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Michael Sanzo Ph.D.

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Vaccines and the Law

Michael Sanzo, Ph.D.*

I. BACKGROUND

In the early part of the eighteenth century, Dr. Zabdiel Boylston inoculated his son and 246 of his neighbors with an extract prepared from the pustules of deceased smallpox victims.¹ When six of the vaccinees died, Boylston was vilified by his medical colleagues. Later, a smallpox epidemic swept the community killing one out of every seven people. Among the survivors were all 241 of Boylston's patients.

The procedure used by Boylston, variolation, had been known for over 2000 years and consisted of introducing live smallpox virus into healthy individuals.² George Washington ordered that this procedure be used to immunize the Continental Army in 1777 and as a result, the incidence of smallpox among soldiers dropped dramatically during the final years of the American Revolution.³

Edward Jenner, an Englishman, introduced a less dangerous immunization procedure in 1796.⁴ On May 14 of that year, Jenner inoculated an eight-year-old boy with material from cowpox lesions taken from the hand of a milkmaid. On July 1, Jenner again inoculated the boy, this time with live smallpox virus. No disease developed thus establishing the efficacy of Jenner's technique.⁵ By 1808, the first state-supported facility for vaccination appeared in England, and by the mid-1800s, nearly all physicians recognized the value of immunization.⁶

* Sr. Research Biochemist, Monsanto Co., PhD, Biochemistry, Albany Medical College (1981); J.D. expected St. Louis University (1992); The views expressed in this paper are the author's and do not necessarily reflect the views of Monsanto.

1. Koskland, *Benefits, Risks, Vaccines, and the Courts*, 227 *SCIENCE* 1289 (1985).

2. Becker, *Letters to the Editor*, 255 *J.A.M.A.* 1881 (1986) (reply to the letter by R. Rabasa entitled "George Washington and Variolation").

3. BAYNE-JONES, *THE EVOLUTION OF PREVENTATIVE MEDICINE IN THE UNITED STATES ARMY* 51-54 (1968).

4. See Jueneman, 27 *RES. & DEV.* 27 (1988).

5. *Id.*

6. *Jacobson v. Massachusetts*, 197 U.S. 11, 31 n.1 (1905). See also Mahoney & Lit-

Today, vaccination is recognized throughout the world as having contributed more to public health than any other medical procedure.⁷ At the time the polio vaccine was first introduced in the United States, greater than 20,000 new cases of paralytic polio were reported annually.⁸ Today, there are less than ten. Similar results have been obtained with vaccines for measles, mumps, rubella, diphtheria, pertussis and tetanus.⁹ On a worldwide scale, one of the greatest achievements in medical history came in 1980 when the World Health Organization announced the total eradication of smallpox.¹⁰

With such an impressive history of medical success, it might be expected that American manufacturers would be actively competing in the production of commonly administered vaccines and vigorously developing new products. In fact, this is not the case, and the reasons are legal rather than medical.¹¹ This paper examines the profound effect that the law has had on vaccination and the vaccine industry in the United States.

II. INFLUENCE OF THE LAW ON VACCINATION AND THE VACCINE INDUSTRY IN THE UNITED STATES — AN OVERVIEW

The law has influenced vaccination in the United States in three distinct ways. During the early part of the twentieth century, states passed compulsory immunization laws, which had the effect of promoting not only public health, but also a thriving vaccine industry.¹² All fifty states have enacted laws requiring that children be immunized before entering school causing gross income from vaccine sales to grow to between 500 and 600 million dollars annually.¹³

Beginning in the 1970s, a second and more destructive aspect of the law began to influence the vaccine industry. Products liability lawsuits and punitive damages awards increased the risk associated with

tlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 SCIENCE 1395 (1989).

7. Huber, *Will the New Vaccine Statute Give a Shot in the Arm to Tort Reform*, LEGAL TIMES, March 9, 1987, at 9; See also H.J. PARISH, VICTORY WITH VACCINES 207-16 (1968); Plotkin & Plotkin, *A Short History of Vaccination*, VACCINES 1-7 (S. Plotkin & E. Mortimer, Jr. ed. 1988).

8. Hinman, *Public Health Considerations, Vaccines* 587, 595 (S. Plotkin & E. Mortimer, Jr. ed. 1988).

9. *Id.*

10. *Decisions of the Health Assembly: Declaration of Global Smallpox Eradication*, 34 WORLD HEALTH 258 (1980).

11. Early, *Can Biotechnology Immunize Vaccine Manufacturers from the Product Liability Crisis?*, 30 JURIMETRICS 351 (1990); DIVISION OF HEALTH PROMOTION AND DISEASE PREVENTION, INSTITUTE OF MEDICINE, VACCINE SUPPLY AND INNOVATION 53 (1985) [hereinafter VACCINE SUPPLY].

12. *Jacobson v. Massachusetts*, 197 U.S. 11, 32-33 (1905) (citing cases upholding mandatory vaccination laws in seven states).

13. Goldbaum & Hunter, *A Big Shot in the Arm*, CHEMICAL WEEK, Mar. 22, 1989, at 13.

the production of vaccines.¹⁴ As a result, all but two American manufacturers have been driven out of the market, and four of the seven compulsory childhood vaccines are being made by a single supplier.¹⁵

Recently, Congress has attempted to offset the destructive effect of products liability by establishing a federal compensation program for people injured as a result of having received one of the compulsory vaccines.¹⁶ The program was established by the National Childhood Vaccine Injury Act in recognition of the fact that the country was dangerously close to losing certain vaccines entirely.¹⁷

As can be seen from the discussion above, the law has played a central role in the development and demise of the American vaccine industry as well as in attempts to revitalize it. The sections that follow will examine aspects of the law that have importance to vaccination and the vaccine industry.

