HEALTH AND SAFETY CODE - HSC

DIVISION 105. COMMUNICABLE DISEASE PREVENTION AND CONTROL [120100 - 122476] *(Division 105 added by Stats. 1995, Ch. 415, Sec. 7.)*

PART 4. HUMAN IMMUNODEFICIENCY VIRUS (HIV) [120775 - 121349.3] *(Part 4 added by Stats. 1995, Ch. 415, Sec. 7.)*

CHAPTER 13. Acquired Immune Deficiency Syndrome (AIDS) Immunization [121250 - 121281] *(Chapter 13 added by Stats. 1995, Ch. 415, Sec. 7.)*

121250. The Legislature finds and declares all of the following:

(a) The rapidly spreading AIDS epidemic poses an unprecedented major public health crisis in California, and threatens, in one way or another, the life and health of every Californian.

(b) The best hope of stemming the spread of the AIDS virus among the general public is the development of an AIDS vaccine to develop an immunity to exposure.

(c) No vaccine has yet been fully developed, tested, or approved for AIDS. An effective vaccine, especially when directed at high-risk groups of unexposed persons, will virtually eliminate the risk of contracting AIDS, just as the risk of contracting polio and smallpox have been virtually eliminated by earlier vaccine development, production, and use among the general public.

(d) Private industry today has the capability of conducting the vaccine research, biological research, immunology, and genetic engineering of appropriate viral components needed to formulate, develop, produce, and test an AIDS vaccine. Whenever these and other appropriate expertise cannot be found within a single company, the formation of multiinstitutional research groups should be encouraged and prioritized, as it is in the public interest to encourage efforts toward vaccine production.

(e) It is of the highest importance and in the public interest to maximize public protection by developing an AIDS vaccine and by establishing high levels of immunization, initially among high-risk populations.

(f) The continuous spread of AIDS and especially the threat of infection spreading among population groups previously considered low-risk demands that the highest of priorities be given to the development of a universal immunoprophylaxis.

(g) The use of vaccines to control the spread of infectious pathogens is recognized as one of the genuinely decisive technologies of modern medicine. Recent advances in pharmaceutical technology combined with better understanding of the immune process offer the hope of an AIDS vaccine that is effective, safe, relatively inexpensive, and relatively easy to administer.

(h) Utilization of this new science may be forestalled, however, by problems that have recently deterred the development of vaccines by traditional means. These problems must be resolved before the full public health benefits of new approaches to vaccine development can be fully and expeditiously realized.

(i) The marketplace conditions facing vaccine manufacturers and developers today have changed considerably over the past 30 years. Private manufacturers and developers of vaccines cannot be forced to produce vaccines, and may choose, under the free enterprise system, not to produce them if marketplace conditions are unfavorable.

(j) Certain market conditions are slowing and threatening to halt the development of an AIDS vaccine. Any delay in the discovery, testing, approval, and production of the vaccine because of these secondary considerations may cost tens of thousands of human lives annually, unnecessary pain and suffering for hundreds of thousands of infected Americans, and billions of dollars in medical costs and in lost productivity.

(k) Resource constraints in the public and private sectors and the time required to bring vaccines to market presently limit investments in vaccines research and development. Although universities constitute a significant resource in AIDS research in particular and vaccines research in general, university funding limitations and conflicting research priorities make reliance on the resources and expertise of the private pharmaceutical industry a necessary supplement to public funding of AIDS research.

(l) There has been a decrease in the willingness of pharmaceutical companies to become involved in vaccine research, development, and manufacturing because of uncertain profitability and perceived and actual marketplace risks and disincentives.

(m) It is clearly in the public interest to provide appropriate and necessary incentives toward the timely development and production of an effective and safe AIDS vaccine.

(n) The development of an AIDS vaccine provides an exceptionally important benefit, making its availability highly desirable. However, certain conditions may preclude that development, including the following:

(1) There is a high cost for capital expenditures for vaccine development (estimated to be from ten million dollars ($10,000,000) to thirty million dollars ($30,000,000)). Testing costs of clinical trials (twenty million dollars ($20,000,000) per vaccine, by some estimates) are particularly burdensome, especially for smaller firms.

(2) There is an uncertain market demand for a vaccine once development costs have been invested and FDA marketing approval has been secured.

(o) Without state intervention to assure minimal profitability of an AIDS vaccine, inadequate incentives may exist for the private sector to commit resources and expertise to the accelerated development of an AIDS vaccine.

(p) In light of the dangers inherent in the AIDS epidemic to the general public of California, it is crucial that to the extent possible any serious obstacles to the development of a vaccine be removed.

