Vaccinating AIDS Vaccine Manufacturers against Product Liability

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NOTES

VACCINATING AIDS VACCINE MANUFACTURERS AGAINST PRODUCT LIABILITY

The unique epidemiology of the human immunodeficiency virus (HIV) makes vaccine development a daunting task. Moreover, in light of the potential liability arising from adverse side effects, vaccine manufacturers may be reluctant to invest in costly research and development. The federal government has authorized programs to alleviate the burdens of liability on manufacturers of other vaccines and to compensate those injured by vaccines through no fault of the drugs' makers. California has enacted a similar law to insulate AIDS vaccine manufacturers from liability. While these laws suggest models for effective programs to protect manufacturers, the programs are not ideally suited for an AIDS vaccine. This note analyzes the issues which must be addressed in such a program to insure manufacturer participation in developing and marketing an AIDS vaccine and to maintain a solvent and efficient compensation fund for vaccine victims.

I. INTRODUCTION

As of November 1990, more than 150,000 Americans had been diagnosed as having Acquired Immune Deficiency Syndrome (AIDS). The death toll from the disease and related complications

1. CENTERS FOR DISEASE CONTROL, HIV/AIDS SURVEILLANCE REPORT 13 (November 1990) [hereinafter HIV/AIDS SURVEILLANCE REPORT]. AIDS is caused by infection with a human immunodeficiency virus (HIV). HIV is thought to come from the subfamily of
is high; more than 94,375 Americans have died as a result.\(^2\) According to one estimate, an additional 1.5 million people may already be infected with HIV.\(^3\) The Centers for Disease Control (CDC) estimates that the number of individuals with AIDS may increase four-fold in the next three years.\(^4\) Understandably, a tremendous push toward development of a vaccine\(^5\) to protect the general population and stop the spread of this disease has been occurring.

As scientists and medical researchers discover more about AIDS and approach development of an effective vaccine, policymakers at the federal and state levels must consider appropriate methods of averting a liability crisis among vaccine manufacturers arising from injuries caused by adverse reactions to the vaccine. On a national level, Congress has faced similar issues on two occasions: the Swine Flu experience of 1976\(^6\) and the early

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\(^1\) Lentiviruses characterized by "slow, progressive infections in which the virus escapes host immune defenses." David A. Katzenstein et al., *Human Immunodeficiency Virus*, in *Vaccines* 558 (Edward A. Mortimer & Stanley A. Plotkin eds., 1988). One of the major problems in developing a cure and stopping the spread of the virus is the variability of the protective "envelope" which surrounds the HIV. *Id.* Because this protective coating can mutate quickly and in an unpredictable manner, researchers are forced to develop a treatment for a multitude of viruses. *Id.* at 558-59.


\(^3\) George R. Seage, III et al., *Effect of Changing Patterns of Care and Duration of Survival on the Cost of Treating the Acquired Immunodeficiency Syndrome (AIDS)*, 80 *AM. J. PUB. HEALTH* 835 (1990).

\(^4\) *Id.*

\(^5\) Vaccinations stimulate the body's immune system to produce antibodies against specific pathogens (disease causing organisms) without development of disease symptoms. *SUBCOMMITTEE ON HEALTH AND THE ENV'T OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 99TH CONG., 2D SESS., CHILDHOOD IMMUNIZATIONS* 4 (Comm. Print 1986) [hereinafter CHILDHOOD IMMUNIZATIONS]. The primary method of producing this result is to introduce into the body small amounts of "modified disease causing agents, which stimulate the immune system to produce antibodies specific for that disease." *Id.* Vaccines can be divided into two major categories: "live" and "killed." Katzenstein, *supra* note 1, at 568-70. A live vaccine is characterized by its ability to replicate within the body. *Id.* Typically, a live vaccine is a virus which has been attenuated (through chemical, genetic or other methods of alteration) with respect to its ability to cause the disease, but is still capable of stimulating antibody production. A "killed" vaccine, on the other hand, is incapable of replicating within the body, but can still stimulate immunity. *Id.*

Each type of vaccine carries with it costs and benefits. Live vaccines are known to produce antibody immunity and also stimulate the cell-mediated immune system, providing a "broad spectrum of immunity." *Id.* In addition, live vaccines provide protection longer than "killed" vaccines. *Id.* However, live vaccines can potentially revert to a pathogenic form, leading to development of the disease itself. *Id.* While "killed" vaccines are noninfectious and less likely to cause adverse reactions, they are also less efficient in producing cell-mediated immunity and require booster shots to provide long-lasting protection. *Id.*

\(^6\) For a discussion of the Swine Flu experience, see infra text accompanying notes.
1980's supply crisis for childhood vaccines that was precipitated by several high profile product liability cases which increased vaccine manufacturers' liability exposure.\(^7\)

Congress responded to each situation differently. In 1976, facing an expected epidemic and responding to a demand from vaccine manufacturers for protection from liability, it developed the National Swine Flu Immunization Program.\(^9\) Under this program, the federal government modified the Federal Tort Claims Act,\(^10\) effectively assuming liability for all adverse reactions to the Swine Flu vaccine not the result of manufacturer negligence or breach of contract.\(^11\)

The response to the childhood vaccine crisis was different. In 1986, Congress established the National Vaccine Program to provide direct and prompt compensation to individuals who suffer injuries as the result of mandatory childhood vaccination.\(^12\) Funding for this program comes from an excise tax levied on each dose of vaccine administered.\(^13\) In order to receive compensation under the National Vaccine Program, an injured party must waive all rights to seek recovery from the vaccine manufacturer.\(^14\)

Recognizing vaccine manufacturers' historical concern with potential liability for vaccine-related injuries and hoping to stimulate research into development of an AIDS vaccine,\(^15\) the California legislature enacted comprehensive legislation establishing an AIDS Vaccine Victims Compensation Fund.\(^16\) This legislation provides compensation to individuals experiencing adverse reactions to

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7. Currently, children are immunized against seven diseases: diphtheria, tetanus, pertussis (whooping cough), measles, mumps, rubella (German measles) and polio. Childhood Immunizations, supra note 5, at 5.

8. See infra notes 114-43 and accompanying text for a discussion of the childhood vaccine crisis and the subsequent legislative response.


an AIDS vaccine approved by the Food and Drug Administration, and it guarantees the purchase of at least 500,000 units of the vaccine.\textsuperscript{17} The compensation fund is this country’s first direct response to liability and compensation issues likely to arise in conjunction with development of an AIDS vaccine.\textsuperscript{18} Its design resembles that of the National Vaccine Program.\textsuperscript{19}

This note examines various alternatives for handling liability and compensation problems associated with development of an AIDS vaccine. First, the note reviews the relevant common law decisions which have set the standard for vaccine manufacturer liability. Next, previous attempts at limiting vaccine manufacturer liability are examined. Specifically, this note analyzes the swine flu and childhood vaccine acts and compares them with the California legislation. Finally, this note concludes that a vaccine victim’s compensation policy based on an insurance model\textsuperscript{20} promotes the dual goals of stimulating an appropriate amount of research into development of an AIDS vaccine and protecting manufacturers from unpredictable operating costs.

In order to achieve these goals, the method of compensating victims developed by the National Vaccine Injury Compensation Program and adopted and modified by the California legislature should be further changed to reflect the unique epidemiology of the AIDS virus. Specifically, the California legislation fails to provide the flexibility needed to deal with a new disease and vaccine. This note suggests that a compensation fund which accounts for the unusual characteristics of the AIDS virus be implemented as the primary recovery mechanism for those injured by an AIDS vaccine.

\section*{II. Judicial Treatment of Vaccine Manufacturer Liability}

Vaccines are not completely safe; there is always a chance that side effects ranging from mild, short-lived discomfort to disabling, life-threatening injuries may occur with administration of any vaccine.\textsuperscript{21} However, society has implicitly decided that the risks of vaccination are worth the benefits produced, and it there-
fore requires that children be vaccinated before enrolling in public schools. Nonetheless, parties injured by these vaccines continue to seek recovery from vaccine manufacturers.

Injured parties have three common law avenues for bringing a product liability cause of action against a vaccine manufacturer: (1) negligence liability in tort, (2) strict liability for breach of an express or implied warranty, and (3) strict liability in tort for physical harm. Strict liability differs from negligence liability in that the former focuses on whether or not the product is defective while the latter focuses on the manufacturer's conduct. Under the doctrine of strict liability, a manufacturer can be liable without any showing of fault.

The theory of strict liability was first enunciated in a concurring opinion by Justice Traynor in *Escola v. Coca Cola Bottling Co.* Under Traynor's rationale, the focus for determining liability shifted from the manufacturer to the product itself based on the theory that the relationship between manufacturers and consumers had changed so that consumers "no longer approach products warily but accept them on faith." Justice Traynor felt that in modern business, the manufacturer, not the consumer, was in the best position to provide protection against dangerous products.

The idea of strict product liability expressed in *Escola* became law in California with the holding in *Greenman v. Yuba Power Products, Inc.* Relying on the rule of *Greenman*, a plaintiff could show a manufacturer's liability by demonstrating that (1) an injury occurred during use of a product in the manner it was in-

22. See id. at 16-22.
24. Id.
25. For a discussion of breach of warranty claims, see generally JAMES J. WHITE & ROBERT S. SUMMERS, HANDBOOK OF THE LAW UNDER THE UNIFORM COMMERCIAL CODE 286-95 (1972); ROBERT J. NORDSTROM, HANDBOOK OF THE LAW OF SALES 235-36 (1970). In addition, much of remedies law in warranty cases is governed by the Uniform Commercial Code § 2-313 (express warranty), § 2-314 (implied warranty of merchantability), and 2-315 (implied warranty of fitness for a particular purpose).
26. KEETON et al., supra note 23, § 99.
27. Id.
28. See id. ("In strict liability, the plaintiff is not required to impugn the conduct of the maker.").
29. 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring).
30. Id.
31. Id. at 443.
32. Id.
33. 377 P.2d 897 (Cal. 1963).
tended to be used and (2) the injury resulted from a defect in the
design or manufacture of the product of which the plaintiff was not
aware.34 After Greenman, the American Law Institute adopted
section 402A of the Restatement (Second) of Torts reflecting the
rule of strict product liability.35 Almost every state has adopted
section 402A.36

The California Supreme Court further defined the doctrine of
strict liability in Cronin v. J.B.E. Olson Corp.37 and Barker v.
Lull Engineering Co.38 In Cronin, the court held that liability
could be imposed when a product was used in a manner reason-
ably foreseeable to the manufacturer, regardless of whether that use
was unintended or improper.39 In addition, the court found the
"unreasonably dangerous" language used in section 402A unneces-
sary40 and determined that a mere showing of a manufacturing or
design effect was sufficient to satisfy the conditions of strict prod-
uct liability.41

In 1978, Barker defined "design defect" in terms of strict
liability.42 Barker proposed three types of product defects which
could lead to a manufacturer being held strictly liable: (1) a manu-
facturing flaw resulting in a product different than originally
planned by the manufacturer (e.g., an exploding Coca-Cola bottle
as described in Escola); (2) a design defect such as the absence of

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34. Id. at 901.
35. Section 402A provides:
(1) One who sells any product in a defective condition unreasonably dangerous
to the user or consumer or to his property is subject to liability for physical
harm thereby caused to the ultimate user or consumer, or to his property, if
(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without
substantial change in the condition in which it is sold.
(2) The rule stated in Subsection (1) applies although
(a) the seller has exercised all possible care in the preparation and
sale of his product, and
(b) the user or consumer has not bought the product from or entered
into any contractual relation with the seller.