III. STATE COMPELLED MEDICAL TREATMENT AND MANDATORY IMMUNIZATION

A. Compulsory Vaccination

The law has addressed the states' power to compel its citizens to undergo medical treatment in a number of different contexts. Laws dealing with involuntary vaccination, involuntary sterilization and involuntary treatment of patients whose religious beliefs preclude conventional medical therapies have received the most attention.¹⁸ Of these, laws authorizing mandatory vaccination have been the least controversial. The Supreme Court first considered such laws in *Jacobson v. Massachusetts*,¹⁹ which upheld the constitutionality of a law that made smallpox vaccinations mandatory in the city of Cambridge.²⁰ The Court stated that:

[T]he police power of a state must be held to embrace, at least, such reasonable regulation established directly by legislative enactment as will protect public health and safety. . . . [T]he liberty secured by the Constitution of the United States does not import an absolute right in each person to be, at all

14. VACCINE SUPPLY, *supra* note 11, at 53.

15. *Id.* at 5-11 (discussing these seven vaccines: polio, measles, mumps, rubella, diphtheria, pertussis and tetanus).

16. See 42 U.S.C. §§ 300aa-10 to -33 (1989). See also H.R. REP. NO. 908, 99th Cong., 2d Sess. 4-5 (1986).

17. H.R. REP. NO. 908, 99th Cong., 2d Sess. 4-5 (1986).

18. Gelman, *Mental Hospital Drugs, Professionalism, and the Constitution*, 72 GEO. L.J. 1725 (1984); Litman, *A Common Law Remedy for Forcible Medication of the Mentally Ill*, 82 COLUM. L. REV. 1720 (1982).

19. 197 U.S. 11 (1905).

20. *Id.* at 39.

times, and in all circumstances, wholly freed from restraint. . . . Upon the principle of self-defense, of paramount necessity a community has the right to protect itself against an epidemic of disease which threatens the safety of its members.²¹

Later in its opinion the Court emphasized that arbitrary or oppressive laws would not be upheld.²² Thus, a law requiring the immunization of people who have a disproportionately high risk of injury would be invalid.

The Court reaffirmed this position on compulsory vaccination in 1922²³ and, since, has favorably cited *Jacobson* many times.²⁴ The power of the state to mandate vaccination has been uniformly asserted in lower federal courts²⁵ and in state courts throughout the country.²⁶

The uniform holdings in these cases may be attributable to the similarity of the facts presented.²⁷ For example, in all of these cases, the vaccine in question targeted a highly contagious disease affecting all segments of the population. The vast majority of the cases dealt with the compulsory immunization of children as a prerequisite for entering school. Insight into how the Court might act in other circumstances may be gained by examining the Court's position on compulsory sterilization and the compulsory treatment of patients who oppose medical treatment on religious grounds.

21. *Id.* at 25-27.

22. *Id.* at 38.

23. *Zucht v. King*, 260 U.S. 174 (1922).

24. *See, e.g.*, *Employment Div., Dept. of Human Resources v. Smith*, 485 U.S. 660 (1988); *United States v. Lee*, 455 U.S. 252, 263 (1982) (Stevens, J., concurring); *Gillette v. United States*, 401 U.S. 437 (1971); *Robinson v. California*, 370 U.S. 660 (1962); *Bates v. City of Little Rock*, 361 U.S. 516 (1960); *Falbo v. United States*, 320 U.S. 549 (1944).

25. *See, e.g.*, *Reynolds v. McNichols*, 488 F.2d 1378 (10th Cir. 1973); *United States v. Collura*, 139 F.2d 345 (2d Cir. 1943); *Johnson v. City of Opelousas*, 488 F. Supp. 433 (W.D. La. 1980); *Rogers v. Okin*, 478 F. Supp. 1342 (Mass. 1979); *Jehovah's Witnesses v. King County Hosp. Unit No. 1*, 278 F. Supp. 488 (W.D. Wash. 1967); *Gillin v. Board of Public Ed.*, 250 F. 649 (E.D. Pa. 1918).

26. *See, e.g.*, *Niemiera v. Schneider*, 114 N.J. 550, 555 A.2d 1112 (1989); *Brown v. Stone*, 378 So. 2d 218 (Miss. 1979); *Cude v. State*, 237 Ark. 927, 377 S.W.2d 816 (1964); *People v. Lavac*, 357 Ill. 554, 192 N.E. 568 (1934); *Commonwealth v. Childs*, 299 Mass. 367, 12 N.E.2d 814 (1938).

27. State courts have differed with respect to statutes that grant exemption from compulsory vaccination on religious grounds. The question arises as to whether exempting only recognized religions violates the First Amendment. The Supreme Court has held that there is no requirement for states to grant exemptions to people who oppose vaccination merely for secular reasons. *Wisconsin v. Yoder*, 406 U.S. 205 (1972). Nevertheless, states have expressed different views on what constitutes a religious belief as opposed to a secular belief. *Compare Syska v. Montgomery County Bd. of Educ.*, 45 Md. App. 626, 415 A.2d 301 (1979) (holding that mandatory vaccination of school children did not violate rights of a mother who had philosophical objections to vaccination even though religious objections were exempted) *with Dalli v. Board of Educ.*, 267 N.E.2d 219 (Mass. 1971) (holding a similar statute which exempted religious but not non-religious objections to vaccination).

B. Compulsory Sterilization

The state's power to compel the sterilization of mentally retarded patients was sustained in the 1927 decision of *Buck v. Bell*.²⁸ It is important to note that the decision did not depend on the operation being of benefit to the patient; the sterilization was justified on the basis of its benefit to society alone. The court noted:

We have seen more than once that the public welfare may call upon the best of its citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the state for these lesser sacrifices, often not felt to be such by those concerned, in order to prevent our being swamped with incompetence. It is better for all the world if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover the cutting of fallopian tubes.²⁹

Although *Buck* has never been formally overruled, in 1942, the Court struck down an Oklahoma law which sanctioned the involuntary sterilization of habitual criminals.³⁰ Commentators have recently referred to the *Buck* decision as "an aberration in [the Supreme] Court's fundamental rights jurisprudence."³¹ It appears that the Court's present position is that compulsory sterilization can still be constitutionally enforced by a state, but only in cases where there is a clear benefit to *both* society and the patient.³²

C. Compulsory Treatment of Jehovah's Witnesses and Christian Scientists

Blood transfusions and certain medical treatments violate the religious beliefs of Jehovah's Witnesses and Christian Scientists.³³ Hospitals faced with patients whose refusal of treatment has imperiled their own lives or the lives of their children have often sought judicial authority to compel therapy. When the patient is a minor, courts have consistently authorized treatment despite objections of par-

28. *Buck v. Bell*, 274 U.S. 200 (1927).

