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Mass Immunization Cases: Drug Manufacturers'Liability for Failure to Warn

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I. INTRODUCTION

In recent years, the manufacturers of polio[1] vaccines, administered in mass immunization programs at public health clinics, have been beseiged with a flurry of cases in which they have been held liable for failing adequately to warn of the dangers inherent in the use of an otherwise pure, unadulterated drug.[2] As a result of the relatively large judgments awarded in these cases[3] and the almost insurmountable practical problems of preventing further liability, drug manufacturers have ceased, or are threatening to cease, production of these essential, life-saving vaccines.[4] Consequently, these recoveries threaten the effectiveness of the nation's preventative health care programs and contravene the strong public policy of combatting infectious disease through widespread vaccination campaigns.[5] Furthermore, as community health care centers increase in number and expand in function to meet the emerging needs of the nation's medical patients, the drug manufacturer's potential liability is multiplied.[6] In addition, although the scenario for most of the

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1. "Poliomyelitis" and "polio," a popular name for poliomyelitis, will be used synonymously and interchangably throughout this Note.

2. For the purposes of this Note, vaccines will be referred to as "drugs." The medical profession, however, generally refers to vaccines as "biologics."

3. *See, e.g.*, Givens v. Lederle, Docket No. 73-59-CIVTK (S.D. Fla. 1975) ($262,000 awarded to plaintiff for injuries resulting from contact with child who had received defendant's oral Sabin polio vaccine); Tinnerholm v. Parke-Davis & Co., 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969) ($651,783.52 awarded to parents of child for injuries resulting from administration of quadrigen vaccine); Stromsodt v. Parke-Davis & Co., 257 F. Supp. 991 (D.N.D. 1966), *aff'd*, 441 F.2d 1390 (8th Cir. 1969) ($500,000 awarded in quadrigen case).

4. *Bad Omen for U.S. Vaccine Supplies*, MED. WORLD NEWS, Sept. 8, 1975, at 75. *See also* Curran, *Immunization Programs: Further Legal Developments*, 59 AM. J. OF PUB. HEALTH 349 (Feb. 1969) (predicting the discouragement of private drug concerns from entering certain preventative medicine immunization fields).

5. See discussion of amici curiae briefs filed by the American Academy of Pediatrics and the Conference of State and Territorial Epidemiologists in Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1293 (5th Cir.), *cert. denied*, 419 U.S. 1038 (1974); *see* text accompanying note 179 *infra*.

6. *See generally* Comment, *Drug Manufacturers, Public Clinics and the Duty to Warn*, 56 GEO. L.J. 1016-17, 1022 (1968). The author notes that while medical practice in the U.S. increasingly is becoming a public function through the use of public health clinics, these clinics can provide only impersonal mass treatment to the client. *Id.* at 1016-17. Community health care centers, however, are essential to serve the poor, disabled, chronically ill, aged, industrial workers, mothers, and children. *Id.* at 1017 n.2, citing NATIONAL COMMISSION ON

mass immunization cases thus far has been the administration of polio vaccine at a public health clinic, the holdings foreshadow the extension of their rationale to other immunization agents or drugs distributed at a clinic, or at any in-patient or out-patient facility, in an impersonal "assembly-line" fashion in which nurses perform important dispensing functions without direct physician supervision.[7]

Because the primary "mass immunization" cases have involved the imposition of liability for injuries resulting from the administration of a polio vaccine,[8] this Note initially will discuss the history of the development of this vaccine to provide a more complete understanding of the factual background surrounding these cases. The holdings of the "mass immunization" cases and the rationales proffered to support the imposition of liability on the drug manufacturers will be examined. Further, this Note will investigate in depth the practical problems faced by drug manufacturers because of these cases and, lastly, will propose possible solutions to those problems.

II. History of the Development of the Polio Vaccine

For an adequate understanding of the mass immunization cases, the history of the development of the polio vaccine must be examined.[9] Prior to 1950, the dread disease of poliomyelitis was a major crippler of children in the United States and throughout the world.[10] In 1952 alone, 57,879 cases of polio were reported in the United States, of which 21,269 cases resulted in crippling paralysis to the victims.[11] By 1971, the number of reported cases of poliomye-

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Community Health Services, Report of the Task Force on Health Care Facilities 36 (1967) and Metzler, *Public Health in a Troubled World*, 56 Am. J. of Pub. Health 161, 164 (1966).

7. Curran, *Public Warnings of the Risk in Oral Polio Vaccine*, 65 Am. J. of Pub. Health 501 (May 1975); *cf.*, note 140 *infra* and accompanying text.

8. Although many other vaccines are marketed and used throughout the United States today, including diphtheria, pertussis, tetanus, influenza, measles, rabies, and rubella vaccines, few cases have been brought for injuries sustained therefrom. The reasons probably are twofold: the risk associated with the vaccine is well known, as with the rabies vaccine; or, the harmful effects of the vaccine or disease generally are not very serious, as with the measles vaccine. Perhaps the recently developed rubella vaccine, which may cause serious harm to an unborn fetus if the vaccine is administered to a pregnant mother, may be the exception. The public health clinics and physicians, however, have engaged in a careful screening process to combat this risk.

9. *See generally* A. Klein, Trial by Fury (1972) [hereinafter cited as Klein]; J. Paul, A History of Poliomyelitis (1971) [hereinafter cited as Paul]; J.R. Wilson, Margin of Safety (1963).

10. Griffin v. United States, 351 F. Supp. 10, 23 (E.D. Pa. 1972), *modified*, 353 F. Supp. 324 (E.D. Pa. 1973), *aff'd*, 500 F.2d 1059 (3d Cir. 1974); Paul, *supra* note 9, at 468.

11. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1269 (5th Cir. 1974).

litis was reduced to nineteen,[12] primarily due to the development of an effective vaccine to combat the disease.

It was not until about 1950 that scientists really began to understand how poliomyelitis attacks its victims.[13] Scientists discovered that polio is caused by an enterovirus that is introduced into the body orally and begins to reproduce rapidly in the intestinal tract.[14] At this point the disease is termed an "infection" to which over eighty percent of the population has acquired immunity,[15] and from which only about one per cent will manifest clinical symptoms of poliomyelitis.[16] When the disease does result, it is caused by a spread of the virus from the intestinal tract to the spinal column, where it will cause damage to the nervous system, which results in the characteristic muscular paralysis.[17]

The initial breakthrough for scientists studying the disease was the discovery that only three types of the virus existed—Type I, Type II, and Type III—in contrast to the enormous number of types that exist for most viruses.[18] To provide protection, a vaccination would have to immunize the vaccinee against all three types of virus.[19] The first effective vaccine to be perfected was a killed virus vaccine developed by Dr. Jonas Salk.[20] A killed virus vaccine is produced by growing virus in a tissue culture and killing it chemically to render it incapable of causing disease, but capable of acting as an antigen to stimulate the production of antibodies.[21] Then, if a wild or virulent strain of polio virus enters the body, the antibodies will destroy the live virus and prevent the contraction of polio.[22] In 1955, after extensive testing, the Salk vaccine was released for general use. The vaccine was determined to be completely safe unless it inadvertently contained some unkilled virulent strains of the

12. CENTER FOR DISEASE CONTROL, POLIOMYELITIS SURVEILLANCE, ANNUAL SUMMARY 1972, App., (Oct. 1974); *see* Horstmann, *Enterovirus Infections of the Central Nervous System*, 51 MED. CLINICS OF NO. AM. 681 (May 1967) (Dr. Horstmann discusses the decline in the incidence of poliomyelitis throughout the world).

13. 498 F.2d at 1295.

14. *Id.*; Griffin v. United States, 351 F. Supp. 10, 23 (E.D. Pa. 1972).

15. Many cases of poliomyelitis do not result in paralysis of the limbs or breathing muscles. Some are mild, with no more symptoms than a cold, perhaps accompanied by a little stiffness in the neck. 2 SCHMIDT, ATTORNEYS' DICTIONARY OF MEDICINE, at P-121 (1975).

16. 498 F.2d at 1296.

17. *Id.*; 351 F. Supp. at 23.

18. 498 F.2d at 1296; 351 F. Supp. at 23. *See also* Sabin, *Oral Poliovirus Vaccine*, 194 J.A.M.A. 872, 873 (1965).

19. 498 F.2d at 1296.

20. 351 F. Supp. at 23.

21. *Id.* at 23-24; 498 F.2d at 1296.

22. 498 F.2d at 1296; 351 F. Supp. at 24.

virus, as happened in the "Cutter incident" of 1955,[23] from which a total of 207 vaccine-associated cases occurred.[24] Although the Salk vaccine became the primary weapon against polio, it had certain drawbacks that made it less than the ideal vaccine for the nationwide immunization against polio, a disease which struck hardest in the lower socio-economic groups. First, to remain effective the Salk vaccine required three separate hypodermic injections followed by booster shots every few years. Secondly, it did not immunize the intestinal tract against infection, so that vaccinees still could pass the virus to non-immune persons with whom they came in contact.[25] Consequently, an effort was made to develop a vaccine that could be distributed more easily, that could provide intestinal immunity, and that could afford permanent immunity that would make booster shots unnecessary.[26]

In the late 1950's, after many years of work, Dr. Albert Sabin developed an oral vaccine consisting of living but attenuated virus particles. These virus particles were rendered incapable of producing disease by extensive laboratory processes, but were sufficiently strong to cause the production of antibodies in the recipient's system.[27] Three types of "monovalent" vaccines were produced to combat each type of polio virus, as well as a "trivalent" vaccine to combat all three types.[28] After three years of extensive internationally cooperative studies and tests, the vaccine was licensed for sale and distribution as a prescription drug in the United States in 1960.[29]

Concurrently, in the fall of 1960, an advisory committee was established by the Surgeon General of the United States to review all phases of polio prevention. In February 1962 the Communicable Disease Center[30] of the United States Public Health Service, of the

23. The "Cutter incident" refers to an outbreak of poliomyelitis that resulted from innoculations with the Salk killed virus vaccine, manufacturered by Cutter laboratories, which inadvertentently contained some live virus particles. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1296 (5th Cir. 1974). For a discussion of the "Cutter incident," see PAUL, *supra* note 9, at 437-39; KLEIN, *supra* note 9, at 11-25, 149-50. *See also* 13 STAN. L. REV. 645 (1961), discussing the case of Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960), which resulted from this mishap.

