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Faye F. Spence

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NOTES

ALTERNATIVES TO MANUFACTURER LIABILITY FOR INJURIES CAUSED BY THE SABIN-TYPE ORAL POLIO VACCINES

Fewer than fifty years ago, the spread of poliomyelitis was a major health crisis in the United States.¹ When research scientists finally developed an effective vaccine against the dreadful disease,² public health officials and society at large viewed the discovery as a modern miracle. Unfortunately, however, the long-awaited vaccine has brought serious illness to a small number of its recipients.³ In order to compensate these victims, many courts have imposed legal liability on the vaccine manufacturers.⁴ This judicial response raises serious competing policy concerns⁵ which Congress recently tried to resolve with legislation intended to compensate injured vaccine recipients without compromising the effectiveness of public health programs.⁶

This Note examines the legal dilemma which led to the current legislative proposal. The Note presents background information on

1. See *infra* text accompanying notes 7-10.

2. See *infra* text accompanying notes 12-14.

3. See *infra* text accompanying notes 26-30.

4. *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Fraley v. American Cyanamid Co.*, 589 F. Supp. 826 (D. Colo. 1984); *Williams v. Lederle Laboratories*, 591 F. Supp. 381 (S.D. Ohio 1984); *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969); *Stahlheber v. American Cyanamid Co.*, 451 S.W.2d 48 (Mo. 1970). *Contra* *Berry v. American Cyanamid Co.*, 341 F.2d 14 (6th Cir. 1965); *Sheehan v. Pima County*, 135 Ariz. 235, 660 P.2d 486 (Ct. App. 1982); *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985); *Johnson v. American Cyanamid Co.*, 239 Kan. 279, 718 P.2d 1318 (1986); *Dunn v. Lederle Laboratories*, 121 Mich. App. 73, 328 N.W.2d 576 (1982); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377 (Okla. 1975).

5. See *infra* text accompanying notes 175-96.

6. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). For a brief discussion and comment on the Act, see *infra* notes 197-210 and accompanying text.

poliomyelitis and its vaccines and analyzes the legal theories under which courts have allowed injured vaccine recipients to recover from manufacturers. After discussing the competing policy concerns these cases raise, the Note considers alternative solutions to the problem, including the recently enacted legislation. The Note concludes that courts should not impose liability on the manufacturers of these properly produced vaccines, but that the public treasury instead should bear the cost of compensating those few individual victims of vaccination programs that benefit the vast majority of their recipients.

POLIOMYELITIS AND THE POLIO VACCINES

Poliomyelitis was once a devastating disease in this country, crippling and killing thousands of children each year. In 1952 alone, polio struck 57,879 people, permanently paralyzing 21,296 victims.⁷ Scientists were unable to pinpoint the source of the incurable disease until 1950, when they discovered that polio is caused by a highly contagious virus that enters the body through the mouth and attacks the intestinal tract.⁸ More than eighty percent of the population acquires a natural immunity to the disease,⁹ but when polio strikes a vulnerable individual the virus spreads from the intestines to the spinal column, causing damage to the nervous system and muscular paralysis.¹⁰

In contrast to the innumerable varieties found in most viruses, only three variations of the polio virus exist—Type I, Type II, and Type III.¹¹ Combatting the illness, therefore, requires only three variants of vaccine. Dr. Jonas Salk developed the first set of effective vaccines by chemically killing samples of each cultured virus type and injecting the dead virus into a human body. The presence of the dead virus stimulates the production of antibodies which

7. *Reyes v. Wyeth Laboratories*, 489 F.2d 1264, 1269 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

8. *Id.* at 1295.

9. Note, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235, 237 (1976).

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

11. Note, *supra* note 9, at 237 n.18 (citing Sabin, *Oral Poliovirus Vaccine*, 194 J.A.M.A. 872, 873 (1965)).

fight off any polio virus that subsequently enters the body.¹² After the United States government and research groups thoroughly tested the Salk vaccines and found them to be completely safe,¹³ manufacturers marketed these medications in 1955. Vaccinees then received three initial shots, one for each type of virus, and "booster shots" every few years.¹⁴

Later in the 1950s, Dr. Albert Sabin developed the oral polio vaccine, consisting of *live* but weakened virus particles.¹⁵ After thorough government testing, licensed manufacturers marketed Sabin-type oral vaccines in 1960.¹⁶ The Division of Biologic Standards, a branch of the Department of Health and Human Services, continues to test each lot of oral polio vaccine before manufacturers market the drug.¹⁷

Testing has demonstrated that the Sabin-type vaccine is more effective than the Salk vaccine¹⁸ mainly because the oral dose actually immunizes the recipient's intestinal tract, where the virus normally breeds.¹⁹ The oral vaccine also protects unvaccinated persons by suppressing the full-strength virus—wild virus—which otherwise could spread throughout the community.²⁰ The lack of need for syringes or followup treatments also makes the oral vaccine

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

13. The Salk vaccine is completely safe only when properly manufactured. A well-publicized manufacturing accident, in which live virus inadvertently remained in the killed-virus vaccine, occurred in *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960).

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

15. *Id.*

16. Note, *supra* note 9, at 238.

17. *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 123 (9th Cir. 1968). The extensive regulations pertaining to oral polio vaccines are codified in 21 C.F.R. §§ 630.10-.17 (1986). Manufacturing or selling the vaccine in violation of these regulations is a crime. 42 U.S.C. § 262 (1982).

18. Until recently, Finland and Sweden used the Salk vaccine exclusively. Between October 1984 and January 1985, however, five people in Finland became infected with polio. Two of these victims had received *five* previous Salk vaccine injections. These incidents forced the Finnish government to reevaluate the effectiveness of the Salk-type vaccines. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 818 n.1, 218 Cal. Rptr. 453, 455 n.1 (1985).

19. *Griffin v. United States*, 351 F. Supp. 10, 24 (E.D. Pa. 1972), *modified*, 500 F.2d 1059 (3d Cir. 1974).

20. Boffey, *Polio: Salk Challenges Safety of Sabin's Live-Virus Vaccine*, 196 SCIENCE 35 (1977). *But see id.* (contact with recent vaccinee may cause contraction of the disease); *see also infra* note 30 and accompanying text.

easier and less expensive to administer. This simplicity makes the vaccine more useful in mass immunization programs.²¹ Finally, the oral polio vaccine is available in trivalent form, which means that a single dose vaccinates against all three types of polio.²² For these reasons, the United States Public Health Service and all interested medical advisory organizations prefer the Sabin oral polio vaccine over the Salk—killed virus—vaccine.²³ Consequently, American manufacturers have stopped producing the Salk vaccine; it has been unavailable commercially in the United States since 1968.²⁴

The mass immunization campaigns launched after the development of these vaccines have been very successful; in 1970, for example, physicians diagnosed only thirty-three cases of polio.²⁵ Two years after the marketing of Sabin-type vaccines, however, the Public Health Service noticed that a small number of people contracted the disease within thirty days of receiving the oral vaccine.²⁶ The service responded by establishing an advisory committee to study these incidents. In 1964, the committee published a report concluding that investigators could not link conclusively any individual case of polio to the vaccine,²⁷ but the committee still believed that a causal connection existed between the vaccine and some cases of polio.²⁸ The estimated risk of contracting polio directly from an oral vaccine is one chance in 11.5 million distributed doses.²⁹ Scientists also believe that unvaccinated people may be capable of contracting the disease from contact with a recent vac-

21. Note, *supra* note 9, at 238.

22. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1296 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

23. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 818, 218 Cal. Rptr. 453, 455 (1985).

24. Franklin & Mais, *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes*, 65 CAL. L. REV. 754, 761 (1977).

25. *Reyes*, 498 F.2d at 1269-70. Part of the campaign against polio included the passage of state laws requiring children to be vaccinated before attending school. See *infra* note 151 and accompanying text.

26. Note, *supra* note 9, at 239.

27. SPECIAL ADVISORY COMMITTEE ON ORAL POLIOMYELITIS VACCINE, REPORT TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 5 (1964).

28. *Id.* at 4.

29. Boffey, *supra* note 20, at 35. The risk varies depending on the type of polio involved. The vaccine against virus Type III poses the highest risk—approximately 1 chance per 1 million doses—but the risk to adults is greater than the risk to children. *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 124 (9th Cir. 1968).

cinee; when contact polio victims are included in the statistics, the total risk of vaccine-related illness is close to one chance in 2.5 million doses.³⁰ After courts began imposing liability on manufacturers for these alleged vaccine-related injuries,³¹ manufacturers began warning physicians of the risks associated with Sabin-type vaccines.³²

30. Boffey, *supra* note 20, at 35.

31. *E.g.*, *Davis*, 399 F.2d at 131; *Stahlheber v. American Cyanamid Co.*, 451 S.W.2d 48 (Mo. 1970).