29. *Id.* at 207 (citing *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)).

30. *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

31. Brief for the American College of Physicians as Amicus Curiae in Support of Petitioners at 16 n.7, *Cruzan v. Director of Missouri Dept. of Health*, 110 S. Ct. 2841 (1990) (No. 88-1503).

32. See generally *Skinner*, 316 U.S. 535; *Cruzan*, 110 S. Ct. 2841.

33. See, e.g., *Winters v. Miller*, 446 F.2d 65 (2d Cir. 1971) (involving a Christian Scientist); *Jehovah's Witnesses v. King County Hosp.*, 278 F. Supp. 488 (W.D. Wash. 1967), *aff'd*, 390 U.S. 598 (1968); *Mercy Hosp., Inc. v. Jackson*, 62 Md. App. 409, 489 A.2d 1130 (1985) (involving a Jehovah's Witness).

ents.³⁴ In *Prince v. Massachusetts*,³⁵ the Supreme Court stated that the right to practice religion freely does not include liberty to expose the community to communicable disease or the child to ill health or death. "Parents may be free to become martyrs themselves. But it does not follow they are free in identical circumstances to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."³⁶

More recently, in *Wisconsin v. Yoder*,³⁷ the Court reaffirmed in dicta its willingness to abrogate parental religious convictions when such beliefs jeopardize the well being of minors.³⁸ Lower courts have not generally interpreted the abridgment of rights to require a medical emergency. It is enough that a child is in pain³⁹ or that a malady is interfering with his education.⁴⁰

The Supreme Court has not yet examined a case involving a state's ability to compel medical treatment when the life of an adult is imperiled. Lower courts in different jurisdictions have ruled both for⁴¹ and against⁴² state power. In general, adults have been allowed to refuse treatment on religious grounds even when the decision jeopardizes their lives.⁴³ However, courts carefully weigh the effect that a patient's death would have on others.⁴⁴ For example, a determining factor might be the amount of family and financial support available to the children of the patient.⁴⁵

Cases involving the compulsory medical treatment of adult Jehovah's Witnesses and Christian Scientists may be distinguished from those involving the compulsory vaccination of adults in that refusal of the former only involves risk to the individual, while refusal of vaccination puts society at risk.

34. See, e.g., *State v. Perricone*, 37 N.J. 463, 181 A.2d 751 (1962).

35. 321 U.S. 158 (1944).

36. *Prince*, 321 U.S. at 169.

37. 406 U.S. 205 (1972).

38. *Yoder*, 406 U.S. at 220.

39. *In re Karwath*, 199 N.W.2d 147 (Iowa 1972).

40. *In re Samson*, 278 N.E.2d 918 (N.Y. 1972).

41. See, e.g., *In re President of Georgetown College, Inc.*, 331 F.2d 1000 (D.C. Cir. 1964); *John F. Kennedy Memorial Hosp. v. Heston*, 58 N.J. 576, 279 A.2d 670 (1971); *Collins v. Davis*, 44 Misc. 2d 622, 254 N.Y.S.2d 666 (N.Y. Sup. Ct. 1964).

42. See, e.g., *In re Conroy*, 98 N.J. 321, 486 A.2d 1209 (1985); *In re Osborne*, 294 A.2d 372 (D.C. 1972); *Erickson v. Dilgard*, 44 Misc. 2d 27, 252 N.Y.S.2d 705 (N.Y. Sup. Ct. 1962).

43. See generally *McAninch, A Catalyst for the Evolution of Constitutional Law: Jehovah's Witnesses in the Supreme Court*, 55 CIN. L. REV. 997 (1987).

44. See *Mercy Hosp., Inc. v. Jackson*, 62 Md. App. 409, 489 A.2d 1130 (1985), vacated as moot, 306 Md. 556, 510 A.2d 562 (1986).

45. Compare *In re President of Georgetown College, Inc.*, 331 F.2d 1000 (mother of seven-month-old child) with *In re Osborne*, 294 A.2d 372 (D.C. 1972) (father of two children).

D. Conclusions

Today, the State may compel medical treatment only in situations where both society and the patient will benefit. Moreover, the interest of society must be compelling in order to justify forced treatment.⁴⁶ Where the well-being of minors is at issue, courts have been nearly uniform in finding for the state.⁴⁷

With regard to adults, the law has been more deferential. If refusing treatment results only in harm to the patient, courts generally accede to his wishes.⁴⁸ However, if refusing treatment affects others in the community, courts will balance the interests of society against those of the individual and may approve involuntary medical intervention.⁴⁹

Applying these principles to vaccination, it is clear that vaccines directed at highly contagious diseases affecting all members of the population may be made compulsory. In contrast, a vaccine directed against a disease such as AIDS may not be legally compelled because the vast majority of the population is not at risk for the disease.

A more difficult question is whether the state can compel the vaccination of those segments of the population most likely to contract AIDS (*e.g.*, individuals convicted of using intravenous drugs). In view of the case law considered above, it appears that vaccination can be made mandatory only when the interest of the community is compelling *and* those receiving the vaccine would be benefitted. However, laws making vaccination mandatory under such circumstances may raise constitutional due process and equal protection questions which have not yet been addressed by the courts.

46. For a discussion of possible state interests justifying mandatory medical treatment, see *Superintendent of Belchertown State School v. Sackewicz*, 373 Mass. 728, 370 N.E.2d 417 (1977).

47. One exception occurred in *In re Seiferth*, 309 N.Y. 80, 127 N.E.2d 820 (1955). The court denied a petition by the county health department to have surgery performed on a 14-year-old boy with a cleft palate and a harelip. There were a number of special factors which contributed to this decision. First, the boy's condition posed no immediate threat to his life or well being. Second, the boy shared his father's belief in self-healing and had a fear of surgery so pronounced that compelling treatment might result in psychological harm. Finally, the boy's progress after surgery would depend upon his cooperating in speech therapy. The court thought that it would be better to postpone surgery in the hope that the boy's attitude toward the operation would become more favorable and that he would become more amenable to post-operation treatment.