Restatement (Second) of Torts § 402A (1965) [hereinafter Restatement].
36. Keeton et al., supra note 23, § 98.
38. 573 P.2d 443 (Cal. 1978).
39. 501 P.2d at 1158.
40. Id. at 1162. The court observed that the "unreasonably dangerous" language "rings
of negligence." Id.
41. Id.
42. Barker, 573 P.2d at 453.
a safety device; and (3) lack of adequate warnings or instructions on how to use a product safely.\textsuperscript{43}

An injured party can more easily state a valid cause of action under strict liability than under a negligence theory. As a result, most early suits brought against vaccine manufacturers asserted claims based on the doctrine of strict liability.\textsuperscript{44} However, comment k of Restatement section 402A provides special "protection" from strict product liability for unavoidably unsafe products.\textsuperscript{45} Comment k specifically mentions vaccines as an example of such a product.\textsuperscript{46}

Comment k recognizes the social value of vaccines and protects producers who satisfy safe manufacturing requirements when consumers suffer adverse reactions. Comment k effectively eliminates most claims in strict liability against vaccine manufacturers.

\textsuperscript{43} Id.
\textsuperscript{45} RESTATEMENT, supra note 35, 402A cmt k (1965). Comment k states:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

\textsuperscript{46} Id. Although comment k indicates that protection from strict liability should be provided to "many other drugs, vaccines and the like, . . ." it does not automatically extend to all vaccines protection from strict liability. Therefore, in order for a vaccine manufacturer to avoid strict liability, its vaccine must first be classified as an unavoidably unsafe product. The criteria for receiving this protection are a subject of considerable judicial debate. See infra notes 70-81 and accompanying text.
who have shown their products to be unavoidably unsafe. Thus, with the exception of manufacturing defects such as a "bad" batch of vaccine, plaintiffs must proceed under a negligence standard and satisfy courts that defendant vaccine manufacturers have breached a duty owed to their customers.

Nonetheless, several plaintiffs have been successful in asserting strict liability claims against vaccine manufacturers. These cases have focused on the precise meaning of comment k's "proper directions and warnings" language. Many courts interpreting comment k have found the warning requirement to mean direct manufacturer warning to the intended vaccine recipient. This rule was first enunciated by the Ninth Circuit in *Davis v. Wyeth Laboratories, Inc.* While the *Davis* court agreed that vaccines were covered by comment k, the court held that a manufacturer of the Sabin polio vaccine who knew that warnings of the inherent risks of the vaccine were not reaching the ultimate consumers had failed to satisfy its duty to warn. The court found the warnings communicated to the administering physician inadequate because the vaccine was distributed at a mass immunization clinic where there were no procedures for assuring that the physician would

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47. See *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding that the manufacturer is responsible for seeing "that warnings reach the consumer either by giving warning itself or by obligating the purchaser to give warning" where polio vaccines are not individually prescribed by physicians); see also *Givens v. Lederle Laboratories*, 556 F.2d 1341, 1345 (5th Cir. 1977) (holding a drug manufacturer responsible for directly warning the consumer even if a polio vaccine is administered by a private physician instead of by a public health clinic); *Reyes v. Wyeth Laboratories, Inc.*, 498 F.2d 1264, 1275-76 (5th Cir.) (relying on *Davis* in holding that a polio vaccine manufacturer has a duty to warn the ultimate consumer of the drug's risk), *cert. denied*, 114 U.S. 1096 (1974); *Feldman v. Lederle Laboratories*, 479 A.2d 374, 388-89 (N.J. 1984) (concluding that a manufacturer who knows or should know of a drug's dangers has a duty to warn prescribing doctors and must warn consumers directly if knowledge of risks is subsequently obtained). *But see Foyle v. Lederle Laboratories*, 674 F. Supp. 530, 533-36 (E.D.N.C. 1987) (absolving the manufacturer of liability under the learned intermediary doctrine where a physician who administered a DPT vaccine had been warned of the drug’s risks).

48. 399 F.2d 121 (9th Cir. 1968).

49. Id. at 128.

50. The Sabin polio vaccine is a live-virus oral vaccine considered by many to be superior to the Salk "killed-virus" vaccine for preventing transmission of the disease. The main advantage of the Sabin vaccine is that it provides both antibody and cell-based immunity to the polio virus so that recipients do not require the booster shots characteristic of the Salk vaccine. See supra note 5.

51. *Davis*, 399 F.2d at 130-31.
communicate the warning to the patients.\textsuperscript{52}

Six years later, in \textit{Reyes v. Wyeth Laboratories, Inc.},\textsuperscript{53} the court extended the \textit{Davis} ruling by holding that failure to provide an adequate warning constituted a design defect and was sufficient to hold a manufacturer strictly liable.\textsuperscript{54} The \textit{Davis} and \textit{Reyes} opinions led to decisions in a number of lawsuits finding vaccine manufacturers liable for failing to provide direct warning of potential harmful side effects from vaccine use.\textsuperscript{55} Although in many cases there was questionable evidence of causation, juries tended to return verdicts in favor of the injured plaintiffs.\textsuperscript{56}

In later cases, vaccine manufacturers argued that imposing a duty to warn on the vaccine producer was unfair and often impossible. Manufacturers asserted that administering physicians are in a better position to inform intended vaccine recipients of the risks inherent in taking vaccines.\textsuperscript{57} The manufacturers' argument led courts to develop the "learned intermediary doctrine." This doctrine holds that a vaccine manufacturer has a duty to warn administering physicians, but not vaccine recipients, of foreseeable risks in using a vaccine.\textsuperscript{58} The learned intermediary doctrine does not prevent vaccine recipients from bringing actions against manufacturers if a recipient can prove the manufacturer failed to warn the prescribing

\textsuperscript{52} Id.
\textsuperscript{53} 498 F.2d 1254 (5th Cir.), \textit{cert. denied}, 419 U.S. 1096 (1974).
\textsuperscript{54} Id. at 1275-77.
\textsuperscript{55} \textit{See, e.g.}, Unthank v. United States, 732 F.2d 1517 (10th Cir. 1984) (swine flu vaccine); Ezagui v. Dow Chemical Corp., 598 F.2d 727 (2d Cir. 1979) (DPT and polio vaccines); Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977) (Sabin polio vaccine).
\textsuperscript{56} \textit{See McKenna}, \textit{supra} note 44, at 955.
\textsuperscript{57} \textit{See, e.g.}, Schindler v. Lederle Laboratories, 725 F.2d 1036, 1039-40 (6th Cir. 1983) (holding that the "warnings given by [the drug manufacturer] . . . were adequate to put a reasonably competent pediatrician on notice regarding the danger associated with giving oral polio vaccine to a child suffering from an immunity deficiency"); Stanback v. Parke, Davis & Co., 657 F.2d 642, 644 (4th Cir. 1981) (finding an influenza vaccine manufacturer's warning to doctors sufficient); Johnson v. American Cyanamid Co., 718 F.2d 1318, 1324 (Kan. 1986) (holding warning to a doctor of the polio vaccine's dangers sufficient); Dunn v. Lederle Laboratories, 328 N.W.2d 576, 579-80 (Mich. 1983) (doctors, not patients, must be warned of the dangers of the polio vaccine).
\textsuperscript{58} \textit{Reyes}, 498 F.2d at 1276. The \textit{Reyes} court explained that:

where \textit{prescription} drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use . . . As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient . . . Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.
physician adequately of all the risks accompanying vaccine use.59

The learned intermediary doctrine gained broad acceptance in the early 1980's when several pharmaceutical companies proved that warnings provided to physicians administering prescription drugs or vaccines were sufficient to meet the comment k warning requirement and thus protect the companies from strict liability.60 For instance, in Dunn v. Lederle Laboratories,61 the court reversed a judgment for a plaintiff who contracted polio after being vaccinated, holding that where a doctor must decide whether a patient should receive treatment with a specific drug or vaccine, "the doctor, and not the patient, must be warned by the manufacturer" of potential risks attendant upon use of the product.62 The Kansas Supreme Court concurred in this view in Johnson v. American Cyanamid Co.,63 where it found a manufacturer's warning to a private physician adequate and refused to hold the manufacturer liable under a failure to warn theory.64

The learned intermediary doctrine has been accepted by every jurisdiction that has examined the duty to warn doctrine.65 Some commentators believe that the learned intermediary doctrine will protect manufacturers of an AIDS vaccine from potential liability for adverse reactions to such a vaccine.66 Their position is premised on the theory that all recipients of an AIDS vaccine will be from high risk categories67 and that decisions to immunize will be made on a patient-by-patient basis.68 Since a decision to immunize would be the result of a careful balancing of risks and benefits, the prescribing physician and the recipient would necessarily be fully

59. MARDEN G. DIXON, DRUG PRODUCT LIABILITY § 9.02(1) (1986) (describing the traditional duty of the manufacturer to warn physicians of a drug's possible side effects).
60. McKenna, supra note 44, at 957.
61. 328 N.W.2d 576 (Mich. 1982).
62. Id. at 579.
63. 718 P.2d 1318 (Kan. 1986).
64. Id. at 1326.
65. McKenna, supra note 44, at 958.
66. See id. at 956-58. Of course, protection for AIDS vaccine manufacturers by the learned intermediary doctrine assumes that (1) an AIDS vaccine falls within the comment k exception to strict liability, (2) there are no manufacturing defects in the vaccine and (3) warnings to administering physicians are adequate.
67. Individuals considered to be at high risk to contract AIDS include individuals engaging in unsafe sexual practices, intravenous drug users, persons receiving blood transfusions and, to a lesser extent, those who have contact with blood and other body products of persons infected with the virus. HIV/AIDS SURVEILLANCE REPORT, supra note 1, at 10.
68. McKenna, supra note 44, at 953.
informed of potential adverse reactions. Under these circumstances, there would be no question as to whether a manufacturer satisfied its duty to warn, either directly or through a learned intermediary.69

In any case alleging liability by a vaccine manufacturer, the learned intermediary and direct warning doctrines limit only that liability based on a breach of the manufacturer's duty to warn noted in comment k. Moreover, these doctrines can be employed to shield vaccine manufacturers from strict product liability only if another comment k criterion — classification of the vaccines as unavoidably unsafe — is also satisfied.70 The holding in *Kearl v. Lederle Laboratories*71 suggests one test to determine whether a vaccine, or any other drug, deserves comment k protection.

Recognizing that no widely-accepted method for determining whether or not a product merited comment k protection existed, the *Kearl* court proposed the following test:

A trial court should take evidence as to: (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product both was "substantial" and "unavoidable"; [sic] and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review.72

Before rejecting strict liability arguments, trial courts must determine if each element of this test is satisfied.73 Furthermore, the *Kearl* court held that even if all requirements of the test were met, manufacturers would be exempt only from strict liability for

69. Id. If mass immunization for AIDS were required, the learned intermediary would probably not protect manufacturers because administering physicians and vaccine recipients in this setting do not interact in a way that warnings are likely to be communicated. In this case, a vaccine manufacturer would have to satisfy the courts that a sufficient warning had actually been given to recipients.

70. See supra notes 45-46 and accompanying text.

71. 218 Cal. Rptr. 453 (Ct. App. 1985), overruled by Brown v. Superior Court, 751 P.2d 470 (Cal. 1988). The *Kearl* court reversed a jury award of $800,000 for a child who contracted polio after being vaccinated and remanded the case to the trial court with instructions to determine whether or not the the polio vaccine was an "unavoidably unsafe" product under comment k.