24. PAUL, *supra* note 9, at 437.

25. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1296 (5th Cir. 1974); Griffin v. United States, 351 F. Supp. 10, 24 (E.D. Pa. 1972); PAUL, *supra* note 9, at 451.

26. 351 F. Supp. at 24.

27. 498 F.2d at 1296.

28. *Id.*

29. Sabin, *supra* note 18, at 874. *See also* Davis v. Wyeth Laboratories, 399 F.2d 121, 122 (9th Cir. 1968).

30. The Communicable Disease Center is now called the Center for Disease Control.

Department of Health, Education, and Welfare, recommended a mass immunization campaign to eliminate completely paralytic poliomyelitis from the United States.[31] Accordingly, mass immunization centers were established throughout the United States, and many states enacted statutes requiring all children to be immunized before entering elementary school.[32] Nevertheless, despite the years of testing and the general recognition that the Sabin oral vaccine was safe and effective, by Augnst 1962, evidence came to light of a number of cases of poliomyelitis occurring within thirty days of immunization with the live attenuated virus.[33] In response to this evidence, the Public Health Service set up a committee to investigate the matter. The Special Advisory Committee studied these cases extensively and in its 1964 Report reached the following conclusion:

> 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 vaccine.[34]

The Committee then attempted to estimate the extent of the risk inherent in the vaccine from the incidence rates per million doses of the vaccine that had been distributed for use: for Type I, 0.16 per million doses; for Type II, 0.02 per million doses; for Type III, 0.40 per million doses.[35] Although the Committee recommended that the

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31. 399 F.2d at 123.

32. *See, e.g.*, FLA. STAT. ANN. § 232.032 (Cum. Supp. 1975), which provides in part:

(1) . . . Immunizations shall be required for poliomyelitis, smallpox, diphtheria, ruheola, ruhella, pertussis, and tetanus, ... The manner and frequency of administration of the immunization or testing shall conform to recognized standards of medical practice. The division of health shall supervise and secure the enforcement of the required immunization.

(2) The scbool board of each district . . . shall require each pupil who is otherwise entitled to admittance to kindergarten or first grade, . . . to present a certification of immunization for tbe prevention of those communicable diseases for which immunization is required by the division of health.

(3) The provisions of this section shall not apply if:

(a) The parent or guardian of the child objects in writmg that the administration of immunizing agents conflicts with his religious tenets or practices, or

(b) A competent medical authority certifies in writing that the child should be exempt from the required immunization for medical reasons, or

(c) The division of health determines that according to recognized standards of medical practice any required immunization is unnecessary or hazardous.

33. PAUL, *supra* note 9, at 465.

34. SPECIAL ADVISORY COMMITTEE ON ORAL POLIOMYELITIS VACCINE, REPORT TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE, at 5 (1964) [hereinafter cited as REPORT].

35. *Id.*

nonepidemic use of Type III oral vaccine be restricted to children,[36] it re-emphasized the need to continue the mass immunization programs in full force.[37] It is noteworthy, however, that Dr. Albert Sabin, a member of the Committee, filed a dissenting report in which he basically contended that the Committee's findings regarding vaccine-associated cases of poliomyelitis were not supported by an examination of the cases and the corresponding statistical data.[38] Nevertheless, despite the controversy over the risks associated with the Sabin oral vaccine among scientific and medical circles, the courts generally have accepted the proposition that poliomyelitis may be induced by the ingestion of the oral vaccine.[39] This finding ultimately has led to the imposition of liability on the vaccine manufacturers for failing adequately to warn the consuming public of these risks.

III. LIABILITY OF MANUFACTURER

Prior to an examination of the case law imposing liability on vaccine manufacturers, a distinction must be drawn between two types of drugs that may cause injury to the user[40]—pure and impure drugs. Impure drugs exist in a condition, or are used in a manner, other than that intended by the manufacturer, and cause harm to the user because of the presence of certain foreign substances, or because of their improper labeling or directions for use.[41] In such cases, the plaintiff ordinarily can prove negligence on the part of the manufacturer.[42] Pure drugs, on the other hand, exist in a condition and are used in a manner intended by the manufacturer, but cause harm as a side effect because of some inherent quality of the drug

36. *Id.* at 6; *see* Henderson, White, Morris & Langmuir, *Paralytic Disease Associated with Oral Polio Vaccines*, 190 J.A.M.A. 41 (1964).

37. REPORT, *supra* note 34, at 6.

38. REPORT, *supra* note 34, Comments by Albert B. Sabin, M.D. *See also* Sabin, *Vaccine-associated Poliomyelitis Cases*, 40 BULL. WORLD HEALTH ORG. 947 (1969); Sabin, *Commentary on Report on Oral Poliomyelitis Vaccines*, 190 J.A.M.A. 52 (1964); Sabin, *Is There an Exceedingly Small Risk Associated with Oral Poliovirus Vaccine?*, 183 J.A.M.A. 268 (1963) (Dr. Sabin points out that in recent years certain Coxsackie A, Coxsackie B, ECHO, and even mumps viruses have been proved to cause paralytic illnesses, indistinguishable from the clinical spectrum of paralytic poliomyelitis).

39. *See, e.g.*, Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1297 (5th Cir. 1974); Davis v. Wyeth Laboratories, 399 F.2d 121, 124-25 (9th Cir. 1968).

40. *See* Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947 (1964) [hereinafter cited as Rheingold], citing U.S. Public Health Service estimates that approximately 1.3 million drug reactions occur annually, requiring medical attention or resulting in lost work.

41. *Id.* at 970-71.

42. *See* notes 62-64 *infra* and accompanying text.

itself, or because of some physiological peculiarity of the user.[43] All prescription drugs can cause some side effects,[44] and, inevitably, some users will experience an adverse reaction to a drug regardless of its harmless appearance or composition. For example, more than twenty persons die annually from the use of aspirin.[45] Additionally, because of the almost indefinite number and variety of idiosyncratic, allergic, and hypersensitive users, drug reactions never are entirely predictable.[46] Thus given these two factors and the present state of medical knowledge, unavoidable injuries may occur from use of a pure, unadulterated drug, despite all due care by the manufacturer.[47]

Because of the inherent risks associated with any drug, federal control has become essential for adequate public protection.[48] After extensive and carefully regulated premarket testing and analysis, the Food and Drug Administration (FDA) determines which drugs are "safe for use" by balancing the potential risks with the therapeutic benefits sought to be achieved through use of the drug.[49] The FDA also regulates the manner in which a drug will be promoted and sold, and prescribes the labeling requirements, which typically emphasize precautions, side effects, and hazards associated with the drug.[50]

Although drug manufacturers are required to obtain FDA approval before marketing a new drug, compliance with FDA regulations does not fully protect a manufacturer.[51] Rather, the majority of courts have held that these regulations create only a minimal standard, and that compliance therewith merely is evidence of due

43. Rheingold, note 40 *supra*, at 970.

44. Peterson, *Products Liability of Drug Manufacturers*, 16 DEFENSE L.J. 277, 285 (1967) [hereinafter cited as Peterson].

45. *Id.*

46. *Id.* at 286. *See also*, Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, at 24-25 (1973) [hereinafter cited as Merrill]; Teff, *Products Liability in the Pharamaceutical Industry at Common Law*, 20 MCGILL L.J. 102 (1974) [hereinafter cited as Teff], noting that drugs may also produce synergistic effects when taken in combination with other suhstances, such as alcohol or barbituates.

47. *See* Peterson, *supra* note 44, at 286; RESTATEMENT (SECOND) OF TORTS § 402A, comment *k* at 353-54 (1965).

48. Elser, *Medical Products—An Area of Growing Concern*, 1974 INS. L.J. 539 [hereinafter cited as Elser].

49. Elser, *supra* note 48, at 539; Merrill, *supra* note 46, at 8-9. For vaccines, this function has been delegated to the Division of Biologic Standards (D.B.S.), which is a subdivision of the National Institutes of Health of the Department of Health, Education, and Welfare. Griffin v. United States, 351 F. Supp. 10, 25 (E.D. Pa. 1972).

50. Elser, *supra* note 48, at 539; Merrill, *supra* note 46, at 11.

51. Noel, *Products Defective Because of Inadequate Directions or Warnings*, 23 S.W.L.J. 256, 286 (1969) [hereinafter cited as Noel].

care.[52] Contrariwise, however, is the decision in *Lewis v. Baker*,[53] in which the court held that a drug properly tested, labeled with appropriate warnings, approved by the FDA, and marketed under federal regulation, is, as a matter of law, a reasonably safe product.[54] The *Lewis* approach has the obvious advantage of simplifying litigation, but seems inconsistent with the generally accepted notion that legislative safety standards are not conclusive evidence of due care.[55]

Governmental approval also may have particular significance for the plaintiff by providing a potential source of recovery against the federal government under the Federal Tort Claims Act.[56] In *Griffin v. United States*,[57] the Third Circuit recently affirmed an award against the Government for injuries the plaintiff allegedly sustained from the ingestion of a federally approved oral polio vaccine.[58] Rejecting the Government's contention that recovery was barred by the discretionary function exception to the Federal Tort Claims Act, the court found the Division of Biological Standards of the Department of Health, Education and Welfare negligent in approving the vaccine absent full compliance with federal testing regulations.[59] Further, the court approved the award of $1,500,000 to the plaintiff as not "in any way shocking, unfair or biased,"[60] but upheld the joint tort-feasor release executed by the plaintiff in favor of the manufacturer, which reduced the judgment against the federal government by the amount of the manufacturer's pro rata share.[61]

A. Theories of Recovery

In general, plaintiffs allegedly injured from use of defendant-drug manufacturers' products have advanced three basic theories of

52. *See, e.g.*, Sterling Drug Co. v. Cornish, 370 F.2d 82 (8th Cir. 1966); Stromsodt v. Parke-Davis & Co., 257 F. Supp. 991 (D.N.D. 1966).