48. See *McAninch*, *supra* note 43.

49. See *Mercy Hosp., Inc. v. Jackson*, 62 Md. App. 409, 489 A.2d 1130 (1985).

IV. THE PRODUCTS LIABILITY CRISIS AND VACCINES

A. *Strict Liability and Standards of Manufacturer Conduct*

Under section 402A of the Restatement (Second) of Torts, the manufacturer of a defective product is strictly liable for injuries caused by the defect.⁵⁰ Liability may be imposed even though a manufacturer has exercised all possible care in the preparation and sale of the product.⁵¹ Although strict liability is the standard applied to most products, certain exceptions have been recognized. According to section 402A, comment k:

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 An outstanding example is the vaccine for the Pasteur treatment of rabies Such a product, if properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.⁵²

On its face, comment k would appear to set a standard for vaccines, which, in the context of products liability, is unusually deferential to manufacturers. A manufacturer is protected from liability for the inherent dangers of his product unless he has been negligent either in his method of preparation or in failing to supply adequate warnings. Unfortunately for manufacturers, what constitutes a properly prepared product and an adequate warning is subject to many different interpretations.⁵³ As may be seen in the material which follows, some courts have adopted standards which are virtually impossible for manufacturers to meet and which, in effect, impose absolute liability upon them for injuries caused by vaccines.

1. Adequate Warning — The *Davis, Reyes* and *Givens* Decisions

Perhaps the most common claim made by plaintiffs in products liability cases is that a manufacturer has failed to provide an adequate warning concerning the possible consequences of using the product.⁵⁴ With regard to immunization, most jurisdictions have adopted the "learned intermediary" rule under which a prescription drug manufacturer may fulfill his duty to warn by providing appropriate information to the health care worker performing the vaccination.⁵⁵ Unfortunately, not all courts have followed suit.

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

51. See, e.g., *Gravis v. Parke Davis & Co.*, 502 S.W.2d 863, 868 (Tex. Civ. App. 1973).

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

53. *Maedgen & McCall, A Survey of Law Regarding the Liability of Manufacturers and Sellers of Drug Products and Medical Devices*, 18 ST. MARY'S L.J. 395 (1986).

54. *Id.*

55. For a discussion of the learned intermediary rule, see *Ethicon, Inc. v. Parten*, 520 S.W.2d 527 (Tex. Civ. App. 1975). For examples of the rule's application in different jurisdictions, see annotation, *Liability of Manufacturers of Oral Live Polio (Sabin) Vaccine for Injury or Death From Its Administration*, 66 A.L.R.4TH 83 (1988); Annotation, *Product Liability: Pertussis Vaccine Manufacturers*, 57 A.L.R.4TH 911 (1987).

The first indication that some courts might require that warnings be given directly to patients came in 1968. In *Davis v. Wyeth Laboratories*,⁵⁶ the Ninth Circuit Court of Appeals held that a manufacturer has a duty to warn patients directly when vaccinations are performed at mass immunization clinics.

Here, however, although the drug was denominated a prescription drug, it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing . . . of the risks involved. In such cases (as in the case of over-the-counter sales of nonprescription drugs) warning by the manufacturer to its immediate purchaser [i.e., the physician or other health care provider] will not suffice . . . [J]ust as the responsibility of choice is not one that the manufacturer can assume for all comers, neither is it one that he can allow his immediate purchaser to assume. In such cases, then, it is the responsibility of the manufacturer to see that warnings reach the consumer . . .⁵⁷

The manufacturer included a package insert with the vaccine, but the clinic, where inoculation occurred, failed to convey the warnings contained in the insert to Davis.⁵⁸ Even though there was nothing in the record to indicate negligence, and the court conceded that there had been "scrupulous attention in the matter of preparation and testing," the court held the manufacturer liable.⁵⁹

The Fifth Circuit adopted the view that manufacturers must warn patients directly in *Reyes v. Wyeth Laboratories*.⁶⁰ In *Reyes*, a child contracted polio after being given the Sabin vaccine at a public health clinic. The manufacturer had enclosed a package insert, and although the administering nurse read the warning, she failed to convey its information to the parents of the child.⁶¹ The court held that, even with compulsory immunization under state law, a warning was necessary because the two available polio vaccines (the Salk and Sabin types) differed in their risk of adverse reactions.⁶²

In *Givens v. Lederle Laboratories*,⁶³ the Fifth Circuit considered a case in which a mother contracted polio subsequent to her child's vaccination.⁶⁴ Unlike *Davis* and *Reyes*, the physician who failed to

56. 399 F.2d 121, 131 (9th Cir. 1968).

57. *Id.* at 131.

58. *Id.* at 125.

59. *Id.* at 126.

60. 498 F.2d 1264 (5th Cir. 1974).

61. *Id.* at 1270.

62. *Id.* at 1293-94. The court was responding to an argument, set forth in an amicus brief from the American Academy of Pediatrics, that a duty to warn patients serves no purpose when vaccination is compulsory. *Id.* For an example of a decision holding that compulsory immunization laws afford no protection to manufacturers of vaccines, see *Flood v. Wyeth Laboratories, Inc.*, 183 Cal. App. 3d 1272, 228 Cal. Rptr. 700 (1986).

63. 556 F.2d 1341 (5th Cir. 1977).

64. *Id.*

convey the warnings contained in the manufacturer's insert to the mother of the vaccinated child, was in private practice.⁶⁵ In spite of the presence of the patient's personal physician, and the absence of any claim that the vaccine was defective, the manufacturer was found to be liable.⁶⁶

The *Givens* decision represents a serious departure from the "learned intermediary" principle with regard to vaccines administered without a prescription and, if adopted by other jurisdictions, would substantially increase the number of lawsuits against manufacturers. This holding alone constituted a major setback for vaccine producers. However, the court went further, stating that even if the package insert had been supplied directly to the patient, the manufacturer still would have been liable because the warning was inadequate.⁶⁷ The insert stated that there had been reports of individuals in close contact with vaccine recipients having developed polio, but only in less than one in three million vaccinations. The FDA's Division of Biological Standards, had approved this warning and its accuracy was not disputed.⁶⁸ Nevertheless, the court declared the warning insufficient, because in the subjective view of the administering physician, the label suggested that the vaccine was safe.⁶⁹

The predicament of manufacturers after the *Davis*, *Reyes* and *Givens* decisions is readily apparent. In order to fully meet their duty to warn in all jurisdictions in the United States, manufacturers must directly inform patients of the risks associated with vaccines. To fulfill this duty, manufacturers are completely dependent upon the health care workers who administer their product. Thus, a manufacturer could be found liable due solely to the negligence of one of these workers. Even if vaccine producers could insure that these workers would convey warnings to patients, it is not at all clear what sort of warning would be considered adequate in every jurisdiction. The decisions in the cases above suggest that neither reciting statistics of the likelihood of an adverse reaction occurring, nor FDA approval of the content of a warning, is sufficient.⁷⁰ In effect, manufacturers are left with little or no power to prevent potentially disastrous liability.

