The AIDS Vaccine: Legislation to Limit Manufacturer's Liability

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THE AIDS VACCINE: LEGISLATION TO LIMIT MANUFACTURER'S LIABILITY

I. INTRODUCTION

The first reports of a disease affecting the immune system of homosexual men emerged over ten years ago. The medical community quickly recognized a new and potentially devastating threat to the health of the world, acquired immunodeficiency syndrome (AIDS). Although researchers have identified the infectious agent responsible for AIDS, human immunodeficiency virus (HIV), the scientific community has continued its diligent study of the etiology of the disease. The ultimate goal of researchers remains eradication of AIDS through the production of a safe and effective vaccine.

The existence of several formidable barriers blocks the realization of this goal. For example, the target of the virus, the immune system, is also the target of the potential vaccine. In other words, infection with the virus causes deterioration of the very system which the vaccine would be designed to stimulate. Thus, the candidate vaccine must successfully block the interaction between the virus and the immune system. Early research efforts focused, therefore, on gaining an understanding of the host immune response to HIV in order to design a vaccine which would trigger the appropriate protective response.

Perhaps the greatest barrier to the production of a successful vaccine, however, may not be imposed by the virus, but rather by the United States legal system. Potential legal liability for injuries resulting from a


vaccination severely restricts the large pharmaceutical manufacturers' willingness to participate in the development and testing of a vaccine against the AIDS virus. This article analyzes current legislative attempts to reduce the negative impact of tort liability on vaccine production and offers suggestions for future legislation. This legislation must not only grant immunity from tort liability to vaccine researchers and manufacturers, but also provide a source of funding to compensate the few inadvertent victims of a process designed to protect and save the lives of many.

II. BACKGROUND AND DEVELOPMENT

A. The Need for an AIDS Vaccine

The incidence of AIDS increased at an alarming rate during the initial decade following its identification. In 1982, 1080 cases of AIDS were reported to the Centers for Disease Control (CDC). Through June of 1991, 182,834 cases had been reported. During the middle of 1987, the reported incidence of AIDS in the United States began to decrease. In fact, new cases of AIDS reported to the CDC for the first 6 months of 1991 show a marked reduction from the number for 1991 predicted in 1986 based on epidemiological data available at that time. This decline may be due to the identification of the modes of transmission of HIV and the groups at risk of becoming infected, as well as the subsequent education of these groups concerning the dangers of the disease and means of avoiding exposure. Although the declining infection rate in the United States is encouraging, the disease continues to spread rapidly in many

6. Dr. Jonas Salk, the researcher credited with developing the polio vaccine, informed a meeting of the Association of Trial Lawyers of America (ATLA) that legal concerns threaten a vaccine's marketability, and that manufacturers fear that "someone will come along and make some kind of claim regardless of whether or not there is any scientific basis for it." Andrew Blum, AIDS Research Faces Hurdle: Who's Liable?, NAT'L L.J., July 29, 1991, at 36. See also Laurie Garrett, The Waiting Game in AIDS Research; Giant Drug Companies are Watching the Little Guys in the Quest for a Vaccine, NEWSDAY, Sept. 18, 1990, at 5.
8. Id. at 5, 12.
10. Centers for Disease Control, supra note 7, at 5. For the first 6 months of 1991, 9,885 new cases of AIDS were reported to the CDC. Id. at 13.
12. See Centers for Disease Control, supra note 7, at 18.
parts of the world, especially in developing countries. Thus, the need for continued research directed toward prevention and, ultimately, eradication of the disease has not diminished.

The loss to the U.S. economy, in terms of lost life years, is staggering. AIDS most frequently strikes young men, age twenty-five to forty-four years. The median age in this range is thirty-five years. Assuming a death at thirty-five years of age represents thirty years of lost life, then the 24,600 deaths caused by AIDS in 1990 accounted for 738,000 years of lost life. In 1989, it was estimated that the net value of losses to the economy attributable to lives cut short by the AIDS virus was more than $600,000 per person. Through June 1991, the CDC had reported 114,338 adult deaths from AIDS. That translates to roughly $70 billion lost to the economy. Of course, the true loss cannot be measured in economic terms alone.

Prevention of these losses can be effected by halting the spread of AIDS. The traditional approach to prevention of a disease caused by a virus is to develop a vaccine. With a view toward preventing AIDS, it is necessary to analyze whether the development of a vaccine against AIDS is a realistic goal. Resolution of this question requires a basic understanding of vaccines and the science of immunology.

B. Vaccines and the Immune System

A vaccine is a preparation designed to stimulate the immune system, that part of the body responsible for eliminating pathogens and distinguishing "self" from "non-self," to neutralize the pathogen responsible for the disease. Specific cells within the immune system are capable of recognizing foreign molecules, antigens, on the surface of the infectious agent and remembering the antigen in case of subsequent exposure.

15. See Centers for Disease Control, supra note 7, at 12.
16. See id. at 13.
19. See generally Joseph Earley, Can Biotechnology Immunize Vaccine Manufacturers from the Products Liability Crisis?, 30 JURIMETRICS J. 351, 353-56 (1990) (providing general background information on the immune system and vaccines). See also GOLUB & GREEN, supra note 4, at 684.
20. See Earley, supra note 19, at 353-54.
21. See id. (describing the special cells of the immune system activated upon recognition of the
The ability of the immune system to remember an antigen and mount a rapid response when confronted by it upon subsequent exposures, supplies the foundation for the functional success of vaccine therapy. Basically, the vaccine represents a "safe," non-infective form of the antigen which triggers the primary immune response, leaving the vaccinee's immune system primed for a more rapid response upon subsequent exposure to a pathogenic form of the antigen.