53. 243 Ore. 317, 413 P.2d 400 (1966) (plaintiff allegedly injured from use of MER/29); *cf.*, McEwen v. Ortho Pharmaceutical Corp., ___ Ore. ___, 528 P.2d 522, 534 (1974) (in which the Oregon Supreme Court rejected the *Lewis* approach and followed the majority rule).

54. 243 Ore. at 320, 413 P.2d at 404.

55. Keeton, *Some Observations About the Strict Liability of the Maker of Prescription Drugs: The Aftermath of MER/29*, 56 CALIF. L. REV. 149, 153 (1968).

56. 28 U.S.C. §§ 1346, 2671-80 (1970). For a discussion of the potential for recovery against the federal government, see Merrill, *supra* note 46, at 70-87; Annot., 24 A.L.R. FED. 467 (1975).

57. 500 F.2d 1059 (3d Cir. 1974), *aff'g* 351 F. Supp. 10 (E.D. Pa. 1972).

58. *Id.* at 1073.

59. *Id.* at 1063-69.

60. *Id.* at 1071, citing Frankel v. Heym, 466 F.2d 1226, 1228 (3d Cir. 1972).

61. *Id.* at 1071-73.

recovery—negligence, breach of implied warranty, and strict liability in tort. When a drug proves to be dangerous because it contains impurities,[62] it was tested inadequately,[63] or it was labeled improperly,[64] the plaintiff normally will allege and prove that the manufacturer was negligent. The more difficult problem arises when a drug proves to be dangerous even though it was produced, without negligence, just as the manufacturer intended.[65] As indicated by the holding in *Carmen v. Eli Lilly & Co.*,[66] the plaintiff will have difficulty establishing negligence when adequate warnings are given and the drug contains no impurities. Instead, the plaintiff may seek recovery based on breach of implied warranty of merchantability and fitness for intended use or strict liability in tort.[67]

Although the plaintiff may characterize the cause of action as one for breach of implied warranty, the courts generally have recognized that in light of the recent trend toward broader recovery for injuries arising from defective products, the theory of strict liability virtually has superseded the concept of implied warranty.[68] A few courts still maintain the distinction that privity is required in a warranty action,[69] but the majority have dispensed with this requirement.[70] The first drug case to sustain an implied warranty action by a party not in privity with the drug manufacturer was

62. *See, e.g.*, Gottsdanker v. Cutter Laboratories, Inc., 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960); *see* note 23 *supra* and accompanying text.

63. *See, e.g.*, Tinnerholm v. Parke-Davis & Co., 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd as modified*, 411 F.2d 48 (2d Cir. 1969).

64. *See, e.g.*, Alman Bros. Farms & Feed Mill, Inc. v. Diamond Laboratories, Inc., 437 F.2d 1295 (5th Cir. 1971).

65. *See* Wade, *Strict Tort Liability of Manufacturers*, 19 S.W.L.J. 5, 14-15 (1965) [hereinafter cited as Wade].

66. 109 Ind. App. 76, 32 N.E.2d 729 (1941) (in action for death allegedly caused by antirabies vaccine, court held that evidence established that printed pamphlet furnished by manufacturers adequately informed deceased that paralysis and death were possible results of the treatrent); *accord*, Brown v. H.K. Mulford Co., 198 Mo. App. 586, 199 S.W. 582 (1917) (label on bottle of hog cholera vaccine contained sufficient warnings of the dangers associated with its use). *See generally* Rheingold, *supra* note 40, at 982-83. To assess negligence in the case of adequate warnings, the court would have to find that the drug manufacturer was negligent in distributing the product at all, due to the unreasonable risk of harm, notwithstanding the warning. Realistically, the FDA would not approve such a drug. *Id.*

67. For a discussion of these two theories, see Mendel v. Pittsburg Plate Glass Co., 25 N.Y.2d 340, 253 N.E.2d 207, 305 N.Y.S.2d 490 (1969) and Greenman v. Yuba Power Prod., Inc., 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963). *See generally* Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1103-14 (1960) [hereinafter cited as Prosser]; 13 STAN. L. REV. 645 (1961).

68. Grinnell v. Charles Pfizer & Co., 274 Cal. App. 2d 424, 432, 79 Cal. Rptr. 369, 373 (1969).

69. *See, e.g.*, Berry v. American Cyanamid Co., 341 F.2d 14 (6th Cir. 1965).

70. *Id.* at 16. *See generally* Annot., 75 A.L.R.2d 39 (1961); UNIFORM COMMERCIAL CODE § 2-318.

Gottsdanker v. Cutter Laboratories, Inc.,[71] in which the court, characterizing a drug as a product for human consumption, analogized to the impure food cases in which the privity requirement first was eliminated.[72] When privity is not compelled, the courts have characterized the difference between warranty and strict liability in tort as merely one of terminology and have considered the basic elements of the two causes of action to be the same.[73] Consequently, in *Reyes v. Wyeth Laboratories*,[74] the Fifth Circuit, observing that the outcome of a products liability action, especially when drugs are involved, did not appear to depend on which theory of recovery was relied upon by the parties,[75] disregarded the differences between the two approaches. The court noted that "whatever contractual trappings of warranty have not been destroyed by the citadel of privity need not detain us," and turned instead to an examination of strict products liability as embodied in Section 402A of the *Restatement (Second) of Torts*.[76] Section 402A subjects a seller or manufacturer of a product sold in a "defective condition unreasonably dangerous"[77] to the ultimate consumer to liability for physical or property harm caused thereby, even if he exercised "all possible care in the preparation and sale of his product."[78] Although phrased in terms of "strict liability," the *Restatement*[79] does not compel the manufacturer to be an absolute insurer of the product's safety; for the plaintiff to recover, he must prove that: (1) the product in question was defective; (2) the defect existed at the time the product left the

71. 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960). Prior to *Gottsdanker*, the drug cases founded on a theory of implied warranty uniformly denied recovery to a party not in privity. 13 STAN. L. REV. 645, 646 (1961). *See, e.g.*, Dunbrow v. Ettinger, 44 F. Supp. 763 (E.D.N.Y. 1942), Wechsler v. Hoffman-LaRoche, Inc., 198 Misc. 540, 99 N.Y.S.2d 588 (Sup. Ct. 1950).

72. 182 Cal. App. 2d at 607, 6 Cal. Rptr. at 323.

73. Hornung v. Richardson-Merrill, Inc., 317 F. Supp. 183, 184 (D. Mont. 1970); *accord*, Davis v. Wyeth Laboratories, 399 F.2d 121, 126 (9th Cir. 1968); Grinnell v. Charles Pfizer & Co., 274 Cal. App. 2d 424, 432, 79 Cal. Rptr. 369, 373 (Ct. App. 1969).

In Greeno v. Clark Equipment Co., 237 F. Supp. 427, 429 (N.D. Ind. 1965) the court noted that the doctrine of strict liability is "hardly more than what exists under implied warranty when stripped of the contract doctrines of privity, disclaimer, requirements of notice of defects, and limitation through inconsistencies with express warranties." *See generally* Prosser, *supra* note 67.

74. 498 F.2d 1264 (5th Cir. 1974).

75. *Id.* at 1271.

76. *Id.* A similar approach was taken in Givens v. Lederle, Docket No. 73-59 CIVTK (S.D. Fla. 1975).

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

78. *Id.* For a general discussion of strict liability in tort, see Keeton, *Products Liability—Some Observations About Allocation of Risks*, 64 MICH. L. REV. 1329 (1966); Noel, *supra* note 51; Prosser, *supra* note 67; Wade, *supra* note 65; Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825 (1973).

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

hands of the manufacturer; (3) because of the defect, the product was unreasonably dangerous; (4) plaintiff suffered damages or was injured; and (5) the defect was the proximate cause of the injuries sustained.[80] As the court in *Reyes*[81] pointed out, in the case of a plaintiff allegedly injured from the use of a "defective" drug, these five requirements may be reduced to two—that the product was defective as marketed, and that the defect was the proximate cause of the plaintiff's injuries.[82] Normally no question exists that the plaintiff has been injured, or that the alleged defect was present at the time the product left the hands of the manufacturer. The defect is usually, by definition, the result of the manufacturer's dereliction. Furthermore, the *Reyes* court stated that the requirements that the product be "unreasonably dangerous" and in a "defective condition" are essentially synonymous, and thus only one must be proved.[83]

The first requirement, that the plaintiff show the product was defective as marketed, may be satisfied in one of three ways: (1) the product may have been manufactured imperfectly; (2) it may have been designed improperly; or (3) it may have been labeled inadequately regarding the risks and dangers involved in the use of the product.[84] Because of the difficulties involved in establishing that defendant-drug manufacturer's product was defective in design, when no impurities are present, plaintiffs have turned with increasing frequency to allegations of inadequate directions for use or insufficient warnings of the dangers.[85] Relevant to the issue of warnings are comments *j* and *k* of the *Restatement*.[86] Comment *k* recognizes that given the present state of human knowledge, some products, including vaccines, are incapable of being made safe for their intended and ordinary use. Thus a properly prepared vaccine accompanied by proper directions and warnings is neither defective nor unreasonably dangerous, despite the risk involved, because the socially desirable results achieved through use of the drug justify its marketing and make the unavoidable risk a reasonable one.[87] Comment j re-emphasizes that to prevent a drug from being unreasona-

80. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1272 (5th Cir. 1974).

