behalf of these victims may recover the flat $250,000 in case of death, their ability to secure compensation for loss of earnings and pain and suffering in addition to the victim's future medical and rehabilitative expenses, is restricted.[149] In contrast to their counterparts injured subsequent to the Program's effective date, this class of victims is entitled to compensation for lost earnings, pain and suffering, and reasonable attorney's fees and costs not exceeding a total of $30,000.[150]

Once the Court of Claims has accepted or modified the Special Master's determination of the appropriate amount of an award, if any, the petitioner has ninety days within which to file an election to receive or reject the award and proceed against the vaccine manufacturer in a civil action.[151] Should a petitioner proceed in the latter course of action, the Act significantly limits chances for recovery in two crucial ways. First, vaccine manufacturers are immune from liability for "unavoidable" side effects stemming from the administration of a vaccine manufactured in compliance with applicable law.[152] Second, the Act effec-

145. *Id.* § 300aa-15(a)(1)(A)(II).

146. *Id.* § 300aa-15(a)(3)(A)(B). The Program distinguishes between claimants injured before and after the age of eighteen for purposes of determining the appropriate award of damages. For claimants injured after attaining the age of eighteen, the Act provides for compensation for actual and anticipated loss of earnings. For claimants injured before the age of eighteen, however, the Program awards loss of earnings corresponding with the average gross weekly earnings of workers in the private non-farm sector. *Id.*

147. *Id.* § 300aa-15(a)(4).

148. *Id.* § 300aa-15(b).

149. *Id.*

150. *Id.*

151. *Id.* § 300aa-21(a).

152. *Id.* § 300aa-22(b). The relevant statutory text reads as follows:

(b) UNAVOIDABLE ADVERSE SIDE EFFECTS; DIRECT WARNINGS. (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of [the Program] if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper warnings . . . .

(4) The Act establishes liability for injuries not manufactured in compliance with these

tively abrogates manufacturer liability under *Davis* and its progeny for failure to warn the vaccinee directly of the risks inherent in vaccination.[153] The Act does not on its face, however, address the issue of manufacturers' liability pursuant to the learned intermediary doctrine.[154]

B. The First Year of Operation of the National Childhood Vaccine Injury Compensation Program

1. The Department of Justice Response

Evaluating the Act's efficacy during its first year in achieving the Congressional goal of awarding compensation is hampered somewhat by the Department of Justice's approach to dealing with early petitions for compensation filed under the Program. After limited participation in a claim filed on November 2, 1988, the Department of Justice, on behalf of the Department of Health and Human Services, filed a motion to suspend the proceedings in the case at hand, as well as in all other cases filed under the Program to that point.[155] The reason given for this extraordinary motion was a lack of resources necessary to contest claims, combined with the Department of Justice's perception that there were "systemic problems" with the Program as it had been enacted.[156]

In response to the court's denial of its motion,[157] the Department of Justice notified the court on May 26, 1989 that given the resources available to the government at that time, its attorneys would withdraw

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regulations. *Id.*

153. *See id.* § 300aa-22(c) which provides:

> DIRECT WARNINGS. No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of [the Program] solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

Id.

154. On the significance of this omission, see *supra* text accompanying notes 114-118.

155. Clark v. Secretary of Dep't of Health & Human Servs., 19 Cl. Ct. 113 (1989).

156. *Id.*

157. In denying the government's motion, Chief Judge Smith observed:

> While the court sympathizes with the respondent's recitation of the problems resulting from a confluence of pressures—the Vaccine Act's 365-day decision timeframe, respondent's lack of resources and the procedures for determining entitlement to compensation under the Vaccine Act—the court is convinced that it is respondent's (both the Department of Justice and the Department of Health and Human Services) lack of resources that has precipitated the respondent's extraordinary request to suspend all vaccine cases. However, the government's lack of resources cannot be allowed to penalize petitioners. When the United States undertakes a statutory program, this court must presume that it has the minimal resources required to carry[]out the statute.