Vaccines in use today can be divided into two broad groups: conventionally produced and biotechnologically produced. Conventional vaccines include those utilizing either attenuated (live, modified) pathogen; whole, killed pathogen; or a purified fraction of the pathogen. Although all three types of conventional vaccines are highly effective in preventing infection upon subsequent exposure to the pathogen, each of these vaccines is also capable of causing the infectious disease it was intended to prevent.

The second major group of vaccines, biotechnologically synthesized vaccines ("biotech" vaccines), apply the most recent discoveries in molecular biology to principles of immunology to produce efficient and, theoretically, safer vaccines. The increased safety potential arises because the antigen delivered to trigger the primary immune response has been synthetically produced. In other words, the antigen is artificially derived rather than naturally derived from the actual pathogen. Thus, the biotech vaccines confer immunity to a pathogen without exposure to any form of the pathogen itself and avoid the inherent danger associated with exposure to the pathogen itself.

antigen, T-cells (thymus-derived lymphocytes), which proliferate and differentiate into three functionally specialized types of T-cells: those responsible for killing cells which carry the antigen (cytotoxic T-cells), those which remember the antigenic segments (T memory cells), and those which can suppress response to the antigen (T suppressor cells).

See also Golub & Green, supra note 4, at 695-98 (describing components of the immune system).

22. See Earley, supra note 19, at 354.
23. See id. at 354-55.
24. See id. at 355. An example of an attenuated live pathogen vaccine is the Sabin polio vaccine. See generally id. at 355-56.
25. The Salk polio vaccine relies on whole, killed pathogen. See generally id.
26. Hepatitis B and whooping cough (pertussis) vaccines exemplify vaccines composed of purified fractions of the pathogen. Id.
27. See generally Reyes v. Wyeth Lab., 498 F.2d 1264 (5th Cir. 1974) (involving a live, modified vaccine, the Sabin polio vaccine, which was remodeled to the pathogenic form), cert. denied, 419 U.S. 1096 (1974); Gottsdanker v. Cutter Lab., 6 Cal. Rptr. 320 (Cal. Dist. Ct. App. 1960) (Involving a killed whole virus vaccine, the Salk polio vaccine, which contained live virus); Carlenstolpe v. Merek & Co., 819 F.2d 33 (2d Cir. 1987) (involving an allegation that a purified fraction vaccine, Hepatitis B, contained an undisrupted pathogen).
28. See Earley, supra note 19, at 362.
29. See id. at 364.
30. See id. at 362-65.
with conventional vaccines, inadvertent infection with the infectious agent.

Although the conventional approach to production of an HIV vaccine has been proven valuable in animal studies designed to increase understanding of the human immune response to HIV, it is generally accepted that the HIV vaccine will utilize a recombinant DNA-derived antigen. Biotech vaccines are considered safer than conventional vaccines. However, they are not risk-free. Therefore, the potential for legal liability of the manufacturer cannot be discounted.

C. Efforts to Produce an AIDS Vaccine

Although several unanswered questions haunt researchers, the scientific community is optimistic about the future of an AIDS vaccine. This optimism results from studies which successfully demonstrate that conventional killed-virus vaccines have worked efficiently in animal models, that substantial progress has been made in the identification of immunological targets on both the free virus and the infected cell, and

31. Id.
32. See id. at 364.
33. See id. at 365-67. A non-defective biotech vaccine may prove to be unreliable due to the unique quality of each individual's immune response. For example, a vaccine presenting a narrow target may not elicit the desired immune response in each individual. In addition, it is possible that the immune system could select an irrelevant site on the antigen, leaving the immune system unprimed and unable to respond to the infectious agent upon subsequent exposure. Id.
34. See Andreas Meyerhans et al., Temporal Fluctuations in HIV Quasispecies In Vivo Are Not Reflected by Sequential HIV Isolations, 58 CELL 901 (1989). This study cautions against over-interpretation of data collected from in vitro conditions which may not accurately reflect the in vivo situation. See id. at 906-07. See also Bolognesi, supra note 3, at 1234. Some efforts designed to prevent infection have actually enhanced disease progression. These results indicating enhanced disease progression rather than prevention are limited to in vitro systems.
35. See generally Michael Murphy-Corb et al., A Formalin-Inactivated Whole SIV Vaccine Confers Protection in Macaques, 246 SCIENCE 1293 (1989) (demonstrating the utility of the simian model which couples the similarities in viral composition of SIV, simian immunodeficiency virus, and HIV with the similarities of disease symptoms in rhesus monkeys and humans); R. C. Desrosiers et al., Vaccine Protection Against Simian Immunodeficiency Virus Infection, 86 PROC. NAT'L ACADEM. SCI. USA 6353 (1989) (describing the advantages of the simian model which include a high mortality rate and a relatively rapid onset of disease symptoms following exposure to SIV); Putkonen et al., supra note 5, at 436 (describing data which indicate that monkeys treated with various forms of an inactivated whole virus receive protection from subsequent challenges with live SIV); E. Stott et al., Preliminary Report: Protection of Cynomolgus Macaques Against Simian Immunodeficiency Virus by Fixed Infected-Cell Vaccine, 336 LANCET 1538 (1990) (describing data which indicate protection against subsequent challenges attributable to an inactivated whole virus vaccine).
36. See generally Rebecca H.R. Ward et al., Prevention of HIV-1 IIIB Infection in Chimpanzees by CD4 Immunoadhesin, 352 NATURE 434 (1991) (indicating that a special type of protein found on the outer envelope of HIV, identified as gp120, binds to its receptor, CD4, on the surface of a T-cell to initiate the infection process); Daniel J. Capon & Rebecca H.R. Ward, The CD4-gp120 Interaction and AIDS Pathogenesis, 9 ANN. REV. IMMUNOLOGY 649 (1991) (confirming that the focus of AIDS therapeutics has become the CD4-gp120 interaction, crucial to the progression of the disease due to
that data have been generated indicating a favorable response by humans to candidate immunogens.37