81. *Id.*

82. *Id.*

83. *Id.* For a discussion of the meaning of these two phrases, see Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 831-33 (1973).

84. Keeton, *Products Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 33-34 (1973).

85. Noel, *supra* note 51, at 260.

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

87. *Id.*, comment *k* at 353-54.

bly dangerous, the manufacturer may be required to give warnings concerning its use. Furthermore, if the product contains an ingredient to which a substantial segment of the population is allergic, and the ingredient is one whose danger generally is not known, the manufacturer is required to warn against it if he knows or should know of the presence of the ingredient and the danger involved.[88] If a warning is given, the manufacturer safely may assume that it will be read and heeded.[89]

It is obviously advantageous for the plaintiff to allege that the drug manufacturer is strictly liable for failing to warn of the risks inherent in the product. Once the plaintiff proves a breach of the defendant's duty to warn, he has sustained the burden of showing that the product was defective or unreasonably dangerous, as required by Section 402A of the *Restatement*.[90] Moreover, the plaintiff may establish his case without the necessity of expert testimony or the preservation of physical evidence essential to establish a design defect. And, more importantly, the plaintiff's case is much easier for the jury to understand.[91]

B. Warning Cases

The most critical question encompassed by the failure-to-warn cases is whether the defendant-drug manufacturer had a duty to warn the plaintiff of the particular dangers. In *Davis v. Wyeth Laboratories, Inc.*,[92] the Ninth Circuit held the manufacturer of Sabin oral polio vaccine strictly liable for failing to warn the plaintiff of the risks involved in taking the vaccine. The plaintiff, age thirty-nine and in good health, received the Sabin oral Type III polio vaccine at a clinic as part of a mass immunization program sponsored by the local medical society. Shortly after taking the vaccine, the plaintiff contracted paralytic poliomyelitis and suffered paralysis from the waist down. Although the plaintiff stated claims based on negligence, failure to warn of known dangers, strict liability, and breach of implied warranty of fitness,[93] the court limited the scope of its decision to the theory of strict liability in tort. Citing comments *l* and *k* of the *Restatement*, the court stated that strict liability could be avoided in this case only if the drug was marketed

88. *Id.*, comment *j* at 353.
89. *Id.* Noel, *supra* note 51, at 261.
90. Noel, *supra* note 51, at 261.
91. *Id.* at 260.
92. 399 F.2d 121 (9th Cir. 1968).
93. *Id.* at 125.

with full disclosure of the existence and extent of the risks involved, so that the consumer might make a voluntary and informed choice whether to submit himself to such risks.[94] While recognizing that the personal risk in some cases is "so trifling in comparison with the advantage to be gained as to be de minimis,"[95] the court rejected a purely statistical approach. Instead, the court held that a warning must be given 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."[96] Based on the Surgeon General's Reports, which recognized a danger in taking the Sabin Type III vaccine,[97] the court concluded that at the time the plaintiff was immunized, the manufacturer had a duty to warn the consumer of the risks involved. Failure to meet this duty rendered the drug unreasonably dangerous, and strict liability attached to its sale in the absence of warning.[98]

The California Court of Appeals took a similar approach in *Grinnell v. Charles Pfizer & Co.*,[99] in which plaintiffs brought an action against the manufacturer of Sabin Type I vaccine, which was administered in a mass immunization program, after which both plaintiffs contracted polio. Although both plaintiffs' and defendant's experts testified that it was impossible to prove that any individual case of poliomyelitis was vaccine-induced,[100] the court stated that the jury was not precluded from finding that the vaccine caused plaintiffs' injuries in light of the circumstantial evidence presented. The plaintiffs introduced testimony of their physicians and a report of the Surgeon General's Special Advisory Committee, which found these plaintiffs to be members of the "compatible" group—that is, compatible with the possibility of vaccine-induced illness.[101] Imposing on the defendant the duty of superior knowledge of all possible contraindications of the vaccine, based on evidence

94. *Id.* at 128-29.

95. *Id.* at 129.

96. *Id.* at 129-30; *see* 5 SAN DIEGO L. REV. 422 (1968).

97. 399 F.2d at 130; *see* notes 31-37 *supra* and accompanying text.

98. 399 F.2d at 130; *see* Curran, *Mass Immunization Programs: A Special Legal Area?*, 59 AM. J. OF PUB. HEALTH 137 (Jan. 1969); 18 DE PAUL L. REV. 829 (1969).

99. 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969).

100. *Id.* at 436, 79 Cal. Rptr. at 375.

101. *Id.*, 79 Cal. Rptr. at 376. In 1964, the Surgeon General's Special Advisory Committee reviewed all cases of paralytic poliomyelitis that had occurred within 4 to 30 days following receipt of the oral polio vaccine, and in which paralysis had not occurred sooner than 6 days after the feeding. CENTER FOR DISEASE CONTROL, POLIOMYELITIS SURVEILLANCE, ANNUAL SUMMARY 1972 (Oct. 1974) at 8 [hereinafter cited as CDC Summary].

existing at the time plaintiffs were immunized, the court held that defendant-manufacturer breached its duty to warn of the risks involved, and thus the vaccine was defective as manufactured.[102]

A similar factual situation was presented in the 1974 case of *Reyes v. Wyeth Laboratories*,[103] in which the plaintiffs' infant child contracted paralytic poliomyelitis two weeks after being given the Sabin oral polio vaccine at a public health center. Plaintiffs alleged that the live polio virus in the vaccine caused the child's injuries, and that the manufacturer was liable for her injuries for failing to warn her parents of this danger.[104] The one important factual distinction in *Reyes* is that the child was immunized in the midst of an epidemic outbreak of poliomyelitis in the area in which the child lived.[105] The child was diagnosed as suffering from a severe case of paralytic poliomyelitis caused by a Type I virus, the same type that was wild in the community at that time.[106] The defense presented a number of expert witnesses from the various special medical and scientific fields involved, along with depositions of federal officials from the Bureau of Biological Standards and the Center for Disease Control, who testified that the child's disease most probably was caused by the wild virus. One epidemiologist estimated that the child's risk of contracting polio naturally at that time was one in 3,000, whereas the package insert distributed with the defendant's product estimated that the risk of contracting Type I polio from the vaccine itself was approximately one in 5.88 million.[107] Nevertheless, the jury found that the child's disease was caused by the vaccine rather than from the wild strain in the community, and furthermore, that the manufacturer was liable in the amount of $200,000 for failing to give a direct warning to the parents of the child about the risk of contracting polio from the vaccine itself.[108] In fully upholding the jury's verdict,[109] the Fifth Circuit engaged in a two-step analysis to determine, first, whether the vaccine was so unsafe that marketing it at all was "unreasonably dangerous per se," and, if not, whether the vaccine had been introduced into the stream of commerce without sufficient safeguards and thus was "unreasonably

102. 274 Cal. App. 2d at 441-42, 79 Cal. Rptr. at 379.
103. 498 F.2d 1264 (5th Cir. 1974).
104. *Id.* at 1269.
105. Curran, *Case Summary and Comment on Reyes v. Wyeth Laboratories* at 1 (copy available through *Vanderbilt Law Review*).
106. *Id.*
107. *Id.* at 1-2.
108. 498 F.2d at 1269.
109. *Id.* at 1282.

dangerous as marketed."[110] The court found that on balance, marketing of the product was justified, despite the danger, since although the danger that vacinees may contract polio qualitatively is devastating, it statistically is miniscule.[111] With respect to the second step of its analysis, the court, citing the *Restatement*, stated that mere failure to give a required warning will cause the product to be "unreasonable dangerous as marketed."[112] The court returned to the *Davis* test[113] and found that a sufficient "true choice judgment" existed to require that the warning be given. The court cited three reasons in support of its holding: first, the risk was foreseeable statistically, although unknowable individually; second, a choice, if given, had an opportunity to be efficacious, since reasonable alternatives to taking the oral vaccine existed;[114] third, public policy favored allocating the risk of loss between members of the marketing chain, who could pass the cost on to the public in the form of price increases.[115]

The most recent "warning" case is *Givens v. Lederle*,[116] originally heard by a federal district court in June of 1974, at which time the jury returned a verdict for the defendant-drug manufacturer.[117] The case was retried a year later in light of *Reyes*, at which time the jury reversed its earlier verdict and awarded $262,000 to the plaintiff, who allegedly contracted polio by handling her infant's diapers after the child had been administered an oral polio vaccine.[118] The drug manufacturer was held strictly liable for failing to warn the child's physician of the risk of "contact-associated" cases.[119] Although not a mass immunization case, the *Givens* deci-

110. *Id.* at 1273.

111. *Id.* at 1274.

112. *Id.* at 1275.

113. 399 F.2d at 129-30; *see* notes 95-96 *supra* and accompanying text.

114. 498 F.2d at 1294. The only possible alternative to use of the oral vaccine was the use of the Salk killed virus vaccine. During an epidemic outbreak, the Salk vaccine probably would not provide immediate immunization, and thus it is questionable whether a reasonable alternative actually existed. *See* MORBIDITY & MORTALITY WKLY. REP. 279 (Aug. 19, 1967) (recommending use of a monovalent oral polio vaccine).

115. 498 F.2d at 1294.

116. Docket No. 73-59-CIVTK (S.D. Fla. 1975); *see* The Tennessean (Nashville), June 7, 1975, at 26, col. 5. The case is presently on appeal to the Fifth Circuit. Appeal docketed Dec. 22, 1975.

117. Interview with Hugh Nilsen Smith, Attorney for Defendant Lederle, in Clearwater, Fla., Jan. 2, 1976.

118. The Tennessean (Nashville), June 7, 1975, at 26, col. 5.

119. Contact cases refer to those cases of paralytic illness occurring in persons with a history of close relationships to oral polio vaccine recipients. The definition of a contact vaccine-associated case specifies that the onset of illness shall have occurred between 4 and 60 days following feeding of the vaccine, and that the person contracting polio shall have had

sion is important in that it holds the manufacturer liable for injuries sustained in a "contact-associated" situation. Left unanswered is the question whether the drug manufacturer in a mass immunization case would be liable for failing to warn the "contact," as one of those endangered by the use of the vaccine, of the risks involved. An even more difficult question is presented when the "contact" is not a parent or relative of the vaccinee. Presumably in the latter case, the drug manufacturer at most would be required to warn only those foreseeably endangered by the use of the drug.