(q) Because an AIDS vaccine provides an exceptionally important public benefit, it is in the public interest to take uncommon action to facilitate the development and production of a vaccine.

(r) It is as well in the public interest to assure fair compensation, if necessary at public expense, to any innocent victim who may be injured by an AIDS vaccine, as a part of implementing the socially beneficial policy of establishing high levels of AIDS immunization.

(s) In light of the high incidence of AIDS amongst Californians, the California Legislature must lead our country into the 20th century in this effort.

(t) It is therefore fitting and proper that the State of California enact uncommon and exceptional legislation in order to prevent the further spread of the AIDS epidemic.

(Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.)

121255. The Legislature further finds and declares all of the following:

(a) Acquired immune deficiency syndrome (AIDS) is caused by the virus human T-cell lymphotropic virus, type III (HTLV-3) that initially cripples the body's immune system and eventually leaves the body open to an array of lethal opportunistic infections.

(b) So far, there is no known cure for AIDS and once a person is AIDS infected, the virus remains throughout the rest of his or her life.

(c) The AIDS virus has a three-to-seven year incubation period, making it one of the most difficult diseases to combat and trace.

(d) An easily administered blood test can determine whether a person has been exposed to the AIDS virus.

(e) In 1979, when AIDS was first diagnosed in the United States, the number of newly diagnosed victims was doubling every six to nine months; today the number of people diagnosed with AIDS doubles each year.

(f) Nationally, between 500,000 and 2,000,000 Americans are estimated to have been exposed to the AIDS virus. Of those exposed, between 25,000 and 500,000 persons (5 percent–25 percent) may be expected to die of AIDS.

(1) Another 25,000 to 500,000 persons may be expected to develop AIDS Related Complex (ARC). The range of illnesses these individuals will suffer from may range from minor ailments to brain damage.

(2) The remaining majority of those exposed may never suffer its consequences, but may carry and transmit the disease unknowingly.

(3) Some experts estimate as many as 1,000 additional people are exposed daily.

(g) The department, in its report to the Legislature (March 1986) estimated conservatively that over 30,000 Californians shall have contracted AIDS by 1990, about 50 percent having succumbed. The disease is believed to be fatal within 18 months of diagnosis. To date, more than half the 16,000 people with AIDS in the United States have died.

(h) The AIDS virus is transmitted primarily through sexual contact, and also through the sharing of hypodermic needles, contaminated blood transfusions, and during pregnancy to the fetus.

(i) While the earliest spread of the AIDS virus was primarily among homosexuals, the virus is now found and spreading among heterosexuals as well.

(j) Additionally, drug abusers are highly susceptible to the AIDS virus since the drugs diminish the ability of the body's immune system to function. Intravenous drug abusers traditionally come into contact with the virus from sharing hypodermic needles.

(k) Persons sexually active in the heterosexual community are also at risk. Until a vaccine is developed, the AIDS virus will cross over from the high-risk groups to the lower risk groups. At this time, it is not known how fast the AIDS virus will penetrate other population groups, but it is not expected to be nearly as rapid. To date, partners of high-risk groups (bisexual men and intravenous drug users) are considered the main means of transmitting the AIDS virus to the heterosexual population. Other means include pregnant women who pass the infection on to the child and prostitutes who pass on the infection to their clients.

(l) Of the first 9,000 AIDS cases diagnosed in the United States, almost 1,000 were women. Fourteen percent of these women developed AIDS through sexual contact. Recent studies have demonstrated that the virus can be transmitted by women to their male sexual partners. Sexual contact with an infected partner may transmit the virus and fatally infect the partner.

(Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.)

121260. The Legislature further finds and declares all of the following:

(a) The average cost per patient in the treatment of AIDS until death is now one hundred fifty thousand dollars ($150,000). It is estimated that total costs including health care of the first 10,000 AIDS cases in the United States totaled more than six billion three hundred million dollars ($6,300,000,000). By 1990, according to the department, Californians will spend almost five billion dollars ($5,000,000,000) in medical costs alone in care and treatment of 30,000 AIDS patients, with no realistic hope for their remission or cure. This cost does not include money spent on education, research, and lost income.

(b) To date, the costs of caring for people with AIDS related complex (ARC) has not been officially calculated. However, it is safe to assume the costs are substantial over time. Experts fear that the illnesses of ARC patients, although they may not be fatal, are severe. For example, the virus invades the brain rendering the patients incapable of caring for themselves. It is, therefore, plausible that a percentage of ARC patients will need to be institutionalized.

(c) The Legislature intends by this chapter to take uncommon action to remove the impediments to the expeditious development of an AIDS vaccine.