72. Id. at 464.

73. Id.
design defects; a plaintiff could pursue an action under a negligence theory or under strict liability for manufacturing defects.74

In Brown v. Superior Court,75 the Supreme Court of California acknowledged the merit in the Kearl court’s endeavor, but nevertheless overruled the result.76 The Brown court admitted that “[i]f some method could be devised to confine the benefit of the comment k negligence standard to those drugs that proved useful to mankind while denying [the comment k] privilege to those that are clearly harmful, it would deserve serious consideration.”77 However, the court concluded that no method of identifying such drugs had been developed which would not “substantially impair[] the public interest in the development and marketing of new drugs.”78 The court’s criticism of the Kearl test focused on the subjective discretion it gave to trial judges for determining “what constitutes an ‘exceptionally important benefit’ of a drug.”79

The Brown court’s determination to provide comment k protection for all drugs reflects a policy geared at providing incentives for manufacturers to continue research into new treatments and cures for various illnesses. The court was concerned that the possibility of manufacturers being held strictly liable would deter the marketing of new products for fear of “large adverse monetary judgments.”80 Furthermore, the court was concerned that the additional cost of insuring against such liability might place the cost of obtaining new medicines out of reach of those most in need of them.81

III. LEGISLATIVE ATTEMPTS TO LIMIT MANUFACTURER LIABILITY

The common law has developed to a point where a vaccine manufacturer who produces a high quality vaccine and provides adequate warning of potential side effects will generally be shielded from strict liability for design and warning defects. While this provides many manufacturers with protection from large judgments,

74. Id. at 465.
75. 751 P.2d 470 (Cal. 1988). The Brown court held that comment k may be applied to a prescription drug without a finding by the trial court that the drug is unavoidably dangerous. The plaintiff’s claim was based on injuries caused by use of DES.
76. Id. at 482.
77. Id. at 481.
78. Id.
79. Id. at 482.
80. Id. at 479.
81. Id.
it does not prevent injured plaintiffs from bringing claims against them. The rising litigation costs manufacturers incur to defend these suits could encourage some manufacturers to leave the vaccine market. Likewise, common law decisions do not solve the problem of providing relief for those individuals who are injured by use of an unavoidably unsafe vaccine. This section discusses various attempts to provide compensation to those victims.

A. The Swine Flu Epidemic of 1976

In October 1976, facing an expected epidemic outbreak of an influenza strain known as swine flu, Congress enacted legislation geared toward providing Swine Flu vaccine manufacturers with immunity from liability for injuries caused by adverse reactions to the vaccine. In total, Congress appropriated almost $135 million for the program. As of 1985, the federal government, which had assumed liability for adverse reactions to the vaccine, had incurred legal costs of close to $100 million, pushing the program well over its initial budget.

The swine flu experience began with the identification of flu traceable to the swine flu virus in four army recruits at Fort Dix, New Jersey. The strain of flu was similar to one which caused 20 million deaths worldwide. Public health officials were extremely concerned about the possibility of a similar outbreak because there was evidence that the recruits could have been infected through human-to-human contact. Recognizing the potential for crisis, the public health bureaucracy advised President Ford that a
large scale immunization program was necessary to avert an epidemic. On March 24, 1976, Ford announced to the nation his intent to seek the inoculation of "every man, woman, and child in the United States."90

After the influenza strain responsible for the swine flu had been isolated and identified, drug manufacturers and public health officials collaborated to develop a vaccine for it.91 The vaccine was ready to be distributed as early as July 1976,92 well in advance of the October 1976 deadline after which the usefulness of the vaccine as a preventive mechanism would decrease drastically. However, the drug manufacturers, on advice of their insurance companies, refused to release the vaccine to the federal government.93 The insurance industry, reacting primarily to the decision in Reyes v. Wyeth Laboratories,94 refused to insure the vaccine manufacturers and the manufacturers, in turn, refused to dispense the vaccine without insurance coverage.95

Facing a fast approaching deadline for dispensing the vaccine, Congress considered a number of methods for alleviating the insurance industry's and vaccine manufacturers' concerns. Of the many alternatives suggested, two received the most serious consideration. The first was to have the federal government indemnify the vaccine manufacturers except where there was negligence in manufacturing or failure to satisfy contractual obligations. The second was to have the government reinsure the insurance companies which provided coverage to the vaccine manufacturers.96 Eventually, Congress settled the controversy by amending the Federal Tort Claims Act (FTCA)97 to allow those injured by the vac-

90. Id. at 46. For a detailed analysis of the political and scientific issues involved in the development and implementation of the swine flu vaccination program, see generally NEUSTADT & FINEBERG, supra note 6.
91. Baynes, supra note 85, at 63.
92. See 122 CONG. REC. 26,807 (1976) (statement of Rep. Rogers) (emphasizing the importance of implementing an immunization program prior to a fall or winter epidemic outbreak).
93. Id. The federal government was to be solely responsible for distributing the vaccine. Id.
95. See Baynes, supra note 85, at 64; Reitze, supra note 86, at 175.
96. Baynes, supra note 85, at 66.

The Federal Tort Claims Act is the statute which allows the United States government to be sued for the tortious act of its employers. Prior to enactment of the Federal Tort Claims Act in 1946, the only form of citizen redress had
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...cine to seek recovery directly from the federal government.98

Under this scheme, parties were required to seek recovery for injuries caused by adverse reactions to the vaccine through use of the Federal Tort Claims Act. However, the following exceptions to the FTCA applied: (1) recovery from the United States could be based on any theory of liability recognized in the state where injury from vaccination occurred; (2) discretionary function immunity could not be used as a defense by the United States; and (3) the prejudice of the FTCA against plaintiffs who fail to file an administrative claim as a preliminary step to litigation was altered.99 Although the federal government accepted liability for injuries resulting from swine flu vaccinations, the United States retained the right to seek indemnification from the vaccine manufacturers for negligence in manufacturing and breach of contract. This necessitated that vaccine manufacturers insure themselves for liability arising from negligence.100

By enacting this legislation, Congress guaranteed that the swine flu vaccine would be available for use before the illness became a public health problem. As soon as the vaccine was released by the manufacturers, the general public, at the urging of health officials, lined up to receive their shots. By the time the program ended on December 16, 1976, more than 40 million individuals were immunized.101 Soon after the mass immunization program began, there were reports of adverse side effects. The most common injury was

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98. Reitze, supra note 86, at 178-79.

99. See, Baynes, supra note 85, at 67. The exceptions ensured that all parties injured by the Swine Flu vaccine had a mechanism for recovery. Id. The first exception provided an opportunity for recovery under the product liability laws of every state. Id. The second exception was necessary because, in cases brought under the FTCA, the federal government cannot ordinarily be held liable for the discretionary actions of one of its employees. 28 U.S.C. § 2680(a). Thus, without this exception, victims could not seek recovery if the individual administering the swine flu vaccine was acting in a "discretionary fashion." Id. Finally, by relaxing the procedural aspects of the FTCA, those parties who filed suit against vaccine manufacturers in state courts were not prejudiced from refiling their claims in compliance with the requirements of the FTCA and the Swine Flu Act. Baynes, supra note 85, at 67.

100. See Baynes, supra note 85, at 68. The federal government can recover from a manufacturer all costs, judgments and settlements arising from the manufacturer's negligence or breach of contract.

101. Reitze, supra note 86, at 179.
Guillian-Barré Syndrome. This devastating disease has been the primary injury for which recovery under the Swine Flu Program has been sought.

By 1985, the number of administrative claims brought under the Swine Flu Program reached 4,165. At least 1,604 lawsuits for vaccine-related injuries were filed after administrative claims were denied. The cost of those cases which have settled or in which judgments have been awarded had reached approximately $83 million. As the remaining cases are handled, it is clear that this number will continue to increase.

As the first modern attempt to develop a comprehensive and large-scale immunization program, the Swine Flu experience offered valuable lessons. For example, the president, Congress and the public health establishment were “forced” to make decisions without complete information about the epidemiology of the disease. In addition, the president and Congress were not fully informed of changes in scientific data and in the opinions of experts about how to proceed with immunization. This suggests that future immunization programs should include a formal, ongoing review process in which the assumptions and expert opinions...
upon which action is predicated can be continually reevaluated.\textsuperscript{108}

The swine flu experience suggests that government should proceed carefully when dealing with a disease which is not well understood and where scientific knowledge is incomplete.\textsuperscript{109} In recommending a large-scale immunization program, public health officials lost sight of the fact that they did not have a complete understanding of the swine flu virus.\textsuperscript{110} Their experience treating and preventing more common diseases such as measles and polio served as the basis for their recommendations.\textsuperscript{111} However, reliance on such information was not adequate to predict the potential for adverse reactions to the swine flu vaccine\textsuperscript{112} or the liability expenses which the federal government experienced.\textsuperscript{113}

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\textsuperscript{108} Id. The value of an ongoing review process lies in maintaining a continuing debate about the need for government action. As more information becomes available, the appropriate course of action may change. For instance, throughout the political and scientific debate surrounding a swine flu immunization program, little attention was given to the fact that there was only one reported case of swine flu anywhere in the United States. Id. at 94. In hindsight, experts now believe that if that information had received the attention it deserved, the large-scale immunization program could have been geared to treat only those in high risk categories, the elderly and children. Id. at 104.

\textsuperscript{109} Id. at 132-37. Neustadt and Fineberg conclude that swine flu was a “slippery disease” because of the lack of information available regarding the number of actual cases, effective treatments, symptoms of the disease, the possibility of other ailments mimicking the underlying ailment and the year-to-year impact of the virus on the general population. Id. Comparing swine flu to other targets of government immunization (for example, childhood diseases) highlights the vast differences in knowledge regarding the “newer” swine flu. Id.

\textsuperscript{110} NEUSTADT & FINEBERG, supra note 6, at 132-33.

\textsuperscript{111} Id. at 134.

\textsuperscript{112} See Reitze, supra note 86, at 179, 182-84. The connection between the swine flu vaccine and Guillain-Barré Syndrome was unknown at the time the swine flu program commenced. Had the connection been known before the program was implemented, additional research may have produced a safer vaccine or, in the alternative, a different compensation plan for injured individuals might have been devised.

\textsuperscript{113} See Reitze, supra note 86, at 185 (suggesting that the total litigation cost to the government including settled claims, verdicts, and administrative costs was $83,235,714).
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B. National Childhood Vaccination Program

Unlike the swine flu situation, childhood vaccinations have been a fact of life for years and the underlying diseases are well understood.\footnote{See supra note 5 and accompanying text. Childhood immunizations begin at the age of approximately two months with the oral polio vaccine (OPV) and a combined vaccine for diphtheria, tetanus and pertussis (DTP). \textit{Childhood Immunizations}, supra note 5, at 17-20. At 15 months, the vaccine for measles, mumps and rubella (MMR) is administered. \textit{Id}.} Thus, lawmakers had had cause to debate the issue of whether a national vaccination policy was necessary and if so, how it should be designed. Nevertheless, Congress had not settled on any plan when vaccine manufacturers began to pull out of the market in 1967.\footnote{Institute of Medicine, \textit{Vaccine Supply and Innovation} 46 (1985) [hereinafter \textit{Vaccine Supply and Innovation}]. In 1984, there were 15 institutions licensed to produce and distribute vaccines in the United States, eight of which were licensed to produce vaccines for childhood diseases. \textit{Childhood Immunizations}, supra note 5, at 67. The eight producers of childhood vaccines include four commercial enterprises (Connaught Laboratories Inc.; Lederle Laboratories, a Division of the American Cyanamid Co.; Merck, Sharp & Dohme, a Division of Merck & Co., Inc.; and Wyeth Laboratories, a Division of American Home Products Corp.), two State governments (Bureau of Laboratories, Michigan Department of Public Health and Massachusetts Public Health Biologics Laboratory) and two foreign producers (the Instituto Sieroterapico Vaccinogeno Tuscano Scavo in Italy and the Wellcome Foundation, Ltd. in Britain). \textit{Vaccine Supply and Innovation}, supra, at 161-62.} It was not until early 1984 when the nation faced a short term disruption in the supply of the DTP vaccine that the withdrawal of manufacturers from this market became a cause for concern.\footnote{\textit{Id}. at 70.} Although the DTP vaccine supply crisis was resolved without substantial interruption of normal immunization plans,\footnote{\textit{Id}. at 68-70.} it was the impetus Congress needed to enact legislation to safeguard the nation’s supply of childhood vaccines.\footnote{\textit{Id}. at 70.}

Drug manufacturers chose to leave the vaccine market for a
number of reasons. Among the most common reasons cited were the small market for vaccines, the high cost of entry into the market with a new product and skyrocketing litigation costs and damage awards for injuries resulting from the use of childhood vaccines. In response to the crisis situation which existed with the dwindling stockpile of childhood vaccines and in order to stem the flow of vaccine manufacturers from the market, Congress enacted the National Vaccine Program in 1986.