In summary, the cases beginning with *Davis* have required a warning to the consumer to apprise him of the risks inherent in the use of the manufacturer's product.[120] In balancing the competing public policy considerations of the individual's right to be informed and the achievement of a public health objective,[121] the courts uniformly have favored the individual's privilege of making a personal decision whether the benefits sought to be derived from use of the drug justify assumption of the risks involved.[122] The rationale underlying this general philosophy is analogous to the rationale underlying the informed consent cases in the medical malpractice area—that is, a person has a right to determine what will be done with his own body.[123] The theory itself does not seem unjust or inequitable. The problem for the drug manufacturer, however, is how to fulfill the duty judicially imposed upon him.[124]

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contact with the recipient of the vaccine within 50 days prior to the onset of illness. CDC SUMMARY, *supra* note 101, at 9-10.

120. 5 SAN DIEGO L. REV. 422, 425 (1968).

121. *Id.* at 430.

122. *Id.* at 425.

123. For a discussion of the informed consent theory, see Alsobrook, *Informed Consent: A Right to Know*, 40 INS. COUNSEL J. 580 (1973). The more recent opinions speak of the doctrine of informed consent in terms of the patient's right to know of the risks involved in a specific procedure. Under this interpretation, the patient's substantive right is not based on any duty imposed on the physician by the medical community. Instead, the court views the right as a natural corollary to the proposition that all normal adults have the right to determine the disposition of their own body. *Id.* at 584, citing Hunter v. Brown, 4 Wash. App. 899, 484 P.2d 1162 (1971); Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972); Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

124. One exception to this general rule that traditionally has been recognized by the courts is that a manufacturer may not have a duty to warn the idiosyncratic, allergic, or hypersensitive user. Rheingold, *supra* note 40, at 1003. *See generally* Noel, *supra* note 51, at 289-98. In general, for the plaintiff to prove that the manufacturer had a duty to warn of the allergenic propensities of his product, he must show that a substantial number of users will suffer an allergic reaction. 17 LOYOLA L. REV. 221, 222 (1970); *see, e.g.*, Braun v. Roux Distrib. Co., 312 S.W.2d 758 (Mo. 1958). This theory is consistent with § 402A, comment *j*, RESTATEMENT (SECOND) OF TORTS, (1965), which imposes a duty to warn of ingredients "to which a *substantial* number of the population are allergic . . . ." (Emphasis added). Because the decisions, as evidenced by the *Davis* holding, have rejected a blind adherence to statistical

(1) Warning to the Ultimate Consumer

One aspect of the courts' holdings causing particular practical problems for the drug manufacturers is the requirement that the warnings must run to those the manufacturer should expect to use the product, or be endangered by its probable use.[125] This poses immense practical problems for the drug companies who do not sell to, do not advertise to, or do not directly communicate with the ultimate consumer.[126] Nonetheless, the requirement is in keeping with general products liability law, which requires a warning to the intended or foreseeable consumer, even when an intermediary exists in the chain of distribution.[127] The reasoning in these cases often is that it is foreseeable to the manufacturer that the intermediary may fail to discover and correct a defect or to pass on a warning.[128] An exception, however, is made in products cases in which the intermediary is not a mere conduit of the product, but administers or recommends it on an individual basis, implying an independent duty to evaluate the risks and transmit the relevant warnings to the consumer.[129]

Accordingly, the law generally imposes a duty on the manufacturer of non-prescription drugs to use reasonable care in warning

probabilities and have demanded instead a consideration of the gravity of the potential harm, recent cases demonstrate a trend of requiring a warning whenever the manufacturer is aware of the possibility that his drug may cause a harmful reaction in even a small group of users. Rheingold, *supra* note 40, at 1005; 17 LOYOLA L. REV. at 226. *See generally* Schattman, *A Cause of Action for the Allergic Consumer*, 8 HOUSTON L. REV. 827 (1971). Nevertheless, the manufacturer will be required to warn only of those dangers of which he has knowledge, or, in the exercise of reasonable skill and foresight, he should have knowledge. Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d 640 (Tex. Civ. App. 1965), *cert. denied*, 385 U.S. 1003 (1967). The key to this latter requirement is foreseeability, since the court will not impose liability for drug reactions so unique that the harmful results could not reasonably have been foreseen by the manufacturer. *Id.*; *accord*, Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1278 (5th Cir. 1974); Esborg v. Bailey Drug Co., 61 Wash. 2d 347, 358, 378 P.2d 298, 304-05 (1963). In such unpredictable cases, even if a warning was given, it might prove meaningless because frequently neither the consumer nor his physician would be able to recognize the peculiar reaction in advance. Merrill, *supra* note 46, at 24-25. When a warning is required, however, the duty is directed to an ascertainable and foreseeable class of persons possessing the particular allergy in question. Davis v. Wyeth Laboratories, 399 F.2d 121, 129 (9th Cir. 1968). These cases, involving the allergic or idiosyncratic plaintiff, may be distinguisbed from the vaccine cases and other drug cases in which the risk in some degree affects all or a significant portion of those who use the drug. *Id.* In the vaccine cases, the duty to warn is directed to the entire class of ultimate consumers.

125. Noel, *supra* note 51, at 281.

126. Curran, *supra* note 98.

127. Rheingold, *supra* note 40, at 986.

128. *Id.*

129. *See, e.g.*, Stottlemire v. Cawood, 213 F. Supp. 897 (D.D.C. 1963); Crotty v. Shartenberg's—New Haven, Inc., 147 Conn. 460, 162 A.2d 513 (1960).

consumers of the drugs' risks. In contrast, the manufacturer of prescription drugs must use reasonable care to warn the consumer's physician of the drug's risks, since the physician acts as a learned intermediary between the manufacturer and the patient.[130] The court in *Davis* recognized that a warning to the medical profession in such cases is the only effective way in which a warning could help the patient, since the physician is able to assess the risks in light of his knowledge of his patient's needs and susceptibilities.[131] Furthermore, the manufacturer may have extreme difficulty in reaching the consumer with a warning.[132] The problem arises, however, when a prescription drug, such as a polio vaccine, is not dispensed on a personalized basis. Rather, in the mass immunization cases, courts presume that the vaccine is administered to all comers at mass clinics without an individualized balancing of the risks by a "learned intermediary."[133] The Ninth Circuit in *Davis* held that when no individualized medical judgment intervenes between the manufacturer of a prescription drug and the ultimate consumer, "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning."[134] The court reasoned that in such a case, the very justification for the prescription drug evaporates.[135]

130. *See, e.g.*, Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969); Davis v. Wyeth Laboratories, 399 F.2d 121, 130 (9th Cir. 1968); Love v. Wolf, 226 Cal. App. 2d 378, 394, 38 Cal. Rptr. 183, 192 (1964); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969), *aff'g* 263 F. Supp. 159 (D.S.D. 1967).

131. Query whether warnings to a physician are really effective. In order to be effective, warnings and instructions must be carefully read and understood by the physician. But pharmaceutical companies spend over $3,000 a year per physician to promote their products, and thus drug advertising becomes a means of distorting the balance hetween risks and benefits. Furthermore, a drug's official labeling is required only to accompany the package distributed to the pharamacist and thus may never even reach the physician himself. Merrill, *supra* note 46, at 26. This problem arose in Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969), a suit against the drug manufacturer for permanent eye injury sustained by plaintiff as a result of the manufacturer's alleged failure to warn plaintiff's doctor of the side effects of its prescription drug Aralen. The Eighth Circuit affirmed the district court's findings that plaintiff's physician (and other general practitioners) receive so much literature on drugs that it is impossible to read it all; that plaintiff's physician relied on "detail men," medical conventions, medical journals, and conversations with other doctors for information on drugs he prescribed; and, that a change in literature and an additional letter were insufficient to present new information to him. *Id.* at 990. Rather, the court found that the most efficient means of presenting drug information to doctors entails the use of "detail men," who should have been informed of the change in information and should have brought this to the doctor's attention. *Id.* at 993.

132. Davis v. Wyeth Laboratories, 399 F.2d 121, 130 (9th Cir. 1968).

133. *Id.* at 131; *accord*, Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974).

134. 399 F.2d at 131.

135. *Id.*; *see* 36 Mo. L. REV. 570, 575-76 (1971), in which the autbor points out that if

The Fifth Circuit in *Reyes* adopted this holding in rejecting the defendant's argument that its warning to the State Health Department was sufficient. The court concluded that just as the manufacturer cannot balance the risks and benefits of a given medication for its ultimate consumers, it cannot allow its immediate purchaser to make this choice for them.[136] Likewise, in *Davis*, the defendant argued that its duty to warn was satisfied by its disclosure of the dangers to the medical society dispensing the vaccines through a printed insert accompanying each bottle of vaccine.[137] The court disagreed, finding that when drugs are sold over the counter, warnings normally can be given by proper labeling, but such a method of warning is not available in the mass immunization setting where the bottles and inserts are never seen by the consumer.[138] Instead, the court recognized that other means of communications such as "advertisements, posters, releases to be read and signed by recipients of the vaccine, or oral warnings" were available and could have been undertaken or prescribed by the drug manufacturer to reach the ultimate consumer.[139]

Whether a valid distinction can be drawn between prescription drugs administered by a physician and those administered through a public health clinic is questionable. In a well-designed public health program, a doctor normally has investigated thoroughly all risks involved in the use of the vaccine, has taken all possible preventative measures to gnard against mishap, and has trained specially those working in the clinic to administer the particular vaccine. Compare this situation to that of the general practitioner who deals with a countless number of drugs in treating numerous diseases, and who cannot possibly specialize in the administration of one particular kind of vaccine. Furthermore, just as the physician generally does not inform the patient that the risk of contracting polio from the ingestion of the oral vaccine is one in several million, because he considers the benefits to far outweigh the potential harm, the doctor or medical society conducting the public health program likewise makes a deliberative and informed decision that the risks are not significant enough to justify their disclosure. Thus medical supervision and individualized judgment seem no less pres-

courts did not require a warning to consumers in the mass immunization cases, they would be in the anomalous position of requiring a warning to consumers for non-prescription drugs, but not requiring one for certain prescription drugs.