Id. at 116.

from participation in all cases under the Program until such time as circumstances permitted.[158] Moreover, the government announced that neither the Department of Justice nor the Department of Health and Human Services would henceforth be designating attorneys to participate in the proceedings.[159] In the face of the Court of Claims' refusal to suspend proceedings, appearances by the government in resolving petitions filed under the Program have been sporadic at best.[160]

2. The Resolution of Petitions for Compensation Under the Program: The Raw Data

Notwithstanding the Department of Justice's unwillingness or inability to participate fully in the administration of the Program, the Court of Claims has continued to process petitions for compensation. This Section provides data from the first year of awards under the Program.[161] The information presented here was processed from all reported cases under the Program during a period dating from the first decision by the Court of Claims in April 1989 through March 1990.[162]

Total Number of Claimants Under the Program	81
Number of Reported Resolved Crimes	79
Number of Claimants Awarded Compensation Under the Program	69
Number of Successful Claimants Receiving Flat $250,000 Award for Death of Vaccinee	45
Number of Successful Claimants Receiving	

158. *Id.* at 117.

159. *Id.*

160. The government has not eliminated its participation in the proceedings altogether. In a relatively small number of petitions, the government has appeared before the Claims Court to contest the Special Master's findings and recommendation of award. *See, e.g.*, Davis v. Secretary of Dep't of Health & Human Servs., 19 Cl. Ct. 395 (1990) (government objected to Special Master's determination of petitioner's unreimbursable future medical and rehabilitative expenses).

161. Given the start-up times inherent in any government program of this magnitude, the time period examined by this paper was chosen based on the theory that the first year of actual awards under the Program would provide a more accurate gauge of its functioning rather than consideration of the Program's first year of actual operation.

162. The data presented in this Section are derived from cases located by the authors through computerized searches on LEXIS and WESTLAW databases. Where cases have proceeded through a number of stages of litigation, only the final awards have been processed.

Awards for Injuries Other than Death	24	
Number of Claimants Denied Compensation Under the Program	10	
Number of Claimants Awarded Attorneys' Fees & Costs	77	
Number of Claimants Denied Attorneys' Fees & Costs	2	
Total Compensation Awarded Under the Program		$40,637,410.49[163]
Total Compensation Awarded to Claimants		$38,895,056.19
Avg. Compensation Awarded to Successful Claimants		$563,696.47
Avg. Compensation Awarded to Successful Claimants Not Receiving Flat $250,000 Award for Death of Vaccinee		$1,162,294.01
Total Awards of Attorneys' Fees & Costs		$1,742,354.30
Average Award of Attorneys' Fees & Costs		$22,627.98

IV. THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION PROGRAM: ESTABLISHING AN EVALUATIVE FRAMEWORK

As indicated previously, in implementing the Program, Congress sought to pursue the dual purpose of protecting vaccine manufacturers from potentially crushing liability and providing swift no-fault compensation for those victims suffering unavoidable vaccine-related injuries. This Part examines the efficacy of the Program as a mechanism for the achievement of each of these goals.

A. The Program as Shield Against Manufacturer Liability for Unavoidable Vaccine-Related Injuries

In the first year of the Program's operation, no petitioner under the Program has elected to pursue his or her possible common law remedies in a civil suit against a vaccine manufacturer. This reversal of a

163. This figure does *not* take into account cases where the Claims Court has awarded attorneys' fees, but has not specified the amount being awarded. *See, e.g.*, Badman v. Secretary of the Dep't of Health & Human Servs., No. 89-89v (Cl. Ct. March 19, 1990) (LEXIS, Genfed library, Courts file). Accordingly, the actual figure is likely somewhat higher.

trend toward increasing litigation over vaccine-related injuries prior to the Act's passage[164] is undoubtedly due to the barriers to such suits erected under the Program.[165] Accordingly, the evidence suggests that during the first year of awards the Program has initially succeeded in protecting vaccine manufacturers from potentially crushing liability.

It remains an open question, however, whether this result ultimately will continue. This Section examines a number of possible avenues whereby a plaintiff suffering an unavoidable vaccine-related injury may seek to evade the Act's restrictions on common law suits to secure greater awards than those possible under the Program's no-fault compensatory mechanism. The Section concludes that such efforts are likely to fail. As a result, the Program's success on this score thus far will probably continue into the future.