32. The major reference manual on pharmaceutical products contains the following warning on Orimune, the most popular Sabin-type vaccine currently used:

Adverse Reactions: Paralytic disease following the ingestion of live poliovirus vaccines has been, on rare occasion, reported in individuals receiving the vaccine, . . . and in persons who were in close contact with 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 ingestion of the vaccine or contact with a recent vaccinee are based on epidemiological analysis and temporal association between vaccination or contact and onset of symptoms. Most authorities believe that a causal relationship exists.

The risk of vaccine-associated paralysis is extremely small for vaccinees, susceptible family members, and other close personal contacts . . . [D]uring the years 1969 through 1980 approximately 290 million doses of [oral polio vaccine] were distributed in the United States. In the same 12 years, 25 "vaccine-associated" and 55 "contact vaccine-associated" paralytic cases were reported.

PHYSICIANS DESK REFERENCE 1023 (40th ed. 1986) (footnote omitted). The warning also advises doctors to warn patients about these risks and recommends Salk-type vaccine as an alternate or introductory vaccine. *Id.* The same information appears on the package inserts accompanying each lot of vaccine sold to doctors, pharmacists, and clinics. *Williams v. Lederle Laboratories*, 591 F. Supp. 381, 384 (S.D. Ohio 1984). Furthermore, at mass immunization clinics, vaccine recipients or their guardians sign consent forms containing the following similar warning:

IMPORTANT INFORMATION ABOUT POLIO AND POLIO VACCINE.

Please read this carefully. [The risk of contracting polio is very low] even for someone who is not vaccinated . . . [Oral polio vaccine is] one of the best ways to prevent polio . . .

POSSIBLE SIDE EFFECTS FROM THE VACCINE: Oral live polio vaccine rarely produces side effects. However, once in about every 4 million vaccinations, persons who have been vaccinated or who come in close contact with those who have recently been vaccinated are permanently crippled and may die. Even though these risks are very low, they should be recognized. The risk of side effects from the vaccine must be balanced against the risk of the disease, both now and in the future.

. . . Besides the oral polio vaccine, there is also a killed polio vaccine given by injection which protects against polio after several shots. It has no known risk of causing paralysis. Most experts do not feel it is as effective as the oral vaccine for controlling polio in the United States. It is recommended for persons needing polio vaccination who have low resistance to infections (or those

THEORIES OF RECOVERY

Parties seeking damages from a manufacturer for injuries caused by its product have three alternative theories of recovery: negligence, breach of warranty—express or implied, and strict liability in tort.³³ In cases involving vaccine-induced polio or contact polio, most plaintiffs have proceeded under strict liability in tort,³⁴ but courts have allowed recovery for vaccine-related injuries under all three theories.

Negligence

Courts impose negligence liability on manufacturers who cause foreseeable harm by marketing a product without exercising reasonable care under the circumstances.³⁵ A manufacturer's negligence may involve either marketing a flawed product—one that is different from the product intended—or failing to warn about the product's inherent risks.³⁶ Sabin-type oral polio vaccines are not flawed products; they are exactly what the manufacturer intended.³⁷ Any negligence liability imposed on the manufacturers of Sabin-type vaccines, therefore, must arise from a negligent failure to warn.

The crux of negligence is foreseeability; thus, a manufacturer's duty to warn extends only to risks that are known or that should be known in the exercise of ordinary care—constructively known

who live with them) and for unprotected adults traveling to a place where polio is common. It is not widely used in this country at the present time, but it is available. If you would like to know more about this type of polio vaccine, please ask us.

Kearl v. Lederle Laboratories, 172 Cal. App. 3d 812, 819, 218 Cal. Rptr. 453, 456 (1985).

33. W. PROSSER & W. KEETON, THE LAW OF TORTS § 96, at 683-84 (1984).

34. See *infra* notes 59-173 and accompanying text.

35. W. PROSSER & W. KEETON, *supra* note 33, § 96, at 683-84.

36. *Id.* at 685.

37. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1273 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974). The court stated:

Wyeth Vaccine Lot No. 15509 was exactly what its makers . . . intended it to be: trivalent live-virus Sabin oral polio vaccine. The live virus which the jury concluded caused Anita's poliomyelitis was not inadvertently included in the mixture. Indeed, it is the presence of the living but attenuated Type I, II, and III viruses which makes the Sabin vaccine so effective

Id. (footnote omitted).

risks.³⁸ In *Stahlheber v. American Cyanamid Co.*,³⁹ the Supreme Court of Missouri upheld a jury verdict against the manufacturer of a Sabin-type vaccine for negligent failure to warn. The manufacturer admitted that no warning had been given at all.⁴⁰ The court stated that the manufacturer should have known the vaccine might cause polio because of information contained in the Advisory Committee Report to the Surgeon General.⁴¹ Because the manufacturer knew of the risk, at least constructively, it should have warned about the foreseeable danger.⁴²

Stahlheber differs from the more recent vaccine-induced polio cases because manufacturers now give physicians and vaccinees some warning about the dangers of oral polio vaccines.⁴³ A manufacturing company may nevertheless violate its duty to warn of known or constructively known risks by giving an inadequate warning; an inadequate warning may be too vague or may not be calculated to reach those people to whom harm is reasonably foreseeable.⁴⁴ Courts determine the adequacy of a warning under negligence standards in the same manner as they do under the strict liability theory:

[I]n all warning cases—even if the plaintiff or the court claims to analyze failure to warn or inadequacy of warning in the context of a strict products liability claim—the tests actually applied condition liability on the defendant's having actually or constructively known of the risk that triggers the warning.⁴⁵

Because of this similarity, the adequacy-of-warning issue is analyzed in the discussion of strict liability.⁴⁶

38. Comment, *Foreseeability in Product Design and Duty to Warn Cases—Distinctions and Misconceptions*, 1968 WIS. L. REV. 228, 229, 240-41.

39. 451 S.W.2d 48 (Mo. 1970).

40. *Id.* at 59.

41. *Id.* at 58.

42. *Id.*

43. See *supra* note 32 and accompanying text.

44. W. PROSSER & W. KEETON, *supra* note 33, § 96, at 685.

45. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 832, 218 Cal. Rptr. 453, 465-66 (1985).

46. See *infra* notes 97-122 and accompanying text.

Breach of Warranty

A manufacturer's warranty may be either express or implied. An express warranty exists when the manufacturer makes a promise or a statement of fact about the quality of certain goods, and the statement becomes part of the basis of the bargain.⁴⁷ If the goods are not the same quality as the manufacturer has promised, the manufacturer has breached the express warranty. The breach occurs even if the manufacturer's misrepresentation was made in good faith and without actual or constructive knowledge of the true quality of the goods.⁴⁸

In *Grinnell v. Charles Pfizer & Co.*,⁴⁹ the California Court of Appeals upheld a jury's determination that the manufacturer of a polio vaccine breached its express warranty.⁵⁰ The package insert accompanying the subject vaccine stated that "there are no known contraindications to oral polio virus vaccines."⁵¹ The court held that the statement was an express warranty because consumers reasonably rely on the superior knowledge of pharmaceutical manufacturers.⁵² The fact that the plaintiff developed polio therefore constituted a breach of this warranty.⁵³

Grinnell differs from more recent cases because manufacturers no longer expressly represent oral polio vaccines to be harmless.⁵⁴ Even in the absence of such representations, however, the law may impose certain implied warranties on manufacturers.⁵⁵ Subject to certain defenses,⁵⁶ a manufacturer is liable for breach of an implied

47. U.C.C. § 2-313 (1978).

48. *Mary Pickford Co. v. Bayly Bros., Inc.*, 12 Cal. 2d 501, 510, 86 P.2d 102, 111 (1939).

49. 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969).

50. *Id.* at 441-42, 79 Cal. Rptr. at 379.

51. *Id.* at 439, 79 Cal. Rptr. at 377.

52. *Id.* at 440, 79 Cal. Rptr. at 378.

53. *Id.* at 441-42, 79 Cal. Rptr. at 379.

54. *See supra* note 32 and accompanying text.

55. Under the implied warranty of merchantability, a manufacturer implicitly promises that the product is reasonably fit for the ordinary purposes for which such products are used. U.C.C. § 2-314 (1978). When the manufacturer knows the buyer's purpose and knows that the buyer is relying on the manufacturer's skill and judgment in furnishing suitable goods, an implied warranty of fitness for a particular purpose arises. *Id.*, § 2-315.

56. Lack of privity is a major defense to breach of warranty actions. In *Berry v. American Cyanamid Co.*, 341 F.2d 14 (6th Cir. 1984), the court denied breach of warranty recovery to an injured polio vaccinee because he lacked privity with the manufacturer. *Id.* at 17. Other

warranty regardless of fault.⁵⁷ Because the theory of strict liability in tort has superseded implied warranty concepts in most jurisdictions, however,⁵⁸ this Note does not discuss the implied warranty theory.