2. Properly Prepared Vaccines — Design Defects

Some courts have taken a position concerning proper vaccine preparation that has added to the potential liability faced by manufactur-

65. *Id.* at 1346.

66. *Id.* at 1345.

67. *Id.*

68. The fact that the FDA had approved the warning was brought out in a later case, *Fraley v. American Cyanamid Co.*, 570 F. Supp. 497, 504 (D. Colo. 1983).

69. *Givens*, 556 F.2d at 1345.

70. *Fraley*, 570 F. Supp. at 504. See also *Davis*, 399 F.2d at 130.

ers. In *Toner v. Lederle Laboratories*,⁷¹ the court held that a manufacturer was liable for injuries resulting from the use of his product because a safer vaccine could have been used.⁷² The plaintiffs were awarded 1.3 million dollars in spite of the fact that the allegedly safer vaccine had been taken off the market because of concerns voiced by the FDA over its efficacy.

FDA certification represents only the FDA's opinion, albeit an informed one, of the safety and efficacy of the drug . . . We hold that FDA certification of a drug is evidence but not conclusive evidence of the drug manufacturer's reasonableness; the trier of fact may assign FDA approval the weight it deserves.⁷³

Presumably, had the less efficacious yet safer vaccine been administered, and the vaccinee had later developed the disease, the manufacturer also would have been liable for knowingly selling a product whose ability to confer immunity had been called into question.

It appears that the court in *Toner* was less concerned with evaluating the conduct of the manufacturer than insuring that the plaintiffs received compensation for their injuries. The court in *Reyes* supplied a justification for this attitude. After acknowledging that vaccine-induced polio was unavoidable, the court said: "[A] strong argument can be advanced that the loss ought not lie where it falls (on the victim), but should be borne by the manufacturer as a foreseeable cost of doing business, and passed on to the public in the form of a price increase to customers."⁷⁴ The *Reyes* and *Toner* courts failed to appreciate that manufacturers, faced with absolute liability, conflicting views concerning their responsibilities, and huge damage awards, might simply stop making vaccines entirely.

B. Causation

The risk to vaccine manufacturers has also been increased by the acceptance of relaxed standards for the establishment of causation by plaintiffs.⁷⁵ Juries have generally not questioned whether vaccina-

71. 112 Idaho 328, 732 P.2d 297 (1987).

72. *Id.*

73. *Id.* at 342 n.12, 732 P.2d at 311 n.12. In a concurring opinion, Justice Hanley elaborated: "Perhaps the reason that no state has done so [permitted a showing of compliance with FDA regulations to shield a manufacturer from liability] is that no state supreme court has yet become convinced that the FDA has either adequate staffing, expertise, or data base to warrant its being substituted for the judicial system." *Id.* at 344, 732 P.2d at 313 (Hanley, J., concurring).

74. *Reyes*, 498 F.2d at 1294.

75. For a discussion of changing standards in product liability cases, P. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES 98-113 (1988) [hereinafter P. HUBER].

tion was the proximate cause of the injury where plaintiffs are injured soon after being inoculated, and the injury was known as one of the adverse effects associated with the vaccine. For example, the jury in *Reyes* assumed that the plaintiff developed polio from vaccination in spite of the existence of a polio epidemic in the area at the same time he was inoculated.⁷⁶ This kind of casual attitude toward causation is disturbing.

Each year, a statistically predictable portion of the population is seriously injured by infections and a variety of diseases. Each year, millions of people are vaccinated. The fact that these two events occasionally occur in the same individual and in close temporal proximity does not establish a causal connection.⁷⁷ Courts should look more carefully into the circumstances surrounding the injury and consider the possibility that it was not caused by the vaccine. Closest attention should be paid to situations where there is good reason to think that a plaintiff's injury may have occurred independently of his vaccination.

Courts have also helped plaintiffs by relieving them of the burden of proving that they would have refused immunization had they been properly warned. For example, the court in *Reyes* held that:

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 defendant's product was the producing cause of the plaintiff's injury would be sufficient to hold him liable.⁷⁸

C. Punitive Damages

A final factor which has aggravated manufacturer uncertainty over potential liability has been the dramatic increase in awards of punitive damages.⁷⁹ Prior to 1976, punitive damages in products liability cases in the United States were almost unknown.⁸⁰ This has changed dramatically, especially with regard to suits brought against pharmaceutical manufacturers. Punitive damages were awarded in thirty-five pharmaceutical products liability cases from 1985 to 1989 while only six such awards were made in the 1970s.⁸¹

76. *Reyes*, 498 F.2d at 1274.

77. For a discussion of the error of assuming that injury and drug administration are causally connected rather than independent events, see P. HUBER, *supra* note 75, at 100-05 (1988).

78. *Reyes*, 498 F.2d at 1294.

79. Mahoney & Littlejohn, *supra* note 6.

80. Bittle, *Punitive Damages and the Eighth Amendment: An Analytical Framework for Determining Excessiveness*, 75 CALIF. L. REV. 1433 (1987).

81. Brief for the Pharmaceutical Mfrs. Ass'n, *Browning Ferris Indus. v. Kelco Disposal, Inc.*, 492 U.S. 257 (1990) (No. 88-556).

