The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus

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In August 1987, the Food and Drug Administration announced that it had approved plans for the first human trials in the United States of an experimental vaccine against human immunodeficiency virus ("HIV"), the virus that causes acquired immune deficiency syndrome ("AIDS"). While federal officials cautioned that a useful vaccine would probably not be available until "well into the 1990's," their announcement was nonetheless a cause for some optimism given previous projections that an effective vaccine would probably "not become available in this century." Even as scientific advances bring the world closer to development of an HIV vaccine, however, the pharmaceutical industry and others argue that these advances also hasten an inevitable conflict between medical hopes and the realities of a tort law system that already has jeopardized the production of most major existing vaccines. One commentator has predicted that "under present legal conditions, even if [an HIV] vaccine were available tomorrow, no one would produce it." Another recently stated that "worries about product-liability lawsuits could stop any company from marketing a vaccine unless government assumes much or all of the risk." The California State Assembly, reacting to similar state-


1 See Philip M. Boffey, U.S. Announces Decision to Test AIDS Vaccine, N.Y.Times § 1 at 8 (Aug. 19, 1987). This comment uses the more precise term "HIV vaccine" for what is popularly known as the "AIDS vaccine."

2 Id.

3 No Quick Advances Expected on AIDS Vaccine, Chi.Trib. § 1 at 3 (Mar. 30, 1987).


ments by companies that have invested heavily in HIV vaccine research, adopted a statute that protects the manufacturer of an FDA-approved HIV vaccine from suits brought on theories of strict liability for design or warning defects, or for breach of implied warranty.⁶

The concerns behind these warnings stem from the liability crisis that has threatened the production and availability of vaccines against many childhood diseases. A series of product liability cases and damage awards that began in the late 1960s has driven most manufacturers of childhood vaccines out of the market, to the point where single manufacturers supply almost all childhood disease vaccines at vastly increased prices. The premise underlying the concerns about HIV vaccine production, then, is that the legal liability associated with existing vaccines will prevent full development and production of an HIV vaccine.

The pharmaceutical industry and a number of commentators have proposed a variety of responses to this grim possibility: (1) federal assumption of liability for injuries caused by privately manufactured vaccines; (2) statutory modification of the prevailing common law standard that makes vaccine manufacturers strictly liable for design and warning defects; and (3) judicial modification of the strict liability standard. Models for legislation in the first category are the Swine Flu Act of 1976⁷ and the National Childhood Vaccine Injury Act of 1986,⁸ both of which established federal programs to compensate victims of vaccine-related injuries and deaths. In the second category is the California statute. The third category is exemplified by a California case, decided prior to enactment of that statute, which adopted a negligence standard for defects in a manufacturer's warnings to vaccinees.⁹

In contrast to the prevailing view, this comment argues that it is incorrect to assume that the liability associated with existing vaccines will carry over to HIV vaccine; therefore, it is unnecessary to enact legislation or to modify the common law in order to guarantee that pharmaceutical companies will develop and produce the vaccine. Almost all of the pharmaceutical industry's liability for existing vaccines has arisen from the mass immunization programs through which most Americans traditionally have been inoculated.

In these programs, persons administering the vaccines make no individualized medical judgments of the risks and benefits of inoculation for each vaccinee and give few warnings of potential side effects to vaccinees. As a result, vaccine manufacturers usually have not met their duty under product liability law to warn vaccinees directly of known dangers associated with their vaccines.

HIV's epidemiology, however, makes mass immunization against HIV unnecessary. Compared to influenza or the major childhood diseases, HIV is not transmitted easily. Moreover, it does not spread rapidly beyond the groups whose members have been its primary victims. Public officials can therefore target immunization efforts at members of those groups. Universal inoculation is unwarranted. In addition, HIV vaccine is likely to be too scarce and too expensive to dispense indiscriminately, making universal inoculation impossible even if it were to become the preferred option of public health officials. For these reasons, the decision to vaccinate against HIV—whether it is made in an immunization clinic or in a doctor's office—will necessarily be that of a physician capable of making an individualized medical judgment. Consequently, the "learned intermediary" doctrine will protect manufacturers of HIV vaccine from the liability that is associated with existing vaccines. This doctrine provides that a drug manufacturer is not liable for inadequate warnings to a drug recipient where a physician evaluates the recipient's personal circumstances and then decides to prescribe the drug. Existing standards of liability for warning defects, therefore, will adequately protect the manufacturers of HIV vaccine from the frequent lawsuits that have driven most producers of other vaccines out of the market.

Moreover, manufacturers of HIV vaccine also will not face undue liability because scientists are developing the vaccine by using the new technology of genetic recombination, and thus the HIV vaccine should prove much safer than conventional vaccines. The HIV vaccine will not infect a recipient with the virus from which it is made and will be so pure that it will not cause the adverse side effects associated with other vaccines. The HIV vaccine should cause few, if any, serious injuries and therefore should generate very few lawsuits.

Part I of this comment describes the AIDS epidemic and explains why immunization against HIV will be on a scale that allows for the type of individualized medical judgments that the learned intermediary doctrine requires. Part I further explains why a vaccine is the best hope in the battle against AIDS, and why the HIV vaccine should be much safer than existing vaccines. Part II ana-
lyzes the rise and impact of the strict liability standard for vaccines in general, and discusses how the learned intermediary doctrine protects drug manufacturers from product liability. Part III briefly evaluates the 1986 California legislation regarding manufacturer's liability for vaccines in light of these arguments. The Comment concludes that the legislative measures sought by the companies developing an HIV vaccine are largely unnecessary.