The AIDS research community continues to progress toward the realization of a successful vaccine against HIV.38 With this progress has come the first clinical trials39 in the United States involving human volunteers for testing potential AIDS biotech vaccines. These trials began, with the approval of the U.S. Food and Drug Administration (FDA), in 1988.40 The initiation of clinical trials in the United States brought to the forefront the fears of the research community concerning the potential for legal liability connected with an AIDS vaccine,41 as well as questions concerning the ethics of using human volunteers in the trials.42 An historical analysis of litigation by injured plaintiffs against vaccine manufacturers justifies the manufacturers' concern about liability exposure.

destruction of the CD4 subset of T-cells); Phillip Berman et al., Protection of Chimpanzees from Infection by HIV-1 after Vaccination with Recombinant Glycoprotein gp120 but not gp160, 345 NA-
TURE 622 (1990) (reporting that the CD4-gp120 interaction can be effectively blocked by pre-treat-
ing healthy chimpanzees with CD4 analogues that compete for gp120 binding, and thus prevent infection).

37. See generally Bolognesi, supra note 3, at 1234; Achour et al., supra note 5, at 7049 (demon-
strating that a synthetic peptide, HGP-30, may serve as a subvaccine candidate based on its ability to induce cell-mediated immunity against HIV infection in volunteers participating in clinical trials in Europe); O. Picard et al., Aids Vaccine Therapy: Phase I Trial, 336 LANcET 179 (1990) (indicating that AIDS patients in Paris immunized with preparations made from killed autologous cells infected with recombinant vaccinia virus containing some HIV genes and gene products show an enhance-
ment of natural defense mechanisms).

38. Several “biotech” companies have made the development of an AIDS vaccine a top prior-
ity. See NATIONAL AIDS NETWORK, AIDS INFORMATION SOURCEBOOK 213 (H. Robert Malinow-
sky & Gerald J. Perry eds., 2d ed. 1989-90). However, only one “pharmaceutical giant,” Bristol-
Myers Co., is conducting in-house AIDS vaccine research. Garrett, supra note 6, at 5.

Clinical trials are divided into 3 phases. Phase I, involves fewer than 20 volunteers who are not
members of any of the high risk groups, during which the candidate vaccine's safety and ability to
trigger an immune response is evaluated. Phase II, involves 40 to 200 volunteers representing both
high and low-risk groups, during which dose-response and timing studies are conducted. Phase III,
requires a large number of volunteers in order to generate meaningful statistics, during which the
efficacy of the vaccine will be determined. Id. Only during Phase III testing is the volunteer exposed
to the pathogen, in this case, HIV. Id.


41. Weisburd, supra note 39, at 330. Weisburd predicts that:
Because of the unusually complicated nature of the AIDS virus, the urgency to develop a
vaccine against it and the potential for a vaccine's unforeseen side effects, it's likely that the
development of an AIDS vaccine will bring to a head long-standing legal problems associated
with distributing vaccines in the country—especially since plaintiffs injured by vac-
cines have been increasingly successful in suing companies for damages.

Id.

42. Carol O. Tacket & Robert Edelman, Ethical Issues Involving Volunteers in AIDS Vaccine
III. VACCINE MANUFACTURERS AND TORT LIABILITY

The use of the legal system and the concomitant application of tort law to supply compensation for people injured by a vaccine provides an interesting perspective to the development of the law of strict liability. Cases involving injuries allegedly attributable to vaccines fall squarely into that area of tort law initially proposed by Judge Traynor in his concurring opinion in *Escola v. Coca-Cola Bottling Co.* In that opinion, Judge Traynor suggested that the manufacturer be held absolutely liable if a defective product placed on the market without adequate inspection caused injury. This doctrine, known as strict liability, can now be found in the *Restatement (Second) of Torts* § 402A.

Although conventional vaccines have been proven invaluable to society, it is technologically impossible to guarantee the elimination of the risks of inadvertent infection or deleterious side effects. In other words, vaccines could be classified as "unavoidably unsafe" products. Comment k to § 402A establishes an exception to strict liability for products which are, by their nature, unavoidably unsafe. It would appear, therefore, that comment k shelters vaccine manufacturers from strict liability.

However, two decisions in vaccine litigation, *Davis v. Wyeth Laboratories, Inc.* and *Reyes v. Wyeth Laboratories,* established that a vaccine manufacturer could be held strictly liable for a plaintiff’s injuries in spite of the shield provided by comment k if it failed to adequately warn of the risks. The plaintiff in *Davis,* a thirty-nine year old man, received the Sabin live attenuated polio vaccine at a mass immunization clinic. In *Reyes,* the plaintiff, an eight-month old girl, contracted paralytic polio.

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43. 150 P.2d 436 (1944).
44. Id. at 440.
45. Restatement (Second) of Torts § 402A (1) & (2)(a) (1965). “One who sells any product in a defective condition unreasonably dangerous to the user or consumer... is subject to liability for physical harm thereby caused to the ultimate user or consumer... [even though] the seller has exercised all possible care in the preparation and sale of his product...” Id.
47. See Earley, supra note 19, at 365-67. See also Garrett, supra note 6, at 5 (quoting Dr. Jonas Salk, “There is no one-hundred-percent safe and effective vaccine. That’s impossible.”).
48. Restatement (Second) of Torts § 402A cmt. k (1965).
49. Drugs and, specifically, vaccines are mentioned in comment k as examples of products which carry risk of injury but are nonetheless in high demand due to the benefits conferred upon the vast majority of recipients and to society as a whole. Id.
50. 399 F.2d 121 (9th Cir. 1968).
52. Reyes, 498 F.2d at 1295; Davis, 399 F.2d at 131.
53. Davis, 399 F.2d at 122.
after being administered a dose of the Sabin vaccine at a public health clinic.\textsuperscript{54} In these cases, Wyeth failed to adequately warn the ultimate consumers about the inherent risks of the vaccine and, therefore, failed to comply fully with the requirements specified in comment k.\textsuperscript{55} In effect, an inadequate warning itself is considered a product defect which results in the product being "unreasonably dangerous as marketed."\textsuperscript{56} Both courts held Wyeth strictly liable for the plaintiffs’ injuries.\textsuperscript{57} The American Academy of Pediatrics and the Conference of State and Territorial Epidemiologists (CSTE) warned the Reyes court that this holding threatened both the nation’s preventive medicine programs and the strength of public policy concerning the value of mass immunization programs.\textsuperscript{58}

