Assembly Bill No. 1487

Passed the Assembly August 26, 2010

Chief Clerk of the Assembly

Passed the Senate August 12, 2010

Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2010, at _____ o'clock ___M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 1635, 1644, and 1644.5 of the Health and Safety Code, relating to tissue donation, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 1487, Hill. Tissue donation.

Existing law prohibits the transfer of any tissues, as defined, into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), human T lymphotrophic virus-1 (HTLV-1), and syphilis, except as provided.

This bill would require testing for evidence of infection with HTLV only in tissues that are rich in viable leukocytes.

Existing law requires that all donors of sperm be screened and found nonreactive under the above provisions, except as provided. Under existing law, a sperm donor who has tested reactive for HIV or HTLV-1 may be used for insemination or advanced reproductive technology for a recipient who has tested negative only after processing to minimize the infectiousness of the sperm. The State Department of Public Health is required to adopt regulations by January 1, 2010, regulating facilities that perform this processing.

Existing law further requires the physician providing insemination or advanced reproductive technologies to, among other things, inform the recipient that the processing may not eliminate the risk of infection, that the sperm may be tested to ensure that it is free from HIV or HTLV-1, and about the potential adverse effects of testing on the sperm.

This bill would extend until January 1, 2014, the date for adopting regulations and would allow the department to adopt initial regulations based on the "Guidelines for Reducing Risk of Viral Transmission During Fertility Treatment" using a specified process. The bill would also require the physician to inform the recipient that she must provide documentation to the physician providing insemination or advanced reproductive technology services prior to treatment that she has established an ongoing

physician relationship with another physician to provide for her medical care during and after completion of fertility services and about the medical guidelines for testing after use of sperm from an HIV or HTLV reactive spouse, partner, or designated donor.

Under existing law, the physician performing insemination or advanced reproductive technology is required to provide prophylactic treatments, followup testing, and monitoring, as specified, to the recipient to minimize the risk of infection.

This bill would remove those requirements but would require the physician to recommend followup testing of the recipient for HIV and HTLV, as specified.

Existing law allows the use of sperm from a donor who has tested reactive for HIV or HTLV-1 if the recipient has also previously been documented with HIV or HTLV-1 and where mutual consent has been obtained.

This bill would remove this provision. The bill would also make all of the provisions above applicable to donors who have tested reactive for any of the human T lymphotrophic viruses.

This bill would declare that it is to take effect immediately as an urgency statute.

The people of the State of California do enact as follows:

SECTION 1. Section 1635 of the Health and Safety Code is amended to read:

1635. (a) "Donor" means an individual, living or deceased, from whom tissue is removed.

(b) "Person" means an individual, corporation, business trust, estate trust, partnership, association, state or local government, or subdivision or agency thereof, or any other legal entity.

(c) "Tissue" means a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body.

(d) "Tissue bank" means a place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings.

(e) "Transplantation" means the act or process of transferring tissue, including by ingestion, from a donor to the body of the donor or another human being.

(f) "Department" means the State Department of Public Health.

SEC. 2. Section 1644 of the Health and Safety Code is amended to read:

1644. (a) For purposes of this chapter, "donor," "person," "tissue," "transplantation," and "department" shall have the meaning as defined for those terms in Section 1635.

(b) For purposes of this chapter, "HIV" shall mean human immunodeficiency virus.

SEC. 3. Section 1644.5 of the Health and Safety Code is amended to read:

1644.5. (a) Except as provided in subdivision (c) or (d), no tissues shall be transferred into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive by laboratory tests for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), and syphilis. For tissues that are rich in viable leukocytes, the tissue shall be tested for evidence of infection with human T lymphotrophic virus (HTLV) and found nonreactive. The department may adopt regulations requiring additional screening tests of donors of tissues when, in the opinion of the department, the action is necessary for the protection of the public, donors, or recipients.

(b) Notwithstanding subdivision (a), infectious disease screening of blood and blood products shall be carried out solely in accordance with Article 2 (commencing with Section 1602.5) of Chapter 4.

(c) All donors of sperm shall be screened and found nonreactive as required under subdivision (a), except in the following instances:

(1) A recipient of sperm, from a sperm donor known to the recipient, may waive a second or other repeat testing of that donor if the recipient is informed of the requirements for testing donors under this section and signs a written waiver.

(2) A recipient of sperm may consent to therapeutic insemination of sperm or use of sperm in other advanced reproductive technologies even if the sperm donor is found reactive for hepatitis B, hepatitis C, syphilis, HIV or HTLV if the sperm donor is the spouse of, partner of, or designated donor for that recipient. The physician providing insemination or advanced reproductive technology services shall advise the donor and recipient of the potential medical risks associated with receiving sperm from a

reactive donor. The donor and the recipient shall sign a document affirming that each comprehends the potential medical risks of using sperm from a reactive donor for the proposed procedure and that each consents to it. Copies of the document shall be placed in the medical records of the donor and the recipient.