Strict Liability in Tort

The basic theory of strict liability in tort is codified in section 402A of the Second Restatement of Torts, which imposes liability on a seller for injuries caused by products "in a defective condition unreasonably dangerous to the user,"⁵⁹ regardless of the seller's fault.⁶⁰ To prove liability, the plaintiff must prove that the product was defective when it left the seller/manufacturer's control and that the defect proximately caused the plaintiff's injury.⁶¹ Because of the large number of vaccine-induced polio cases decided under strict tort liability principles, this Note analyzes these issues separately.

Defectiveness

Section 402A applies to products "in a defective condition unreasonably dangerous."⁶² The drafters intended "unreasonably

defenses include disclaimer and lack of notice. *Grinnell*, 274 Cal. App. 2d at 443 n.3, 79 Cal. Rptr. at 373 n.3.

57. See, e.g., 274 Cal. App. 2d at 433, 79 Cal. Rptr. at 373.

58. *Id.* at 432, 79 Cal. Rptr. at 373. Further, the court noted that the defenses available in actions for breach of warranty are not available in actions based on strict liability. *Id.* at 433 n.3, 79 Cal. Rptr. at 373 n.3.

59. RESTATEMENT (SECOND) OF TORTS § 402A (1965). The section provides in full:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if:
•(a) the seller is engaged in the business of selling such a product, and
•(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in subsection (1) applies although

•(a) the seller has exercised all possible care in the preparation and sale of his product, and
•(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Id.

60. *Id.* at comment a.

61. Note, *supra* note 9, at 244-45.

62. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

dangerous" to define or modify "defective,"⁶³ but some courts have treated the terms as two separate elements.⁶⁴ One commentator has suggested that "defective" was used to indicate that something must be wrong with the product before strict liability will attach.⁶⁵ This Note, however, considers a "defective" product under section 402A as one more dangerous than a reasonable consumer would expect.

A product may be defective in either manufacturing, design, or warning.⁶⁶ A manufacturing defect exists when some error in the manufacturing process produces a product different in quality from that intended.⁶⁷ As previously mentioned,⁶⁸ however, the Sabin vaccines are exactly what they are supposed to be; they are not the result of any manufacturing error. If the Sabin-type vaccine is to be considered defective, then the defect must be either its design or its warning.

Design Defects

The Sabin oral polio vaccines are "designed" so that weakened live polio virus will enter the body's intestinal tract and stimulate the body's immune system. Unfortunately, this attenuated virus allegedly causes polio in a minute number of recipients.⁶⁹ Because a reasonable recipient would not expect to contract from a vaccine the very disease that he or she sought vaccination against, the Sabin-type vaccine might be considered defectively designed under the traditional definition of defect.

63. *Id.* at comment i; see also Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 32 (1973).

64. *E.g.*, *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 822, 218 Cal. Rptr. 453, 458 (1985).

65. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 830 (1973).

66. *Kearl*, 172 Cal. App. 3d at 821, 218 Cal. Rptr. at 457-58; Note, *supra* note 9, at 245.

67. W. PROSSER & W. KEETON, *supra* note 33, § 99, at 695. For a case involving a manufacturing defect, see *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960). In *Gottsdanker*, a batch of defectively manufactured Salk (killed-virus) polio vaccine inadvertently contained live polio virus and caused injury to two vaccine recipients. *Id.* at 605, 6 Cal. Rptr. at 322; see also Comment, *Strict Liability for Drug Manufacturers: Public Policy Misconceived*, 13 STAN. L. REV. 645 (1961) (discussing *Gottsdanker*).

68. See *supra* note 37 and accompanying text.

69. See *supra* notes 18-32 and accompanying text.

The drafters of the Restatement, however, recognized that some highly useful products, especially drugs, are "unavoidably unsafe," and that given the present state of scientific knowledge, those products cannot be made any safer.⁷⁰ When manufacturers properly produce unavoidably unsafe products that are accompanied by an adequate warning, the seller "is not to be held to strict liability for unfortunate consequences attending their use."⁷¹ In other words, the law will not impose liability *without fault* on the manufacturers of such products.

Several policy considerations support the Restatement position against strict liability for manufacturers of unavoidably unsafe drugs. First, imposition of strict liability may delay the marketing of badly needed medications while manufacturers conduct cumulative safety tests on new drugs.⁷² Additionally, the prohibitive cost of insuring new drugs against strict liability may prevent manufac-

70. RESTATEMENT (SECOND) OF TORTS §402A comment k (1965). The comments provides:

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 unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or 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 such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Id.

71. *Id.*

72. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 822, 218 Cal. Rptr. 453, 459-60 (1985); Note, *supra* note 9, at 261. Consider the potentially fatal consequences to many AIDS victims if manufacturers refuse to release AZT until further tests are run on the drug. Daily Press/Times Herald (Newport News, Va.), Sept. 20, 1986, at C4, col. 1.

turers from developing and selling new products.⁷³ Companies conceivably might stop manufacturing vital products already in existence; for example, only one company continues to manufacture Sabin vaccines.⁷⁴ Finally, potential strict liability may force manufacturers to raise the prices of such medications in order to distribute their losses. Such price increases might make medications unaffordable to those who need them most.⁷⁵

Those who favor imposition of strict liability even for unavoidably unsafe drugs argue that manufacturers are so profit-oriented that they will not use adequate care in developing and marketing new drugs unless they are threatened with such liability.⁷⁶ This argument is not persuasive, however, because manufacturers already are highly motivated to market safe and useful products. Strict government regulations, stiff competition in the pharmaceutical industry, concern for reputation, and fear of negligence liability all provide strong incentives for drug manufacturers to exercise the utmost care.⁷⁷ Imposition of strict liability merely would make manufacturers insurers of their products, a result not intended by section 402A.⁷⁸

To determine whether a potentially dangerous medication is unavoidably unsafe, courts employ in essence a risk-benefit analysis. If the medication's risks outweigh its benefits, the drug is "unreasonably dangerous per se," and the manufacturer is liable for any resulting injuries.⁷⁹ If the benefits outweigh the risks, the product

73. *Kearl*, 172 Cal. App. 3d at 824, 218 Cal. Rptr. at 459; Note, *supra* note 9, at 262. For example, many companies were reluctant to market a swine flu vaccine. Baynes, *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 21 St. Louis U.L.J. 44, 71 (1977).

In addition to insurance costs, the research and development costs incurred to introduce a new drug are staggering. "At the present time, it can cost more than \$100 million to move a new drug from the laboratory through the FDA approval process to the consumer." STAN-
DARD & POORS, *INDUSTRY SURVEYS* H 22 (1987).

74. Comment, *Informed Consent to Immunization: The Risks and Benefits of Individual Autonomy*, 65 CAL. L. REV. 186, 1286 n.2 (1977); see also Note, *supra* note 9, at 235.

75. *Kearl*, 172 Cal. App. 3d at 825, 218 Cal. Rptr. at 460-61.

76. Comment, *An Escape from Strict Liability: Pharmaceutical Manufacturers' Responsibility for Drug-Related Injuries Under Comment k to Section 402A of the Restatement (Second) of Torts*, 23 DUQ. L. REV. 199, 216 (1984).

77. Note, *supra* note 9, at 261.

78. *Id.* at 244.

79. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1273 (5th Cir.), cert. denied, 419 U.S. 1096 (1974).

is unavoidably unsafe, and the manufacturer is not subject to strict liability, as long as an adequate warning accompanies the product.⁸⁰

Because the only alternatives to the Sabin vaccine are the Salk vaccine or no vaccine at all, the risk-benefit analysis clearly places the Sabin vaccine in the unavoidably unsafe category. The relevant factors to consider in a risk-benefit comparison of two different prescription medications are cost, ease of administration, effectiveness, and individual safety.⁸¹ Compared to the Salk vaccine, the Sabin vaccine is inexpensive and easy to administer. Only one oral dose is required, rather than three costly—and painful—injections.⁸² The Sabin vaccine also reduces the risk of the dreadful disease more effectively because many unvaccinated people become immunized merely from contact with orally vaccinated individuals and because the oral vaccine suppresses the wild polio virus in the intestines, thereby reducing the transmission of wild virus to the environment.⁸³ Although the same factors which make the vaccine more effective also create the slight risk of contact polio, eliminating this risk would reduce the vaccine's effectiveness—its major benefit. This benefit to the population at large outweighs the minimal risk⁸⁴ to individual safety.