Another case involving the Sabin vaccine subsequent to Davis and Reyes found the manufacturer strictly liable.\textsuperscript{59} In addition, lawsuits alleging negligence and products liability causes of action against manufacturers of other vaccines, specifically DPT (diphtheria, pertussis, tetanus)\textsuperscript{60} and swine flu,\textsuperscript{61} have also resulted in discouraging the manufacture of vaccines. For example, in Toner v. Lederle Laboratories,\textsuperscript{62} the Court of Appeals for the Ninth Circuit held Lederle liable based on a negligence cause of action for injuries sustained by the plaintiff, a three-

\textsuperscript{54} Reyes, 498 F.2d at 1274.
\textsuperscript{55} Davis, 399 F.2d 122, 125; Reyes, 498 F.2d at 1274. Comment k to § 402A provides in pertinent part:

\begin{quote}
The seller of such products, again with the qualification that they are properly prepared and marketed, and \textit{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.
\end{quote}

\textbf{Restatement (Second) of Torts} § 402A cmt. k (emphasis added).

\textsuperscript{56} Comment h to § 402A provides that:

\begin{quote}
Where, however, he (the seller) has reason to anticipate that danger may result from a particular use, as where a drug is sold which is safe only in limited doses, he may be required to give adequate warning of the danger . . . and a product sold without such warning is in a defective condition.
\end{quote}

\textbf{Restatement (Second) of Torts} § 402A cmt. h (1965).

\textsuperscript{57} Reyes, 498 F.2d at 1295; Davis, 399 F.2d at 131.
\textsuperscript{58} Reyes, 498 F.2d at 1293.
\textsuperscript{60} See Hurley v. Lederle Lab., 815 F.2d 1536 (5th Cir. 1988); Toner v. Lederle Lab. (\textit{Toner I}), 779 F.2d 1429 (9th Cir.), \textit{cert. denied}, 485 U.S. 942 (1986); Toner v. Lederle Lab. (\textit{Toner II}), 828 F.2d 510 (9th Cir.), \textit{modified}, 831 F.2d 180 (9th Cir. 1987).
\textsuperscript{61} See Unthank v. United States, 533 F. Supp. 703 (D. Utah 1982), \textit{aff’d}, 732 F.2d 1517 (10th Cir. 1984); Petty v. United States, 740 F.2d 1428 (8th Cir. 1984).
\textsuperscript{62} 828 F.2d 510 (9th Cir.), \textit{modified}, 831 F.2d 180 (9th Cir. 1987).
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month old child, following vaccination with Lederle's Tri-Immunol, a triple antigen vaccine for DPT.\(^{63}\) The plaintiff suffered a rare condition of the spine, transverse myelitis.\(^{64}\) Although the exact cause of this condition is unknown, the plaintiff's permanent paralysis was attributed to the pertussis portion of the vaccine.\(^{65}\) The court held that Lederle had negligently failed to develop a less toxic form of the pertussis vaccine, Tri-Solgen, a fractionated cell product found to be unreliable which had not received FDA approval.\(^{66}\) The trial judge instructed the jury that "[a] manufacturer of vaccines has the duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products."\(^{67}\) The jury found that Lederle was liable for negligent failure to meet this standard of due care and, therefore, awarded $1.1 million to the plaintiff.\(^{68}\)

IV. LEGISLATIVE EFFORTS TO PROTECT MANUFACTURERS

A. Federal Efforts

In 1976, fearing a swine flu epidemic and recognizing the reluctance of vaccine manufacturers and their insurance underwriters to become involved due to the risks of litigation,\(^{69}\) Congress enacted the National Swine Flu Immunization Program of 1976 (Swine Flu Act).\(^{70}\) The Swine Flu Act provided plaintiffs an exclusive remedy against the United States, transferring liability for all injuries attributable to the swine flu vaccine from the manufacturer to the United States.\(^{71}\) Mass immunization against swine flu proceeded, and over 45 million people were inoculated.\(^{72}\)

The fact that many public school districts across the country require that children entering school receive certain vaccinations convinced Congress to address the question of liability for injuries resulting from these

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63. Id. at 514.
64. Toner I, 779 F.2d at 1430.
65. Id.
66. Toner II, 828 F.2d at 512.
67. Toner I, 779 F.2d at 1431. Toner I represents a trend in vaccine litigation where the jury is asked to engage in a risk-benefit analysis of the manufacturer's product to determine whether the benefit to the consumer outweighs the risks to the public. See Prins-Stairs, supra note 46, at 716.
68. Toner I, 779 F.2d at 1430.
71. Id. § 247b(k)(l)(A).
72. Rosenfeld, supra note 69, at 199 (reflecting the strength of the endorsement of the vaccine by the United States government).
mandatory vaccines.\textsuperscript{73} The resulting legislation, the National Childhood Vaccine Injury Act of 1986 (NCVIA),\textsuperscript{74} requires that injured vaccine recipients adjudicate their claims through the federal compensation program before bringing a civil action in court.\textsuperscript{75} The Act requires that the injury alleged to have been caused by the vaccine fall within the Vaccine Injury Table defined in the Act.\textsuperscript{76} If the victim elects compensation from the NCVIA, then the victim waives his right to subsequent civil actions against the manufacturer.\textsuperscript{77} However, if the victim refuses compensation under the Act, the victim is limited in any subsequent civil action to a cause of action for negligent product preparation or distribution of the vaccine.\textsuperscript{78}