The objective of the National Vaccine Program is “to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.” To this end, the major goals of the Program are:

1. improving coordination of vaccine research, development, use and evaluation;
2. assuring an adequate supply of vaccines;
3. assessing benefits and risks of vaccines and ensuring that the public and practitioners are aware of the benefits and risks;
4. ensuring adequate regulatory capacity to evaluate

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119. In 1982, the aggregate sales of vaccines in the United States was $172 million. Id. at 72. In comparison, a survey by the Pharmaceutical Manufacturers Association indicates that total pharmaceutical sales for 1982 reached almost $14 billion. VACCINE SUPPLY & INNOVATION, supra note 115, at 49. One reason for the relatively small size of the vaccine market is that most vaccines provide life-long immunity and do not require booster shots. CHILDHOOD IMMUNIZATIONS, supra note 5, at 72. Therefore, the market for vaccines varies with the number of children needing immunizations. Id. It is possible that vaccine manufacturers were leaving the market simply because they could foresee a stable market with limited potential for profits and potentially large liability costs. Id. at 72-73, 85.

120. The Institute of Medicine estimates that developing a new vaccine costs between $20-30 million. VACCINE SUPPLY AND INNOVATION, supra note 115, at 45.

121. CHILDHOOD IMMUNIZATIONS, supra note 5, at 72. A survey of vaccine manufacturers conducted by the House Subcommittee on Health and the Environment found that between January 1980 and March 1985, 299 lawsuits were filed against childhood vaccine manufacturers for injuries allegedly caused by vaccines. Id. at 86. These suits resulted in compensatory damages of $2.5 billion and punitive damages of $960 million. Id. Of the suits that had been settled or adjudicated during the period of the survey, manufacturers paid at least $16.2 million. Id. at 87. Litigation costs (not covered by insurance) for 1983 and 1984 were estimated at $4.7 million and $9.8 million, respectively. Id. The holdings in the Davis and Reyes cases have been identified as instrumental in the explosion of vaccine liability litigation. See James A. Newhard, Note, Immunity From AIDS Awaits Immunity for Vaccine Manufacturers: How Products Liability Law May Affect the Development of an AIDS Vaccine, 19 U. TOL. L. REV. 885, 897-908 (1988).


123. 42 U.S.C. § 300aa-1.
vaccines;
5. improving surveillance of adverse events;
6. establishing research priorities;
7. promoting rapid development and introduction of improved pertussis vaccines; and
8. ensuring optimal immunization levels in all high risk and target groups.\textsuperscript{124}

As part of the Act, Congress developed the National Vaccine Injury Compensation Program.\textsuperscript{125} The compensation fund is “a no-fault, nontort compensation alternative for individuals injured by compulsory childhood immunization.”\textsuperscript{126}

Under the Act’s compensation program, an individual who is injured after receiving one of the compulsory childhood vaccines is automatically entitled to compensation if the injury suffered is listed on the Vaccine Injury Table.\textsuperscript{127} Injuries not listed on the Table or those occurring outside the statutory time-frame are evaluated on a case-by-case basis.\textsuperscript{128}

To be eligible for compensation, a plaintiff must file a petition with the United States Claims Court.\textsuperscript{129} This petition must be accompanied by affidavits or supporting documentation indicating that the petitioner sustained an injury listed on the Vaccine Injury Table.\textsuperscript{130} Compensation will be awarded if the special master or court reviewing the petition finds that the petitioner has “demonstrated by a preponderance of the evidence” that his or her injury was the result of receiving a compulsory childhood vaccine.\textsuperscript{131}

Compensation is divided into four categories: medical and rehabilitative care, a death benefit ($250,000), lost earnings and pain and suffering ($250,000).\textsuperscript{132} Notably, the compensation program does not allow recovery for punitive or exemplary damag-
es. In order to receive compensation under this program, petitioners must waive all rights to bring suit against the vaccine manufacturer. However, a petitioner not satisfied with compensation under the program may irrevocably reject his right to such compensation and file suit directly against the vaccine manufacturer.

The compensation program is funded by an excise tax on vaccines which became effective in January 1988. To insure the solvency of the trust fund established for the program, the number of compensation “awards” is limited to 150 per year. If the number of “awards” exceeds this amount, all persons in the system will continue to be eligible for compensation, but no new petitions will be considered. However, recovery under traditional tort law theories remains available.

Since the National Vaccine Program is relatively new, its effectiveness is difficult to judge. However, available data indicate that, as of July 17, 1990, $56.8 million had been awarded to petitioners and attorney fees and legal costs had reached only $1.6 million.

133. Id. § 300aa-15(d). Section 300aa-15(g) also prohibits payment of compensation under the Program for any service or item to the extent that payment has been made or is expected from a state compensation program, an insurance policy, any state or federal health benefits program or from an organization providing prepaid health care. Further, the trust fund from which compensation is paid is “subrogated to all rights of the petitioner with respect to vaccine-related injury or death for which compensation was paid . . . .” Id. § 300aa-17.

134. Id. § 300aa-21 (“If a person elects to receive compensation [under the Program] . . . such person may not bring or maintain a civil action for damages . . . .”).

135. Id. § 300aa-21. The Act holds that all applicable state laws shall apply if an injured party chooses to seek recovery directly from a vaccine manufacturer. Id. § 300aa-22(a). However, the federal statute also holds that “[n]o vaccine manufacturer shall be liable in a civil action for damages . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.” Id. at § 300aa-22(b). In addition, the federal statute prohibits an injured party from recovering under a direct warning theory. Id. § 300aa-22(c). Thus, the National Vaccine Program effectively limits recovery from manufacturers to cases involving manufacturing defects or failure to warn learned intermediaries adequately. These limitations highlight one of the policy rationales behind the statute — to limit manufacturer liability by making recovery through the compensation program attractive to injured parties.


approximately three percent of the total awarded.\textsuperscript{139} In addition, vaccine prices have stabilized and some vaccine manufacturers who had left the market are considering re-entry.\textsuperscript{140}

The National Vaccine Program and the Vaccine Injury Compensation Program have provided a unique method of promoting benefits of mass immunization while affording some protection for individuals injured by childhood vaccines. The National Vaccine Program recognizes that mass immunization benefits society by ensuring a healthier population and reducing health care costs.\textsuperscript{141} In addition, the Program acknowledges that as a result of this policy, a certain number of individuals will inadvertently be injured each year by immunizations.\textsuperscript{142} Although compensation under the plan cannot make these injured individuals “whole,” it does ensure relatively quick compensation as compared to recovery through the courts.

The Program also recognizes that compensation through the trust fund will not always be adequate.\textsuperscript{143} Thus, plaintiffs retain the right to sue manufacturers directly. This right is important for two reasons. First, an injured party who is not satisfied with compensation awarded under the program can seek a larger judgment directly from a manufacturer. Second, in those instances where the injury is the result of manufacturer negligence, the manufacturer will be forced to bear without government assistance those costs which it has imposed on others. Allowing recovery for negligence directly from manufacturers provides an incentive to manufacturers to continue producing safe, high quality vaccines.

Moreover, in theory, the National Vaccine Program creates a more stable market for vaccine manufacturers. The compensation program provides relief to those parties who are injured without fault on the part of the manufacturer, thereby reducing the number of cases and lowering legal costs. In addition, because manufacturers are better able to predict their costs, they may be less hesitant


\textsuperscript{140} H.R. REP. NO. 101-247, 101st Cong., 1st Sess. (1989), \textit{reprinted in} 1989 U.S.C.C.A.N. 2235. It is unclear whether those manufacturers considering re-entry into the vaccine market are doing so because of the National Vaccine Program, which presumably has lead to more predictable costs of doing business, or because of potential opportunities for an expanding market as the number of children increases.


\textsuperscript{142} Id.

\textsuperscript{143} See \textit{supra} note 135 and accompanying text.
to enter or remain in the vaccine market, stabilizing the vaccine supply.

C. California AIDS Vaccine Victims Compensation Fund

Recognizing the experience of childhood vaccine manufacturers, the California legislature enacted a statute in 1986 to provide an incentive for vaccine manufacturers to develop and produce a vaccine for the AIDS virus.\textsuperscript{144} In addition, this statute established a fund to compensate those injured by use of an approved vaccine.\textsuperscript{145} Although this program is modeled after the National Vaccine Program,\textsuperscript{146} there are some significant differences.

The California act is designed with the specific goal of developing an effective AIDS vaccine.\textsuperscript{147} To this end, the legislation takes a two-step approach. First, it guarantees a market for any FDA approved vaccine.\textsuperscript{148} Second, the law attempts to limit litigation costs manufacturers may face by compensating those injured by the vaccine.\textsuperscript{149} Under the program, an injured party receives compensation of up to $550,000 for personal injuries, lost income, and pain and suffering.\textsuperscript{150} The compensation fund is to be main-

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144. CAL. HEALTH & SAFETY CODE §§ 199.45-.51. In its comprehensive findings, the California legislature determined that vaccine manufacturers often faced severe hurdles when deciding to enter the vaccine marketplace. Among the chief concerns cited by the legislature were: "uncertain profitability and perceived and actual marketplace risks and disincentives," id. § 199.45(1); the high cost (estimated by the legislature to be between $10 and $30 million) of developing a new vaccine, id. § 199.45(n)(1); and an uncertain market for an AIDS vaccine once developed and approved, id. § 199.45(n)(2).

145. Id. § 199.50.

146. Like the federal program, the California plan attempts to encourage manufacturers to develop and market an AIDS vaccine by providing for fixed levels of compensation for injured parties funded by an excise tax on the vaccine. Id.

147. Among the findings and declarations included in the law's introductory section, the legislature noted its commitment to work on an AIDS vaccine. "Because an AIDS vaccine provides an exceptionally important public benefit, it is in the public interest to take uncommon action to facilitate the development and production of such a vaccine." Id. § 199.45(g). The legislature concluded this section by declaring, "[i]t is therefore fitting and proper that the State of California enact uncommon and exceptional legislation in order to prevent the further spread of the AIDS epidemic." Id. § 199.45(t).

148. California guarantees that at least 175,000 people will be vaccinated and that within three years of the initial marketing of an AIDS vaccine, at least 500,000 units of the vaccine will have been purchased from all manufacturers. Id. § 199.51(a). If 500,000 units are not purchased throughout the United States, the State will acquire the remaining units at a cost of no more than $20 per dosage. Id.

149. See id. § 199.50 (establishing the AIDS Vaccine Victims Compensation Fund).

150. Id. § 199.50(b)(3). Compensation under the act is not available for injuries resulting from the comparative negligence of the injured party, the negligence of the vaccine manufacturer or for injuries occurring during a clinical trial. Id. § 199.50(c)(1)-(3).
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tained by a surcharge of no more than $10 on each dose of vaccine dispensed in California. The compensation fund is subrogated to any claim an injured party receiving compensation is otherwise entitled to assert. The fund may also seek indemnity for compensation it provides from third parties found to be liable for injuries resulting from use of an AIDS vaccine.