The Sabin vaccine is *certainly* better than *no* vaccine. The proper analysis, again, weighs the risk and magnitude of harm against the vaccine's utility.⁸⁵ The year before any vaccine was available, polio afflicted more than 50,000 people, killing or crip-

80. *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 129 (9th Cir. 1968).

81. *Franklin & Mais*, *supra* note 24, at 766. Professor Wade has suggested the following seven factors for a risk-benefit analysis: 1) the usefulness of the product; 2) the availability of safer products to meet the same need; 3) the likelihood of injury and its probably severity; 4) the obviousness of the risk; 5) public expectations; 6) the avoidability of injury; and 7) whether the danger can be eliminated without impairing the product's effectiveness. Wade, *Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5, 17 (1965). Regardless of which test is used, all courts have agreed that the benefits of the Sabin-type vaccine outweigh the risk of harm. *Reyes*, 408 F.2d at 1274; *Davis*, 399 F.2d at 128; *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 825, 218 Cal. Rptr. 453, 460-61 (1985); *Johnson v. American Cyanamid Co.*, 239 Kan. 279, —, 718 P.2d 1318, 1323 (1986).

82. See *supra* notes 21-22 and accompanying text.

83. See *supra* notes 18-20 and accompanying text; see also Boffey, *supra* note 20, at 35.

84. Health officials report only one apparent case of vaccine-induced or contact polio for every 2.5 million vaccinations given. See Boffey, *supra* note 20, at 35.

85. *Reyes*, 408 F.2d at 1274.

pling nearly half of them.⁸⁶ Eliminating such a disease is clearly highly beneficial to society. Admittedly, the potential harm from contracting vaccine-related polio is severe, but this risk is "statistically miniscule."⁸⁷ Although some courts and commentators have observed that the risk of contracting polio from the vaccine is now practically equal to the risk of catching it from a wild virus,⁸⁸ the risk of wild polio will increase substantially if large segments of society discontinue vaccination programs.⁸⁹ The benefits of the Sabin-type vaccine clearly outweigh its harms; each court that has discussed the issue and its policy implications has found correctly that the Sabin oral polio vaccine is unavoidably unsafe within the meaning of the Restatement.⁹⁰ Accordingly, the vaccine's manufacturers are not subject to strict liability for defective design; courts will impose liability on the manufacturers only if the warning accompanying the vaccine is inadequate.⁹¹

Warning Defects

Most courts impose a duty to warn based on negligence standards, requiring the manufacturer to warn only of foreseeable risks.⁹² One commentator, however, argues that manufacturers should be liable even for failing to warn of unknown, undiscoverable, and unforeseeable risks because the purpose of strict liability is to place the burden of injury on one who markets the product, regardless of fault.⁹³ This minority view too closely resembles absolute liability and would place unfair financial burdens on manufacturers. Obviously, a manufacturer cannot warn of scientifically undiscoverable risks. In the face of such a requirement, soundly managed companies understandably would refuse to develop and

86. See *supra* note 7 and accompanying text.

87. *Reyes*, 408 F.2d at 1274.

88. *Franklin & Mais*, *supra* note 24, at 760 (citing *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 130 (9th Cir. 1968)).

89. Comment, *supra* note 74, at 1310 n.117.

90. *Reyes*, 408 F.2d at 1273; *Davis*, 399 F.2d at 128; *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 825, 218 Cal. Rptr. 453, 460-61 (1985); *Johnson v. American Cyanamid Co.*, 239 Kan. 279, —, 718 P.2d 1318, 1323 (1986).

91. *Johnson*, 239 Kan. at —, 718 P.2d at 1323.

92. *Franklin & Mais*, *supra* note 24, at 762; see *supra* text accompanying note 38.

93. Comment, *supra* note 76, at 203.

market new products.⁹⁴ This loss of progressive research would be particularly unfortunate in the pharmaceutical industry, and almost certainly would affect the life and health of many people. In cases involving vaccine-related polio, therefore, courts properly have followed the majority rule, imposing a duty to warn only of foreseeable risks.⁹⁵ Under either negligence or strict liability standards, however, manufacturers do have a duty to warn about the *known* risks of the Sabin vaccine.⁹⁶ The critical issues, then, are whether the present warnings are adequate and whether these warnings are given to the proper individuals.

Adequacy of Warning

An adequate warning must be accurate and clear.⁹⁷ The warning must state the dangers honestly and understandably. Further, the forcefulness of the warning must be proportionate to the risk and must be sufficient to create caution in the user.⁹⁸ Several plaintiffs have alleged that the warnings accompanying the Sabin-type vaccine do not meet these requirements.

In *Givens v. Lederle Laboratories*,⁹⁹ for example, the warning stated that "it could not definitely be established that any such case was due to the vaccine strain."¹⁰⁰ The court agreed that this warning actually conveyed the idea that no true risk existed.¹⁰¹ Likewise, in *Williams v. Lederle Laboratories*,¹⁰² the court held that a jury could find the warning inadequate because it "lacked a sense of urgency and was reluctant in tone."¹⁰³ The current warning, however, states that on rare occasions the Sabin vaccine causes

94. See *supra* notes 73-74 and accompanying text.

95. *Williams v. Lederle Laboratories*, 591 F. Supp. 381, 384 (S.D. Ohio 1984); *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 832, 218 Cal. Rptr. 453, 465-66 (1985); *Johnson v. American Cyanamid Co.*, 239 Kan. 279, ___, 718 P.2d 1318, 1324-25 (1986); *Dunn v. Lederle Laboratories*, 121 Mich. App. 73, ___, 328 N.W.2d 579-80 (1982).

96. See *supra* notes 38-42 and accompanying text.

97. Note, *supra* note 9, at 254.

98. *Id.* at 255.

99. 556 F.2d 1341 (5th Cir. 1977).

100. *Id.* at 1345.

101. *Id.*

102. 591 F. Supp. 381 (S.D. Ohio 1984).

103. *Id.* at 385.

polio in vaccine recipients or to those who come in contact with recipients.¹⁰⁴

In *Johnson v. American Cyanamid Co.*,¹⁰⁵ the plaintiff objected to the manufacturer's warning¹⁰⁶ for several reasons. First, the plaintiff argued that the reported risk was inaccurate because the manufacturer did not take into account the number of distributed but unused doses or the number of already vaccinated recipients.¹⁰⁷ The Kansas Supreme Court rejected this argument, noting that the risk was "very low" no matter which calculation the manufacturer used.¹⁰⁸ The plaintiff also argued that the warning failed to state that the risk of vaccine-related polio was greater for persons who were not immune to polio, but the court considered that fact to be obvious.¹⁰⁹ Finally, the plaintiff contended that the warning failed to discuss the Salk vaccine as an alternative.¹¹⁰ The court rejected this argument because the Salk vaccine ceased to be a viable alternative after United States manufacturers stopped producing it.¹¹¹ Upon rejecting each of these arguments, the court held the warning to be adequate and sufficient as a matter of law.¹¹²

The California Court of Appeals upheld the adequacy of a similar warning in *Kearl v. Lederle Laboratories*.¹¹³ The warning in *Kearl* plainly stated both the risk of contracting polio from the Sabin vaccine and the possibility of the Salk vaccine as a safer but less effective alternative.¹¹⁴ Nevertheless, the plaintiff argued that an adequate warning should have stated that the risk of contracting vaccine-related polio was equal to the risk of contracting the wild polio virus.¹¹⁵ The court rejected this argument because

104. See *supra* note 32 and accompanying text.

105. 239 Kan. 279, 718 P.2d 1318 (1986).

106. The warning in that case was very similar to the current warning. The only difference was that the *Johnson* warning reported statistics for a smaller number of years. Compare note 32, *supra*, with 239 Kan. at ____, 718 P.2d at 1325.

107. *Id.* at ____, 718 P.2d at 1326.

108. *Id.* at ____, 718 P.2d at 1326.

109. *Id.* at ____, 718 P.2d at 1326.

110. *Id.* at ____, 718 P.2d at 1326.

111. *Id.* at ____, 718 P.2d at 1326; see also Franklin & Mais, *supra* note 24, at 761.

112. 239 Kan. at ____, 718 P.2d at 1326.

113. 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

114. *Id.* at 834, 218 Cal. Rptr. at 467.