B. State Efforts

Two states, California\textsuperscript{79} and Connecticut,\textsuperscript{80} have taken legislative action to encourage production of an AIDS vaccine by granting immunity to AIDS vaccine manufacturers. However, key differences exist between the two enactments. The California law was enacted to protect vaccine manufacturers from strict liability claims by the creation of an AIDS Vaccine Victims' Compensation Fund.\textsuperscript{81} This fund will serve to compensate applicants injured by an FDA-approved\textsuperscript{82} AIDS vaccine. Compensation is limited to $550,000 for direct medical costs, lost earnings, and the amount required to compensate for non-economic losses, including pain and suffering.\textsuperscript{83} The source of funds for the Compensation Fund will be a surcharge, not to exceed ten dollars, placed on the sale of each unit of the vaccine sold or delivered, administered, or dispensed in California.\textsuperscript{84} The California statute also provides for the creation of an AIDS Vaccine Guaranteed Purchase Fund designed to assure


\textsuperscript{74} 42 U.S.C.A. §§ 300aa-10 to -34 (West Supp. 1990).

\textsuperscript{75} See Rosenfeld, supra note 69, at 197 (interpreting 42 U.S.C.A. § 300aa-11(2)(A)).

\textsuperscript{76} 42 U.S.C.A. § 300aa-14(a).

\textsuperscript{77} Id. § 300aa-22(b)-(c).

\textsuperscript{78} Id. § 300aa-22(b)(1).


\textsuperscript{81} Cal. Health & Safety Code § 199.50(a) (West 1990).

\textsuperscript{82} Id. § 199.50(b)(1)(B).

\textsuperscript{83} Id. § 199.50(b)(3).

\textsuperscript{84} Id. § 199.50(a).
purchase of at least 500,000 doses of an FDA-approved vaccine.\footnote{85. \textit{Id.} § 199.51. This portion of the statute should encourage the production of a vaccine because "[t]he problem of a limited market is [a] significant obstacle to the production of an affordable vaccine." \textit{See} Robert McKenna, \textit{The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus}, 55 U. Chi. L. REV. 943, 963 (1988).}

While the California statute was drafted both to protect vaccine manufacturers and to compensate victims of the vaccine \textit{after} the realization of an FDA-approved vaccine, the 1991 Connecticut statute was designed to protect research scientists and institutions from liability during the development and testing stages of the vaccine \textit{before} FDA approval.\footnote{86. 1991 Conn. Pub. Acts 91-349, §§ 4-8.} The manufacturer, research institution, or researcher is immune from liability to a research subject for civil damages resulting from administration of any AIDS vaccine.\footnote{87. \textit{Id.} § 6.} However, liability follows if the injury was caused by gross negligence or reckless, willful, or wanton misconduct by the manufacturer or researcher, or if the research subject is inadequately warned of the risks associated with the research and does not give informed consent.\footnote{88. \textit{Id.}} Observers are hopeful that this law "may be the spark" necessary for serious review of the liability issue.\footnote{89. \textit{See supra} note 6.}

V. ANALYSIS

A. \textit{Negative Impact of Previous Vaccine Litigation}

The contribution of vaccines to our quality of life is incalculable. Thousands of people have been spared death or the agony of a life marred by paralysis. Parents of today rarely confront the hopeless despair experienced by parents in the recent past when polio, measles, or whooping cough outbreaks threatened the health of their children. Yet, as a new health crisis ravages a portion of our population, the large pharmaceutical companies are increasingly reluctant both to remain in the
market\textsuperscript{90} and to research new products,\textsuperscript{91} such as an AIDS vaccine.\textsuperscript{92}

The negative impact of past vaccine litigation, such as \textit{Reyes}, \textit{Davis}, and \textit{Toner} accounts for the reluctance of the vaccine manufacturers.\textsuperscript{93} These decisions served to create legal uncertainty for the manufacturers by finding liability in spite of compliance with marketing and safety requirements.\textsuperscript{94} Juries could still grant huge punitive damage awards against the manufacturers although policy-makers, scientists, and FDA doctors testify that the manufacturers achieved the highest level of safety possible with current technology.\textsuperscript{95}

Adding to the legal uncertainty faced by manufacturers and researchers is the increased leniency with which courts have treated the issue of causation.\textsuperscript{96} For example, in \textit{Reyes},\textsuperscript{97} the jury found that the vaccine was the direct cause of the disease.\textsuperscript{98} This finding controverted expert testimony that the infecting viral strain was not the vaccine strain, that it appeared to be a wild seed, and that the child's vaccination occurred during a polio outbreak in the area.\textsuperscript{99}

Similarly, courts have shown a tendency to hold DPT vaccine manufacturers liable for injuries in spite of a scarcity of scientific evidence linking pertussis vaccine and severe neurological disorders.\textsuperscript{100} In \textit{Toner II},\textsuperscript{101} the court found that the DPT vaccine caused transverse myelitis just as the swine flu vaccine was found to be the cause of transverse myelitis in \textit{Unthank v. United States}.\textsuperscript{102} The only conclusion the vaccine

\begin{itemize}
\item \textsuperscript{90} See generally Edmund W. Kitch, \textit{The Vaccine Dilemma}, \textsc{Issues in Sci. and Tech.}, Winter 1986, at 108. The Sabin oral polio vaccine and the measles, mumps, rubella, and rabies vaccines are now made by sole suppliers. \textit{Id.} at 108. This situation produces several unsatisfactory results. Unexpected difficulties in production can produce shortages and increase prices. Also, the risk associated with safety of the vaccine increases. As a result, the immunization programs responsible for reducing the incidence of paralytic polio from 57,000 in 1952 to 4 in 1984, and the incidence of measles from 894,134 reported cases and 2,250 deaths in 1941 to 1,497 reported cases and 2 deaths in 1983, have been seriously jeopardized. \textit{Id.} 108-11.