1. Apparent Availability of the Learned Intermediary Doctrine

Although the Act eliminated manufacturer liability under common law for failure to provide warnings directly to the vaccinee, it did not expressly effect a similar result with respect to manufacturer liability for failure to provide warnings to "learned intermediaries"[166] such as the administering physician. As a result of the Program's dissimilar treatment of the two doctrines, an argument exists that the risk of crushing manufacturer liability that prompted the Act's passage continues to pose a threat to the nation's vaccine supply. Accordingly, one student commentator has proposed that the Program be amended to eliminate manufacturer liability for failure to warn under *any* theory.[167]

Notwithstanding the arguments for such an amendment, this action is unnecessary. Rather than serving as an avenue of compensation for victims of vaccine-related injuries, the learned intermediary doctrine was developed by courts as a *bar* to recovery by plaintiffs proceeding under the *Davis* theory of liability.[168] Given that the doctrine, as judicially articulated, required only that manufacturers communicate the inherent dangers of their products to the administering health care professional, the issue in cases such as *Johnson* revolved around the

164. *See supra* text accompanying note 126.

165. *See supra* notes 152-53 and accompanying text.

166. *See* Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149 (1988). "Retaining this cause of action only continues to create uncertainty for manufacturers . . . . The continued threat of litigation, even where recovery is unlikely, may induce manufacturers to continue to withdraw from vaccine production." *Id.* at 165.

167. *Id.*

168. *Id.* at 154.

sufficiency of the warning included in the vaccine's packaging.[169]

Whether such an issue exists under the Act, however, is doubtful. Before placing their products on the market, vaccine manufacturers must comply with rigorous federal regulations including those requiring the approval from the FDA of warning labels attached to the vaccine's packaging.[170] Although compliance with these regulations did not shield manufacturers from liability in pre-Act litigation,[171] 42 U.S.C. §300aa-22(b)(2) now provides that "a vaccine shall be presumed to be accompanied by proper warnings if the manufacturer . . . complied in all material respects with all [federal] requirements."[172] Accordingly, vaccines placed on the market in compliance with federal labeling requirements apparently satisfy the required standard of sufficiency under the learned intermediary doctrine. Notwithstanding the apparent availability of the learned intermediary doctrine, therefore, recovery under it is ultimately foreclosed.[173]

2. Constitutional Challenges to the Program

Given the relative unavailability of state common law suits under the Program, it is possible that would-be petitioners ineligible for com-

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169. *Id.*

170. Johnson v. American Cyanamid Co., 239 Kan. 279, 289, 718 P.2d at 1318, 1326 (1986). In *Johnson*, the government-approved warning read as follows:

ADVERSE REACTIONS

Individual patients have at times attributed symptoms or conditions to the vaccine by reason of time relationship, but these in general have been minor and apparently unrelated.

Expert opinion is in agreement that the administration of live oral poliovirus vaccines is generally an effective and safe method of protecting populations against the natural disease. Paralytic disease following the ingestion of live poliovirus vaccines has been reported in individuals receiving the vaccine, and in some instances, in persons who were in close contact with subjects who had been given live oral poliovirus vaccine. Fortunately, such occurrences are rare, but considering the epidemiological evidence developed with respect to the total group of "vaccine-related cases" it is believed by some that at least some of the cases were caused by the vaccine.

The estimated risk of vaccine-induced paralytic disease occurring in vaccinees or those in close contact with vaccinees is extremely low. A total of approximately 30 of such cases were reported for the 8 year period covering 1963 to 1970, during which time about 147,000,000 doses of the vaccine were distributed nationally. Even though this risk is low, it should always be a source of consideration.

Id. at 288, 718 P.2d at 1325 (emphasis omitted). The *Johnson* court held this warning sufficient as a matter of law. *Id.* at 288-90, 718 P.2d at 1326.

171. *See, e.g.*, Abbott v. American Cyanamid Co., 844 F.2d 1108 (4th Cir. 1988) (compliance with applicable FDA regulations did not grant vaccine manufacturer absolute immunity from liability under state common law suits because federal vaccine-labeling laws do not preempt causes of action under state statutes).

172. 42 U.S.C. § 300aa-22(b)(2) (1988).