The most obvious difference between the California Act and the National Vaccine Program is that an injured party can seek recovery concurrently from both the compensation fund and the vaccine manufacturer. Unlike the National Vaccine Program which effectively acts as an insurance fund, the California plan provides for victims’ compensation through both an insurance mechanism and recovery in tort. The apparent rationale of the California scheme is to ensure that injured parties have a quick method of compensation for any injuries sustained while allowing the injured party to seek additional compensation directly from the vaccine manufacturer.

Although the effectiveness of the California plan cannot be assessed until an AIDS vaccine has been manufactured and marketed, the plan offers some insight into development of a comprehensive AIDS vaccination policy.

IV. ANALYSIS AND RECOMMENDATIONS

Any strategy developed to combat the AIDS virus will necessarily be complicated. The epidemiology of the virus is not well understood, no effective treatment has yet been identified,
and many in society continue to view those afflicted with the disease with disdain because of the common means by which the AIDS virus is transmitted.\textsuperscript{158} Although the scientific community continues to work on developing a vaccine for the disease, there is no clear indication about when one will be available.

Furthermore, as demonstrated by the childhood vaccine supply crisis\textsuperscript{159} and the Swine Flu experience,\textsuperscript{160} when or if an AIDS vaccine is developed, manufacturers may be hesitant to release it for fear of potential liability. Thus, it is imperative that a comprehensive policy be developed before another vaccine "crisis" arises.

Two potential strategies exist for handling the legal issues associated with providing an AIDS vaccine for general public use. The first option is to rely solely on the tort system for compensation of parties injured by an AIDS vaccine. In such a system the government would not be involved and the common law would provide relief for aggrieved parties. The second option is to implement some type of government-sponsored insurance program.\textsuperscript{161} The Swine Flu Program, the National Vaccination Program and the California AIDS Vaccine Victims Compensation Fund are examples of possible insurance approaches which may satisfy the goals of a comprehensive AIDS vaccination policy.

A. Common Law Methods of Recovery

The traditional tort system is based on the premise that by making parties responsible for the consequences of their activities, the parties will be encouraged to act in the most efficient manner possible.\textsuperscript{162} Thus, a vaccine manufacturer held liable for injuries caused by its vaccines should internalize the costs of such injuries producing an AIDS vaccine).


\textsuperscript{158} Seventy-six percent of infected individuals were exposed to HIV through homosexual/bisexual contact among men or by sharing intravenous (IV) drug needles. HIV/AIDS SURVEILLANCE REPORT, \textit{supra} note 1, at 15.

\textsuperscript{159} See \textit{supra} notes 114-43 and accompanying text.

\textsuperscript{160} See \textit{supra} notes 83-113 and accompanying text.

\textsuperscript{161} See \textit{infra} text accompanying notes 204-34.

\textsuperscript{162} KEETON et al., \textit{supra} note 23, § 4.
and incorporate those costs into its production and marketing decisions.

In theory, this rationale is sound. As long as injured parties are able to show that a vaccine manufacturer has breached a duty of care to its customers, those plaintiffs will be entitled to compensation for their injuries. However, the theory underlying common law recovery deteriorates when all the costs and benefits of immunization are considered. For example, problems of proof and variations in traditional common law rules can deny injured plaintiffs compensation. Moreover, the effects of tort actions extend beyond the parties to individual cases. Vaccine manufacturers anticipating increased costs due to liability may elect to halt production of vaccines, a decision which could lead to layoffs and to an inadequate supply of vaccines available to the public. Finally, the tort system subjects defendant vaccine manufacturers to the possibility they will be held responsible for harms they did not cause.

1. Burden of Proof

In any cause of action for recovery from a vaccine manufacturer, the burden of proving a causal relationship between use of a vaccine and injury falls on the injured party. Often this element is not difficult to establish. For instance, injuries resulting from use of certain childhood vaccines are well documented and occurrences of Guillian-Barré Syndrome following the swine flu immunization program were quickly traced to the vaccine.

163. See infra text accompanying notes 166-72.

164. Although some would argue that a vaccine manufacturer which expects to incur liability for adverse reactions to a vaccine can recoup those costs by increasing the price of its goods, there are limits to the success of this strategy. For instance, consumers may be unwilling or unable to pay the increased costs or government regulations may limit what a manufacturer can charge customers. See generally William D. Douglas, Vicarious Liability and Administration of Risk, 38 YALE L.J. 584, 720 (1929) (discussing issues involved in shifting risks to the public).

165. For example, recent studies suggest that the causal relationship believed to exist between the childhood vaccine for pertussis and serious brain injury may not be valid. See Gerald S. Golden, Pertussis Vaccine and Injury to the Brain, 116 J. PEDIATRICS 854 (1990) (study showing no evidence of increased risk for seizures following DPT vaccine); Marie R. Griffin et al., Risk of Seizures and Encephalopathy After Immunization with the Diphtheria-Tetanus-Pertussis Vaccine, 263 JAMA 1641 (1990) (concluding that new data do not support the existence of pertussis vaccine encephalopathy). See infra notes 181-84 and accompanying text.

166. See CHILDHOOD IMMUNIZATIONS, supra note 5, at 21. See also supra notes 83-113.

167. See NEUSTADT & FINEBERG, supra note 6, at 100 (reporting that those receiving the swine flu vaccine were 11 times more likely to contract Guillian-Barré Syndrome than
However, the *Restatement (Second) of Torts* recognizes that vaccines are often unavoidably unsafe products and that a manufacturer should not be strictly liable for injuries resulting from use of a properly designed and manufactured vaccine.168 Recent decisions with respect to vaccine manufacturers' liability suggest courts are unwilling to extend notions of strict liability beyond established lines in this area.169 Thus, a plaintiff is now likely to face the onerous burden of showing that the manufacturer negligently prepared the vaccine or failed to provide an adequate warning of the risk associated with its use. Difficulty in proving negligence for failure to warn has increased as a result of judicial acceptance of the learned intermediary doctrine.170

The result of these common law developments is that plaintiffs injured by an AIDS vaccine may not be able to satisfy their burden of proof and will not be compensated by vaccine manufacturers. As a result, injured parties may have to rely on other forms of compensation, such as government assistance programs.171 Furthermore, while recovery from vaccine manufacturers for negligent preparation and failure to warn is justified and is effective as a means of providing incentives for safer practices, a number of individuals will be injured by vaccines despite proper preparation and administration.172 Thus, reliance solely on the traditional tort

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169. See supra text accompanying notes 57-81. Much of the common law precedent dealing with vaccines and vaccine manufacturer liability comes from California. See supra notes 48-52, 71-81 and accompanying text. Although many other jurisdictions have followed the lead of the California courts, nothing prevents other states from breaking with these precedents. For instance, different courts could adopt different methods of applying § 402A, comment k of the *Restatement (Second) of Torts*. Some scholars continue to support the approach of the *Kearl* court, see supra notes 71-81 and accompanying text, even though that case is no longer controlling in California since the decision in *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988). See, e.g., *Newhard, supra* note 121, at 916; *Mariner & Gallo, supra* note 156, at 22. The *Kearl* approach could be adopted in whole or in part by another jurisdiction.

170. See supra text accompanying notes 57-69. The learned intermediary doctrine shields a manufacturer from liability if the manufacturer provides adequate warning of all known consequences of using the vaccine to the party distributing the vaccine, usually a family physician or government health agency.

171. A dramatic shift in the sources of funding for treatment of AIDS patients has already been documented. Between 1984-85 and 1986-87 the proportion of inpatient care for AIDS treatment financed by Medicaid rose from 25% to 41%. Jesse Green & Peter S. Arno, *The ‘Medicaidization’ of AIDS*, 264 JAMA 1261 (1990). Over the same period, the proportion of AIDS care financed by private insurance dropped from 49% to 43%. Id.

system may leave many injured by an AIDS vaccine without an effective means of obtaining compensation.

2. Increased Costs to Vaccine Manufacturers

If parties injured by an AIDS vaccine were limited to recovery solely through traditional tort causes of action, vaccine manufacturers could expect an increase in the number of lawsuits. Notwithstanding the difficulty plaintiffs may have succeeding on their claims, injured parties faced with no alternative methods of compensation are likely to find litigation a more attractive alternative than foregoing the possibility for compensation altogether. The experience of childhood vaccines manufacturers prior to implementation of the National Vaccine Program supports this scenario. Increased litigation against vaccine manufacturers would increase their costs of operation. As a result, manufacturers may find continued production of vaccines unreasonable.

Even though the common law imposes a high burden of proof in a case against a vaccine manufacturer and thereby decreases the potential for large damage awards, the costs of defending against a large number of lawsuits might be substantial enough to force a manufacturer to withdraw from the market.

If manufacturers of an AIDS vaccine were “forced” from the market by excessive legal costs, there would likely be a ripple ef-

173. Injured parties who have private insurance or are eligible for government assistance would, of course, be able to rely on those sources to pay expenses incurred in treating the injury caused by the vaccine.

174. See supra note 121 and accompanying text.

175. Such a situation lead to the DPT vaccine supply crisis in 1984. See supra notes 116-18 and accompanying text. Similarly, distribution of the swine flu vaccine was delayed because manufacturers were not able to obtain liability insurance without guarantees from the government that the manufacturers would not be liable for injuries caused by adverse reactions to the vaccine. See supra text accompanying notes 93-95.

176. As demonstrated by the holding in Johnson v. American Cyanamid Co., 718 P.2d 1318 (Kan. 1986), courts are less willing to let large jury awards stand against vaccine manufacturers where the vaccine-related injury is one for which the manufacturer can claim the protection provided by comment k.

177. Manufacturers of childhood vaccines faced litigation costs of $4.7 million and $9.8 million, respectively for 1983 and 1984 in defending against tort claims resulting from adverse reactions to vaccines. These costs were one reason that many manufacturers chose to leave the market. CHILDHOOD IMMUNIZATIONS, supra note 5, at 85-87. It is impossible to predict the litigation costs an AIDS vaccine manufacturer might face. However, absent any government program designed to limit liability claims, manufacturers of an AIDS vaccine can anticipate substantial litigation expenses if there are any adverse reactions to such a vaccine.
fect increasing the "costs" to the general public of vaccine-related injuries. First, vaccine manufacturers would likely lay off workers employed to make vaccines and shift their production efforts into more profitable areas of business.\textsuperscript{178} Second, manufacturers and researchers might discontinue work on new, safer or more effective vaccines out of fear they would be subject to large legal expenses if they chose to enter the AIDS vaccine market. As a consequence, vaccine development would be delayed, at best, and could be prevented completely. Third, some of those individuals unable to obtain the AIDS vaccine would, presumably, develop AIDS. Not only would society be faced with the cost of treating the disease,\textsuperscript{179} but individuals in the prime of their lives would be unable to work or support a family,\textsuperscript{180} adding indirectly to the costs of AIDS.

3. Scientific Uncertainty

The last major problem with reliance solely on common law forms of recovery is that vaccine manufacturers could be liable for injuries not caused by use of their vaccines.\textsuperscript{181} For instance, recent research suggests that the causal connection between the pertussis vaccine and injury to the brain could be "chance temporal associations of neurological conditions that occur in the target age

\textsuperscript{178} As the nation's experience with childhood vaccines demonstrates, manufacturers will not hesitate to leave a market where the cost of doing business is unreasonable. See supra note 116 and accompanying text. Moreover, the Institute of Medicine's 1985 report \textit{Vaccine Supply and Innovation}, supra note 115, suggests that through the 1970's and the early 1980's research and development of pharmaceutical products other than vaccines increased while research spending on new and improved vaccines remained steady or declined. \textit{Id.} at 46-49. This shift of resources suggests that manufacturers have found other areas of the drug business more profitable.