I. THE HIV EPIDEMIC AND THE NEED FOR AN EFFECTIVE VACCINE

A. Epidemiology and the Structure of an HIV Immunization Program

One leading scientist has chillingly described AIDS as "a modern plague: the first great pandemic of the second half of the twentieth century." This comment refers to the incidence of HIV as epidemic, not pandemic, because the latter is a disease "occurring over a wide geographic area and affecting an exceptionally high proportion of the population." The distinction is important, since the epidemiology of a virus ultimately affects the legal liability associated with the vaccine that is used to combat it. If the virus is capable of spreading easily and rapidly throughout the population, as are influenza and most of the major childhood diseases, then vaccination against it must be universal and rapid—that is, on a large scale and at a high rate. Thus, all states require vaccination of school-age children against the major childhood diseases; school clinics typically administer the necessary vaccines to children in an assembly-line. Similarly, health workers administered the swine flu vaccine on a massive scale to 45 million Americans. In such settings, no one makes an individualized medical judgment of the risks and benefits of inoculation for each recipient, nor does anyone directly and individually warn the recipient or the recipient's parents about potential hazards.

In contrast to the epidemiology of the childhood diseases and influenza, HIV does not spread in a manner that demands vaccination on a scale or at a rate that precludes individualized medical judgments prior to inoculation. It is true that, until recently, the

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11 Webster's Ninth New Collegiate Dictionary 850 (1986) (emphasis added). Given that the number of HIV carriers in the United States is estimated to be between 350,000 and one million (see note 15 and accompanying text) AIDS cannot accurately be described as pandemic. It certainly is epidemic, however, particularly among male homosexuals and intravenous drug users.
12 See notes 52 and 85 below.
Centers for Disease Control ("CDC") had estimated that HIV had infected more than 1.5 million Americans, and the CDC had projected 324,000 diagnosed cases of AIDS in the United States by the end of 1991. Many believed that HIV was spreading rapidly into the heterosexual population and that HIV was transmitted at least as readily as other sexually transmitted diseases, such as hepatitis B.

More recent estimates, however, have put the number of HIV-positive persons at between 350,000 and one million, and several studies report that the rate of increase in new AIDS cases is beginning to level off. There are other indications that HIV is not spreading rapidly among heterosexuals, except among intravenous drug users, and that the virus is actually much more difficult to transmit than was previously believed:

Whereas mere juxtaposition of genitalia is enough to transmit syphilis, gonorrhea, herpes simplex II, and chlamydia, all of which require only direct contact with the mucous membrane, HIV (like hepatitis B) is bloodborne, the most inefficient mode of transmission [a sexually transmitted disease] can enjoy. A sore, even an undetectably small one such as often accompanies herpes, might offer a passageway for these viruses, but some sort of passageway is needed and in the case of most Americans such passageways do not exist. . . . Even where they do, moreover, AIDS is more difficult to contract than, for example, hepatitis B. Thus, while approximately 27 percent of hospital workers who have accidentally been stuck with hepatitis B-contaminated needles contract the disease, HIV infection occurs in less than 1 percent of those stuck with HIV-contaminated needles.

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13 See Marilyn Chase, AIDS Costs, Wall St.J. § 1 at 1 (May 18, 1987).
14 See, for example, Katie Leishman, Heterosexuals and AIDS, Atlantic 39, 43-44 (Feb. 1987).
15 See John Crewdson, U.S. AIDS Projection Down, Chi.Trib. §1 at 1, 22 (Nov. 15, 1987).
16 See James W. Curran, et al., Epidemiology of HIV Infection and AIDS in the United States, 239 Sci. 610 (1988) ("The proportion of reported [AIDS] cases associated with heterosexual contact increased from 1.1% in 1982 to 2.3% in 1986. Approximately 70% of the index partners for these cases were IV drug abusers; 18% of the index partners for female cases were bisexual men.").
17 Michael A. Fumento, AIDS: Are Heterosexuals at Risk?, Commentary 21, 22 (Nov. 1987). Fumento goes on to discuss why some sex practices are so much more conducive to HIV transmission than others:

[With sexually-transmitted AIDS, the overwhelming risk factor, especially for the passive or recipient partner, is anal sex. . . . The reason anal as opposed to vaginal sex is
Surgeon General C. Everett Koop, who once estimated that by 1990 ten percent of AIDS victims would be heterosexual, recently stated that “it does not appear there will be a heterosexual explosion.”

Thus, AIDS will continue to afflict primarily homosexual men, intravenous drug users, and the sexual partners of IV drug users. The CDC estimates that by 1991 heterosexuals will account for just 5 percent of AIDS cases, almost all of which will have resulted from IV drug use or sexual transmission from an individual in a high-risk group to that individual’s steady sexual partner. Once a vaccine is available, therefore, immunization efforts will need to reach only the members of these high-risk groups. In addition, as this Comment will show below, the new HIV vaccine will be too expensive and its supply too limited to allow indiscriminate or universal distribution. Health workers will have to conserve the vaccine and administer it only to high-risk groups where it can have the greatest impact.

B. The Vaccine Imperative and the Promise of a Safe HIV Vaccine

There presently exists no effective treatment for AIDS. It is always fatal. Scientists cannot predict the percentage of HIV carriers who eventually will fall ill from AIDS or other HIV pathologies because they do not know the maximum latency or incubation period of the virus. A long term study of infected homosexual

so dangerous has to do with the difference in tissue construction between the male urethra and rectum and the female vagina. While the vagina is constructed of tough platelike cells that resist rupture and infectious agents, and are designed to withstand the motions of intercourse and childbirth, the urethra and rectum are constructed primarily of columnar cells which tear or rupture easily. This allows semen to enter the more readily accessible blood vessels of the rectum. . . . [Another factor of importance is that] the condom, which many have touted as the way to turn unsafe homosexual sex into safe sex, has an alarmingly high breakdown rate during anal intercourse.