173. A manufacturer might arguably be liable pursuant to the learned intermediary doctrine if it failed to include warnings altogether. Under the Act, however, this failure would constitute a violation of federal law sufficient to remove manufacturers completely from its protection.

pensation under the guidelines established by the Act may elect instead to proceed against the constitutional validity of the Program itself, in the hopes of removing its restrictions on state law suits.[174] This Section addresses the viability of several potential constitutional challenges to the Program. It concludes that the Program is likely immune from constitutional attack.[175]

a. Equal Protection Challenges

The Program is potentially subject to equal protection challenges[176] by two groups of plaintiffs. First, individuals contracting diseases covered by the Program through contact with wild contagions may contest the Program's different treatment of them as compared with petitioners suffering from vaccine-related injuries. Second, petitioners wishing to pursue common law remedies may object to the heightened evidentiary burdens under the Program not faced by victims of the adverse side effects of other drugs.

Under the Supreme Court's framework for evaluating equal protection challenges, however, challenges by either of these classes of plaintiffs are likely to fail. The Court has to date proven unwilling to recognize a fundamental right to sue under the fourteenth or fifth amendments.[177] Similarly, it has declined to declare petitioners to administrative compensation systems a suspect class.[178] Accordingly, the appropriate standard for evaluating legislative action in the area is not strict scrutiny, but rather a healthy deference: "The constitutional safeguard is offended only if the classification rests on grounds wholly irrelevant to the achievement of the [government's] objective."[179]

The Program easily satisfies this standard. Removal of plaintiffs from the tort system through limitations on the ability of vaccine victims to sue manufacturers at common law is rationally connected to

174. As noted earlier, the United States Supreme Court upheld mandatory immunization programs against a constitutional challenge in Jacobson v. Massachusetts, 197 U.S. 11 (1905). *See generally supra* text accompanying notes 18-20.

175. To date, no constitutional attack has been mounted on the Program.

176. *See* U.S. CONST. amend. V (proscribing federal deprivation of life, liberty, and property without due process of law); Bolling v. Sharpe, 347 U.S. 497 (1954) (incorporating fourteenth amendment equal protection methodology into fifth amendment's due process clause).

177. *See, e.g.*, Loving v. Virginia, 388 U.S. 1 (1967) (generally discussing fundamental rights).

178. *See, e.g., Id.* at 9 (generally discussing suspect classes).

179. McGowan v. Maryland, 366 U.S. 420, 425 (1961); *see also* New Orleans v. Dukes, 427 U.S. 297, 303 (1976) ("[T]his Court consistently defers to legislative determinations as to the desirability of particular statutory discriminations."); Lindsley v. Natural Carbonic Gas Co., 220 U.S. 61, 78 (1911) ("classification not having some reasonable basis does not offend [the equal protection] clause merely because it is not made with mathematical nicety or because in practice it results in some inequality.

protection of the nation's vaccine supply. Similarly, restricting eligibility for benefits under the Program to those individuals actually participating in mandatory state vaccination programs is directly related to the financial viability of the Program. Accordingly, equal protection challenges to the Program are unlikely to succeed.

b. Seventh Amendment Challenges

Like equal protection challenges, attacks on seventh amendment grounds against programs such as those established by the Act have also failed.[180] In sustaining the constitutionality of a no-fault program in the related context of workers' compensation, the Supreme Court observed in *Mountain Timber Co. v. Washington:*

> It is conceded that the [seventh amendment's provision of a right to trial by jury] has no reference to proceedings in the state courts, but it is urged that the question is material for the reason that if the act be constitutional, it must be allowed in the federal courts in cases that are within its provisions. So far as private rights of action are preserved, this is no doubt true; but with respect to these we find nothing in the act that excludes a trial by jury. As between employee and employer, the act abolishes all right of recovery in ordinary cases, and therefore leaves nothing to be tried by jury.[181]

An application of this standard to the Program reveals that any seventh amendment challenge which claims the right to jury trial will prove unsuccessful. As is the case with workers' compensation statutes, the Program allows the right to a jury trial under limited circumstances, namely where recovery is sought for avoidable vaccine-related injuries.[182] Under the rationale of *Mountain Timber,* Congressional abrogation of potential plaintiffs' causes of action for failure to warn leaves nothing to be tried by a jury, and thereby obviates the need for an evaluation of the Program's compatibility with the seventh amendment.[183]

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180. *See, e.g.,* Mountain Timber Co. v. Washington, 243 U.S. 219 (1917).