Paralleling the increase in the number of awards has been a dramatic increase in their size. Prior to 1959, the highest punitive damages award for all types of actions granted in California was \$10,000.⁸² This jumped to \$250,000 in the 1960s and to \$740,000 in the 1970s.⁸³ By the end of 1988, the California Court of Appeals had approved awards of greater than fourteen million dollars.⁸⁴

The general trend of escalating punitive damages awards has been reflected in those made to plaintiffs injured by vaccines. For example, in *Johnson v. American Cyanamid Company*,⁸⁵ a plaintiff who had been injured as a result of having received an inoculation of the Sabin polio vaccine was awarded two million dollars in actual damages and eight million dollars in punitive damages.⁸⁶ This award was given in spite of the fact that the manufacturer had fully complied with all of the requirements of the FDA.⁸⁷

Although the number of cases where punitive damages are awarded is small relative to the number of lawsuits filed, the threat of such awards has coerced manufacturers into paying higher amounts in out-of-court settlements.⁸⁸ Not surprisingly, insurance costs to manufacturers have soared.⁸⁹ It has been estimated that 95% of the sale price of vaccines is attributable to products liability.⁹⁰ The price of vaccines has skyrocketed as a direct result of both the increased costs generated by products liability lawsuits and fears that the trend may continue. For example, the price of the DPT vaccine increased from ten cents per dose in 1982 to more than three dollars per dose in 1986.⁹¹ By 1988, the price had increased to more than eleven dollars per dose.⁹²

82. See Mahoney & Littlejohn, *supra* note 6, at 1396.

83. *Id.*

84. *Id.*

85. 239 Kan. 279, 718 P.2d 1318 (1986), *aff'd*, *Johnson v. American Cyanamid Co.*, 243 Kan. 291, 758 P.2d 206 (1988).

86. *Id.* at 280, 718 P.2d at 1320. The decision was subsequently set aside by the Kansas Supreme Court in a narrow 4 to 3 decision. Nevertheless, the case illustrates the willingness of some courts to impose extremely large punitive damages upon vaccine manufacturers. A reversal sustained by the margin of a single vote could not be terribly reassuring to the vaccine industry.

87. *Id.* at 284, 718 P.2d at 1326.

88. See Mahoney & Littlejohn, *supra* note 6. Among all types of actions, punitive damages awards in product liability cases are the least likely to be reduced on appeal.

89. Marwick, *Pediatric Vaccine Tax Seeks to Cover Injury, Not All Manufacturers Passing on Increase*, 259 J.A.M.A. 1292 (1989).

90. P. HUBER, *supra* note 75, at 155-61.

91. Dark, *Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DPT Controversy*, 19 U. TOL. L. REV. 799, 855 (1988).

92. See Marwick, *supra* note 89, at 1292.

D. Effects on New Product Development

Perhaps the greatest impact that the products liability revolution has had on pharmaceuticals is in the area of new product development.⁹³ In the case of vaccines that have been on the market for many years, the courts have created uncertainties concerning potential liability. The risks inherent in the vaccines have been well established.⁹⁴ This is not true for new vaccines. Although testing will provide information regarding safety, a manufacturer must, of necessity, extrapolate from a very small population to a very large one. When complications may occur at a rate of only one in 100,000, the true effects of a vaccine only become apparent after a massive program has been initiated. The resulting liability could be devastating. This point may be illustrated by considering the swine flu vaccination program.

In January of 1976, several soldiers at Fort Dix, New Jersey became ill and one soldier died.⁹⁵ The causative agent was identified as a strain of influenza virus, which had been responsible for a mammoth epidemic in 1918.⁹⁶ As a result, Congress committed itself to a program of immunizing "every man, woman and child" in the United States.⁹⁷

Pressed by a desire to complete immunizations before the approaching flu season arrived, and faced with manufacturers reluctant to produce the vaccine for fear of products liability, Congress quickly passed the National Swine Flu Immunization Program of 1976 Act.⁹⁸ Under this Act, manufacturers were immunized from liability; all lawsuits were to be brought against the United States Government.⁹⁹ The vaccine was then manufactured, and over forty-five-million people were inoculated. No new cases of swine flu occurred, but it was found that the vaccine caused or promoted Guillian-Barre syndrome,

93. Mahoney & Littlejohn, *supra* note 6, at 1399.

94. With regard to the seven vaccines commonly administered to children in the United States, statistics indicate that "based on a population of 3.5 million children receiving the DPT vaccine annually, an average of fifty suffer permanent brain damage, nine thousand collapse after DPT inoculation [and] 25,000 suffer very high fevers. An average of eight contract polio from the oral polio vaccine. About forty to sixty children go into shock after receiving the vaccine against mumps, measles and rubella or DPT". Sun, *The Vexing Problems of Vaccine Compensation*, 227 SCIENCE 1017 (1985) (citing testimony of Edward Brandt, Jr., then Assistant Secretary of Health at the Department of Health and Human Services).

95. See Dark, *supra* note 91, at 834-35. See also, Reitze, *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169, 169 (1986).

96. During 1918 and 1919, 20 million people died from swine flu worldwide, including 500,000 people in the United States. Reitze, *supra* note 95, at 170.

97. See Dark, *supra* note 91, at 835. For a general discussion of the governmental policy behind the program, see NEUSTADT & FINEBERG, *THE SWINE FLU AFFAIR* (1978).

98. 42 U.S.C. § 247 (1976). See also Rheingold & Shoemaker, *The Swine Flu Litigation*, 8 LITIGATION 28, 28 (1981).

99. 42 U.S.C. § 247b(k)(3) (1978).

a disabling neurological disorder.¹⁰⁰ As a result, the immunization program was quickly halted. Thousands of claims were subsequently filed, and the Government has paid out nearly 80 million dollars in damages.¹⁰¹ It has been argued that without federal intervention, the amount awarded would have been substantially greater.¹⁰² In light of the potential for liability demonstrated by the swine flu episode, it is hardly surprising that manufacturers are reluctant to place new vaccines on the market.

V. THE NATIONAL CHILDHOOD VACCINE INJURY ACT AND THE REVITALIZATION OF THE AMERICAN VACCINE INDUSTRY

Recognizing that the supply of certain vaccines in the United States was in serious jeopardy, Congress passed the National Childhood Vaccine Injury Act in November of 1986 (the "Act").¹⁰³ The Act was designed to protect vaccine manufacturers from strict liability for injuries due to the unavoidable risks of their products.¹⁰⁴ It established a no-fault federal program for compensating individuals injured as the result of having received one of the seven compulsory childhood vaccines.