(d) It is further the intent of the Legislature to provide to any person, whose injury is proximately caused by the use of the vaccine, except to the extent the injuries are attributable to the comparative negligence of the claimant in the use of the vaccine, all of the following:

(1) Compensation for related medical costs associated with the care and treatment of the injury.

(2) Compensation for the loss of any and all earnings caused by the injury.

(3) Compensation for pain and suffering caused by the injury, except that in no action shall the amount of damages for noneconomic losses exceed five hundred fifty thousand dollars ($550,000).

(e) It is further the intent of the Legislature to establish the AIDS Clinical Trials Testing Fund that will be available to not more than three California manufacturers of an AIDS vaccine approved by the federal Food and Drug Administration (FDA) or the department pursuant to Part 5 (commencing with Section 109875) of Division 104 for clinical trials with humans.

(f) The AIDS Vaccine Research and Development Advisory Committee shall review requests from California manufacturers for funds from the AIDS Clinical Trials Testing Fund and shall make recommendations to the department regarding the award of funds, including the appropriate amount of funding. The department, taking into consideration the committee's recommendations, may allocate the funds to the manufacturers specified in the protocol approved by the FDA or the department pursuant to Part 5 (commencing with Section 109875) of Division 104 for administering the clinical trials.

(g) A California manufacturer seeking the approval of the FDA, rather than the department, for administering clinical trials of an AIDS vaccine may apply while FDA approval is pending to the AIDS Vaccine Research and Development Advisory Committee for the committee's recommendation that the manufacturer receive funds from the AIDS Clinical Trials Testing Fund upon FDA approval.

(Amended by Stats. 1997, Ch. 294, Sec. 22. Effective August 18, 1997.)

121265. "State," as used in this chapter, has the same meaning as set forth in Section 900.6 of the Government Code.

(Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.)

121270. (a) There is hereby created the AIDS Vaccine Victims Compensation Fund.

(b) For the purposes of this section, the following definitions apply:

(1) "AIDS vaccine" means a vaccine that (A) has been developed by any manufacturer and (B) is approved by the FDA or the department pursuant to Part 5 (commencing with Section 109875) of Division 104 as a safe and efficacious vaccine for the purpose of immunizing against AIDS.

(2) “Damages for personal injuries” means the direct medical costs for the care and treatment of injuries to any person, including a person entitled to recover damages under Section 377 of the Code of Civil Procedure, proximately caused by an AIDS vaccine, the loss of earnings caused by the injuries, and the amount necessary, but not to exceed five hundred fifty thousand dollars ($550,000), to compensate for noneconomic losses, including pain and suffering caused by the injuries.

(3) “Fund” means the AIDS Vaccine Victims Compensation Fund.

(c) The Department of General Services shall pay from the fund, contingent entirely upon the availability of moneys as provided in subdivision (o), damages for personal injuries caused by an AIDS vaccine that is sold in or delivered in California, and administered or dispersed in California to the injured person except that no payment shall be made for any of the following:

(1) Damages for personal injuries caused by the vaccine to the extent that they are attributable to the comparative negligence of the person making the claim.

(2) Damages for personal injuries in any instance when the manufacturer has been found to be liable for the injuries in a court of law.

(3) Damages for personal injuries due to a vaccination administered during a clinical trial.

(d) An application for payment of damages for personal injuries shall be made on a form prescribed by the Department of General Services within one year of the date that the injury and its cause are discovered. This application may be required to be verified. Upon receipt, the Department of General Services may require the submission of additional information necessary to evaluate the claim.

(e) (1) Within 45 days of the receipt of the application and the submission of any additional information, the Department of General Services shall do either of the following:

(A) Allow the claim in whole or part.

(B) Disallow the claim.

(2) In those instances of unusual hardship to the victim, the board may grant an emergency award to the injured person to cover immediate needs upon agreement by the injured person to repay in the event of a final determination denying the claim.

(3) If the claim is denied in whole or part, the victim may apply within 60 days of denial for a hearing. The hearing shall be held within 60 days of the request for a hearing unless the injured person requests a later hearing.

(f) At the hearing, the injured person may be represented by counsel and may present relevant evidence as defined in subdivision (c) of Section 11513 of the Government Code. The Department of General Services may consider additional evidence presented by its staff. If the injured person declines to appear at the hearing, the Department of General Services may act solely upon the application, the staff report, and other evidence that appears on the record.

(g) The Department of General Services may delegate the hearing of applications to hearing examiners.

(h) The decision of the Department of General Services shall be in writing and shall be delivered or mailed to the injured person within 30 days of the hearing. Upon the request by the applicant within 30 days of delivery or mailing, the Department of General Services may reconsider its decision.