181. *Id.* at 235; *cf.* Crowell v. Benson, 285 U.S. 22 (1932) (upholding federal scheme providing compensation for injuries occurring on navigable waters using administrative method not applying technical rules of evidence and procedure in determining issues of fact).

182. *Compare, e.g., Mountain Timber,* 243 U.S. at 235 *with* 42 U.S.C. §§ 300aa-1 to 33 (1988) (National Childhood Vaccine Injury Act of 1986).

183. *Cf.* New York Cent. R.R. v. White, 243 U.S. 188, 201-02 (1917). The court in sustaining New York's workers' compensation law stated:

> The statute under consideration sets aside one body of rules only to establish another system in its place. If the employee is no longer able to recover as much as before in case of being injured through the employer's negligence, he is entitled to moderate compensation in all cases of injury, and has a certain and speedy remedy without the difficulty and expense of establishing negligence or proving the amount of the damages. . . . [I]n such an adjustment, the particular rules of the common law affecting the subject-matter are not

c. Substantive Due Process Challenges

The Program is likewise immune from attack on substantive due process grounds. Pursuant to the Court's doctrine in the post-*Lochner v. New York*[184] era, "[l]egislative bodies have broad scope to experiment with economic problems,"[185] and the Court will not subject such bodies " 'to an intolerable supervision hostile to the basic principles of our Government and wholly beyond the protection which the [due process clauses were] intended to secure.' "[186] Accordingly, "legislative [a]cts adjusting the burdens and benefits of economic life come . . . with a presumption of constitutionality, and . . . the burden is on one complaining of a due process violation to establish that the legislature has acted in an arbitrary and irrational way."[187]

As was the case for seventh amendment challenges to no-fault programs, *Mountain Timber* also provides the relevant inquiry for evaluating substantive due process challenges.[188] Pursuant to that decision, a

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> placed by [constitutional due process considerations] beyond the lawmaking power of the [government].

Id.

184. 198 U.S. 45 (1905) (recognizing due process right to freedom of contract).

185. Ferguson v. Skrupa, 372 U.S. 726, 730 (1963) (*quoting* Sproles v. Binford, 286 U.S. 374, 388 (1932)).

186. *Id.*

As the Court has observed of its evolving doctrine:

> Under the system of government created by our Constitution, it is up to legislatures, not courts, to decide on the wisdom and utility of legislation. There was a time when the Due Process Clause was used by this Court to strike down laws which were thought unreasonable, that is, unwise or incompatible with some economic or social philosophy. In this manner the Due Process Clause was used, for example, to nullify laws proscribing maximum hours for work in bakeries, outlawing yellow dog contracts, setting minimum wages for women, and fixing the weight of loaves of bread . . . .
>
> The doctrine that prevailed in [these] cases — that due process authorizes courts to hold laws unconstitutional when they believe that the legislature has acted unwisely — has long since been discarded. We have returned to the original constitutional proposition that courts do not substitute their economic and social beliefs for the judgment of legislative bodies, who are elected to pass laws.

Id. at 729-30 (citations omitted).

187. Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 15 (1976); *see also* Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59, 83 (1978) (upholding federal limits on liability for accidents at federally licensed power plants as valid economic regulation designed to "structure and accommodate 'the burdens and benefits of economic life' ") (*quoting Usery*, 428 U.S. at 15); *cf.* Tyson & Brother v. Banton, 273 U.S. 418, 445-46 (1927) (Holmes, J., dissenting). Justice Holmes stated in his dissent in *Tyson*:

> I think the proper course is to recognize that a state legislature can do whatever it sees fit to do unless it is restrained by some express prohibition in the Constitution of the United States or of the State, and that courts should be careful not to extend such prohibitions beyond their obvious meaning by reading into them conceptions of public policy that the particular court may happen to entertain.

Id. at 446.

court examining the constitutionality of economic statutes must ask:

> (1) Whether the main object of the legislation is, or reasonably may be deemed to be, of general and public moment[;] (2) [w]hether the charges imposed [to finance the program] are reasonable in amount, or, on the other hand, so burdensome as to be manifestly oppressive[; and] (3) whether the burden is fairly distributed, having regard to the causes that give rise to the need for the legislation.[189]

Under this standard, the Program clearly passes constitutional muster. It directly addresses the crisis in the nation's vaccine supply that led to its passage, thereby fulfilling the first *Mountain Timber* criterion. Similarly, excise taxes of the sort employed by Congress to finance the program have withstood constitutional scrutiny in other contexts, thereby satisfying the second prong.[190] Finally, application of the tax to the manufacture of the vaccine allocates the cost of supporting the Program to its beneficiaries, namely the vaccinated American public, thereby fairly distributing the burdens associated with it.[191] Accordingly, under existing law, courts are likely to view any substantive due process challenges to the Program with a jaundiced judicial eye.