Id. at 22-23.

18 Quoted in William Raspberry, AIDS: Progress and New Concern, Chi.Trib. § 1 at 17 (Nov. 2, 1987).


men in San Francisco reports that, after seven years of HIV infection, about 80 percent of the men either had developed an advanced case of AIDS or had other signs or symptoms of the disease.\(^2\) A West Germany study estimates that 75 percent of HIV carriers will eventually die of AIDS.\(^2\)

HIV primarily invades white blood cells called T-lymphocytes, an essential component of the human immune system. Following infection of the lymphocyte, the virus synthesizes a DNA molecule corresponding to the code carried in its RNA. This molecule then works its way into the cell's nucleus and integrates itself among the cell's genes, where the virus remains latent until an infection stimulates the lymphocyte:

Then the virus bursts into action, reproducing itself so furiously that the new virus particles escaping from the cell riddle the cellular membrane with holes and the lymphocyte dies. The resulting depletion of [lymphocytes]—the hallmark of AIDS—leaves the patient vulnerable to "opportunistic" infections by agents that would not harm a healthy person.\(^2\)

This massive suppression of the immune system is the most common effect of HIV, but HIV is also known to have a pathogenic effect on the central nervous system of some of its carriers that is independent of the immune deficiency. Furthermore, scientists have linked the virus to increased risk of at least three types of cancer.\(^2\)

Increasingly, scientists agree that the "only certain barrier to further spread of [AIDS] is a vaccine."\(^2\) The availability of new technologies such as genetic recombination have enabled relatively brisk progress in development of an HIV vaccine and are likely to result in the production of something much safer than existing conventional vaccines. Because it should be much safer, the HIV vaccine should give rise to very few lawsuits and hence, unlike its conventional counterparts, should not be a major source of legal

\(^2\) See Bill Johnstone, German Survey's Gloomy Outlook, Nature 199 (Nov. 20, 1986).
\(^2\) Gallo, 256 Sci.Am. at 47 (cited in note 10).
liability for its producers.

To understand why the HIV vaccine should be safer, some background is appropriate. Vaccines work by introducing antigens which stimulate the body's production of antibodies against a particular virus prior to one's infection by the virus. The most potent forms of vaccines against viruses such as polio, rabies, and measles are those scientists prepare from the whole virus, called "whole-cell vaccines." Whole-cell vaccines come in two forms. Scientists make the first, called "live" vaccine, from a whole virus that has been attenuated but not killed completely. They make the second from the killed whole virus. Research has demonstrated that live vaccines induce longer lasting immunity than vaccines prepared from killed viruses, probably because the live vaccines are more efficient at introducing the viral antigens necessary for stimulation of antibody production. Another advantage of live vaccines is that their potency requires only one dose; they therefore involve shorter treatment. This means that they will have less of a tendency to elicit resistance in the viral population than will prolonged use of weaker doses.

Although whole-cell vaccines have the greatest potency, they pose two kinds of risks. First, they sometimes infect the vaccinee with the virus they are designed to combat. The live oral Sabin polio vaccine, for example, elicits one case of polio in every 3.2 to 8 million vaccine doses distributed. Whole-cell vaccines are capable of transmitting the target virus because they contain all of its genetic material; a virus reproduces itself by inserting its genetic material into the host cell's nucleus. The second risk posed by whole-cell vaccines is that they occasionally cause unpredictable side effects. These reactions occur because whole-cell vaccines "contain contaminating materials far exceeding, in mass, the im-

28 An antigen is "any substance which is capable, under appropriate conditions, of inducing the formation of antibodies and of reacting specifically in some detectable manner with the antibodies so induced." Dorland's Illustrated Medical Dictionary 108 (25th ed. 1974).
munogenically active ingredients." 33

Thus, whole-cell vaccines are somewhat risky. There are several factors, however, that would make a whole-cell HIV vaccine even riskier than existing whole-cell vaccines. First, there is the long latency period of the virus, the maximum length of which has never been established. Clinical testing of whole-cell HIV vaccine would necessarily produce uncertain results of doubtful predictive value since the virus could remain latent in the vaccinee far longer than the period of testing. In addition, anyone who would receive the vaccine would thereafter test positive for the virus because current tests identify the antibodies that the vaccine would stimulate the body to create. 34 It therefore would be impossible to determine whether a vaccinee only had the antibodies or had been inadvertently infected with the virus itself. As a result, health workers could administer whole-cell HIV vaccine for many years before doctors discovered its infectiousness.

The possibility that a whole-cell HIV vaccine could infect a recipient with the virus has led most researchers to reject the whole-cell approach in the fight against HIV. 35 Instead, most research focuses on the development of an “acellular” or “subunit” vaccine. A subunit vaccine cannot infect a recipient because it contains only a fragment of the target virus, a fragment lacking the genetic material necessary for the virus’s reproduction. 36 Subunit vaccines are also much less likely to produce adverse side effects, since they contain only a few essential proteins and lack the contaminating materials that inevitably accompany whole-cell preparations. 37 The subunit vaccines already in use, such as the hepatitis B and acellular whooping cough vaccines, have demonstrated that they are much safer than whole-cell preparations. 38 An extensive