115. *Id.* at 834, 218 Cal. Rptr. at 467.

the two probabilities, if measurable at all, would vary constantly.¹¹⁶ Further, because the possibility of injury from either source was remote, as the warning had explained, the court saw no reason to require manufacturers to provide statistical comparisons.¹¹⁷

Finally, the Michigan Court of Appeals also held that a manufacturer's warning was adequate even though the warning did not advise its readers how to avoid contact polio.¹¹⁸ The court stated that methods of avoiding danger were too variable and individualized to be a necessary part of manufacturer warnings.¹¹⁹

These recent decisions of the Kansas, California, and Michigan courts are sensible. The manufacturer's current warning conveys the potential danger and its frequency. To require additional information in the warning would be counter-productive. As one commentator has noted, recipients may become desensitized and ignore excessive warnings.¹²⁰ Further, such exhaustive warnings could confuse potential vaccine recipients and frighten them away from important medical treatment. One could even argue that the current warning places too much emphasis on the *risks* of vaccination and not enough emphasis on its *benefits*.¹²¹ Finally, the Food and Drug Administration has approved the manufacturer warning.¹²² If the government is satisfied that the warning is adequate, then courts should not hold manufacturers liable for any alleged inadequacy.

Recipient of Warning

Product liability law generally requires that a manufacturer warn the intended or foreseeable users of any danger associated

116. *Id.* at ____, 218 Cal. Rptr. at 468.

117. *Id.* at 835, 218 Cal. Rptr. at 467.

118. *Dunn v. Lederle Laboratories*, 121 Mich. App. 73, ____, 328 N.W.2d 576, 580 (1982).

119. *Id.* at ____, 328 N.W.2d at 581.

120. Franklin & Mais, *supra* note 24, at 764 n.40; *see also* Twerski, Weinstein, Donaher, & Piehler, *The Use and Abuse of Warnings in Product Liability—Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495, 514-15 (1976) (arguing that placing too many warnings on a product is like "crying wolf;" significant warnings no longer have an impact on the user).

121. Comment, *supra* note 74, at 1309.

122. *Johnson v. American Cyanamid Co.*, 239 Kan. 279, ____, 718 P.2d 1318, 1326 (1986); Note, *supra* note 9, at 241.

with a product.¹²³ The law has developed an exception, however: when the product is a prescription drug, a manufacturer may satisfy its duty by warning the prescribing physician of the medication's dangers.¹²⁴ Several policy considerations justify this "learned intermediary" exception. First, manufacturers would have great difficulty warning the ultimate users of prescription drugs, because such medications are regulated strictly and may be obtained only through pharmacists or physicians.¹²⁵ Second, the user may lack sufficient medical knowledge to understand the warning without the help of his or her doctor.¹²⁶

In spite of the exception for prescription medication, some courts have imposed liability on the manufacturers of the Sabin vaccine for failing to warn the ultimate recipient about the vaccine's dangers. In *Davis v. Wyeth Laboratories, Inc.*,¹²⁷ the plaintiff was vaccinated at a mass immunization clinic sponsored by Idaho public health officials and the local medical society. Manufacturer warnings accompanied the sale of the Sabin vaccine to the medical society, but no one communicated the warnings directly to the vaccine recipients. The United States Court of Appeals for the Ninth Circuit held that although the prescription medication exception applies to drugs dispensed by a private physician, it did not apply to drugs dispensed at mass clinics.¹²⁸ The court reasoned that a private doctor would make an individualized evaluation of the risks based on his knowledge of the patient's medical history but that such a balancing of risks would not occur at public clinics.¹²⁹ The manufacturer, therefore, had a duty to warn the ultimate vaccine recipient, either by advertisements, posters, or consent forms.¹³⁰ Having failed to give such a warning, the court held the manufacturer liable for the plaintiff's injuries.¹³¹

123. Note, *supra* note 9, at 251.

124. *E.g.*, *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966).

125. Note, *supra* note 9, at 251-52.

126. *Id.*

127. 399 F.2d 121 (9th Cir. 1968).

128. *Id.* at 131.

129. *Id.*

130. *Id.*

131. *Id.*

The United States Court of Appeals for the Fifth Circuit followed the same reasoning in *Reyes v. Wyeth Laboratories*.¹³² Elaborating on the *Davis* decision, the court stated that public clinics usually dispense Sabin vaccines "in an 'assembly line' fashion; there is often neither time nor personnel to make an 'individualized medical judgment' of the vaccinee's needs or susceptibilities."¹³³ Further, the court noted that because most manufacturers know that the vaccines will be distributed in this fashion, they easily can foresee that clinic patients will not receive adequate warnings unless the manufacturers themselves provide a warning or contractually obligate the clinic to provide one. This knowledge and foreseeability obligated the manufacturers to warn ultimate recipients about the dangers of the Sabin vaccine.¹³⁴

Based on the decisions in *Davis* and *Reyes*, manufacturers whose medications are dispensed at public clinics now provide the clinics with warnings and consent forms which vaccine recipients or their guardians must sign before the clinic will administer a vaccine.¹³⁵ This practice should not be necessary. The risk of a vaccinated person contracting polio from the vaccine approximately equals the same risk of an unvaccinated person contracting the disease from a wild virus.¹³⁶ The social utility of these warnings is minimal; furthermore, the warnings may in fact be detrimental. Misunderstood warnings from the manufacturer would frighten potential vaccinees unnecessarily and unreasonable fear could seriously hamper the success of important public health programs.¹³⁷

Additionally, many of the negative presumptions about mass clinics are unwarranted. Although clinics cannot provide the same degree of "personalized" service as a family practitioner, they are managed by public health experts. In a well-designed vaccination program, a doctor investigates the risks underlying the use of a

132. 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

133. *Id.* at 1277.

134. *Id.*

135. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 819, 218 Cal. Rptr. 453, 456 (1985).

136. *See supra* note 115 and accompanying text.

137. *Franklin & Mais, supra* note 24, at 759. The problems that could arise from misunderstood warnings are not limited to a select few; most people lack sufficient knowledge to understand the warnings accompanying prescription drugs. *See supra* note 126 and accompanying text.

particular vaccine, takes measures to limit such risks, then trains support personnel to administer the vaccine.¹³⁸ The family doctor cannot afford to make the same background investigation surrounding the use of any one particular vaccine.

At the same time, mass clinics reasonably might choose not to warn vaccinees of the risk. Doctors have a duty to act in their patients' best interests; if disclosure of the risks will frighten a patient out of receiving medically recommended treatment, the doctor is not required to disclose that risk.¹³⁹ For that very reason, many doctors do not warn their patients about the risks of the Sabin polio vaccine, and the failure to warn does not constitute medical malpractice.¹⁴⁰ In such cases, the ultimate vaccinee does not receive a warning, but the manufacturer is not held liable for this failure to warn. For the same reasons, manufacturers should not be held liable if public clinics choose not to warn their patients.¹⁴¹

These factors indicate that courts should not require Sabin vaccine manufacturers to give warnings directly to vaccinees. Clinics are fully capable of providing any necessary warnings, in their discretion, just as doctors do. Any further requirements might unreasonably frighten the public and jeopardize medical efforts to eradicate the polio virus. Nevertheless, manufacturers have begun providing consent form warnings for Sabin vaccines. As long as courts follow the precedent established in *Davis* and *Reyes*, manufacturers probably will continue their efforts to warn the ultimate vaccine recipient.

Causation

In actions based on strict liability in tort, a plaintiff cannot recover from the manufacturer of a defective product unless the de-

138. Note, *supra* note 9, at 253.

139. Comment, *supra* note 74, at 1299.

140. *Dunn v. Lederle Laboratories*, 121 Mich. App. 73, ___, 328 N.W.2d 576, 583-84 (1982). The court stated that "the jury could find that reasonable physicians would have acted no differently The doctor testified that, knowing the low incidence of vaccine-associated polio cases, he chose not to warn Mrs. Dunn and that this was the customary practice in the profession." *Id.*

141. Note, *supra* note 9, at 253-54; cf. Comment, *supra* note 75, at 1294-96 (comparing manufacturer's duty to warn with a doctor's duty to obtain informed consent).

fect proximately caused some injury.¹⁴² Courts should not impose liability on Sabin vaccine manufacturers either for giving inadequate warnings or for failing to warn the ultimate vaccinee unless the plaintiff can prove that the vaccine and the defective warning proximately caused the injury. Unfortunately, courts have not enforced proof of this element as stringently as they should.

Cause in Fact

As a preliminary issue, a plaintiff must prove that the vaccine was a cause-in-fact of his injury. In other words, the plaintiff must show that the vaccine itself, and not some external virus, produced the polio.¹⁴³

Medical experts have recognized the impossibility of proving that a Sabin-type vaccine caused any particular case of polio.¹⁴⁴ At most, doctors can determine whether a patient's disease is "compatible with the possibility of vaccine-induced illness."¹⁴⁵ The causal link is even more tenuous when the victim allegedly contracted the disease from contact with a vaccinee. In spite of this lack of conclusive medical evidence, all courts have allowed juries to find that the Sabin-type vaccine did cause polio in a *particular* plaintiff, reasoning that juries can infer causation from such circumstantial evidence as the length of time between vaccination and onset of illness.¹⁴⁶

This approach is unfair to manufacturers because juries may ignore the evidence and return a verdict based on sympathy for the injured plaintiff. In *Reyes v. Wyeth Laboratories*,¹⁴⁷ for example, the plaintiff was vaccinated during a polio epidemic in the community. Fourteen days after vaccination, she manifested symptoms of the disease.¹⁴⁸ In spite of expert testimony that the plaintiff's type

142. Note, *supra* note 9, at 245.

143. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1279 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

144. See, e.g., *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 434, 79 Cal. Rptr. 369, 375 (1969); see also *supra* note 27 and accompanying text.