\textsuperscript{179} The estimated lifetime medical costs for an individual with AIDS range from $20,320 to $147,000 per patient. Seage et al., \textit{supra} note 3, at 835. As advances in treatment of AIDS lengthen the life expectancies of those infected, the lifetime costs of care will rise. \textit{Id.} at 838.

One report suggests that the lifetime cost of treating those individuals already diagnosed with AIDS will top $4 billion. \textit{Id.} at 839. Using this study's estimated lifetime cost of $42,399 for treatment of an individual with AIDS, \textit{id.}, and assuming that 1.5 million additional cases of AIDS will develop among those already infected with HIV, \textit{id.} at 835, the estimated cost of treating just these individuals could exceed $50 billion. These figures will grow as the number of those infected with HIV continues to increase. Thus, it is clear that an effective AIDS vaccine could save society billions of dollars and, conversely, the price of manufacturers' withdrawal from the AIDS vaccine market because of extraordinary legal costs would be substantial.

\textsuperscript{180} Current data from the Centers for Disease Control indicate that 76 percent of men with AIDS are between the ages 25 and 44; 71 percent women with AIDS are in this age group. HIV/AIDS \textit{Surveillance Report}, \textit{supra} note 1, at 12.

\textsuperscript{181} See \textit{supra} note 165 and accompanying text.
group, even in the absence of immunization.” These findings have led to at least one commentator to demand that the “national nonsense” of linking pertussis immunization to encephalopathy be stopped and to call for a change in the Vaccine Injury Table to reflect this new evidence.

These studies reassessing the causal link between a widely used vaccine and certain maladies later detected highlight the possibility that an AIDS vaccine could be incorrectly linked with adverse side effects. Under a common law means of recovery, a manufacturer who produces and markets an AIDS vaccine believed to cause certain injuries could incur legal costs for medical problems not actually caused by the vaccine. Although the possibility that injuries will be mistakenly linked to the AIDS vaccine may be remote, such a connection would subject manufacturers to costs they should not have to bear. As a result, society’s resources would be inefficiently allocated and manufacturers would have a legitimate excuse to stay out of the vaccine market and avoid unwarranted liability.

4. Economic Structure of Vaccine Marketplace

Much of the preceding analysis regarding the effect of the common law on vaccine manufacturers is based on the assumption that potential liability for adverse reactions to vaccines is the major reason manufacturers are hesitant to enter or remain in the market. However, liability costs explains only part of the turmoil.

183. See supra note 127 and accompanying text.
184. James D. Cherry, M.D., Editorial, ‘Pertussis Vaccine Encephalopathy’: It Is Time to Recognize It as the Myth That It Is, 263 JAMA 1679, 1680 (1990) (suggesting the need for development of new vaccines to stop the many unfortunate reactions that are caused by the pertussis vaccine).
185. See supra notes 121, 135 and accompanying text. In 1985, the Institute of Medicine reported that vaccine operations at major pharmaceutical companies are “responsible for a disproportionate number of liability claims (about 40 percent) or related costs (e.g., insurance, about 60 percent) when compared with their pharmaceutical operations, even though the vaccines contribute[d] significantly less to total sales (5 to 15 percent).” VACCINE SUPPLY AND INNOVATION, supra note 115, at 53.

It should be noted that the Institute of Medicine derived these figures from information it collected in a survey of the pharmaceutical industry. Id. The author of this note was unable to locate any economic information relating to the vaccine market which did not involve some form of voluntary participation by or on behalf of vaccine manufacturers. Although the source of available data raises the possibility that the data could be skewed in favor of the position that liability claims are a major reason for manufacturers’ unwillingness to enter or remain in the vaccine market, there is no indication that the figures reported by vaccine manufacturers were incorrect or intentionally misleading.
in the vaccine market. In addition to liability concerns, manufacturers also face problems with property rights for newly developed vaccines and related products. Moreover, safety regulations have increased the cost of developing new and improved vaccines and the size of the vaccine market does not provide an opportunity for large profits. These factors have also contributed to manufacturers’ reluctance to participate in vaccine development and marketing.

Vaccine manufacturers protect their property rights in newly developed vaccines by obtaining patents. Traditionally, the government granted process patents for vaccine products. Process patents protect a manufacturer’s method of producing the vaccine rather than the vaccine itself. However by denying patent protection for a vaccine itself, a competitor can enter the vaccine market and offer the same vaccine as long as it is not manufactured in the manner protected by the process patent. Thus, the competitive advantage the developer of the new vaccine originally enjoys can be quickly eroded. The Supreme Court’s holding in *Diamond v. Chakrabarty* that living things are patentable may provide vaccine makers greater protection for their property interests in their vaccines. Vaccines, which are often processed from components of living organisms, may qualify for patent protection under *Diamond*. Such protection should provide an incentive for manufacturers to move back into the vaccine market.

The increase in safety regulations and testing requirements which accompany the marketing of any new vaccine also acts as a barrier to innovation and spending on vaccines. The additional costs imposed by these regulations are borne solely by manufacturers and force manufacturers to compare expected future revenues with current costs of testing. However, recent regulations provide manufacturers the opportunity for expedited testing of new

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186. *Vaccine Supply and Innovation*, supra note 115, at 50. Patents are valuable to manufacturers because they keep competitors from copying the products produced by the patent holders.

187. *Id.* at 51.

188. *Id.*


191. *See Katzenstein et al., supra note 1, at 576-86.*


193. *Id.* Calculation of future benefits is a complicated and risky endeavour. Not only is the market for a vaccine dependant upon consumer demand, but it is always possible that a competitor could develop a more effective vaccine thereby rendering worthless the vaccine being tested.
drug treatments for life threatening and debilitating diseases, including AIDS.\footnote{21 C.F.R. §§ 312, 314 (1988).} Accelerated testing of a new AIDS vaccine could allow producers to avoid much of the "gamble" associated with developing new vaccines because the potential costs and benefits would be realized earlier. Manufacturers should experience less uncertainty when attempting to project future returns on current vaccine innovation investment if their cost and benefit projections span a shorter period of time.

As previously discussed, the market for vaccines is directly related to the size of the target population for treatment with the vaccine.\footnote{See supra note 119 and accompanying text. See also VACCINE SUPPLY AND INNOVATION, supra note 115, at 52 (discussing the factors affecting the size of the vaccine market).} In addition, eradication of a disease, which is the goal of any vaccination plan, works directly against the continued success of a particular vaccine's market.\footnote{VACCINE SUPPLY AND INNOVATION, supra note 115, at 34.} When a disease no longer poses a public health problem, as is the case with smallpox, the market for the vaccine which prevents it disappears.\footnote{Id. at 35. The Institute of Medicine cites the decreased emphasis on preventive care in the United States, illustrated by an over-emphasis on diagnostic and therapeutic treatment, as one reason for an unstable vaccine market. Id. In addition, most health insurance plans do not provide reimbursement for preventive care such as immunization, but are geared to pay for acute care instead. Id.} Although the need for treatment through vaccination continues for many afflictions, such as the childhood diseases, the potential for eradication remains one of the major economic factors working against a healthy vaccine market. Additional factors affecting the vaccine market include a movement away from preventive care in the United States\footnote{Id. at 35. Failure to be vaccinated is an example of the classic "free-rider" scenario. As individuals are immunized, the odds of catching a communicable disease decreases. Id. at 35. Since the individual benefit of being immunized is less than the social benefit of having an immunized population, there is less incentive for an individual to risk the possibility of suffering an adverse reaction to a vaccine. Rather, the individual will enjoy protection from the disease by relying on others to be vaccinated. Id.} and reluctance of individuals to be immunized out of fear of adverse reactions.\footnote{Id.}

Clearly, the problems surrounding the vaccine market are multifaceted. It is impossible to point to any one factor as the reason manufacturers are hesitant to enter or remain in it. However, surveys and commentaries from executives at pharmaceutical companies suggest that a primary concern with the vaccine market is the
unstable liability situation. The lack of independent data verifying vaccine manufacturers' claims regarding liability raises some question as to whether these concerns are founded in fact or are overstated in an attempt to influence future legislative initiatives.

Whatever the cause of problems in the vaccine market, it is imperative that manufacturers remain in it. Given the experience of the early 1980's with the DPT vaccine shortage and the drastic decrease in the number of firms manufacturing vaccines, it is clear that steps should be taken to minimize at least one key drawback of participation in the market — liability. Reliance on the common law to compensate those injured by correctly prepared vaccines is not sufficient to balance a healthy vaccine market with just compensation to the unfortunate individuals who suffer adverse reactions. Government intervention is required to provide a reliable, stable means of compensation.

B. A Government Sponsored Insurance Program

The preceding section of this note established that reliance on common law causes of action against vaccine manufacturers may result in those inadvertently injured by a vaccine being denied compensation. The compensation fund approaches developed by the National Vaccine Program and the California Vaccine Victims Compensation Fund satisfy this goal through use of self-sustaining insurance pools funded by those who use the vaccines.

1. Spreading Risks

The primary goal of insurance is to spread the risks of an activity over a population so that no one individual has to bear the full cost of an injury. All parties bear the cost of the activity equally. This scheme guarantees some level of compensation to all parties who participate in an insurance program. Developing a

200. See supra note 121 and accompanying text.
201. Data is available to show the cost of vaccine-related litigation during the early 1980's, see supra note 121, and to show the cost of compensating those injured by the swine flu vaccine, see Reitze, supra note 86, at 184. However, this data was also supplied by vaccine manufacturers and may be subject to bias. See supra note 185.
202. See supra notes 116-18, and accompanying text.
203. See supra note 115 and accompanying text.
204. See supra text accompanying notes 166-72.
successful insurance plan requires that the drafters have an ade-
quate appreciation of the risks involved in the activity covered.\textsuperscript{206} By anticipating future risks, insurance plans spread the costs of injuries among members over time before injuries are sustained.

Creating insurance to accompany immunization programs spreads the risks of vaccine-related injuries and compensates those injured. In addition, insurance would provide a "buffer" for vaccine manufacturers against liability claims resulting from adverse reactions.\textsuperscript{207} However, as the swine flu experience demonstrated, determining the risks of immunization will be a difficult task.\textsuperscript{208} In contrast, the National Vaccine Program indicates that diseases which are well understood and for which adverse reactions to vaccines are highly predictable are amenable to an insurance-type compensation fund.\textsuperscript{209}

Because scientists do not understand AIDS very well,\textsuperscript{210} even when a vaccine is developed, there will likely be some uncertainty as to its effectiveness.\textsuperscript{211} In addition, it is possible that some un-

\textsuperscript{206} Id. Since no AIDS vaccine is currently available, it is impossible to evaluate the risks associated with such a vaccine. Developing an insurance program at this time is therefore problematic. However, by designing a flexible program, its administrators should be able to adapt the plan to the actual level of risk as that information becomes apparent.

\textsuperscript{207} Both the National Vaccine Program and the California Vaccine Victims Compensation Fund provide those injured by vaccines with some method of recovery. The history of each program's development, however, reflects a governmental objective to provide vaccine manufacturers a stable business environment. The federal government instituted the National Vaccine Program only after the DTP vaccine crisis of the mid-1980's. See supra notes 116-18 and accompanying text. Similarly, in the findings accompanying the AIDS vaccine compensation legislation, the California legislature expressly acknowledged that market disincentives may keep an AIDS vaccine from coming to market without govern-
ment intervention. CAL. HEALTH & SAFETY CODE §§ 199.450)-(t). See also supra note 147 and accompanying text.