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34 On April 28, 1988, Abbott Laboratories announced its application for FDA approval of an HIV test, previously marketed in Europe, that works by identifying the antigens produced by the HIV virus. Telephone conversation with Kathy Babbington, Media Relations, Abbott Laboratories (May 3, 1988). Even if the FDA were to approve this test, it would pose problems of detection similar to those that crop up with the current antibody test.
36 See Barnes, 233 Sci. at 1149 (cited in note 35); Francis and Petricciani, 313 New Eng.J.Med. at 1588 (cited in note 4).
38 On hepatitis B vaccine, see Institute of Medicine, Vaccine Supply and Innovation 80 (1985) (“Vaccine Supply”) (no evidence of side effects other than “minor local reactions” to subunit hepatitis B vaccine); Kohl v. Woodhaven Learning Center, 672 F.Supp. 1226, 1231 (W.D.Mo. 1987) (“The side effects or risks associated with the vaccine are minimal. Less than 5% of those vaccinated will develop a low-grade fever and some irritation at the point
search of the case law reveals only one lawsuit in which it has been alleged that a subunit vaccine was harmful. A trial on the merits of that suit has not been reported.\textsuperscript{39}

One drawback of an acellular HIV vaccine is that it may not be as effective as a vaccine made from the whole virus. A vaccine composed of only a few HIV proteins might fail to stimulate the antibody response necessary for the immune system to recognize the antigens of the whole virus. Alternatively, a subunit vaccine could stimulate production of antibodies that recognize only a few strains of the virus.\textsuperscript{40} A second drawback of subunit vaccines is that they are much more expensive than their conventional counterparts. In 1983, the production cost per dose of the conventional whooping cough vaccine was 3.4 cents; the measles vaccine, 12 cents; and the vaccine against tuberculosis, 5 cents.\textsuperscript{41} Compare this to the production cost per dose of subunit hepatitis B vaccine, which was $30 in 1985.\textsuperscript{42} Furthermore, the final cost of administering vaccines is much higher than their production cost: the actual cost of a whooping cough vaccination was more than $11 in 1986, while hepatitis B vaccinations cost between $150 and $175 in 1987.\textsuperscript{43} Because of its high cost and limited supply, hepatitis B vaccine is “recommended in the United States only for high-risk groups,” even though public health officials believe they could control hepatitis B completely if they administered the vaccine to all children.\textsuperscript{44} It is likely that the same constraints of cost and supply will force the conservation of HIV vaccine, making indiscriminate vaccination uneconomical. In order to reach poor members of high-risk groups, especially IV drug users, the government may have to purchase large quantities of the vaccine for free distribution in public health clinics. But even if the government were to do that, it would still have to limit the vaccine’s administration to members of injection. There is no risk of picking up any other infectious agent through the vaccine.”).
of high-risk groups, out of financial necessity. The high cost of the vaccine will necessitate medical evaluation of each potential recipient, in order to determine whether he or she actually is at risk.

C. Summary

HIV is not spreading nearly as rapidly or as widely as people originally feared. Consequently, the virus does not require vaccination on such a scale and at such a rate as would preclude individualized medical evaluation of every potential vaccinee. The cost of the vaccine will in any event compel individualized medical judgments. Indiscriminate delivery of HIV vaccine will not be an option, just as it is presently not an option for the vaccine against hepatitis B, a virus that is more widespread and more easily transmitted than HIV. Because health workers will make individualized vaccination decisions in the HIV context, the learned intermediary doctrine—discussed in Part II.B—will insulate manufacturers of HIV vaccine from the liability that has plagued manufacturers of vaccines used in mass immunization programs. In addition, while the HIV vaccine will be expensive, it should be much safer than conventional, whole-cell vaccines. It should be incapable of infecting a vaccinee with the virus, should have far fewer and much milder side effects than those vaccines, and therefore should generate few lawsuits.

II. STRICT LIABILITY AND THE LEARNED INTERMEDIARY DOCTRINE

A. The Rise of the Strict Liability Standard for Vaccines and Its Impact on Vaccine Production

The first major intersection of vaccines and American law occurred at the turn of the century when Massachusetts enacted a compulsory smallpox vaccination program. In response to a challenge to the program, the Supreme Court upheld the right of the state to compel its citizens to be vaccinated.45 Mass immunization as a means of controlling epidemics soon became a standard feature of public health programs, and health officials made steady progress against a host of childhood and adult diseases.

In the 1950s and '60s health workers waged a new battle using vaccines, this time against polio. Once again, vaccines enabled the medical community to contain a pandemic; however, the legal costs of doing so began to grow inexorably. An increasing number of polio vaccinees sought compensation for contracting the disease from

the vaccine or for the vaccine's injurious side effects. Some of these suits arose when manufacturers improperly prepared and inadequately tested batches of polio vaccine. In these cases, plaintiffs were able to premise their claims on theories of manufacturer negligence or breach of implied warranty.47

Eventually, a strict liability standard for vaccine manufacturers emerged, a standard that became the mainstay of plaintiffs who had suffered vaccine-related injuries. The Ninth Circuit first enunciated the theory underlying the application of strict liability to vaccine manufacturers in Davis v. Wyeth Laboratories, Inc. In Davis, the court held a manufacturer of the Sabin vaccine, who was not negligent in producing or testing the vaccine, strictly liable for the plaintiff's paralysis from polio because the manufacturer had failed to warn the plaintiff directly that the plaintiff risked contracting polio from the vaccine.48

Reyes v. Wyeth Laboratories extended the Davis principle six years later. There, an infant had contracted paralytic polio two weeks after receiving the Sabin vaccine at a mass immunization clinic. Although the manufacturer included with the vaccine a package insert that warned doctors and nurses of potential dangers, the clinic's staff did not pass on the warnings to individual vaccinees or their guardians.49 In concluding that the defendant had a duty to warn individual vaccinees, the court found that failure to provide an adequate warning "when it is required will itself present a 'defect' in the product and will, without more, cause the product to be 'unreasonably dangerous as marketed.'"50 Thus, the defendants' failure to warn the plaintiffs of the risks inherent in Sabin vaccine made the defendants liable.51

Reyes and Davis precipitated a series of lawsuits in which


48 399 F.2d 121 (9th Cir. 1968). While the court found that Wyeth Laboratories had not been negligent in producing the vaccine, id. at 125-26, and rejected imposition of "absolute enterprise liability" for all unanticipated harm that the vaccine caused, id. at 126, it held that as to foreseeable risks, "we regard failure to warn, where the circumstances of sale imposed that duty, as exposing the vendor to strict liability in tort (or to liability for breach of warranty if that approach is used)." Id. at 127 (footnote omitted).