(i) Judicial review of a decision shall be under Section 1094.5 of the Code of Civil Procedure, and the court shall exercise its independent judgment. A petition for review shall be filed as follows:

(1) If no request for reconsideration is made, within 30 days of personal delivery or mailing of the Department of General Services’ decision on the application.

(2) If a timely request for reconsideration is filed and rejected by the Department of General Services, within 30 days of personal delivery or mailing of the notice of rejection.

(3) If a timely request for reconsideration is filed and granted by the Department of General Services, or reconsideration is ordered by the Department of General Services, within 30 days of personal delivery or mailing of the final decision on the reconsidered application.

(j) The Department of General Services shall adopt regulations to implement this section, including those governing discovery.

(k) The fund is subrogated to any right or claim that any injured person may have who receives compensation pursuant to this section, or any right or claim that the person’s personal representative, legal guardian, estate, or survivor may have, against any third party who is liable for the personal injuries caused by the AIDS vaccine, and the fund shall be entitled to indemnity from that third party. The fund shall also be entitled to a lien on the judgment, award, or settlement in the amount of any payments made to the injured person.

(l) In the event that the injured person, or his or her guardian, personal representative, estate, or survivors, or any of them, bring an action for damages against the person or persons liable for the injury or death giving rise to an award by the Department of General Services under this section, notice of institution of legal proceedings and notice of any settlement shall be given to the Department of General Services in Sacramento except in cases where the Department of General Services specifies that notice shall be given to the Attorney General. All notices shall be given by the attorney employed to bring the action for damages or by the injured person, or his or her guardian, personal representative, estate, or survivors, if no attorney is employed.

(m) This section is not intended to affect the right of any individual to pursue claims against the fund and lawsuits against manufacturers concurrently, except that the fund shall be entitled to a lien on the judgment, award, or settlement in the amount of any payments made to the injured party by the fund.

(n) There is hereby created the AIDS Vaccine Injury Compensation Policy Review Task Force consisting of 14 members. The task force shall be composed of 10 members appointed by the Governor, of which two shall be from a list provided by the California Trial Lawyers Association, one from the department, the Director of Finance, one unspecified member, and one attorney with experience and expertise in products liability and negligence defense work, two representing recognized groups that represent victims of vaccine induced injuries or AIDS victims, or both, and two representing manufacturers actively engaged in developing an AIDS vaccine. In addition four Members of the Legislature or their designees shall be appointed to the task force, two of which shall be appointed by the Speaker of the Assembly and two of which shall be appointed by the Senate Committee on Rules. The chairperson of the task force shall be appointed by the Governor from the membership of the task force. The task force shall study and make recommendations on the legislative implementation of the fund created by subdivision (a). These recommendations shall at least address the following issues:

(1) The process by which victims are to be compensated through the fund.

(2) The procedures by which the fund will operate and the governance of the fund.

(3) The method by which manufacturers are to pay into the fund and the amount of that payment.

(4) The procedural relationship between a potential victim’s claim through the fund and a court claim made against the manufacturer.

(5) Other issues deemed appropriate by the task force.

The task force shall make its recommendations to the Legislature on or before June 30, 1987.

(o) The fund shall be funded wholly by a surcharge on the sale of an AIDS vaccine, that has been approved by the FDA, or by the department pursuant to Part 5 (commencing with Section 109875) of Division 104, in California in an amount to be determined by the department. The surcharge shall be levied on the sale of each unit of the vaccine sold or delivered, administered, or dispensed in California. The appropriate amount of the surcharge shall be studied by the AIDS Vaccine Injury Compensation Policy Review Task Force, which shall recommend the appropriate amount as part of its report, with the amount of the surcharge not to exceed ten dollars ($10) per unit of vaccine. Expenditures of the task force shall be made at the discretion of the Director of Finance or the director’s designee.

(p) For purposes of this section, claims against the fund are contingent upon the existing resources of the fund as provided in subdivision (o), and in no case shall the state be liable for any claims in excess of the resources in the fund.

(Amended by Stats. 2016, Ch. 31, Sec. 175. (SB 836) Effective June 27, 2016.)

121275. (a) Because the development of a vaccine now costs somewhere between twenty million dollars ($20,000,000) and forty million dollars ($40,000,000), and because the last vaccine produced and marketed did not sell well, vaccine manufacturers are hesitant to proceed to invest their resources in a risky venture. It is, therefore, in the public health interest of California to assure that manufacturers proceed to develop this vaccine and protect Californians against this dread disease and protect the State of California against the enormous fiscal costs of treatment for persons getting AIDS. It is a sound and worthwhile investment to provide a guarantee of a market to lessen the risk of loss and assure the development of an AIDS vaccine.