\item \textsuperscript{91} Richard J. Mahoney & Stephen E. Littlejohn, \textit{Innovation on Trial: Punitive Damages Versus New Products}, 246 \textsc{Science} 1395 (1989). The shift from negligence to strict liability has served to generate added lawsuits. \textit{Id.} The potential for huge punitive damages assessed against drug manufacturers, regardless of the attention paid to maximizing safety, has created a level of uncertainty that cannot be managed along with innovation. \textit{Id.}

\item \textsuperscript{92} See Garrett, supra note 6, at 5.

\item \textsuperscript{93} See supra notes 50-68 and accompanying text.

\item \textsuperscript{94} See supra notes 50-68 and accompanying text.

\item \textsuperscript{95} Mahoney & Littlejohn, supra note 91, at 1396.

\item \textsuperscript{96} Earley, supra note 19, at 358-61.

\item \textsuperscript{97} 498 F.2d 1264 (5th Cir. 1974), \textsc{cert. denied}, 419 U.S. 1096 (1974).

\item \textsuperscript{98} \textit{Id.} at 1271. See Earley, supra note 19, at 358.

\item \textsuperscript{99} See Earley, supra note 19, at 358.

\item \textsuperscript{100} See \textit{id.} at 360.

\item \textsuperscript{101} 828 F.2d 510, 514 (9th Cir. 1987).

\item \textsuperscript{102} 732 F.2d 1517, 1518 (10th Cir. 1984).

\end{itemize}
manufacturers and researchers can draw from these decisions is that the legal system is predisposed to attribute a plaintiff’s injury to vaccines even in the face of contradictory scientific evidence.\textsuperscript{103} It thus appears that the courts have been compensating victims, who have no other means of recovering expenses,\textsuperscript{104} by awarding verdicts against manufacturers at the ultimate expense of scientific and medical innovation.

The production of vaccines, a marginal commercial proposition at best, has become a clearly unattractive undertaking given the expense and risk of litigation.\textsuperscript{105} In terms of the effect of tort liability on the development of an AIDS vaccine, “those threatened with [AIDS], who understand that profit is a remarkably powerful incentive for innovation, must view the situation as an all but criminal disaster.”\textsuperscript{106}

B. Problems Presented by the Federal Legislative Efforts

The cases brought against the United States under the Swine Flu Act of 1976 increased manufacturers’ concern.\textsuperscript{107} Although supposedly immune from liability by the provisions of the Act,\textsuperscript{108} at least one court\textsuperscript{109} nonetheless held the manufacturer strictly liable for marketing a defective product, a vaccine which inadequately warned the ultimate consumer of the risks and potential side effects associated with the vaccine.\textsuperscript{110} In other words, the manufacturer, not the government, assumed liability for any resulting inadequacies of the warning. This decision could be viewed by manufacturers as imposing “so stringent a warning requirement as likely to render any future mass inoculation program infeasible, no matter how desirable.”\textsuperscript{111}

Decisions under the Swine Flu Act led manufacturers to observe that the courts again appeared predisposed to stretch the issue of causation. Most claims involved injuries attributable to Guillain-Barre Syndrome (GBS).\textsuperscript{112} According to a CDC study, the occurrence of GBS

\begin{thebibliography}{112}
\bibitem{103} See Earley, \textit{supra} note 19, at 361.
\bibitem{104} See generally Prins-Stairs, \textit{supra} note 46, at 704, 725; Kitch, \textit{supra} note 90, at 109.
\bibitem{105} Kitch, \textit{supra} note 90, at 111.
\bibitem{106} Peter W. Huber, \textit{Liability: The Legal Revolution and Its Consequences} 230 (1988).
\bibitem{107} See Rosenfeld, \textit{supra} note 69, at 199.
\bibitem{109} Petty v. United States, 740 F.2d 1428 (8th Cir. 1984).
\bibitem{110} \textit{Id.} at 1440-41. The court noted, however, that its decision did not defeat the intent of the Act, which is to prevent exposure of manufacturers to unlimited liability. \textit{Id.} The government still had the burden of defending the action as well as bearing the resulting damages. \textit{Id.} at 1441 n.12.
\bibitem{111} \textit{Id.} at 1442 (Bright, J., dissenting).
\bibitem{112} Rosenfeld, \textit{supra} note 69, at 199. Unexpectedly, the vaccine was linked to the occurrence of

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attributable to the swine flu vaccine could not be distinguished from the background incidence.\textsuperscript{113} In other words, the incidence of GBS among the population receiving the vaccine was indistinguishable from the incidence rate of the general population. Vaccine status may not have been a relevant factor at all. Although this issue of causation received little attention from the courts, compensation by the government, "nearly $80 million on about 700 claims," was regarded as fair since the government had strongly urged participation in the vaccination program.\textsuperscript{114} However, vaccine manufacturers viewed the courts' handling of the causation issue with disapproval and increased concern for the future of vaccine development,\textsuperscript{115} a particularly ominous attitude given the subsequent appearance of the AIDS virus.