145. *Grinnell*, 274 Cal. App. 2d at 436, 79 Cal. Rptr. at 376.

146. *Id.*; see also *Reyes*, 498 F.2d at 1271; *Stahlheber v. American Cyanamid Co.*, 451 S.W.2d 48, 57 (Mo. 1970); Baynes, *supra* note 73, at 56.

147. 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

148. *Id.* at 1270.

of polio was more likely to be the wild type spreading through the community, the jury returned a verdict in her favor.¹⁴⁹ By upholding such verdicts, courts allow plaintiffs to recover without proving causation, an essential element for imposing liability.

Proximate Causation

Conceding that some cases of polio may be vaccine-related, a more troubling issue is whether an allegedly inadequate *warning* is the proximate cause of a vaccinee's polio. A plaintiff cannot recover for injuries he or she would have sustained even if the manufacturer had given an adequate warning.¹⁵⁰ Courts, therefore, must determine whether an adequate warning would have deterred the plaintiff from receiving a Sabin-type vaccine.

The strongest argument for the manufacturers is that most states require that children receive polio vaccinations before entering school.¹⁵¹ When considered in conjunction with compulsory education laws, these requirements prevent all but a few people from exercising any real choice as to whether they will take the vaccine. The Sabin vaccine is unlike other products, which consumers may choose to use or reject. Under these circumstances, therefore, presuming that a different warning would deter vaccination is in-

149. *Id.* at 1271. The odds of catching wild-virus polio were one in 3,000, but the risk of vaccine-induced injury was one in 5.88 million, according to experts from Johns Hopkins University. Franklin & Mais, *supra* note 24, at 758.

150. *E.g.*, *Williams v. Lederle Laboratories*, 591 F. Supp. 381, 386 (S.D. Ohio 1984).

151. *See, e.g.*, VA. CODE § 22.1-271.2 (1985). The statute provides in part:

IMMUNIZATION REQUIREMENTS.—A. No student shall be admitted by a school unless at the time of admission the student or his parent or guardian submits documentary proof of immunization to the admitting official of the school or unless the student is exempted from immunization pursuant to subsection C

.....

C. No certificate of immunization shall be required for the admission to school of any student if (i) the student or his parent or guardian submits an affidavit to the admitting official stating that the administration of immunizing agents conflicts with the student's religious tenets or practices; or (ii) the school has written certification from a licensed physician or a local health department that one or more of the required immunizations may be detrimental to the student's health, indicating the specific nature and probable duration of the medical condition or circumstance that contraindicates immunization.

Id. The statute requires vaccinations against diphtheria, tetanus, whooping cough, poliomyelitis, measles, and mumps. VA. CODE §§ 22.1-271.1, 32.1-46 (1985).

appropriate.¹⁵² The court in *Reyes v. Wyeth Laboratories*¹⁵³ rejected this logical argument, stating that an adequately warned patient might choose to receive a Salk-type vaccine rather than Sabin,¹⁵⁴ but the court's decision ignored the fact that Salk vaccines are no longer manufactured in this country.¹⁵⁵ The Arizona Court of Appeals viewed the situation more realistically in *Sheehan v. Pima County*,¹⁵⁶ holding that the unavailability of an alternative vaccine contradicted any presumption that the plaintiff would have heeded an adequate warning.¹⁵⁷

One commentator has suggested imposing liability on manufacturers for inadequate warnings regardless of causation, reasoning that individuals have a right to "informed consent" even when vaccines are required by law.¹⁵⁸ The right of each person to make an intelligent choice in deciding whether to submit to medical treatment is the basic thrust of informed consent.¹⁵⁹ Patients have no choice when the medical treatment is required by law, rendering the doctrine of informed consent meaningless.

A community epidemic is another context in which people might receive the Sabin-type vaccine in spite of an adequate warning. In such a situation, the risk of vaccine-related illness is extremely low, while the risk of contracting a wild virus is higher. In *Cunningham v. Charles Pfizer & Co.*,¹⁶⁰ the court held that reasonable persons might choose vaccination during an epidemic even if they had been warned of the vaccine's risks.¹⁶¹ Accordingly, the plaintiff in *Cunningham* was not entitled to a presumption that the allegedly inadequate warning proximately caused his injury.¹⁶²

Finally, when private physicians act as "learned intermediaries," they may be in the practice of not warning patients about statisti-

152. Note, *supra* note 9, at 258-59.

153. 498 F.2d 1264 (5th Cir.), *cert denied*, 419 U.S. 1096 (1974).

154. *Id.* at 1293. The court suggested the same unrealistic alternative in *Givens v. Lederle*, 556 F.2d 1341, 1346 (5th Cir. 1977).

155. See *supra* note 24 and accompanying text.

156. 135 Ariz. 235, 660 P.2d 486 (Ct. App. 1982).

157. *Id.* at 238-39, 660 P.2d at 490.

158. Comment, *supra* note 74, at 1313.

159. *Id.* at 1295.

160. 532 P.2d 1377 (Okla. 1975).

161. *Id.* at 1382.

162. *Id.*

cally insignificant risks associated with medications.¹⁶³ If so, the adequacy of a manufacturer's warning is irrelevant, because the uninformed patient would almost certainly follow the doctor's advice and receive the vaccine. The doctor's practice of not warning his or her patients about such risks would be the actual proximate cause of any injury, superseding the manufacturer's alleged negligence. The court rejected this argument in *Williams v. Lederle Laboratories*,¹⁶⁴ reasoning that an adequate warning might persuade the doctor to change his practice and warn a potential vaccinee of the risks.¹⁶⁵ In reaching this decision, the court ignored the testimony of the plaintiff's doctor, who admitted that he still chose not to warn his patients about the dangers of the Sabin-type vaccine even after the plaintiff's unfortunate injuries.¹⁶⁶ In *Dunn v. Lederle Laboratories*,¹⁶⁷ however, the Michigan Court of Appeals properly recognized that a physician's failure to warn his patient of a known risk could destroy the causal connection between the manufacturer's allegedly inadequate warning and the plaintiff's injuries.¹⁶⁸

An adequate warning is unlikely to deter people from receiving the Sabin-type vaccine. Competent physicians may choose not to convey such warnings to frightened patients. Even individuals who are warned reasonably may recognize that the risk of vaccine-related illness is too low to be a serious concern. Most significantly, polio vaccines are required by law, and the Sabin-type vaccine is the only effective vaccine available in this country. An allegedly inadequate warning, therefore, could not logically be considered the proximate cause of any vaccine-induced illness.

Summary

Courts have decided most vaccine-induced injury cases on strict liability principles. Because the Sabin-type vaccine is extremely useful to society, however, courts have classified the drug as an un-

163. See *supra* notes 139-40 and accompanying text.

164. 591 F. Supp. 381 (S.D. Ohio 1984).

165. *Id.* at 387.

166. *Id.* at 386.

167. 121 Mich. App. 73, 328 N.W.2d 576 (1982).

168. *Id.* at —, 328 N.W.2d at 582.

avoidably unsafe product, imposing liability on the manufacturer only when the warning accompanying the vaccine is inadequate and this inadequacy proximately causes the plaintiff's illness.¹⁶⁹ Although courts agree on these legal principles, varying applications of these principles has led to inconsistent verdicts and uncertain results for injured plaintiffs.

The more recent better-reasoned decisions have held the revised manufacturer warning to be adequate in content,¹⁷⁰ but most courts require the manufacturer to convey this warning directly to the vaccinee, unless a private physician acts as a "learned intermediary."¹⁷¹ This Note suggests that a warning to public immunization clinics, rather than to ultimate vaccinees, should be sufficient to discharge the manufacturer's duty.¹⁷²

Courts also are divided on whether inadequate warnings have proximately caused the plaintiffs' injuries. The better-reasoned decisions have held that most people would receive the vaccine even if adequately warned about the risks, and therefore, that inadequate warnings are not the proximate cause of these injuries.¹⁷³

PUBLIC POLICY CONSIDERATIONS

In addition to the policy concerns present in the discussion of strict liability,¹⁷⁴ broader public policy considerations permeate the entire area of mandatory vaccination programs. Courts and legislatures must balance the individual's right of autonomy against the public interest in eliminating infectious diseases,¹⁷⁵ and decision makers then must determine who should bear the loss when programs for public benefit injure private individuals.¹⁷⁶

The United States Supreme Court has recognized the individual's constitutional right to privacy in making certain personal de-

169. See *supra* notes 69-91 and accompanying text.

170. See *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 834-35, 218 Cal. Rptr. 453, 467-68 (1985); *Johnson v. American Cyanamid Co.*, 239 Kan. 279, ___, 718 P.2d 1318, 1326 (1986).