It is anticipated that this AIDS vaccine will consist of a three-unit series. The State of California is willing to guarantee that at least 175,000 persons will be vaccinated, and to guarantee the purchase, within three years after the FDA or the department pursuant to Part 5 (commencing with Section 109875) of Division 104 approves marketing of an AIDS vaccine, of at least 500,000 units, at a cost of no more than twenty dollars ($20) per dosage, by all companies, anywhere in the United States.

Therefore, the State of California, by moneys to be appropriated later through the Budget Act, commits itself to purchasing, at the end of three years after the FDA or the department pursuant to Part 5 (commencing with Section 109875) of Division 104 has approved the marketing on a competitive basis, at not more than twenty dollars ($20) per dosage, the difference between 500,000 units and the actual amount sold, delivered, administered, or dispensed by all companies throughout the United States, including units sold to or reimbursed by Medi-Cal, Medicare, or other public programs, providing that fewer than 500,000 units are sold, delivered, administered, or dispensed.

(b) The AIDS Vaccine Guaranteed Purchase Fund is hereby established and shall be administered by the department, which may develop necessary regulations to carry out the purpose of this section.

(c) The department may carry out this section, when those funds are appropriated through the State Budget. In determining which vaccine shall be purchased by the state from among those manufacturers selling or distributing in California, an AIDS vaccine approved by the FDA or the department pursuant to Part 5 (commencing with Section 109875) of Division 104, the department shall take into consideration at least all of the following factors:

(1) The length of time each AIDS vaccine has been in the marketplace in California.

(2) Each AIDS vaccine's history of efficacy since approval by the FDA or the department.

(3) Each AIDS vaccine's history of side effects experienced by previous recipients of the vaccine.

(4) The relative cost of each competing manufacturer's AIDS vaccine.

(Amended by Stats. 2006, Ch. 538, Sec. 443. Effective January 1, 2007.)

121280. (a) In enacting this section the Legislature finds and declares:

(1) It is in the interest of the people of California to develop a vaccine that will prevent the infection of HIV, the agent that causes AIDS.

(2) In order to develop that vaccine, a prototype vaccine must be first given to HIV-negative people to determine the following:

(A) The vaccine's toxicity.

(B) The vaccine's efficacy.

(C) The human immune response to the vaccine.

(3) These studies are currently impossible because vaccine manufacturers fear that, by inoculating HIV-negative individuals with an experimental vaccine, they will elicit a positive immune response as measured by an enzyme linked immunosorbent assay (ELISA), western blot or other federal Food and Drug Administration approved in vitro diagnostic test, thereby placing vaccine volunteers at risk for denial of health or life insurance by insurance carriers as a consequence of their participation.

(4) Insurers need a reliable mechanism by which they can verify the insurability of a vaccine trial participant.

(b) No health care service plan, disability insurer, nonprofit hospital service plan, self-insured employee welfare benefit plan, or life insurer may withhold any settlement or coverage of an individual solely because of his or her participation in an AIDS/HIV vaccine clinical trial studied under an investigational new drug application effective pursuant to Section 312 of Title 21 of the Code of Federal Regulations, or Section 111595.

(c) The sponsor of any such trial shall make a confidential certificate with all the necessary particulars, which shall be determined by the department, for each enrollee and then submit it to the department, which shall endorse it and return it to the vaccine recipient. A copy of this confidential certificate shall be kept on file indefinitely by both the study sponsor and the department.

(d) Release of a confidential certificate shall be by written authorization of the enrollee named in the certificate. If the enrollee is unable to provide the written authorization, a person designated in the certificate by the enrollee may provide the written authorization. The written authorization shall include the name of the person or entity to whom the disclosure would be made.

Disclosure as used in this section means to release, transfer, disseminate or otherwise communicate all or part of any confidential certificate orally, in writing, or by electronic means to any person or entity.

(Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.)

121281. In order to assist pharmacists and pharmacy personnel in the education of consumers who are at risk of bloodborne infections regarding methods and opportunities for improving and protecting their health, and thereby protect the public health, the Office of AIDS shall develop and maintain all of the following information, on its Internet Web site, and the California State Board of Pharmacy shall also post, or maintain a link to, the information on its Internet Web site:

(a) How consumers can access testing and treatment for HIV and viral hepatitis.

(b) How consumers can safely dispose of syringes and hypodermic needles or other sharps waste.

(c) How consumers can access drug treatment.

(Added by Stats. 2011, Ch. 738, Sec. 12. (SB 41) Effective January 1, 2012.)