136. 498 F.2d at 1276.

137. 399 F.2d at 130.

138. *Id.* at 131.

139. *Id.*

ent in the public health clinic than in the practitioner's office; consequently, contrary to present case law, a warning to the doctor or medical society conducting the immunization program should satisfy the manufacturer's duty to warn.[140]

(2) Method and Adequacy of Warning

The court in the *Davis* case took a positive step toward providing guidance to the drug manufacturer by indicating that the use of advertisements, posters, releases, and oral warnings might provide sufficient notice to the consumer to satisfy the manufacturer's obligation. The opinion, however, does not indicate whether the use of one, a combination, or all of the devices mentioned would be required by the court to absolve the manufacturer of liability,[141] and subsequent decisions fail to offer any specific guidance. In general, the warning must be accurate, strong, clear, and placed in a sufficiently prominent position that it readily will be noticed.[142] The manufacturer is aided by the presumption set forth in comment *j* to Section 402A of the *Restatement (Second) of Torts*,[143] that if the manufacturer has warned of the risks by the use of literature or by other means, he reasonably may assume that the protected class has read and will heed the warning given. Furthermore, Section 388 of the *Restatement (Second) of Torts*[144] requires only the exercise of reasonable care on the part of the manufacturer to inform the consumer of the dangers, rather than mandating actual notice.[145]

Not only is the drug manufacturer confronted with the problem of the manner in which to convey a warning, but, additionally, he is faced with the problem of what information must be contained in the warning. This is a particularly arduous task for the drug manufacturer, a member of the private economy, accustomed to thinking primarily in terms of sales in a competitive marketplace.[146] Under the present case law, the manufacturer is expected to convey information to the consuming public regarding the risks, benefits,

140. Interview with Dr. William Schaffner, Assoc. Prof., Dept. of Med., Preventive Med., Vanderbilt Univ. Med. School, in Nashville, Tenn., Jan. 19, 1976.

141. 36 Mo. L. Rev. 570, 575 (1971).

142. 18 De Paul L. Rev. 829, 835 (1969).

143. Restatement (Second) of Torts § 402A, comment *j*, at 353 (1965).

144. *Id.* § 388.

145. *See* Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 991-92 (8th Cir. 1969), in which the Eighth Circuit affirmed the trial court's holding that the "undisputed standard" of duty to warn requires "reasonable efforts to warn the medical profession of the side effects of the drug."

146. 5 San Diego L. Rev. 422, 430 (1968).

and contraindications of his product.[147] A delicate balance must be struck among these factors. Minimization of the dangers through watered-down warnings or warnings containing false assurances of safety may amount to inadequate warnings altogether, resulting in manufacturer liability.[148] As a general rule, the force of the warnings must be equal to the dangers involved, sufficient to raise an appropriate caution in the user.[149] Additionally, a warning may be found deficient because of the use of technical terms, incomprehensible to the ultimate consumer to whom the warning is aimed.[150] Yet, in the medical field, the use of such technical terms seems almost unavoidable. The question of the adequacy of the warnings ordinarily is a question of fact for the jury,[151] which automatically adds another element of unpredictability to the manufacturer's already uncertain task.

(3) Manufacturer Held to Skill of an Expert

An additional problem is presented for the manufacturer by the fact that the courts hold him to the skill of an expert in his field and presume that he possesses an expert's knowledge of the arts, materials, and processes of the pharmaceutical industry.[152] Included in such expertise must be a familiarity with the practices of distribution and administration of pharmaceutical products in the drug industry.[153] Thus the court in *Reyes* rejected the manufacturer's contention that he had no knowledge that the vaccine would not be administered as a prescription drug and, based on expert testimony, concluded that the drug manufacturer had ample reason to foresee the way in which its vaccine would be distributed.[154] Because the drug manufacturer often sells to drug distribution houses, which then sell to the public health clinics or pharamacists, the only procedure for insuring that warnings reach the ultimate consumer is to

147. *See* Curran, *Public Warnings of the Risk in Oral Polio Vaccine*, 65 AM. J. OF PUB. HEALTH 501 (May 1975).

148. Rheingold, *supra* note 40, at 994.

149. 18 DE PAUL L. REV. 829, 835 (1969).

150. Noel, *supra* note 51, at 283.

151. *Id.*

152. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1277 (5th Cir. 1974); *accord*, Wright v. Carter Prod., Inc., 244 F.2d 53 (2d Cir. 1957); Johnston v. Upjohn Co., 442 S.W.2d 93 (Mo. App. 1969).

153. 498 F.2d at 1277.

154. *Id.* Neal Nathanson, Professor of Epidemiology at Johns Hopkins University School of Public Health, testified that it was common knowledge in the drug industry that "a great majority" of vaccines are distributed at mass immunization clinics, manned at least in part by volunteers.

treat all drugs as intended for the public health clinics, since warnings on package inserts to the pharmacist and physician will not discharge the manufacturer's duty to warn the ultimate consumer. Moreover, the manufacturer sometimes argues that the product involved a hazard of which he was unaware. The courts have held, however, that the duty to warn arises not only when the manufacturer actually knows of the danger, but also when, in the exercise of reasonable care, he should know of the danger.[155] As a corollary to the duty to know the nature and effect of the product, the courts have imposed a duty on the manufacturer to use reasonable efforts to investigate to discover this information.[156] In *Davis*, the Ninth Circuit stated that when the Sabin Type III vaccine initially was licensed and produced, the manufacturer was under no duty to warn because there was no known or foreseeable risk involved in taking the drug. But, when the danger became apparent after further experience, a duty to warn attached.[157] Consequently, even after producing and marketing a product, the manufacturer is obliged to keep abreast of new scientific and medical developments of relevance to his drug, and to apply new investigative techniques as they are developed.[158] In *Tinnerholm v. Parke-Davis & Co.*,[159] the drug manufacturer was held negligent in failing to send out warnings to foreseeable users of new developments regarding the harmful side effects produced by its drug.[160] Likewise, the court in *Stromsodt v. Parke-Davis & Co.*[161] found the manufacturer liable for injuries caused by use of its drug on the basis of its failure to warn of dangers that were inherent in its use and that could have been discovered by adequately testing the product, even though the drug manufacturer met all of the government regulations and requirements in production and marketing.[162] Thus while the duty to discover is a relative one, in which the manufacturer only need show that he adhered to scientifically accepted tests and standards currently practiced by manufacturers of like products, the courts have demanded a higher

155. Noel, *supra* note 51, at 265; *see, e.g.*, Tinnerholm v. Parke-Davis & Co., 285 F. Supp. 432, 451 (S.D.N.Y. 1968), *aff'd as modified*, 411 F.2d 48 (2d Cir. 1969); Stromsodt v. Parke-Davis & Co., 257 F. Supp. 991, 997 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969).

156. Rheingold, *supra* note 40, at 996-98.

157. 399 F.2d at 129.

158. Rheingold, *supra* note 40, at 997. *But see* Gielskie v. State, 10 App. Div. 2d 471, 200 N.Y.S.2d 691 (1960), *rev'g* 18 Misc. 2d 508, 191 N.Y.S.2d 436 (N.Y. Ct. Cl. 1959), *aff'd*, 9 N.Y.2d 834, 216 N.Y.S.2d 85, 175 N.E.2d 455 (1961).

159. 285 F. Supp. 432 (S.D.N.Y. 1968).

160. *Id.* at 451.

161. 257 F. Supp. 991 (D.N.D. 1966).

162. *Id.* at 996-97.

degree of testing than with other products because the danger associated with drugs is so acute.[163] As the decision in *Stromsodt* illustrated, compliance with stringent FDA regulations and standards will not constitute due care per se.[164] But, as the court in *Johnston v. Upjohn Co.*[165] indicated, no liability will attach if the failure to detect the danger occurred because it was unknown and due to undetectable factors.

C. *Causation*

Once the plaintiff has established that the product was in a "defective condition, unreasonably dangerous" to the ultimate consumer because of the manufacturer's failure to warn, he still has the burden of proving that the alleged defect was the proximate cause of his injuries.[166] Since, in all other products liability suits, the plaintiff must show that the defect in issue caused his injury, arguably a plaintiff in a "warning" case must prove that he would have suffered no harm but for the absence of the warning.[167] This question was addressed by the Fifth Circuit in *Reyes*, which recognized that in most products cases there are two causation issues: first, whether the defendant's product was the cause-in-fact of the plaintiff's injuries and secondly, whether plaintiff's injuries resulted from the alleged defect in defendant's product.[168] The jury initially found that the child's poliomyelitis was vaccine-induced, and thus defendant's product was the "producing-cause." The more critical issue was whether the manufacturer's failure to warn of the danger inherent in its product could be regarded as the proximate cause of the child's injuries. The *Reyes* court set forth the following test to determine proximate cause:

> Where a consumer, whose injury the 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 defen-

163. Rheingold, *supra* note 40, at 998.

164. 257 F. Supp. at 996-97.

165. 442 S.W.2d 93 (Mo. App. 1969).

166. *See* notes 80-82 *supra* and accompanying text.

167. 50 TEXAS L. REV. 577, 578 (1972).