Section 300aa-14 of the Act provides a "Vaccine Injury Table" which contains a list of injuries that have been associated with the administration of different vaccines and a time period within which adverse effects would be expected to appear. A petitioner is permitted to recover damages if he can establish that he developed one of the listed injuries within the stipulated time.¹⁰⁵ He need not show negligence or establish causation.¹⁰⁶ If a claimant chooses to accept the damages provided under the Act, he is then barred from bringing a civil action against the manufacturers.¹⁰⁷

However, protection of manufacturers by the Act is not absolute. If a claimant is unsatisfied with the statutory award, he may still attempt to recover from the vaccine manufacturer under state tort or contract law.¹⁰⁸ Thus, Congress has carefully preserved traditional

100. See Huber, *supra* note 7.

101. *Id.*

102. See Dark, *supra* note 91, at 837.

103. See 42 U.S.C. §§ 300aa-10 to -33 (1989). See also H.R. REP. NO. 908, 99th Cong., 2d Sess. 4-5 (1986).

104. 42 U.S.C. § 300aa-22(b)(1) (1989).

105. *Id.*

106. *Id.*

107. *Id.* at § 300aa-21(a).

108. *Id.* at § 300aa-21(b).

state authority in compensating citizens injured by defective products.¹⁰⁹ Moreover, the Act only applies to injuries caused by the *unavoidable* risks of vaccines; manufacturers remain liable for their negligence. The crucial question is: What standard will be used to determine whether or not a manufacturer has exercised due care?

Congress recognized the role that the lack of a national standard for negligence played in the abandonment of vaccines by manufacturers. In response, a new standard was established with the intent to preempt state law. In so doing, it limited the liability of manufacturers in three important ways. First, under section 300aa-22(b) of the Act, a manufacturer does not have a duty to provide direct warnings to patients receiving vaccines.¹¹⁰ In effect, this provision overrules *Givens* and re-establishes the “learned intermediary” principle.

Second, the Act provides for a limited preemption of state law by FDA regulations. A manufacturer will not be held liable if he can show that he has complied with all of the requirements of the Federal Food, Drug and Cosmetic Act and Section 351 of the Public Health Service Act.¹¹¹ In this way, Congress has preempted the use of state regulations as a means for establishing negligence without preempting either state regulations themselves or state common law.¹¹² The provision asserts that vaccines properly belong under the comment k exception to section 402A of the Restatement (Second) of Torts and establishes an objective standard for what constitutes due care on the part of manufacturers.

Finally, the Act states that a claimant cannot recover punitive damages from a manufacturer absent a showing of fraud or intentional misconduct.¹¹³

The effectiveness of the Act has yet to be evaluated. While on its face it appears to shield manufacturers from the worst aspects of liability, how much protection it will provide in practice has been questioned. Huber has argued that the provision excusing manufacturers from the “unavoidable side effects” of their product is unacceptably vague.¹¹⁴ Courts desiring to compensate vaccine victims can easily point to procedures and products used in other countries to show that an injury was not truly “unavoidable.” In addition, the relative ease

109. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984); *Abbot v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988); *Rinehart v. International Platex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988); *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483 (D. Kan. 1987); *MacGillivray v. Lederle Laboratories*, 667 F. Supp. 743 (D.N.M. 1987).

110. 42 U.S.C. § 300aa-22(b) (1989).

111. *Id.*

112. Even though state regulations cannot be used as a measure of negligence, states are not prohibited from enacting regulations setting different standards from those set forth by the FDA or using them in other ways. For example, states could fine manufacturers for noncompliance.

113. 42 U.S.C. § 300aa-23 (1989).

114. Huber, *supra* note 7, at 9.

with which compensation can be obtained under the Act may lead to such a proliferation of frivolous claims and awards that the federal compensation system will collapse.¹¹⁵

A final limitation of the Act is that it applies only to the seven compulsory childhood vaccines presently on the market. It does not apply to vaccines used predominantly by adults (*e.g.*, the vaccine for hepatitis) or to noncompulsory vaccines administered to children (*e.g.*, vaccines for meningitis).¹¹⁶ Moreover, it does nothing to encourage corporations to develop new vaccines. Why, for example, should a corporation develop a vaccine for AIDS? Development and testing of such a product will require years of research and millions of dollars; the market will probably be limited to a small subgroup of the adult population; and there is no protection from potentially catastrophic lawsuits.¹¹⁷ Until legislation is passed that offers a corporation some degree of protection for new vaccines, it is unlikely that companies will make substantial investments in the development or manufacture of such products.

VI. CONCLUSION

A. *State Compensation of Those Injured by Compulsory Vaccines*

It is an unfortunate fact of medicine that even the most beneficial of drugs and treatments often carry with them a substantial capacity for harm. Vaccines have prevented the suffering of countless people throughout the world, but in so doing they have occasionally caused the very disease which they were designed to prevent. State governments have balanced the benefits and harms of vaccines and have, in certain instances, determined that it is in the community's interest to make their administration mandatory. Since the state has compelled citizens to assume the risk of vaccination and since the entire state benefits, it seems incumbent upon society as a whole to provide compensation to those injured as a result of the program.¹¹⁸

115. *Id.*

116. *New Hepatitis Vaccine Developed*, 11 *NEW SCIENTIST* 419 (1983) (announcing the development of a new, safe and inexpensive hepatitis vaccine); R. OUELLETTE AND P. CHEREMISINOFF, *APPLICATIONS OF BIOTECHNOLOGY* 108-13 (1985) (discussing vaccines against diseases of man and animals).

117. See Cooper, *The Maker of AIDS Vaccine Will Need Protection from Product Liability Suits*, *MANHATTAN LAW*, June 14, 1988, at 38.

118. Hager, *Civil Compensation and Its Discontents: A Response to Huber*, 42 *STAN. L. REV.* 539 (1990).

B. *State Compensation of Those Injured by Noncompulsory Vaccines*

Where vaccine administration is not compulsory, the responsibility of the state to compensate victims is less clear. It can be argued that where individuals have been adequately appraised of the dangers of vaccination, they assume the risk of injury by permitting themselves to be inoculated.