\textsuperscript{208} See supra note 112 and accompanying text for a discussion of the unexpected consequences of the swine flu immunization. Before immunization commenced, there was no known correlation between the swine flu vaccine and Guillain-Barre Syndrome. See also Neustadt & Feinberg, supra note 6, at 117 which suggests that the outcomes of an immunization program involving "slippery diseases" are difficult to project. AIDS clearly qualifies as a "slippery disease" because of scientists' lack of understanding of it. See supra notes 1-3.

\textsuperscript{209} Scientists' years of experience dealing with childhood diseases makes it possible for them to accurately predict the number of cases of inadvertent injuries due to vaccination. These predictions, in turn, enable calculation of the excise tax which finances the comp-
ensation fund. The excise tax is, in effect, the insurance premium that all individuals re-
ceiving a vaccine must pay. See supra note 136 and accompanying text.

\textsuperscript{210} See supra note 1 and accompanying text.

\textsuperscript{211} The efficacy and safety of any new vaccine are regulated by the Public Health Service and the Food and Drug Administration. Katzenstein et al., supra note 1, at 578-79. As part of the licensing process, all new vaccines must complete clinical trials during
expected side effects will result from such a vaccine.\textsuperscript{212} These factors weigh against reliance on an insurance-type approach to compensate injured vaccine recipients because unknown risks make premium calculations difficult.\textsuperscript{213}

However, the alternatives to an insurance approach, which include not releasing the vaccine or relying solely on the common law system, also have drawbacks.\textsuperscript{214} Thus, it is incumbent upon government to determine the preferable policy. If an insurance-type approach is selected, the insurance fund should be flexible so that it can be adapted to unexpected developments.\textsuperscript{215} The National Vaccine Program makes allowances for changed circumstances by requiring the director of the National Vaccine Program to continually evaluate childhood vaccines for safety and efficacy and to coordinate research to improve vaccines.\textsuperscript{216} In addition, the solvency of the program is insured by setting a limit on the number which the effectiveness of the proposed new vaccine is evaluated and its relative safety is examined. \textit{Id.} at 580. These steps are intended to determine not only the efficacy of a new vaccine but to allow researchers to examine possible adverse reactions to a vaccine. \textit{Id.} However, as the swine flu experience demonstrated, it is not always possible to predict all adverse reactions in a controlled population study. \textit{See Neustadt & Fineberg, supra} note 6, at 100.


The unique nature of HIV and the strong public pressure to dispense an AIDS vaccine which is likely to accompany the development of such a treatment could lead to distribution of an AIDS vaccine without full understanding of all possible side effects. Recent regulations allow for expedited use of new drugs for treatment of life-threatening and seriously debilitating illnesses. \textit{53 Fed. Reg. 41,515 (1988) (interim rule).} Under these rules, clinical testing continues after conditional approval of the treatment. Thus, even as an AIDS vaccine approved under these rules undergoes further official testing and licensing procedures, recipients could develop unanticipated side effects.


An insurance approach like the California model may be inadequate to satisfy all the claims made against it. The California compensation fund is designed to operate only as long as monies from the excise tax are available. \textit{Cal. Health \& Safety Code} \textsection{199.50(o)}. Insufficient funding could prevent injured parties from receiving compensation and could force some of those parties to seek government assistance.

214. \textit{See supra} text accompanying notes 170-72, 178-80.

215. \textit{See Neustadt \& Fineberg, supra} note 6, at 118-26 (suggesting that continuing review of any large scale immunization program is essential to quickly adapt to changed circumstances).

216. \textit{See 42 U.S.C} \textsection{300aa-2(a)(1)-(9)} (detailing the role of the Director of the National Vaccine Program).
of claims that can be satisfied each year. If the California AIDS Vaccine Victims Compensation Fund is actually employed to provide protection against adverse reactions to an AIDS vaccine, the administrators of the fund should be willing to change the amount of the surcharge per dose to reflect the true costs of the vaccine. Alternatively, the administrators should be prepared to limit the amount of compensation distributed so that the fund remains solvent if the number of claims exceeds projections.

2. Adequacy of Compensation

A second important issue which will arise in developing an insurance method of compensation for injuries caused by an AIDS vaccine is the amount of compensation to provide. Potential plans could offer unlimited recovery for all expenses incurred, predetermined levels of compensation or recovery limited by a cap on the amount of compensation available to individual claimants. Both the National Vaccine Program and the California AIDS vaccine plan have adopted variations of the third option.

Each of the three compensation plans possesses advantages and disadvantages. The unlimited recovery approach ensures that injured parties are fully compensated for their injuries. However, this approach complicates attempts to predict the costs of the program. As seen in the swine flu situation, failure to limit the amount of recovery may lead to unexpected liability and costs far in excess of those anticipated.

217. See supra notes 137, 212 and accompanying text.

218. The California compensation fund is administered by the State Board of Control. CAL. HEALTH & SAFETY CODE §§ 199.50(b)(2). The AIDS Vaccine Injury Compensation Policy Review Task Force, however, has the responsibility of making policy recommendations regarding the operation of the fund. Id. § 199.50(n).

219. Although the California plan does not set a limit on the number of claims that can be satisfied each year, the AIDS Vaccine Injury Compensation Policy Task Force does have authority to make recommendations regarding the operation and administration of the compensation fund. Id. § 199.50(n)(2). Presumably, the Task Force's authority includes regulation of the number and size of damage awards that can be paid from the fund.

220. For a description of the compensation system provided by the National Vaccine Program, see supra text accompanying notes 127-35. See supra text accompanying notes 150-52 for a description of the compensation program of the California AIDS Vaccine Victims Compensation Fund.

221. In 1976, Congress appropriated $135 million dollars to administer the Swine Flu Vaccination Program. See supra text accompanying note 85. As a result of its assuming liability for injuries from the vaccine, the federal government had paid out almost $83 million to satisfy judgments and settle claims as of 1985. See supra text accompanying notes 103-05. Legal fees added another $100 million to the program's costs in the same
A system providing predetermined compensation is easy to administer because a party must only show eligibility in order to recover. However, this type of plan could also be potentially inequitable. In order to remain solvent, such a program would necessarily mandate a low level of compensation so that all parties would receive some benefit or, if a higher level of compensation was chosen, charge a larger "premium" up front to cover the costs. Under either option, if the severity of injuries varies but the compensation remains static, individuals with relatively minor injuries would receive a windfall while those with more severe injuries would be under-compensated. Under-compensation would be especially prevalent if the fund were insufficient to provide awards large enough to satisfy the needs of those with severe injuries. Trading larger awards for higher premiums may not be a better option because the higher the "premium," the more likely that certain parties would be unable to participate or that the cost of the program would become altogether prohibitive.

The method of compensation adopted by both the national and California programs is reasonable because payments to injured parties reflect the actual costs incurred by the claimants. This scheme prevents less severely injured parties from receiving a windfall. In addition, a cap set on the total amount of compensation available makes it easier for administrators to maintain the solvency of the fund. On the other hand, this method of compensation is more difficult to administer because individual evaluations must be made of each injured party. Furthermore, the maximum award available may not be satisfactory for those with the most severe injuries. 

3. Exclusivity of Compensation

The final issue involved in evaluating an insurance-type compensation program is the extent to which it provides an exclusive source for recovery. One of the major goals of any insurance fund approach is to stabilize the costs of an immunization program to both the recipients and the manufacturers of vaccines. As previously discussed, one of the primary reasons for the national and

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period. See supra note 86 and accompanying text.

222. This problem is likely to be especially acute in a program involving diseases and vaccines with which the medical community has little experience, such as AIDS.

223. Cf. Heubner, supra note 204, at 6 (explaining how insurance helps contain costs incurred by property owners).
California programs' adoption of an insurance fund was that vaccine manufacturers are hesitant to enter or remain in a market where their costs are unpredictable.\textsuperscript{224} The insurance aspects of both plans provide for a more stable environment. However, limiting recovery solely to an insurance fund potentially removes incentives for vaccine manufacturers to continue producing safe and effective products.

As a means of balancing the twin objectives of stabilizing costs and retaining incentives for manufacturers, the approach used in the National Vaccine Program appears to be the most effective option.\textsuperscript{225} Under the National Vaccine Program, injured parties are provided a quick method of recovery in return for waiving the right to bring suit directly against the manufacturer.\textsuperscript{226} Presumably this provides the manufacturer a more stable business environment\textsuperscript{227} while minimizing the costs individuals would have to bear. However, individuals not satisfied with the compensation available through the fund can bring suit directly against the manufacturer under any theory available in the common law after waiving their rights to recover from the compensation fund.\textsuperscript{228} By allowing a suit in tort directly against the manufacturer, the appropriate incentives to make safe vaccines remain intact.

The California plan offers a similar method of recovery. However, under this program an injured party may seek recovery from both the compensation fund and the manufacturer concurrently.\textsuperscript{229} The fund is entitled to indemnification up to the amount it pays out to an individual from any amount that recipient recovers from

\begin{footnotes}
\item[224] For a discussion of vaccine manufacturers reaction to highly variable transaction costs in the vaccine market, see supra notes 119-21, and accompanying text. See also \textit{Cal. Health \\& Safety Code} § 199.45(k)-(l) (stating the California legislature’s finding that vaccine manufacturers have been hesitant to enter new markets because of the high costs associated with liability for adverse reactions).
\item[225] See supra text accompanying notes 127-35 (describing the program’s compensation system). See also \textit{42 U.S.C.} § 300aa-21 (authorizing injured parties to bring suit directly against vaccine manufacturers after waiving all rights to recovery from the compensation fund).
\item[226] See supra text accompanying notes 127-35.
\item[227] Congress reported that since enactment of the National Vaccine Program, some vaccine manufacturers have considered reentering the market. H.R. REP. NO. 100-391(I) at 693, \textit{reprinted in} 1987 U.S.C.C.A.N. at 2238. However, it is unclear if this trend is due to a more stable business environment or to an increase in the size of the target market for vaccines. See supra note 119.
\item[228] See supra note 135 and accompanying text.
\item[229] See supra text accompanying note 154.
\end{footnotes}
By allowing injured parties to seek compensation through both avenues concurrently, the manufacturers may face a more unstable environment where costs of operation will be more variable. This could defeat the goal of stabilizing the cost of participation in the vaccine market.

However, this aspect of the California plan may be essential to the solvency of the program. If injuries from an AIDS vaccine are severe and numerous and the $550,000 compensation cap available through the fund proves inadequate, then recovery directly from the manufacturer could be the last avenue available for an injured party's treatment and maintenance other than government assistance. Since the California plan retains a right to indemnification, the fund would be "replenished" where injured parties succeed with recovery actions. In addition, allowing recovery from the manufacturer provides opportunities for the market to "communicate" dissatisfaction to the vaccine producer.

The difference between the National and California plans arises from the disparity of information regarding expected costs. Since there is solid information regarding the cost of insuring against injuries from childhood vaccines, it is easier for the federal government to incorporate these costs upfront. This planning helps to create an adequate fund and reduces the need for injured parties to seek recovery directly from the manufacturer. The situation is different with an AIDS vaccine where little information exists regarding the costs that might be imposed on individuals. Thus, the ability to seek recovery from the manufacturer is more valuable because the compensation fund's solvency might depend on successful recovery. Additionally, the level of injury resulting from an AIDS vaccine could be so great as to require even more compensation than provided by the fund. Regardless, the dual recovery aspect of the California plan may remove the protection from uncontrolled liability and legal costs which vaccine manufacturers seek.