171. See *supra* text accompanying notes 123-34.

172. See *supra* text accompanying notes 135-41.

173. See *supra* text accompanying notes 150-68.

174. See *supra* text accompanying notes 72-78.

175. Note, *supra* note 9, at 250.

176. See *Franklin & Mais, supra* note 24, at 768; Comment, *supra* note 76, at 203.

cisions.¹⁷⁷ This right to privacy includes the right to accept or reject medical treatment.¹⁷⁸ The right to privacy is not absolute, however; a compelling state interest, including protection of the public health, can override the rights of a single individual.¹⁷⁹ Preventing the spread of deadly infectious disease is obviously a compelling interest, and the Supreme Court determined long ago that statutory vaccination requirements are constitutional restraints on individual liberty, as long as the laws allow some exception for individuals uniquely endangered by vaccines, such as those with immune system deficiencies.¹⁸⁰ The Court did not consider the inherent risks of vaccination, including possible death or serious injury, to be unique dangers, reasoning that the legislature would evaluate such risks before requiring vaccination.¹⁸¹

State legislatures already have made a policy decision in favor of public health and against personal autonomy by requiring school children to be vaccinated against polio.¹⁸² The contagiousness of this disease and its tragic consequences justify such legislative decisions.¹⁸³ Nevertheless, the vaccination requirement also clearly causes serious injury or death to some individuals. Providing compensation for these victims is of paramount importance.¹⁸⁴

Some commentators suggest that vaccine manufacturers should bear the entire cost of compensating these victims, because manufacturers can distribute the cost evenly by raising their prices.¹⁸⁵ Most scholars, however, recognize that the competitive pharmaceu-

177. See, e.g., *Roe v. Wade*, 410 U.S. 113, 152-56 (1973).

178. E.g., *In re Quinlan*, 70 N.J. 10, —, 355 A.2d 647, 663 (1976).

179. *Roe*, 410 U.S. at 154.

180. *Jacobson v. Massachusetts*, 197 U.S. 11, 38-39 (1904) (upholding mandatory smallpox vaccine).

181. *Id.* at 36.

182. See *supra* note 151 and accompanying text.

183. See *supra* notes 7-10 and accompanying text.

184. Leaving injured persons to bear the entire loss would be grossly unfair and is not a viable option. The facts of *Griffin v. United States*, 351 F. Supp. 10, 36 (E.D. Pa. 1972), modified, 500 F.2d 1059 (3d Cir. 1974), demonstrate the magnitude of losses associated with polio; in that case, the financial costs alone included \$89,223.25 for medical bills and \$49,142.40 in lost future income. *Id.* at 36. Placing a monetary value on the pain and suffering that a quadriplegic experiences is not really possible. *Id.* at 37.

185. See, e.g., Comment, *supra* note 76, at 203.

tical industry prevents drug manufacturers from raising prices,¹⁸⁶ and that the cost of product liability insurance has become prohibitive.¹⁸⁷ Imposing the burden on manufacturers through strict liability, therefore, may drive pharmaceutical manufacturers out of business, leaving people unable to obtain needed medications.¹⁸⁸

One writer recommends a limited no-fault compensation system, a type of absolute liability.¹⁸⁹ Under this system, manufacturers would compensate victims for their actual injuries without regard to the adequacy of the manufacturer's warning; however, injured persons would not recover any damages for pain and suffering. Theoretically, this system would compensate all victims without sending manufacturers into bankruptcy, because money formerly spent on litigation to prove lack of fault could be channeled directly to the victims.¹⁹⁰ Realistically, however, this proposal does not consider the true magnitude of actual damages, which themselves are sufficient to drive a manufacturer out of business, with or without litigation expenses.¹⁹¹ Further, fraudulent claimants might abuse this system, because proving the exact cause of polio is difficult or impossible.¹⁹² Finally, imposing such expenses on a faultless manufacturer is plainly unfair.

The most appropriate recommendation is that the government bear the loss of compensating victims of vaccine-related polio.¹⁹³

186. See Baynes, *supra* note 73, at 44; Note, *supra* note 9, at 262. "Compared with other major domestic industries, the drug industry exhibits below-average concentration, with no one firm accounting for more than 8% of total U.S. sales." STANDARD & POORS, INDUSTRY SURVEYS H 18 (1987). "Drug pricing is highly complicated, with many factors coming into play in the determination of the final market price. Underlying the basic pricing structure are the need to recoup heavy R & D costs, competitive conditions in the marketplace, and the projected patent life of each drug. *Id.* at H 19. Although drug price increases have been larger than the overall inflation rate for the past decade, the increases "reflect . . . a catch-up from prior subinflationary pricing as well as efforts to compensate for [reductions in] foreign earnings . . . [due to] strengthening of the dollar and restrictive foreign pricing regulations." *Id.*

187. See Baynes, *supra* note 73, at 44; Note, *supra* note 9, at 262; see also *supra* note 73 and accompanying text.

188. See *supra* notes 73-74 and accompanying text.

189. Baynes, *supra* note 73, at 72-73.

190. *Id.*

191. See *supra* note 184.

192. Baynes, *supra* note 73, at 72-73.

193. Note, *supra* note 9, at 263.

State governments already require the vaccinations.¹⁹⁴ The federal government has licensed the manufacturers and has approved the distribution of the Sabin-type vaccine.¹⁹⁵ Because of principles of sovereign immunity, the government has not been forced to consider or bear the consequences of its decisions.¹⁹⁶ Imposing liability on the government would force public officials to consider these consequences, and then, if they choose to continue encouraging the use of the Sabin-type vaccine, the public treasury would pay the full cost of the program. Public funds should pay for programs that benefit the whole society. When individual losses result from the implementation of public programs, the public, rather than the companies chosen to carry out the programs, should bear those losses.

THE NATIONAL CHILDHOOD VACCINE INJURY ACT

In response to the number of vaccine-related injuries and the consequent staggering liability imposed on manufacturers, Congress enacted the National Childhood Vaccine Injury Act of 1986.¹⁹⁷ As finally adopted,¹⁹⁸ the Act creates a claims system for persons injured by certain routine vaccines,¹⁹⁹ including Sabin-type

194. See *supra* note 151.

195. Note, *supra* note 9, at 241.

196. *Loge v. United States*, 662 F.2d 1268, 1272 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982) (sovereign immunity barred suit against the government for licensing Sabin-type vaccines); *Franklin & Mais*, *supra* note 24, at 767-68. *But cf.* *Griffin v. United States*, 351 F. Supp. 10 (E.D. Pa. 1972), *modified*, 500 F.2d 1059 (3d Cir. 1974) (allowed suit against the government under Federal Tort Claims Act for failing to comply with its own mandatory testing regulations).

197. Pub. L. No. 99-660, 100 Stat. 3755 (1986).

198. The Senate incorporated the original House bill into S. 1744, 99th Cong., 2d Sess. (1986), a comprehensive package of health legislation covering drug exports, peer review of physicians, state mental health plans, health maintenance organizations, and Alzheimer's disease. See 14 Prod. Safety & Liab. Rep. (BNA) 750 (Oct. 24, 1986). The House had already passed the larger legislative package on Oct. 17, 1986. 132 CONG. REC. H11,615 (daily ed. Oct. 17, 1986).

199. The Act permits "any person who has sustained a vaccine-related injury" or their legal representative to petition for compensation. § 2111(b)(a)(A), 100 Stat. at 3760. The petition must contain an affidavit and supporting documentation that show the injured person received one of the enumerated vaccines or "contracted polio, directly or indirectly, from another person who received an oral polio vaccine." § 2111(c)(1)(A), 100 Stat. at 3760. Those who contract polio from contact with a vaccinee must be United States citizens to file a petition, § 2111(c)(1)(B)(ii), 100 Stat. at 3760; however, those who receive the vaccine need

oral polio vaccines. This system would compensate the families of injured children with federal funds for all medical expenses not otherwise paid by insurance companies; however, the Act limits wrongful death awards and awards for pain and suffering to \$250,000, and bars punitive damages entirely.²⁰⁰ Families not satisfied with the government-awarded amount could reject the automatic compensation and sue the vaccine manufacturer directly, but only under negligence principles—the Act abolishes strict liability lawsuits against manufacturers of the designated vaccines.²⁰¹ Fami-

not be citizens to file. See § 2111(c)(1)(B)(i), 100 Stat. at 3760. A claimant must file a petition to receive compensation under the program, §2111(a), 100 Stat. at 3758, or to bring a civil action against a vaccine manufacturer for damages in excess of \$1000. See § 2111(2)(A), 100 Stat. at 3759.