49 498 F.2d 1264, 1270 (5th Cir. 1974).

50 Id. at 1275 (footnote omitted).

51 Id. at 1277-79. For a general discussion of the development of strict product liability for vaccines, see Note, Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn, 29 Vand.L.Rev. 235, 240-59 (1976).
courts held pharmaceutical companies strictly liable for failing to warn vaccinees directly of risks associated with the vaccines that they received.\textsuperscript{52} Even where the evidence on causation seemed to favor the defendant-manufacturer, as in \textit{Reyes}, juries almost always found for the plaintiff. As two commentators put it, "the courts have been most solicitous of the plaintiffs and have actively sought bases for recovery."\textsuperscript{53}

Recently a few courts have bucked the trend of verdicts for plaintiffs in vaccine injury actions.\textsuperscript{54} Nevertheless, these cases follow two decades of lawsuits in which vaccine manufacturers consistently lost. Those lawsuits have had two major effects: an exodus of companies from vaccine production and dramatic increases in vaccine prices. The case of DPT vaccine, the combination vaccine used to immunize against diphtheria, pertussis (whooping cough), and tetanus, illustrates the first effect. During the 1960s, eight companies manufactured DPT vaccine;\textsuperscript{55} by early 1985, only one company was distributing it.\textsuperscript{56}

Illustrating the second effect, the price of a single dose of DPT vaccine rose by a factor of 100, from 11¢ to more than $11 over the five years ending in 1986.\textsuperscript{57} From 1984 to 1986, the average price paid by the CDC under its vaccine stockpiling program rose from $2 per dose to $12.\textsuperscript{58} Despite these increases, manufacturers claim that revenue from vaccine sales is not keeping pace with their legal costs. According to Lederle Laboratories, the damages claimed against it in whooping cough litigation during 1983 were two hun-

\textsuperscript{52} See, for example, Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977) (Sabin vaccine); Ezagui v. Dow Chemical Corp., 598 F.2d 727 (2d Cir. 1979) (DTP/polio vaccine); Unthank v. United States, 732 F.2d 1517 (10th Cir. 1984) (swine flu vaccine);etty v. United States, 740 F.2d 1428 (8th Cir. 1984) (swine flu vaccine);Fraley v. American Cyanamid Co., 570 F.Supp. 497 (D.Colo. 1983) (Sabin vaccine); Brazzell v. United States, 633 F.Supp. 62 (N.D.Iowa 1985) (swine flu vaccine).


\textsuperscript{54} In \textit{Kearl v. Lederle Laboratories}, 172 Cal.App.3d 812, 218 Cal.Rptr. 453 (1985), for example, the court said that "unavoidably dangerous" products "are subject merely to negligence liability for warning defects." 172 Cal.App.3d at 817 (emphasis in original). Applying this rule, the \textit{Kearl} court found that the Sabin vaccine was unavoidably dangerous and, applying a negligence standard, held that the defendant had met its duty toward the plaintiff by placing warnings in an information sheet given to plaintiff's mother at the immunization clinic to alert her to the risks associated with the Sabin vaccine. Id. at 834.

\textsuperscript{55} See Philip M. Boffey, Vaccine Liability Threatens Supplies, N.Y.Times Cl (June 26, 1984).

\textsuperscript{56} Stephen Engelberg, Maker of Vaccine Quits the Market, N.Y.Times A21 (Dec. 12, 1984).

\textsuperscript{57} See Rovner, Cong.Q.Weekly Rep. at 1828 (cited in note 43).

dred times the company's revenue from the vaccine.\textsuperscript{59}

Because of apprehensions over liability and claimed market uncertainty, the pharmaceutical companies argue that there are no incentives to invest in the development of new or improved vaccines.\textsuperscript{60} Noting that the market seems barely able to supply many existing vaccines, they contend that it could fail to develop and produce a vaccine as complex and costly as that required to immunize against HIV. Yet the reality of massive HIV vaccine research undermines this contention. Several private firms and public institutions are actively engaged in the research and development of an HIV vaccine. By August 1987, two private American firms and a health institute had sought approval for human trials of an HIV vaccine, and an FDA spokesman has confirmed that "other companies are also working on potential vaccines, as are scores if not hundreds of researchers at institutions around the world."\textsuperscript{61}

Thus, fear of legal liability does not appear to be inhibiting the development of an HIV vaccine. Legal liability may continue to pose a serious threat to the availability of many existing vaccines.\textsuperscript{62} But the HIV vaccine probably will not be like these vaccines, either in form or in the way that health workers will administer it to the public. In form, it will be most like the hepatitis B vaccine. Moreover, the inventor of an HIV vaccine will reap enormous accolades and publicity—perhaps even a Nobel prize—and, moreover, be responsible for saving hundreds of thousands of lives. Since AIDS is described as the most frightening and devastating epidemic since polio, the team or individual who solves the HIV vaccine puzzle is likely to be viewed as a latter-day Jonas Salk. The prospect of such an achievement will provide an enormous impetus to researchers worldwide.

That HIV vaccine, like hepatitis B vaccine, may cost $175 or more per vaccinee is likely to be a bigger problem for public health

\textsuperscript{59} See Tamar Lewin, Pharmaceutical Companies Are the Hardest Hit, N.Y.Times § 3 at 1, 9 (Mar. 10, 1985).