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230. See supra text accompanying note 153.
231. It is unclear whether parties would seek recovery from the manufacturer if quick and adequate compensation is available through the compensation fund. Thus, the number of individuals who seek recovery from both sources concurrently may necessarily depend on the type and severity of adverse reactions to an AIDS vaccine.
232. CAL. HEALTH & SAFETY CODE § 199.50(k).
233. Plaintiffs seeking recovery in a tort action who are unable to satisfy the burden of proof applicable against vaccine manufacturers would have to rely solely on the compensation fund or turn to government assistance. See supra text accompanying notes 171-73.
234. See McKenna, supra note 44, at 963 (criticizing the California plan of "dual recov-
C. Proposals for Future Legislation and Policy Decisions

The choice between relying on common law to compensate individuals injured by an AIDS vaccine or developing an insurance-type compensation fund must be made by policymakers.235 The widely acknowledged benefits of vaccination236 suggest that it is in the interest of all parties to have the government provide an insurance fund to compensate individuals injured by an AIDS vaccine.237 An insurance fund which allows a manufacturer to successfully market an AIDS vaccine will satisfy the public health goal of preventing the spread of the disease and reducing health care and other costs associated with treating those infected with AIDS and, at the same time, will provide a stable marketplace in which vaccine manufacturers can operate.

The unique epidemiology and uncertainty surrounding the AIDS virus suggest that a compensation fund designed to satisfy these goals must be flexible and capable of responding quickly to chang-
ing circumstances. To this extent, the model suggested by the National Vaccine Program is ineffective. The National plan is designed for vaccines and illnesses which are predictable and well understood. In addition, the National plan is designed to handle a limited number of adverse reactions each year. However, the method of funding the National program and the exclusivity of compensation under the plan are useful attributes for any future AIDS vaccine compensation fund.

The California AIDS Vaccine Victims Compensation Fund, to the extent that it is modeled after the National plan, is also flawed as a policy option for an AIDS vaccine. It lacks the flexibility needed to deal with a disease which is not well understood. However, with slight modifications it could prove a useful model upon which other state or federal AIDS vaccine compensation funds could be based. Additionally, analysis of the swine flu experience offers useful insights into issues that policymakers should consider.

1. Recognize Uncertainty

AIDS is an elusive disease which medical experts know relatively little about. Thus, any policy must maintain some degree of flexibility so as to be able to adapt to new information and changed assumptions. Along these lines, future legislation should avoid establishing arbitrary values for compensation or for the size of the excise tax which will be necessary to maintain a compensation fund.

The California plan’s selection of a $550,000 cap on compensation and an excise fee of no more than $10 do not take account of the uncertainty surrounding this disease. As the swine flu expe-

238. See supra notes 122-43 and accompanying text.
239. See supra note 137 and accompanying text.
240. NEUSTADT & FINEBERG, supra note 6, at 12.
241. See NEUSTADT & FINEBERG, supra note 6, at 116-22. Neustadt and Fineberg suggest that updating the assumptions upon which an immunization program are based is essential. Id. at 117. In particular, they advocate consideration of supplemental opinions from outside the core group of experts charged with responsibility for the program to prevent only one point of view being considered. Id. at 120.

Ongoing opinions by outside experts will require continual and independent evaluation of the number and severity of expected adverse reactions to an AIDS vaccine, the amount of compensation which should be provided by the fund and, most importantly, the necessity for continuing to distribute the vaccine. It is conceivable that after distribution of the vaccine commences, new information may suggest an alternative or that costs of an AIDS vaccine may begin to outweigh the benefits provided.
rience demonstrated, it is essential that the assumptions upon which
decisions are based continually be reexamined. Thus, when deter-
mining how to compensate injured parties and how to fund the
insurance program, a careful analysis of all information available at
the time should be made.

The job of determining the appropriate method of funding a
compensation program and the size of awards should be made by
the legislature, based upon the advice of appointed health care
experts and other interested parties. The advisory committees
designated by both the National Vaccine Program and the Cali-
ifornia plan should be required to solicit the advice and opinion
of other interested parties. This will help insure that a number of
views are considered.

2. Target Specific Population Groups for Treatment

One legacy of the swine flu experience is that a large scale
immunization program may not be required to protect the general
population from AIDS. Rather, by targeting the groups most at
risk for catching and transmitting the disease, the goal of protecting
the general population might be achieved.

In addition, by inoculating a subgroup of the entire population,
experience with the vaccine can be obtained without putting everyone at risk of being harmed by a vaccine that is not completely understood. Further, by limiting the size of the group immunized, the insurance fund has a better potential to remain solvent because the fewer people vaccinated, the fewer the injured parties who would have a claim for compensation.

3. Funding

Perhaps the most controversial aspect of compensating those suffering from AIDS vaccine-related injuries is determining how to fund such a program. Following are three alternatives, each of which puts the burden on a different "player" in the immunization process. After considering each option, this note concludes that a combination of funding methods produces the optimal result.

a. Subsidy to Vaccine Manufacturers

The first method of compensating those with vaccine injuries would involve subsidizing vaccine manufacturers from general revenues and then requiring the manufacturers to compensate those injured by vaccines they produced. Under such a program the government would provide a subsidy to vaccine manufacturers with the understanding that the manufacturer was free to use the subsidy only for research into developing safer and more effective vaccines and to compensate those suffering adverse reactions to vaccines they had produced. As a further condition of receiving the subsidy, the vaccine manufacturers would have to agree to compensate those suffering vaccine-related injuries in accordance with a compensation schedule.

The rationale behind such a funding alternative is to provide an incentive for manufacturers to produce safe vaccines. If a given manufacturer produced a vaccine which caused few injuries, it would be free to keep the entire subsidy. However, if its vaccines caused adverse side effects, the manufacturer would be forced to pay for the injuries. Under a worst case scenario, a manufacturer would be forced to use both the entire subsidy to compensate injured parties and additional funds from the corporate coffers. By placing the manufacturer "at risk," the incentive would clearly be to produce the best vaccine possible.

A subsidy approach to providing compensation might attract more manufacturers into the market and lead to safer, more effective vaccines. The chance to receive a research subsidy would
create an incentive to enter the market for a manufacturer who feels it has a safe and effective AIDS vaccine. On the other hand, the "at risk" effect of the subsidy approach could be a disincentive for manufacturers to enter the market. The random method in which adverse reactions to vaccines occur could saddle some manufacturers with a disproportionate share of the compensation burden while providing a windfall for those manufacturers whose vaccines fortuitously lead to fewer adverse reactions.

b. General Appropriations

Because vaccines are designed to reduce the spread of disease, it is only reasonable that society in general bear some of the burden of compensating those injured by an AIDS vaccine. Thus, another method of funding a vaccine injury compensation program would be to rely on monies from general tax revenues. Under such a program, the cost of compensation would be determined each year and funds would be set aside during the annual budget process. Under this approach, the government would pay for any claims against the manufacturer from the annual fund directly to the injured party.

This form of funding, however, has a number of disadvantages. Currently, both the federal and state governments are facing huge budget deficits. In an effort to solve these problems,
policymakers are looking for opportunities to cut spending, not to increase it. Although an AIDS vaccine would likely lead to large savings in government provided health care costs,\textsuperscript{253} it is uncertain whether funding for an injury compensation program which ultimately provides benefits for only a limited group of individuals could gain the support necessary to establish it or be properly allocated if approved.\textsuperscript{254} In addition, the initial uncertainty as to the number and cost of adverse reactions would make it difficult to budget the appropriate level of funds for such a program.

c. Excise Tax

The final option for funding a vaccine injury compensation program is for the government to charge an excise tax on each dose of vaccine administered. This is the method used by the National Vaccine Program\textsuperscript{255} and the California AIDS Vaccine Victims Compensation Fund.\textsuperscript{256} An excise tax is an appealing form of funding because the parties receiving direct personal benefit from being vaccinated are bearing the cost of compensating those injured by adverse reactions.\textsuperscript{257} In addition, an excise tax substitutes for general revenues.

The disadvantages of an excise tax are related primarily to the uncertainty of adverse reactions to an AIDS vaccine. If the number and severity of adverse reactions is high, the excise tax will have to be adjusted to compensate for the additional cost. Theoretically, the excise tax could be raised so high that certain individuals would not be able to afford the vaccine. In addition, if the govern-
ment was the major purchaser of an AIDS vaccine, it might decide that immunization against the AIDS virus was not economically prudent. If the size of the excise tax forced the government to suspend nationwide immunization, there would likely be an increase in the number of cases of AIDS. Finally, because of a high cost precipitated by the excise tax, vaccine manufacturers could face a decreased demand for their product.

d. Solution

Development and distribution of an AIDS vaccine will benefit every member of society. In addition, the manufacturers of an AIDS vaccine stand in a position to reap substantial profits from distribution of an effective vaccine. Thus, it is only reasonable that funding for a vaccine injury compensation program should be borne by all parties involved, vaccine recipients, society as a whole which benefits from reduced transmission of AIDS and vaccine manufacturers. To this end, a compensation program funded through a combination of government subsidies and an excise tax should be an equitable method of distributing burdens and providing appropriate incentives.

Under this type of financing scheme, the subsidies to manufacturers would provide an incentive to develop safe and effective vaccines. In addition, because manufacturers benefit from the sale of their vaccines, it is reasonable that they should be responsible for some of the costs from adverse reactions. As for the portion of society which indirectly benefits from an AIDS vaccine through herd immunity, the subsidy would be financed through general revenues. This segment of the population would be helping indirectly to support the compensation fund.

An excise tax should also be an integral part of the financing for a compensation program. Those individuals actually receiving an AIDS vaccine benefit from this treatment should bear part of the cost of compensating injured parties. Determination of what portion of the compensation plan should be financed by subsidies and what portion supplied through an excise tax is a question for policymakers.

A recurring problem with any method of funding a compensation program is how to deal with the uncertainty of the demand.

258. See supra text accompanying notes 248-49.
259. See supra text accompanying note 162.
As discussed previously, there is no way of knowing the number, severity or cost of compensating those injured through adverse reactions to an AIDS vaccine. This highlights the need to maintain flexibility in determining the distribution of burdens and benefits and to review periodically the goals and methods of the compensation program.

V. CONCLUSION

New breakthroughs in the prevention of illnesses and diseases of all sorts are pending. The spread of these illnesses will presumably be curbed by vaccines. However, as the childhood vaccine experience demonstrates, there will most likely be a few unfortunate individuals who will have adverse reactions to these vaccines and either develop the illness against which the vaccine was administered or manifest some other injury. Given the acknowledged social benefits that vaccines produce, it is incumbent upon government to provide a marketplace where vaccine manufacturers will feel comfortable operating and where the cost of doing business is not unduly burdened by astronomical litigation and damage award expenses.

A successful plan to deal with an AIDS vaccine and manufacturer liability should recognize the difference between diseases with well established, successful vaccines and those diseases for which vaccines have only recently been developed and for which the epidemiology of adverse reactions is not as well known. For diseases which have long been treated with the same vaccine and where adverse reactions are documented and predictable, a program similar to the National Childhood Vaccination Injury Act would probably be effective. This system provides compensation for injured individuals from an established fund and an alternative mechanism for recovery if one desires to seek recovery directly from a manufacturer. In addition, it provides manufacturers with a stable litigation environment.

In contrast, new vaccines such as a long-awaited AIDS vaccine should be handled differently. Because adverse reactions to new vaccines and the epidemiology of the underlying disease itself will not be well established, it will be difficult to quickly identify and compensate injured victims. For vaccines which fall into this category, a more flexible approach is needed. Specifically, the assump-

tions upon which compensation is made must continually be evaluated. Later, as more data on the exact number and nature of injuries from vaccination become available, more precise compensation arrangements can be substituted.

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