B. The Program as a Mechanism for Compensating Victims of Vaccine-Related Injuries

As detailed in Part III, Section B, petitioners under the Program enjoyed an eighty-seven percent success rate in securing compensation for vaccine-related injuries during the first year of awards.[192] Rather than negotiating the common law of fifty jurisdictions, petitioners now face only relatively routine procedural requirements satisfied through the expense of attorney fees and costs averaging only $22,627.98 per case. These fees are reimbursable from the government and, in any case, are far less than the typical one-third recovery contingency fee taken out of plaintiffs' awards under the old common law tort system. These figures indicate that the Program is currently achieving its goal of providing swift and effective compensation for those falling within its terms, thus allowing them to escape the frustrations of the common law tort system.

This conclusion begs the question, however, of whether the definition of eligible petitioners established under the Program is an appro-

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189. *Id.* at 238.

190. *See, e.g.*, United States v. Butler, 297 U.S. 1 (1936) (upholding excise tax implemented by provisions of the Agricultural Adjustment Act).

191. *Cf. id.* at 58.

192. This relatively high success rate may be related to the failure of the Department of Justice or Department of Health and Human Services to participate fully in the petition process. *See supra* notes 157-160 and accompanying text.

priate one. Given the lenient standard of scrutiny likely to be applied to the Program in any equal protection challenge,[193] it is clear that Congress can constitutionally draw virtually any lines it chooses in its delineation of which individuals are eligible for compensation. Whether or not the lines drawn in this instance serve to further the purposes of the Program is another matter.

Wiggins v. Secretary of the Department of Health & Human Services[194] illustrates one area in particular where the Program might benefit from a redefinition of eligibility. There, Michael Wiggins suffered severe neurological damage when he was inoculated with the second in a series of three DPT vaccinations. Because the vaccines had been manufactured by the Michigan Department of Public Health, Shirley Wiggins' common law suit in the Michigan courts against the producer on behalf of her son was dismissed on the grounds of governmental immunity.[195] She settled a tort law claim against the physician for an amount far below full satisfaction of her son's damages.[196]

Upon the implementation of the Program, Shirley Wiggins filed a petition with the Court of Claims seeking compensation for her son's future medical expenses. The Special Master, however, dismissed her claim, citing the previous settlement as disqualifying the petition from eligibility under the Program.[197] The Court of Claims, although acknowledging that the result appeared "harsh and dispassionate," upheld the Special Master's finding,[198] thereby denying compensation for Michael Wiggins' vaccine-related injuries in a decision affirmed by the Federal Circuit on appeal.[199]

The holding in *Wiggins* is certainly a correct interpretation of the statutory requirements established by the Act governing eligibility for compensation under the Program. It is doubtless immune from attack on constitutional grounds as well.[200] Yet the result is nonetheless inconsistent with expectations of how individuals such as Shirley Wiggins may reasonably respond to the tragedy of a serious vaccine-related injury. By presumptively eliminating all possible recovery in cases of settlement or recovery in common law suits, the Program rewards those individuals who failed to pursue their legal rights prior to the Act's passage. In contrast, those individuals who did act to secure compensa-

193. *See supra* text accompanying notes 176-179.
194. 17 Cl. Ct. 551 (1989), *aff'd*, 898 F.2d 1572 (Fed. Cir. 1990).
195. *Id.* at 551-52.
196. *Id.*
197. *Id.* at 558.
198. *Id.*
199. *See* Wiggins v. Secretary of Health & Human Servs., 898 F2d 1572 (Fed. Cir. 1990).
200. *See supra* notes 174-191 and accompanying text.

tion before the Program's effective date become victims of their own diligence.