\textsuperscript{60} See Institute of Medicine, Vaccine Supply at 119 (cited in note 38).


\textsuperscript{62} See Institute of Medicine, Vaccine Supply at 119 (cited in note 38).
authors than the threat posed to the supply of HIV vaccine by legal liability. Although manufacturers made hepatitis B vaccine available beginning in 1982, by 1985 only 20 percent of the target population had received it. Its high cost has undoubtedly deterred its administration to the groups who need it most. A steep price for HIV vaccine will deter administration to the same individuals, to the detriment of a successful immunization program.

B. The Learned Intermediary Doctrine

This comment has argued that legal liability will not be a burden on HIV vaccine manufacturers because the vaccine should be safer and because the learned intermediary doctrine will protect manufacturers from strict liability for failure to warn of its side effects. It is precisely the warning burden that has been the major problem for pharmaceutical companies in the contexts of other vaccines.

The relevant history of the learned intermediary doctrine begins in the early 1980s, when pharmaceutical companies won several vaccine injury cases by proving that the warnings they provided to the plaintiffs’ physicians were sufficient to shield the companies from liability. Lederle Laboratories, for example, won two cases involving the Sabin vaccine: Dunn v. Lederle Laboratories and Shindler v. Lederle Laboratories. In Dunn, for example, the plaintiff contracted polio from her daughter, who had been recently vaccinated by her doctor. On appeal from a verdict for the defendant, the court held that a jury could reasonably find that a package insert and subsequent “Dear Doctor” letters contained sufficient warnings of the risk of contracting polio from someone recently inoculated, even though the manufacturer had given those warnings to the plaintiff’s physician and not to the plaintiff herself. The court stated that although “[w]arnings generally must be cal-


64 This has been especially true since Reyes. Inadequate warnings to the vaccinee have been the basis of the vast majority of successful vaccine injury lawsuits. In fact, there are only two cases reported after Reyes in which vaccine manufacturers or others were held liable for negligently produced, defective vaccines. See Ezagui v. Dow Chemical Corp., 598 F.2d 727 (2d Cir. 1979); Vincent v. Thompson, 79 Misc.2d 1029, 361 N.Y.S.2d 282 (1974), rev'd in part, 50 App.Div. 211, 377 N.Y.S.2d 118 (1975).

65 Dunn v. Lederle Laboratories, 121 Mich.App. 73, 328 N.W.2d 576 (1983); Schindler v. Lederle Laboratories, 725 F.2d 1036 (6th Cir. 1983) (affirming a judgment in favor of polio vaccine manufacturer on the grounds that its package insert provided an adequate warning to a pediatrician of the risk of contracting polio).
culated to reach the ultimate consumer,” there is an exception “for drugs dispensed in a manner requiring a physician to weigh the risks and benefits of a drug’s use on a particular patient. . . . With these drugs the doctor, and not the patient, must be warned by the manufacturer.”

The learned intermediary doctrine creates an exception to the general rule that a manufacturer has a duty to warn users of known dangers inherent to the use of its product. Every jurisdiction that has considered whether a drug manufacturer has a duty to warn has adopted the doctrine. According to the Davis court, a direct warning to the patient is unnecessary where a physician prescribes the drug because “[i]n such cases the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician’s knowledge of his patient’s needs and susceptibilities.” Similarly, the Reyes court explained the rationale for the doctrine in this way:

[W]here 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. This special standard for prescription drugs is an understandable exception to the Restatement [of Torts (Second)]’s general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products. . . . As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. . . . The choice he makes is an informed one, an individualized medical judgment bot-

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66 Dunn, 328 N.W.2d at 579-80. See also Johnson v. American Cyanamid Co., 239 Kan. 279, 718 P.2d 1318 (1986), in which the Kansas Supreme Court reversed a lower court judgment awarding $10 million to a plaintiff who contracted polio from his daughter, inoculated by her pediatrician with the Sabin vaccine. The Court found that, as a matter of law, the defendant’s warning to a learned intermediary was reasonable and adequate to warn of the vaccine’s possible side effects.

67 The term “learned intermediary” was first used in Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (1966). The concepts embodied in the doctrine date back to the late 1940s, however. See Margaret Gilhooley, Learned Intermediaries, Prescription Drugs, and Patient Information, 30 St.Louis U.L.J. 633, 642-44 (1986).

68 For a partial list of jurisdictions adopting the doctrine, see Comment, Products Liability: The Continuing Viability of the Learned Intermediary Rule as it Applies to Product Warnings for Prescription Drugs, 20 U.Rich.L.Rev. 405, 411 n.32 (1986). A review of the law in every state and federal jurisdiction, conducted during the research for this Comment, confirmed that the doctrine has been adopted by state courts in 29 states and by federal courts applying the law of 14 other states, for a total of 43 states. It has also been adopted in Puerto Rico and the District of Columbia.

69 Davis v. Wyeth Laboratories, 399 F.2d at 130.
tomed on a knowledge of both patient and palliative. Pharmaceutical companies then . . . are required to warn only the prescribing physician, who acts as a “learned intermediary” between manufacturer and consumer.\textsuperscript{70}

Margaret Gilhooley has criticized the learned intermediary doctrine, arguing that it incorrectly presumes that “the physician can be relied upon to give the appropriate risk information to patients.” Contrary to that presumption, Gilhooley claims, “[l]ittle information is provided for prescription drugs, and surveys indicate that substantial proportions of patients claimed to have received no information on drug risks.” She thus believes that courts should require drug manufacturers “to provide adequate information about a drug’s risks directly to the drug user.”\textsuperscript{71}

This argument misconstrues the learned intermediary doctrine. The doctrine does not assume the physician will substitute for the drug manufacturer as a conduit of warnings to the drug user. Rather, it is the physician who is the consumer by making the decision whether the patient should use a given drug:

In the case of pharmaceuticals, the user has traditionally been the physician who acts as the informed intermediary between the manufacturer and the patient—evaluating patient’s needs, assessing the risks and benefits of drug therapy and other modalities, prescribing the drug, and supervising its use. The physician is the epitome of an intermediary, who exercises independent judgment.\textsuperscript{72}

Hence, whether warnings ultimately reach the patient is irrelevant under the doctrine. The relevant issue is whether the drug manufacturer adequately warned the physician of the drug’s risks.\textsuperscript{73}

There are only two exceptions to the learned intermediary

\textsuperscript{70} Reyes v. Wyeth Laboratories, 498 F.2d at 1276.
\textsuperscript{71} Gilhooley, 30 St. Louis U.L.J. at 670, 674-75, 637 (cited in note 67).
\textsuperscript{72} Frederick H. Fern, The Decline and Fall of the Learned Intermediary Doctrine, For the Defense 10 (Sept. 1986). Fern makes the same mistake as Gilhooley in the sentence preceding the section quoted here, by implying that the doctrine merely recognizes the physician’s role as a conduit of the manufacturer’s warnings. The cases that Fern cites as background for the doctrine emphasize the physician’s independent judgment, however, and make scant reference to his role as a medium for the manufacturer. See id. at 11-12.
\textsuperscript{73} As Gilhooley admits, patients have no legal right to receive drug warnings directly from the manufacturer. See Gilhooley, 30 St. Louis U.L.J. at 641. Gilhooley proposes the creation of such a right, which would only exacerbate what another commentator has called a common law-created “bias, intensified by the discretion left to juries, toward finding all warnings inadequate when judged by the standards of hindsight.” Richard A. Epstein, Legal Liability for Medical Innovation, 8 Cardozo L.Rev. 1139, 1150 (1987).
doctrine. The first, set forth in *Davis* and refined in *Reyes*, involves vaccines administered in mass immunization programs. As explained above, this exception to the rule does not threaten HIV manufacturers because health workers will administer the vaccine on an individualized basis. The second exception is more recent and involves oral contraceptives. In three cases decided in early 1985, a state court in Massachusetts and a federal district court in Michigan held that a manufacturer of oral contraceptives cannot rely solely on the prescribing physician to warn users of possible side effects. Their reasons for distinguishing oral contraceptives from other prescription drugs included the patient’s greater involvement in choosing whether to use the contraceptives and the physician’s correspondingly passive role in the decision; the typical lack of adequate communication between the physician and the patient regarding possible side effects when physicians initially prescribe the contraceptives; the low level of supervision by the physician, who examines the patient once before prescribing the contraceptives and then only once a year upon renewal of the prescription; the known and substantial risks associated with oral contraceptives; and the pharmaceutical companies’ heavy promotion of the products aimed directly at the consumer.

Commentators have criticized the oral contraceptive cases on a number of grounds. Moreover, the holdings in these cases conflict with those in a large number of cases involving oral contraceptives in which courts have applied the learned intermediary doctrine.

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75 See MacDonald, 475 N.E.2d at 69-70; Stephens, 602 F.Supp. at 380-81; Odgers, 609 F.Supp. at 878-79.

76 See, for example, Fern, For the Defense at 15-18 (cited in note 72). Fern criticizes the distinction on three grounds. First, the distinction between oral contraceptives and therapeutic drugs is insupportable, as many pharmaceuticals including oral contraceptives have both therapeutic and non-therapeutic uses. Second, the duty created by these cases is “unpredictable,” since a manufacturer cannot know in advance whether an oral contraceptive is being prescribed for therapeutic reasons. Third, physicians always have to consider the patient’s health and medical history before prescribing oral contraceptives. See also, Comment, 20 U.Rich.L.Rev. at 419-20 (cited in note 68) (the courts’ duty to warn standard is “vague” and “unguided by practical considerations” and may have the effect of imposing absolute liability on contraceptive manufacturers).

77 The *MacDonald* court listed cases from thirteen states in which courts applied the learned intermediary doctrine to oral contraceptives. See 475 N.E.2d at 68 n.9. Since *MacDonald*, *Stephens*, and *Odgers*, no court has considered the applicability of the doctrine to oral contraceptives. As for other prescription drugs, the doctrine continues to hold. See, for example, Rhoto v. Ribando, 504 So.2d 1119 (La.App. 1987) (weight loss drugs); Johnson v. American Cyanamid, 239 Kan. 279, 718 P.2d 1318 (1986) (polio vaccine).
Nonetheless, these cases probably worry drug manufacturers who may fear that courts will not apply the learned intermediary doctrine to their drugs. In particular, HIV vaccine manufacturers might cite these cases as grounds for legislative protection, arguing that HIV vaccines share with oral contraceptives the characteristics that the courts in the oral contraceptive cases cited as the reasons for not applying the doctrine to oral contraceptives.