The Act also sets a limit of one petition per administration of a vaccine. § 2111(b)(2), 100 Stat. at 3760. When referring to the content of the petition, the Act states that “the person who suffered such injury” must provide certain documentation, § 2111(c)(1), 100 Stat. at 3760 (emphasis added); therefore, the Act sets an arbitrary cut-off of one injury per administration.

200. See § 2115, 100 Stat. at 3767-68. Compensation under the program falls into four categories: first, actual unreimbursable expenses, covering costs already incurred and those that will be incurred, § 2111(a)(1), 100 Stat. at 3767; second, wrongful death-type award of \$250,000, § 2115(a)(2), 100 Stat. at 3767; third, loss of earning capacity, §2115(a)(3), 100 Stat. at 3767; and fourth, pain and suffering, limited to \$250,000. § 2115(a)(4), 100 Stat. at 3768. Loss of earning awards for those who are injured after reaching age 18 are much more flexible than awards for those injured before age 18. Compare § 2115(a)(3)(A), 100 Stat. at 3767-68 with § 2115(a)(3)(B), 100 Stat. at 3768. Punitive damages are prohibited specifically in § 2115(d)(1), 100 Stat. 3768.

Although limiting pain and suffering damages and prohibiting punitive damages, the Act does permit recovery of reasonable attorneys’ fees. § 2115(e)(1)(A), 100 Stat. at 3768. The attorney is limited to the statutory recovery; additional fees are prohibited. § 2115(e)(3), 100 Stat. at 3769.

201. Vaccine manufacturers are not liable for injury or death resulting from side effects that were unavoidable if the vaccine was (1) properly prepared and (2) accompanied by proper directions and warnings. § 2122(b)(1), 100 Stat. at 3773. A vaccine is presumed accompanied by proper directions and warnings if it complies materially with the Federal Food, Drug, and Cosmetic Act and § 351 of the Public Health Service Act, and regulations thereunder. Plaintiffs can avoid this presumption (1) if the manufacturer engaged in fraudulent-type conduct or (2) if he shows by clear and convincing evidence the manufacturer was negligent. See § 2122(b)(2), 100 Stat. at 3773. In addition, no manufacturer can be held liable solely for failing to provide direct warnings to the injured party. § 2122(c), 100 Stat. at 3773.

If a plaintiff does choose to sue, the trial occurs in three phases: liability, general damages, and punitive damages. § 2123, 100 Stat. at 3774. In the first stage, liability is determined under § 2122. § 2123(b), 100 Stat. at 3774. General damages are determined in the second stage; here the statute defers to state law by omission. See § 2123(c), 100 Stat. at 3774. Punitive damages are available, but are limited to situations where the manufacturer has

lies would have ninety days to decide whether to accept the government's final award, but suit against the manufacturer would irrevocably forfeit the family's right to compensation from federal funds.²⁰²

Although the Act definitely is a step in the proper direction, the current legislation does not resolve the problem effectively. As adopted, the Act will not take effect until Congress approves a new tax plan to finance the compensation system.²⁰³ Representative Waxman originally proposed to place an excise tax on vaccine manufacturers in proportion to their sales, with the resulting funds to be placed in a special trust fund for victims.²⁰⁴ In order to win support from the House, however, Waxman dropped this proposal from the bill.²⁰⁵ This indicates that Congress may have difficulty enacting an appropriate tax plan to implement the program. Additionally, the Reagan administration, hostile toward both the Act and any tax increases, can be expected to veto any tax plan approved by Congress.²⁰⁶ Without the necessary funding, the Act is useless.

Even if implemented, the Act may not provide enough protection for manufacturers because the program still would allow lawsuits against them. The abolition of strict liability is relatively insignificant because courts already consider the oral polio vaccine unavoidably unsafe and thus exempt manufacturers from strict liability principles as long as manufacturers give an adequate warning.²⁰⁷ The adequacy of a warning is determined under negligence principles, even in strict liability cases.²⁰⁸ Consequently, plaintiffs'

engaged in fraudulent or criminal behavior which "related to the vaccine-related injury or death." § 2123(d)(2), 100 Stat. at 3774.

202. See § 2121(a), 100 Stat. at 3772; see also Rovner & Kaplan, *Vaccine Legislation Advances in House Committee, on Floor*, CONG. Q., Sept. 20, 1986, at 2243.

203. See Act of Nov. 14, 1986, Pub. L. 99-660, § 323, 100 Stat. 3784; see also 14 Prod. Safety & Liab. Rep. (BNA) 750 (Oct. 24, 1986).

204. 14 Prod. Safety & Liab. Rep. (BNA) at 732 (Oct. 17, 1986). In effect, such a plan still would leave the cost on manufacturers. A sales tax, to be paid by the state and local governments who purchase the vaccines, would be more in line with the policy objectives discussed in this Note. See *supra* notes 193-96 and accompanying text.

205. 14 Prod. Safety & Liab. Rep. (BNA) at 732 (Oct. 17, 1986).

206. *Id.*

207. See *supra* notes 90-91 and accompanying text.

208. See *supra* note 92 and accompanying text.

recoveries would not be limited significantly under the new law.²⁰⁹ Admittedly, recovery is unpredictable when plaintiffs resort to the courts, and the most recent cases have held manufacturer warnings to be adequate;²¹⁰ therefore, most rational victims would choose to accept compensation from the government, which is available automatically and without proof of fault. The best legislation, however, would compensate the victims, yet protect manufacturers from *all* liability for highly useful, properly manufactured vaccines.

CONCLUSION

Polio, once a major disease in this country, has been eradicated almost completely since the development of polio vaccines. To prevent the recurrence of devastating epidemics, state governments require school-age children to be vaccinated against polio; furthermore, the state makes free vaccinations available at mass immunization clinics. The vast majority of medical professionals recommend the Sabin-type oral polio vaccine, which is the most effective vaccine—and the only polio vaccine available in the United States today. Unfortunately, the Sabin-type vaccine *causes* polio on rare occasions.

In the past, courts have imposed strict liability on pharmaceutical manufacturers, holding them financially liable to the few victims of vaccine-related polio. Strict liability is improper in these

209. One commentator has developed optimistic and pessimistic scenarios for the implementation of the Act. Under the optimistic scenario, "[n]o more than a couple hundred claims are filed a year" and "[t]wo thirds are dismissed on their face" as nonvaccine related injuries. Huber, *Will New Vaccine Statute Give Shot in Arm to Tort Reform*, Legal Times, Mar. 9, 1987, at 9, col. 1, 10, col. 2. Further, "[r]easonably generous awards are made reasonably quickly," and then the claimants accept the awards without filing suit in the "second round." *Id.*

Under the pessimistic scenario, "[c]laims alleging vaccine related injuries mushroom, and plaintiffs receive overly generous awards, particularly in cases of questionable causation." *Id.* at 10, col. 3. "The word now goes around that the first round is a slush fund for almost anyone and the second round a still-active crap shoot for those with colorable claims." *Id.* Because compensation is geared to the timing and severity of symptoms occurring after receiving the vaccine, *id.* at 10, col. 4, and physician malpractice exposure decreases as government coverage rises, physicians will have an incentive to "fudge just a little bit" in favor of the claimant. *Id.*

Which scenario will occur is unclear, however; the result will depend on the system's ability to ferret out false claims. *See id.*

210. *See supra* notes 105-19, 170 and accompanying text.

cases because the vaccines are not defective nor is any alleged defect the proximate cause of the victims' injuries. The Sabin-type vaccine is exactly what it is intended to be, and scientists are unable to make a safer vaccine of equal effectiveness. Adequately explicit warnings accompany the vaccines; requiring more urgent warnings would not prevent the injuries.

Policy considerations also dictate against strict liability for manufacturers. The high cost of liability may drive pharmaceutical manufacturers out of business entirely, or at least lead them to stop producing vaccines and other valuable medication, thereby seriously jeopardizing public health programs. Admittedly, individual victims deserve compensation for their injuries, but because society has instituted the mandatory vaccination program for its own benefit, society itself should bear the losses the program generates.

Congress recently passed legislation intended to compensate injured vaccinees with government funds. The legislation still permits tort-law suits against manufacturers, however, and therefore does not provide manufacturers with sufficient protection. Further, the compensation system will not be effective unless Congress enacts a plan to finance the proposed government fund. Better legislation would protect manufacturers from *all* liability for unavoidable risks and would ensure the availability of government funds to compensate injured vaccine recipients.

Fay F. Spence