168. 498 F.2d at 1279; *accord*, Stromsodt v. Parke-Davis & Co., 257 F. Supp. 991, 997 (D.N.D. 1966). Note that in Grinnell v. Charles Pfizer & Co., 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969), the court addressed only the issue of whether the injury was vaccine-induced, without deciding whether defendant's failure to warn was the cause-in-fact of the plaintiffs' injuries. *Id.* at 374. *See generally* Keeton, *Products Liability—Inadequacy of Information*, 48 TEXAS L. REV. 398, 413-15 (1970).

dant's product was the producing cause of the plaintiff's injury would be sufficient to hold him liable.[169]

The court reasoned that testimony by the child's parents about what they would have done if proper warnings had been given would be merely self-serving and speculative. To avoid this, the court created a legal presumption that a warning, had it been given, would have been heeded.[170] This holding is in accord with holdings in other products liability cases. In *Technical Chemical Co. v. Jacobs*,[171] the Texas Supreme Court held that it was "incumbent" upon the plaintiff to secure a jury finding that the alleged faulty labeling was the cause of his injuries.[172] The court, however, established a rebuttable presumption that the warning, if given, would have been read, noting that in most warning cases the plaintiff's own testimony usually would be the only proof that the plaintiff could present to show that he would have heeded a warning. The court observed that, at best, this merely would lead to a swearing match between the plaintiff and defendant, with liability depending on the sympathies of the jury; at worst, the plaintiff would be unable to testify because of death or injury, and the burden would be impossible to sustain.[173] The court noted, however, that this presumption of causation may be rebutted if the defendant can show that the plaintiff misused the product in an outrageous manner, or that the plaintiff knew of the risks at the time of using the product.[174] Recovery, however, is insured when jurors could only speculate whether the plaintiff would have heeded a warning had one been given and thus avoided the accident.[175]

Although the legal presumption regarding causation created by the court in *Reyes* accords with general products liability law, a distinction arguably should be drawn between the two. In most products liability cases, when a warning has been given, the con-

169. 498 F.2d at 1281.

170. *Id.*

171. 480 S.W.2d 602 (Tex. 1972), *rev'g* 472 S.W.2d 191 (Tex. Civ. App. 1971). This case involved an action by the buyer of a can of freon coolant against the manufacturer for injuries sustained when the can exploded because plaintiff mistakenly had attempted to put the coolant in the wrong side of the car's air conditioner. Plaintiff based his cause of action on § 402A of the *Restatement (Second) of Torts*, and alleged that the manufacturer was negligent in failing to warn of this danger. Because the plaintiff testified that he had not read the can's label, the jury found that the manufacturer's faulty labeling was not the cause of the plaintiff's injuries. *See* 50 TEXAS L. REV. 577, 578 (1972).

172. 480 S.W.2d at 605.

173. *Id.* at 606.

174. 50 TEXAS L. REV. 577, 580-81 (1972).

175. *Id.* at 583.

sumer has a choice of using or not using the product; when a warning has not been given, the consumer is unable to assess the risks involved; consequently, the court presumes that he would not have used the product had he been aware of the risks. In a vaccination case, however, often no true choice exists whether or not a warning has been given. For a child entering public school for the first time, state statutes generally require a polio immunization,[176] and for an individual immunized during an epidemic outbreak of poliomyelitis no other safe and effective alternative exists.[177] Thus, in the vaccination cases, often the presumption that the plaintiff would have heeded a warning had one been given is a legal fiction, erroneously applied by the courts. Instead of engaging in such a presumption, the courts more appropriately should leave the burden of proof on the plaintiff to show specifically why he would not have taken the vaccine if confronted with an adequate warning.

IV. Potential Solutions

An analysis of the "mass immunization" cases reveals that the manufacturer of a pure unadulterated vaccine may be held strictly liable for failing to warn the ultimate consumer of the dangers inherent in the use of the drug. Pervading these cases is the strong public policy issue of whether these warnings should be given at all because of their potential threat to the nation's preventative medicine programs that favor mass immunization to combat infectious diseases.[178] The American Academy of Pediatrics and the Conference of State and Territorial Epidemiologists filed amici curiae briefs in *Reyes*, arguing that warnings should not be given because, first, any effort to warn vaccinees will be futile and frightening, leading only to confusion, and, secondly, a warning is unnecessary once epidemiologists reach a deliberate medical judgment that universal vaccination is necessary.[179] The courts, in balancing this public policy issue against the right of the individual to be informed, seemingly have resolved this question in favor of the latter. Therefore, unless a radical shift occurs in future cases, the manufacturer must seek a workable solution to fulfill the warning requirement if he is to avoid further liability.

At first glance, the solution appears both simple and obvious—simply provide the consumer with the requisite warning.

176. *See* note 32 *supra*.
177. *See* note 114 *supra*.
178. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1293 (5th Cir. 1974).
179. *Id.*

The practicalities of accomplishing this task, however, involve significant problems because the manufacturer ordinarily has no direct contact with the consumer. Perhaps, as suggested by *Davis*,[180] the manufacturer could try to insure that the consumer was warned by selling only to those "distributors" who guaranteed that the warnings would be communicated to the consumer and signed an indemnification agreement, promising indemnification for any losses sustained by the manufacturer for failure to warn. The guarantee, in and of itself, probably would provide only slight legal comfort to the manufacturer because the general rule in products liability cases is that it is foreseeable to the manufacturer that the distributor-intermediary might fail to pass on a warning. Thus the courts have imposed the more stringent duty of requiring the warning to reach the ultimate consumer.[181] In combination with an indemnification agreement, however, the guarantee might entitle the drug manufacturer to indemnification from the distributor, who failed to pass on the warning. If the negligent distributor were a drug distribution house, the manufacturer might be able to recover. On the other hand, if the distributor were a public health clinic, the indemnification agreement would prove of little value since many health clinics, supported by contributions and volunteer workers, would be financially unable to indemnify the manufacturer for a loss of the magnitude exemplified by past jury awards.[182] Moreover, even if a warning is given, the manufacturer may be found liable for inadequately representing the dangers in a manner comprehensible to the consumer. Also since the adequacy of a warning is a question of fact for the jury, the manufacturer may be faced with incongruous standards from state to state.[183]

In light of the seeming impracticalities for the manufacturer in complying with the requirements of present case law, an initial question raised by the decisions is whether the courts should impose strict liability on the manufacturer of a pure drug[184] or whether they should return to a negligence standard. The traditional justifications advanced for the imposition of strict liability are twofold: to provide incentive for greater care on the part of the manufacturer and to allocate the risk of loss to the manufacturer who is better able to absorb losses.

180. *See* text accompanying note 134 *supra*.
181. *See* text accompanying note 128 *supra*.
182. *See* note 3 *supra*.
183. Merrill, *supra* note 46, at 50.
184. Rheingold, *supra* note 40, at 1014-15. *See generally* Wade, *supra* note 83, at 826.

First, the imposition of a rigorous rule of liability often is justified on the basis that it will produce greater care on the part of the manufacturer. Normally, the manufacturer is in the best position to discover defects or dangers in his product and to guard against them through appropriate safeguards, inspections, and warnings.[185] A significant increase in care, however, will result only if the manufacturer presently is not exercising the highest practicable standard of care.[186] In this regard, vaccines and other types of prescription drugs would seem least to fit this rationale because of the numerous factors that already require a high standard of care on the part of the manufacturers.[187] These factors include exceedingly strict governmental requirements and supervision,[188] internal production controls and a tradition of absolute purity in the drugs manufactured,[189] stiff competition in the industry and concern for reputation,[190] and imposition of liability for negligence.[191] Conceivably, the imposition of strict liability may lead to a higher standard of care, but only at the expense of more deleterious consequences. Strict liability may discourage the expeditious marketing of new and vitally necessary drugs while further testing and experimentation are conducted.[192] Additionally, basic research may be stifled if the drug companies determine that the risks in marketing a new drug are too great to justify the expenditure necessary to develop and produce the drug.[193]

Secondly, the imposition of strict liability has been justified by the theory of "loss distribution," "risk allocation," or "enterprise liability," in which accidents and injuries are considered as an inevitable and statistically foreseeable "cost" of the product's consumption or use.[194] According to this theory, strict liability places the risk of loss on the manufacturers, who are in a better financial position than the injured parties to absorb the losses or distribute them among consumers.[195] Theoretically, the manufacturer will increase

185. Hall v. E.I. duPont de Nemours & Co., 345 F. Supp. 353, 368 (E.D.N.Y. 1972).

186. 13 STAN. L. REV. 645, 646 (1961).

187. Rheingold, *supra* note 40, at 1015.

188. *Id.*; 13 STAN. L. REV. at 647.

189. Rheingold, *supra* note 40, at 1015.

190. *Id.*; 13 STAN. L. REV. at 647.

191. Keeton, *Products Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 34 (1973); Rheingold, *supra* note 40, at 1015; 13 STAN. L. REV. at 647.

192. Rheingold, *supra* note 40, at 1017; 13 STAN. L. REV. at 649.

193. 13 STAN. L. REV. at 649.

194. Hall v. E.I. duPont de Nemours & Co., 345 F. Supp. 353, 368 (E.D.N.Y. 1972). For a discussion of risk allocation see Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L.J. 499 (1961).

195. 13 STAN. L. REV. at 648; *see*, Dickerson, *The Basis of Strict Products Liability*, 1962

his prices to reflect the cost of improvements, liability insurance, and excessive damage recoveries, as will his competitors within the industry.[196] Often, however, a drug manufacturer is unable to make further improvements or to obtain adequate insurance coverage.[197] Furthermore, the distribution of liability costs among faultless drug manufacturers seems merely fortuitous, and thus, if a manufacturer, bludgeoned with an inordinate amount of liability, increased his prices accordingly he would be driven out of the competitive market-place and potentially into bankruptcy.[198] Instead of spreading the risk of loss to the consumer, the imposition of strict liability may result in the drug manufacturer alone bearing the loss.