In spite of the problems encountered with interpretation of the Swine Flu Act, it provided a model for future legislation at the Federal level. The Act underscored the need both to protect the vaccine manufacturer from becoming the vaccinee's insurer against injury and to assure the vaccinee that compensation would be available for injuries resulting from adverse reactions to the vaccine or its administration.\textsuperscript{116} The GBS cases also suggested the need to impose restrictions within the legislation on the time elapsed between vaccination and the onset of disease symptoms alleged to be attributable to the vaccine.\textsuperscript{117}

The second Congressional enactment aimed at relieving vaccine manufacturers liability, the NCVIA, has been criticized on three principal grounds.\textsuperscript{118} First, funding legislation was not enacted until December 22, 1987, and the Act did not become effective until October 1, 1988.\textsuperscript{119} In other words, the Act remained a mere "paper transaction" for over a year since Congress failed to identify a source of funds initially.\textsuperscript{120} Second, the potential for tort liability remains a threat to the

\begin{itemize}
\item a neurological condition, GBS, which resulted in paralysis in approximately one out of 100,000 vaccine recipients. \textit{Id.}
\item \textsuperscript{113} Kitch, \textit{supra} note 90, at 116.
\item \textsuperscript{114} \textit{Id.}
\item \textsuperscript{115} \textit{Id.} at 120.
\item \textsuperscript{117} See Kitch, \textit{supra} note 90, at 116 (discussing the government's stipulation that its acceptance of liability was contingent upon the onset of GBS symptoms within 10 weeks of vaccine administration).
\item \textsuperscript{118} See Rosenfeld, \textit{supra} note 69, at 198.
\item \textsuperscript{119} See Prins-Stairs, \textit{supra} note 46, at 735.
\end{itemize}
manufacturer if the applicant is not satisfied with the award available from the compensation fund. If a compensation fund applicant is unsatisfied with the level of compensation received, the applicant may seek damages from the manufacturer for its negligence. Id.

Finally, the NCVIA does not eliminate the potential for state tort action against the manufacturer.

Application of the NCVIA to the injuries likely to occur with the eventual AIDS vaccine emphasizes the Act's limitations. One of the more innovative provisions of the Act, the Vaccine Injury Table, precisely defines the time period in which the first symptoms or manifestation of onset of injuries must occur after vaccine administration in order for a vaccinee to receive compensation under the Act. Although critical to the dual purposes of insuring compensation for injuries attributable to vaccines while eliminating complaints of injury with no medical or scientific merit, this type of Injury Table would be extremely difficult to apply in the case of AIDS. Given the highly variable and comparatively long time lag typical of the progression of AIDS, the merit of such an injury table becomes questionable. The failure of the NCVIA to eliminate the possibility of state tort liability would leave the manufacturers of an AIDS vaccine open to the interpretive whims of state courts. This result could be eliminated if Congress specifically immunizes the manufacturers from liability for any unavoidable side effects of the vaccine.

Any legislation enacted at the Federal level to address the questions of the liability of AIDS vaccine manufacturers and compensation of victims should reflect the specific conditions posed by AIDS as well as successes and failures of previous legislative attempts in this area, the Swine Flu Act of 1976 and the NCVIA of 1986. For example, the definition of compensable injuries under the ideal act, by necessity, would be broader than those in the Vaccine Injury Table of the NCVIA. Also, the ideal act must define an adequate source of funds for a Compensation Fund and specifically provide immunity for the vaccine manufacturers from

121. See Rosenfeld, supra note 69, at 198. If a compensation fund applicant is unsatisfied with the level of compensation received, the applicant may seek damages from the manufacturer for its negligence. Id.

122. Id.


124. While the time lag between vaccination and the onset of symptoms of adverse reactions is twenty-four hours to three days for the DPT vaccine, twenty-four hours to fifteen days for the measles, mumps, and rubella vaccine, and twenty-four hours (anaphylaxis) or thirty days to six months (paralytic polio) for the polio vaccines, the observed time period between infection with HIV and the onset of disease symptoms may be up to ten years for AIDS.


126. See Prins-Stairs, supra note 46, at 737.
state tort actions, the source of legal uncertainty for past vaccine manufacturers.

C. *The California and Connecticut Statutes*

Recognition of the urgency posed by the threat of AIDS, the concomitant need for research to develop a vaccine, and the failure of the federal government to provide legislation adequate to protect the manufacturers by preemption of state tort liability prompted the California and Connecticut legislatures to take action aimed directly at resolving tort liability and the manufacture of an AIDS vaccine. These efforts provide a starting point in an area where legislation is critically needed.

The ultimate aim of the California statute is to shield the manufacturer of an FDA-approved AIDS vaccine from tort liability while compensating the injured plaintiff with funds drawn from the AIDS Vaccine Victim's Compensation Fund. The strengths of the legislation include the provision of the Compensation Fund with a defined source for the funds, a surcharge placed on the sale of each unit of the vaccine. Those receiving the vaccine and its benefits share the inevitable costs of the vaccination program, compensation of inadvertent injuries. Another component of the California statute, the AIDS Vaccine Guaranteed Purchase Fund, should provide incentive for continued research, clinical trials, and production of the vaccine in the state of California.

However, the California statute fails to protect manufacturers adequately. Although it does offer protection from strict liability, the statute...

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127. *See supra* notes 7-18 and accompanying text.
128. *But see* Rosenfeld, *supra* note 69, at 201-02 n.99. Recent federal efforts address the general liability issues facing drug manufacturers. First, § 303 of the Product Liability Reform Act, S. 1400, 101st Cong., 1st Sess. (1989), established uniform standards for the award of punitive damages. In addition, §§ 201 and 202 of the Act encourage out-of-court settlement in a reasonable manner and for reasonable sums. Second, § 8 of the Uniform Products Liability Act of 1989, H.R. 1636, 101st Cong., 1st Sess. (1989), serves to cap punitive damages awards. Section 4 of the Act grants immunity from civil liability to manufacturers and suppliers of products which cause harm because of aspects of the product which cannot be made safe and are well known to the ordinary consumer with common knowledge. Section 4 of this Act also eliminates both product design and the failure to give an adequate warning, with an adequate warning requiring steps to warn physicians or consumers of dangers known to exist at the time of manufacture, as defects constituting liability. In addition, § 6(a) provides that the manufacturer would not be liable if the product "compiled materially" with design and/or labeling standards imposed by the federal government. *See id.*
129. *See* McKenna, *supra* note 85, at 962.
130. *Id.*
131. Critics of the plan to market an AIDS vaccine warn that the high costs of the vaccine itself combined with a limited market could result in an unaffordable product. *See* McKenna, *supra* note 85, at 963. The guaranteed purchase provision serves to lessen the insecurity of the manufacturers. *Id.* The state of California guaranteed a market and, therefore, an incentive for continued research and development of an AIDS vaccine. *Id.*
specifically states that the injured applicant is not barred from pursuing claims against the fund and lawsuits against the manufacturer concurrently. People with unsubstantiated claims could, in effect, seek compensation from the “deep pocket” of the state while people with stronger claims would not be deterred from filing civil claims in state court. In addition, the California legislation applies only to injuries alleged to have been caused by an FDA-approved vaccine sold and delivered in California. It affords neither protection from liability nor compensation for injuries arising during the development and testing phases prior to FDA approval of the vaccine.