This argument ignores the fact that society benefits in the same way from noncompulsory as from compulsory vaccines. The difference lies not in the nature of benefits derived, but in whether the disease for which the vaccine is administered is so common as to warrant mandatory vaccination. Society benefits by keeping people healthy and avoiding the cost of healing its injured members. The government can encourage people to be vaccinated by providing that if they are injured, it will compensate them directly for their loss. To write off vaccination victims as losers in a kind of health care lottery is both unrealistic and uncompassionate.

C. *Alternative Considerations*

Much of this paper has been devoted to describing how and why the imposition of certain judicial interpretations of strict liability, coupled with the threat of punitive damages, have driven most vaccine producers to withdraw from the market. On the other hand, the attitude of manufacturers is difficult to understand. While it is true that a few courts have been highly deferential to plaintiffs, most have followed comment k and have held manufacturers to a standard of negligence.¹¹⁹

Even prior to the adoption of the National Childhood Vaccine Injury Act, a number of states passed legislation limiting punitive damages awards¹²⁰ and allowed manufacturers to avoid liability entirely if they could demonstrate that they had fully complied with FDA regulations.¹²¹ It seems that manufacturers should be able to adequately protect themselves against products liability losses either by adjusting their prices or by refusing to sell their products in the few

119. See, e.g., *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963). See also Annotation, *Products Liability: Pertussis Vaccine Manufacturers*, 57 A.L.R.4TH 911 (1987); Annotation, *Liability of Manufacturers of Oral Live Polio (Sabin) Vaccine for Injury or Death From its Administration*, 66 A.L.R.4TH 83 (1988).

120. See ALA. CODE § 6-11-21 (Supp. 1988); COLO. REV. STAT. § 13-21-102 (1987); FLA. STAT. ANN. § 768.73(1)(b) (West Supp. 1989); KAN. STAT. ANN. § 60-3701 (1987); OKLA. STAT. ANN. tit. 23, § 9 (West 1987); TEX. CIV. PRAC. & REM. CODE ANN. §§ 41.001-009 (Vernon Supp. 1991); VA. CODE ANN. §§ 8.01-38.1 (1987).

121. See ARIZ. REV. STAT. ANN. § 12-701 (Supp. 1990); N.J. STAT. ANN. § 2A:58c-5(c) (West 1987); OHIO REV. CODE ANN. § 2307.80 (Anderson Supp. 1987); OR. REV. STAT. § 30.927 (1987); UTAH CODE ANN. § 78-18-2 (Supp. 1990).

jurisdictions where court rulings have been unfavorable.¹²²

One suspects that the real fear vaccine manufacturers share extends beyond the mere possibility of liability for unavoidable injuries or even an occasional punitive damages award. Their flight from the vaccine market may reflect, in large measure, a fear that they are not able to adequately guard against negligence or cope with the consequences that might ensue. Suppose, for example, that a batch of DPT vaccine became contaminated with a pathogenic agent which went undetected. By the time the mistake was discovered, the vaccine might well have been administered to thousands of children. Under these circumstances, the company that made the vaccine would be fully liable in all jurisdictions. The consequences for both the children and the company could be catastrophic.

While the manufacturers' fear of such risk is understandable, it is precisely this fear of liability that tort law relies upon to reduce the likelihood of disasters by promoting prudent behavior.¹²³ Arguably, the tort system *has* ensured that vaccine producers will take adequate, perhaps even extreme, measures to ensure that their products are made as safe as possible. Unfortunately, this method of encouraging super-safe behavior is driving most manufacturers out of the market and making the development of new vaccines a highly unattractive proposition.

Congress has attempted to prevent the total collapse of the American vaccine industry by enacting the National Childhood Vaccine Injury Act. Unfortunately, this Act does nothing to protect manufacturers from the potentially catastrophic consequences of negligence or to encourage them to develop new products. Although the Act may serve to maintain the present supply of vaccines used in compulsory childhood immunization programs, as a tool for revitalizing the vaccine industry in the United States, it will almost surely fail.

VII. PROPOSED SOLUTION

The judicial and legislative programs may be able to accomplish together what neither has been able to accomplish alone. One way to fulfill the needs of both manufacturers and the public would be for

122. There is some precedent for such action. A Japanese manufacturer of a vaccine for an Asian form of encephalitis withdrew the product from the U.S. market citing concerns over potential products liability lawsuits. See Hill & Pearson, *Health Advice for International Travel*, 108 ANN. INTERN. MED. 839 (1988).

123. Hager, *supra* note 118.

the federal government to establish a program for testing lots of vaccine before they are distributed for public inoculation. Funding for such a program could come from the vaccine manufacturers and, in exchange, the government could grant manufacturers immunity from lawsuits by private individuals. Since the risk to manufacturers would be substantially reduced, their insurance costs, presently accounting for the majority of the price of vaccines, should be correspondingly reduced.¹²⁴ Thus, it may be possible to fund such a program without a resulting increase in the price of vaccines.

The government could impose its own penalties to insure maintenance of high production standards by imposing fines for contaminated vaccines. In addition, the government could reserve for itself the right to sue manufacturers for fraud or intentional misconduct. Thus, the liability of manufacturers would still be great enough to promote caution, but the danger of an entire corporate bankruptcy resulting from a single bad batch of product would be eliminated. The liability of the government could be limited by setting a cap on the amount of compensation available for different types of injury and by eliminating punitive damages awards entirely.¹²⁵ In effect, the government would be assuming the role of the manufacturers' insurer, but would face less risk by providing an extra layer of testing prior to the release of vaccines.

One advantage of such a system is that it could readily be applied to new products. Thus, manufacturers could develop vaccines knowing that a mechanism existed for bringing them to market without risking the survival of the corporation. This is of great importance. Vaccines offer tremendous potential in the treatment of AIDS, some forms of cancer (particularly melanomas), venereal disease and a host of afflictions common in other parts of the world.¹²⁶ It will be tragic if these products are never developed because of legal obstacles.

124. See *supra* notes 89-90 and accompanying text.

125. In this respect, the National Childhood Vaccine Injury Act can serve as a model. See 42 U.S.C. § 300aa-23 (1989).

126. R. OULLETTE & P. CHEREMISINOFF, *supra* note 116, at 108-13.