As with any government benefits program, lines of eligibility must be drawn somewhere in order to sustain financial viability. There is something unjust, however, with lines that require potential plaintiffs considering common law suits to correctly anticipate future congressional action in the field that might ultimately harm their chances for adequate recovery should they begin litigation at the time of the injury. Such a rule harms lower-income victims and those who were otherwise financially unable to delay seeking compensation.[201]

Accordingly, a more equitable rule would permit those petitioners who recovered compensation through either judicially-ordered damages or settlement agreements prior to the Act's passage to petition for a limited recovery under the Program. This limited recovery should be sufficient to make up the difference between the earlier recovery and the amount the petitioner would ordinarily be entitled to under the Program. Such a rule, by restricting recovery to those petitioners seeking compensation before the Act's passage, would not reward speculation by petitioners seeking to recover from both the tort system and the no-fault mechanism established by the Program.[202] In doing so, however, this modification would avoid the anomaly of offering otherwise similarly situated vaccine victims significantly differing treatment based only on their initial legal response to the injury.[203]

V. CONCLUSION

As enacted, the Program has achieved remarkable success in pur-

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201. *Cf.* J. O'CONNELL & B. KELLY, *supra* note 125, at 126 ("[I]njured persons, with mounting medical expenses and wage losses, are often pressured into settling their cases with a tremendous discount against the delay a jury trial would entail.").

202. In *Wiggins*, it is unclear whether the petitioners actually fell into this category. At the time of their settlement with the administering physician, the Act, which had been passed but not funded, did not bar from compensation those petitioners who had recovered damages from administrators. 17 Cl. Ct. at 554. Subsequent to the settlement, however, Congress amended the Act to bar petitioners such as the Wiggins family who had recovered from any source. *Id.*

203. There are no constitutional barriers to use of the Program to compensate victims injured prior to the Act's passage. *See* Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 18-19 (1976). The Court upheld, as against constitutional challenge, a federal compensation program using taxes applied to coal mine owners and consumers to provide compensation for injuries occurring prior to the passage of governing legislation. *Id.* at 19-20.

> We find . . . that the imposition of liability for the effects of disabilities bred in the past is justified as a rational measure to spread the costs of the employees' disabilities to those who have profited from the fruits of their labor — the operators and the coal consumers. . . . It is enough to say that the Act approaches the problem of cost spreading rationally; whether a broader cost-spreading scheme would have been wiser or more practical under the circumstances is not a question of constitutional dimension.

Id. at 18-19.

suing the dual congressional goals of providing effective, no-fault compensation to victims of vaccine-related injuries while at the same time protecting vaccine manufacturers from potentially crushing liability for unavoidable injuries. Although this article has advocated increasing the scope of potential petitioners eligible for compensation, it is clear that victims already falling within the scope of the Program enjoy a high rate of recovery with little of the procedural and financial barriers characteristic of tort litigation prior to its establishment. Similarly, the higher evidentiary burdens faced by plaintiffs proceeding outside of the Program have resulted in the complete absence to date of new actions against manufacturers, thereby diminishing the vaccine supply crisis existing in 1986.

In light of this success, whether the Program provides a useful blueprint for similar product liability reform proposals is unclear. In contrast to use of other pharmaceutical products, exposure to vaccines is mandated by state law. Because all of society benefits from the salutary results of these vaccination programs, it is appropriate that society as a whole incur the costs when their administration would otherwise result in a small number of individuals bearing a disproportionate share.

Similarly, the nature of the injuries compensable under the Program lend themselves particularly well to the establishment of a no-fault mechanism. Given the relative infrequency of wild contagions for the diseases addressed by the Program, the chances of a vaccinee coming into contact with one immediately following vaccination are sufficiently remote as to justify the Program's presumption that any injuries incurred within the applicable "window of opportunity" are the result of vaccination and not natural infection. Vaccine-related injuries thus feature a clearly identifiable "trigger" that is not a characteristic feature of adverse side effects arguably caused by the administration of other drugs and medicines.

These factors suggest that the Program is best viewed as a reform peculiarly suited to the crisis it addresses. Nevertheless, the Program offers a useful demonstration of how effective innovative tort reform proposals in the drug and medicine field can be if carefully designed and tailored to specific problems. Although the Program's wholesale extension to other drugs and medicines is probably ill-advised, it presents a cogent starting point for consideration of other legislative proposals aimed at modifying the existing common law regime as applied to this area.