The Connecticut statute, introduced to the legislature at the request of MicroGeneSys, Inc., of Meriden, Connecticut, limits the liability of manufacturers and researchers during the development of an AIDS vaccine only to those cases in which “gross negligence, or reckless, willful or wanton misconduct” can be demonstrated. Unlike the California statute, this legislation serves to protect those involved with the development of an AIDS vaccine before FDA approval. The mere existence of the statute is an acknowledgment that inadvertent injuries may occur. However, the statute fails to provide for compensation of the victims inadvertently injured by the vaccine. Protection of the manufacturers does not extend beyond the research and development phase. Although the eventual AIDS vaccine will probably be a biotech vaccine, it will not be completely risk-free. Therefore, the potential for injuries will exist beyond FDA approval of the vaccine. Protection of manufacturers and compensation of victims must also be provided for beyond FDA approval.

The Connecticut statute also fails to provide protection for an “injury” heretofore ignored. Those individuals who volunteer to participate in clinical trials during the development of the AIDS vaccine and are

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132. CAL. HEALTH & SAFETY CODE § 199.50(m) (West 1991).
133. See McKenna, supra note 85, at 963.
134. CAL. HEALTH & SAFETY CODE § 199.50(b)-(c).
135. Id. § 199.50(c)(3).
136. MicroGeneSys, Inc. is one of more than a dozen U.S. companies working on a vaccine. See Blum, supra note 6, at 36.
138. Although the statute does not require FDA approval of the vaccine, an application for an investigational new drug must be both on file with the federal FDA and in effect. Id. § 4(1).
139. The emphasis of the Connecticut statute is clearly on research devoted to the production of an AIDS vaccine. The statute makes no mention of protection for manufacturers after FDA approves a vaccine.
140. See Earley, supra note 19, at 365-67.
seronegative for the presence of anti-HIV antibodies may test seroposi-
tive after participation in the clinical trials. Although they may never
have been exposed to HIV itself, an appropriate response of their im-
mune systems to the candidate vaccine will result in the production of
anti-HIV antibodies. If a clinical trial participant is tested after the
clinical trial, the test would indicate that the participant had been ex-
posed to HIV when the participant had actually been exposed to the can-
didate vaccine. These volunteers should have a guarantee of
protection from the stigma of seropositivity and its accompanying
discrimination.

The ideal statute addressing the liability of AIDS vaccine manufac-
turers would combine the most valuable portions of both the California
and Connecticut statutes. One section should address potential liability
during the research and clinical trials stages, reflecting the Connecticut
approach; another section should address liability post-FDA approval
of the vaccine, reflecting the California approach. The inclusion of an
AIDS Vaccine Victims' Compensation Fund and a specified means of
generating funds for that purpose is necessary to insure that any inad-
vertent injuries will be compensated. The huge medical costs required
for treatment of AIDS patients must be addressed by a Compensation
Fund. Furthermore, compensation must extend to the victim's survivors
who may bear the responsibility of treatment costs. Another area deserv-
ing attention is a guarantee of research subjects' accessibility to insurance
coverage, employment and housing opportunities, and any other rights
currently jeopardized by HIV-positive status, since an HIV-negative vol-
unteer will test positive for the presence of antibodies to the antigen
presented in the vaccine although the individual may not have been chal-
enged by a virulent form of HIV.

141. See Tacket & Edelman, supra note 42, at 356.
142. See supra notes 20-32 and accompanying text.
143. See supra notes 20-32 and accompanying text.
144. See Levine, supra note 13, at 100. Currently, individuals who test seropositive to HIV
encounter difficulties in obtaining insurance, donating blood, joining the military, and traveling
abroad. Id. The National Institute of Allergy and Infectious Diseases (NIAID) provides documen-
tation to participants in approved clinical trials indicating that their seropositivity resulted from
participation in research trials. Id.
145. See supra notes 79-89 and accompanying text.
146. See supra notes 79-89 and accompanying text.
147. Assurance of compensation for medical costs accompanying inadvertent injuries from the
vaccine may be crucial in order to insure participation in vaccine programs by groups at risk for
contracting AIDS.
VI. CONCLUSION

Acquired immunodeficiency syndrome has deeply affected many aspects of our society. The high costs, in terms of both lost lives and losses to the economy, demand that the spread of the virus be halted. A vaccine is urgently needed. However, large pharmaceutical companies are reluctant to enter the market given the risks of litigation associated with unavoidably unsafe products, such as vaccines. Legislative action is required to protect manufacturers of an AIDS vaccine from the uncertainties historically present in vaccine litigation and to insure the realization of a vaccine. This legislation should address issues of tort liability during both the development and testing stages of the vaccine as well as post-FDA approval of the vaccine. The legislation should also provide for the existence of a victims' compensation fund and a source for its funding.

Helen Holt Blake