There are, in fact, a few cases involving vaccines prescribed by a physician in which the doctrine was not allowed as a defense. In *Givens v. Lederle*, a pediatrician administered the polio vaccine in his office, but the Fifth Circuit found that the vaccine "was administered . . . in a manner more like that at a small county health clinic, as in *Reyes*, than by prescription."\(^7\)\(^8\) The court in *Samuels v. American Cyanamid Co.* likewise found that where a vaccine was "administered prophylactically by a physician in connection with overseas travel" in a company's health clinic, there was unlikely to be "in-depth analysis of the benefits and risks to the individual of the vaccine's administration."\(^7\)\(^9\)

*Givens* and *Samuels* illustrate that the applicability of the learned intermediary doctrine cannot be taken for granted and that sometimes the mere presence of a physician does not by itself shield the vaccine manufacturer from liability. The HIV vaccine, however, will differ from oral contraceptives and from the conventional vaccines administered in *Givens* and *Samuels* in four crucial respects. In the first place, the HIV vaccine probably will be prescribed by a physician who will have an especially active role in the vaccination decision, since the vaccine will be too expensive and scarce to administer indiscriminately. Second, communication between the physician and vaccinee will have to be substantial in order for the doctor to determine whether the vaccinee is indeed at high risk for HIV. Third, since health workers probably will not distribute the vaccine in a manner comparable to the method through which "the pill" or conventional vaccines are distributed, it is unlikely that distribution will be accompanied by massive publicity on the part of drug manufacturers aimed directly at potential vaccinees. Finally, the vaccine should be very safe, and hence should not be associated with substantial risks.

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\(^7\) 556 F.2d 1341, 1345 (5th Cir. 1977).

\(^8\) 130 Misc.2d 175, 495 N.Y.S.2d 1006, 1013 (1985).
III. CALLS FOR GOVERNMENT PROTECTION: THE CALIFORNIA MODEL

Drug companies continue to insist that full scale development and distribution of an HIV vaccine may not be feasible under a "legal system [that] has simply run amuck," and they continue to lobby for protection. Such efforts fail to recognize that existing product liability law will adequately protect HIV manufacturers. Moreover, calls for government protection for HIV manufacturers will yield problems of their own.

To understand these additional complications, consider the 1986 California statute designed to encourage development of an HIV vaccine by insulating manufacturers from uncertain liability. The statute (1) protects the manufacturer of an FDA-approved HIV vaccine from strict liability for design or warning defects, or for breach of implied warranty, if the trial judge determines that the vaccine is unavoidably dangerous under the familiar standard of Kearl v. Lederle Laboratories; (2) creates an AIDS Vaccine Victims Compensation Fund, to be funded by a surcharge on sales of an FDA-approved HIV vaccine within California; and (3) guarantees a market for the vaccine by pledging that the state will purchase up to 500,000 units of vaccine at a maximum of $20 per unit within three years of FDA approval.

As Part II has demonstrated, legislation barring strict liability claims is unnecessary in light of the protection already available to HIV vaccine manufacturers under the learned intermediary doctrine. Furthermore, evidence exists that vaccine makers, even within California, began the search for an HIV vaccine before protective law was in place. No special legislation was needed to en-

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80 Brian Cunningham, vice president and general counsel for Genentech, quoted in Barnes, 233 Sci. at 1035 (cited in note 4). There is, of course, an economic rationale for seeking government protection from the costs of liability associated with HIV vaccine. Manufacturers would obviously prefer to obtain an ex ante guarantee of government protection in order to reduce their insurance costs, regardless of whether their liability ends up being lower than they would presently have us believe.

81 The California Assembly expressed its conviction that:
the management decision to go forward with the significant financial investment necessary to the development and approval of an AIDS vaccine is negatively influenced by the potentially disastrous and uncertain risk posed by the application of strict product liability on such a product, regardless of the public benefit that would result from such a vaccine.


82 See Id. at §§ 199.45-199.51. The state will purchase the vaccine only if fewer than 750,000 units have been sold. Id. at § 199.51.

83 See, for example, AIDS Protein Made, Nature at 525 (cited in note 61) (advances made by Genentech, a leading California firm in HIV vaccine research).
courage them.

The California compensation scheme is particularly problematic, because it does not bind individuals injured by an HIV vaccine to recovery through the state fund. Instead, victims may sue the manufacturer directly in tort. The law thus encourages persons with dubious claims to seek compensation through the "deep pocket" of the state while doing nothing to deter those with stronger claims from seeking greater awards in state court.\(^4\) The amount of litigation arising from HIV vaccines will mushroom, with recoveries under the state fund going to persons less likely actually to have been injured by HIV vaccine.\(^5\)

The third feature of the California statute involves the state's guarantee to purchase a specified quantity of vaccine. This is the one feature that could have a beneficial impact on prospects for development of an HIV vaccine. The problem of a limited market is the most significant obstacle to production of an affordable vaccine. While a vaccine will almost certainly be produced, it would be extremely expensive in the absence of the state's pledge.\(^6\) By guaranteeing a minimum market, California will enable manufacturers to spread their fixed costs over a greater number of units, thus lowering the average cost per unit.

**CONCLUSION**

It is imperative that scientists develop an effective HIV vaccine as soon as possible. The pharmaceutical industry and non-profit institutes are working furiously to achieve that end, and although they face considerable obstacles, legal liability is not among them. To assume that the liability burdens imposed on manufac-

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\(^5\) The experience under the California compensation fund is thus likely to mirror that under the National Swine Flu Immunization Program of 1976, Pub.L.No. 94-380, 90 Stat. 1118 (1976), repealed by Pub.L.No. 95-626, Title II § 202, 92 Stat. 3574 (1978).

[1] In the swine flu program, the best scientific evidence indicates that less than 300 people were injured. If we compensated those who had a greater than 50 percent probability of injury..., the compensated group should have numbered 600. To date there has been almost double that number of people compensated.... It can be expected that a compensation system will lead to recovery for those who can present a credible potential claim (a group must larger than the group actually injured). Reitze, 13 B.C.Envtl.Aff.L.Rev. at 211 n. 242 (cited in note 4).

\(^6\) For speculation as to costs, see notes 41-43 and accompanying text.
turers by conventional, whole-cell vaccines will simply carry over to an HIV vaccine—and thereby warrant government protection for manufacturers—misconstrues the nature of the law that has imposed those burdens. This assumption also ignores the important technological characteristics that distinguish the new generation of vaccines from the conventional vaccines that they will replace.