Consequently, the traditional justifications advanced for the imposition of strict liability in most products liability cases seem inapplicable to the drug manufacturer's liability in the mass immunization cases. Rather, negligence seems to provide a more appropriate and equitable standard, imposing liability only when the manufacturer is to some degree at fault. Under a negligence theory, the plaintiff would be denied recovery if the manufacturer had exercised all due care in the production and distribution of his product. Considering the recent trend toward broader recovery in products liability cases, it is unlikely that the courts will revert to this less stringent standard.

Faced with the burden of strict liability, the drug manufacturer's more timely and practicable solution may be to try to shift the risk of loss to another party. The practical problems of placing the risk of loss on the drug manufacturer already have been explored. It would seem unjust for the consumer to bear the cost of adverse reactions caused by drugs that not only have been federally approved for use, but also, as in the case of polio vaccines, have been required to be administered by state statute.[199] As a general proposi-

INS. L.J. 7, 11 (1962) [hereinafter cited as Dickerson].

196. Dickerson, *supra* note 195, at 11.

197. *Cf.* Teff, *supra* note 46, at 113-14, stating that the drug companies, because of their high profit ratios, should be able to insure against all but the most catastrophic losses. There is a problem, however, when the manufacturer seeks to insure against losses caused by *new* drugs because the actuarial process necessarily operates with reference to the past. Thus it may be prohibitively expensive to insure against some drug risks, if indeed they are insurable at all.

198. 13 STAN. L. REV. at 648 n.22. Professor Keeton adds several other lesser justifications for the impositon of strict liability including: (1) it provides a means of recovery in cases in which fault is difficult or impossible to prove, thus giving a deserving plaintiff recovery; (2) it provides redress for the frustration of consumer expectations. Keeton, *supra* note 191, at 34-35.

199. Krugman, *Immunization "Dyspractice": The Need for "No Fault" Insurance*, 56

tion, the mass immunization cases have adhered to this philosophy. Furthermore, of all the parties involved, the consumer can least afford to bear the loss financially.[200] The consumer is in the worst position to reduce the risk of injury by altering his own behavior since with few exceptions, he does not decide whether to purchase or use a prescription drug and, ordinarily, he is neither provided with the information nor is he equipped to understand the type of information essential to safe drug use.[201]

Perhaps the risk of loss for adverse reactions to vaccines, whose use have been federally approved and statutorily required, most appropriately should be allocated to the Government.[202] The possibility of recovery under the Federal Torts Claims Act has been expanded substantially since the *Griffin* decision.[203] To recover under the Act, however, the plaintiff must prove that his injury was caused "by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office of employment. . . ."[204] Furthermore, the Act is riddled with a series of exceptions that could limit the Government's potential liability.[205] Thus numerous obstacles face a plaintiff seeking to recover against the federal government.

A more certain method of placing the risk of loss on the Government probably is through a statutory enactment requiring direct compensation to the injured party by the federal government, without regard to proof of negligence.[206] Since society appears to benefit from these mass immunization programs, as evidenced by the drastic decline in paralytic poliomyelitis,[207] then society logically should bear the loss, through the Government, for injuries that occur without fault.[208] Other countries, such as Denmark, Germany, and Japan, have enacted legislation to compensate those who are victims of the immunization laws.[209] The United States Government already has aided the polio vaccination campaign by granting funds to the states enabling all children, regardless of their ability to pay,

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PEDIATRICS 159 (Aug. 1975) [hereinafter cited as Krugman]; *see* note 32 *supra* and accompanying text.

200. Merrill, *supra* note 46, at 87-88.
201. *Id.* at 90-91, 93.
202. *See* notes 32 & 49 *supra* and accompanying text.
203. *See* notes 56-61 *supra* and accompanying text.
204. Federal Tort Claims Act, 28 U.S.C. § 1346(b) (1970).
205. Merrill, *supra* note 46, at 71-73.
206. 13 STAN. L. REV. 645, 651 (1961).
207. *See* notes 11-12 *supra* and accompanying text.
208. Krugman, *supra* note 199, at 159.
209. *Id.*

to receive an immunization.[210] This federal aid should be extended to compensate the victims of immunization programs through legislation analogous to the Price-Anderson Amendment to the Atomic Energy Act of 1954,[211] which provides compensation to the victims of catastrophic accidents arising out of nuclear reactions.[212] A similar statute could provide direct compensation to individuals, immunized as part of a government program, for injuries allegedly sustained because of the vaccine.[213] Additionally, a government agency, similar to the Workmen's Compensation Board, could carry out such a program. The necessary funds could be raised by allocating tax funds to the programs or by placing a minimal surcharge on each dose of vaccine manufactured.[214] The legislation would serve the dual goals of providing prompt and adequate compensation to the public, without lengthy litigation, and of safeguarding the manufacturers against losses beyond the limit of available insurance.[215]

An alternative solution would be legislation requiring government indemnification of manufacturers for liability above the limit of available private insurance.[216] This method would protect manufacturers from devastating damage awards, yet ensure plaintiffs' recoveries. As a prerequisite to obtaining a license to produce the vaccine, manufacturers would be required to secure a certain amount of insurance or demonstrate the availability of an equal amount of assets.[217] Although this alternative possesses the drawback of requiring litigation to determine the manufacturer's liability, it has the advantage of spreading the cost first to those primarily benefitted by defendant's product, the consumers who pay higher prices to cover the cost of insurance premiums, and, secondly, to the taxpayers in the case of extraordinary losses.[218]

The imposition of liability on the Government should be limited to those cases in which the Government actively has engaged in a federal health care program requiring the administration of a particular drug. Usually in such cases, as was true with the polio vaccine, the development and distribution of the drug is so much a

210. 13 STAN. L. REV. 645, 651 n.39 (1961), citing Poliomyelitis Immunization Assistance Act of 1955, ch. 863, 69 Stat. 704 (1955).

211. Act of Sept. 2, 1957, Pub. L. No. 85-256.

212. *See* ROSENTHAL, KORN, & LUBMAN, CATASTROPHIC ACCIDENTS IN GOVERNMENT PROGRAMS 2-3 (1963) [hereinafter cited as ROSENTHAL].

213. 13 STAN. L. REV. at 651, citing such a proposal that was made to benefit those injured by the Salk vaccine, H.R. 8082, 85th Cong., 1st Sess. (1957).

214. Krugman, *supra* note 199, at 160.

215. ROSENTHAL, *supra* note 212, at 12.

216. *Id.* at 15.

217. *Id.* at 16.

218. 13 STAN. L. REV. at 652.

cooperative venture between government and industry[219] that imposition of at least partial liability on the Government does not seem inequitable. Although government liability arguably may lead to a lesser standard of care by the manufacturers,[220] this problem can be avoided by disallowing compensation or indemnification if the manufacturer has been negligent, or has failed to comply with more stringent regulations that the FDA could promulgate.

Although government liability seems to provide the most workable and equitable solution to the problems presented by the mass immunization cases, it does not provide an immediate solution for the manufacturer since it requires the enactment of new legislation, which is always a time-consuming process. In the meantime, the most practical solution for the drug manufacturers is to attempt to comply with the present case law. To insure freedom from liability, they may "overwarn" of the dangers inherent in the drug through posters, written bulletins, and advertisements at the health clinics. Before selling to any distributors, the manufacturer could demand a contractual undertaking on their part to disseminate these warnings to the patients at the clinics, as well as an indemnification agreement to compensate the manufacturer for liability resulting from failure to warn. In addition, the manufacturer might require each consumer to sign a release, agreeing not to hold the manufacturer liable for any drug-related injuries not attributable to his negligence in producing the drug.[221] Although these procedures may appear both troublesome and inadequate, presently they seem the only immediate solution to the manufacturer's dilemma.

V. CONCLUSION

The incidence of paralytic poliomyelitis has declined remarkably in the United States since the development of the inactivated Salk vaccine and, later, of the attenuated Sabin oral vaccine. The

219. Merrill, *supra* note 46, at 102 n.375.

220. *Id.* at 106.

221. Releases, with a printed warning at the top, presently are being used by many health clinics, and even are disseminated in various foreign languages in an attempt to reach all participants at the clinics. In *Reyes v. Wyeth Laboratories*, the plaintiffs signed a release in favor of the State of Texas. 498 F.2d 1264, 1270 (5th Cir. 1974). For a general discussion of the requirements for, and effect of, a release, see 66 AM. JUR. 2d, *Release* §§ 1-45 (1973). In general, a releasor cannot avoid the effect of a release on the ground that at the time he signed the release he did not read it or know its contents, nor on the ground that he could not read English. Blossi v. Chicago & N.W. Ry., 144 Iowa 697, 123 N.W. 360 (1909). The releasor, however, may be able to avoid the release if he can show ignorance of the nature of the instrument, or mutual mistake regarding the nature or seriousness of the injury. Ricketts v. Pennsylvania R.R., 153 F.2d 757 (2d Cir. 1946); Warren v. Crockett, 211 Tenn. 173, 364 S.W.2d 352 (1962).

use of the oral vaccine has been remarkable for its high degree of safety, and in the United States only a small number of incidents of polio have been associated with the administration of the vaccine.[222] Nevertheless, the cases arising from these incidents have caused great concern and dissatisfaction among manufacturers of the vaccines. To ensure continued freedom from this dread disease, however, regular immunization of all children is essential. This immunization program can be accomplished only if the necessary vaccines are available. If the courts continue to extend strict liability to the manufacturers of pure, unadulterated drugs administered in mass immunization programs, promoted by the federal government, governmental assistance may be the only assurance of maintaining the expeditious production of the vaccines. To ensure the continued success of the nation's preventative health care programs, it is hoped that governmental aid soon will be forthecoming.

MARY ELIZABETH MANN

222. Balduzzi & Glasgow, *Paralytic Poliomyelitis in a Contact of a Vaccinated Child*, 276 NEW ENG. J. OF MED. 796 (Apr. 6, 1969).