(3) (A) Sperm whose donor has tested reactive for syphilis may be used for the purposes of insemination or advanced reproductive technology only after the donor has been treated for syphilis. Sperm whose donor has tested reactive for hepatitis B may be used for the purposes of insemination or advanced reproductive technology only after the recipient has been vaccinated against hepatitis B.

(B) (i) Sperm whose donor has tested reactive for HIV or HTLV may be used for the purposes of insemination or advanced reproductive technology for a recipient testing negative for HIV or HTLV only after the donor's sperm has been effectively processed to minimize the infectiousness of the sperm for that specific donation and where informed and mutual consent has occurred.

(ii) Not later than January 1, 2014, the department shall adopt regulations regulating facilities that perform sperm processing, pursuant to this subparagraph, that prescribe standards for the handling and storage of sperm samples of carriers of HIV, HTLV, or any other virus as deemed appropriate by the department. The department may propose to adopt, as initial regulations, the recommendations made within the "Guidelines for Reducing Risk of Viral Transmission During Fertility Treatment" as published by the American Society for Reproductive Medicine. Notice of the department's proposed adoption of the regulations shall be posted on the department's Internet Web site for at least 45 days. Public comment shall be accepted by the department for at least 30 days after the conclusion of the 45-day posting period. If a member of the public requests a public hearing during the 30-day comment period, the hearing shall be held prior to the adoption of the regulations. If no member of the public requests a public hearing, the regulations shall be deemed adopted at the conclusion of the 30-day comment period. Comments received shall be considered prior to the adoption of the final initial regulations. The department may modify any guidance published by the American Society for Reproductive Medicine. Adoption of initial regulations by the department pursuant to this subdivision shall not be subject

to the rulemaking requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code and written responses to public comments shall not be required. Updates to the regulations shall be adopted pursuant to the same process. Until the department adopts these regulations, facilities that perform sperm processing pursuant to this section shall follow facility and sperm processing guidelines for the reduction of viral transmission developed by the American Society for Reproductive Medicine. Nothing in this section shall prevent the department from monitoring and inspecting facilities that process sperm to ensure adherence to the regulations, or, until regulations are adopted, to the guidelines set forth by the American Society for Reproductive Medicine.

(iii) Prior to insemination or other advanced reproductive technology services, the physician providing the services shall inform the recipient of sperm from a spouse, partner, or designated donor who has tested reactive for HIV or HTLV of all of the following:

(I) That sperm processing may not eliminate all of the risks of HIV or HTLV transmission.

(II) That the sperm may be tested to determine whether or not it is reactive for HIV or HTLV.

(III) That the recipient must provide documentation to the physician providing insemination or advanced reproductive technology services prior to treatment that she has established an ongoing relationship with another physician to provide for her medical care during and after completion of fertility services.

(IV) The recommendations made within the "Guidelines for Reducing the Risk of Viral Transmission During Fertility Treatment" published by the American Society for Reproductive Medicine regarding followup testing for HIV and HTLV after use of sperm from an HIV or HTLV reactive donor and have the recommendations regarding followup testing be documented in the recipient's medical record.

(iv) The physician providing insemination or advanced reproductive technology services shall also verify, and document in the recipient's medical record, that the donor of sperm who tests reactive for HIV or HTLV is under the care of a physician managing the HIV or HTLV.

(v) The physician providing insemination or advanced reproductive technology services shall recommend to the physician who will be providing ongoing care to the recipient recommended followup testing for HIV and HTLV according to the "Guidelines for Reducing the Risk of Viral Transmission During Fertility Treatment" published by the American Society for Reproductive Medicine, which shall be documented in the recipient's medical record.

(vi) In the event that the recipient becomes HIV or HTLV positive, the physician assuming ongoing care of the recipient shall treat or provide information regarding referral to a physician who can provide ongoing treatment of the HIV or HTLV.

(4) The penalties of Section 1621.5 shall not apply to a sperm donor covered under this subdivision.

(d) Subdivision (a) shall not apply to the transplantation of tissue from a donor who has not been tested or, with the exception of HIV and HTLV, has been found reactive for the infectious diseases listed in subdivision (a) or for which the department has, by regulation, required additional screening tests, if both of the following conditions are satisfied:

(1) The physician and surgeon performing the transplantation has determined any one or more of the following:

(A) Without the transplantation the intended recipient will most likely die during the period of time necessary to obtain other tissue or to conduct the required tests.

(B) The intended recipient already is diagnosed with the infectious disease for which the donor has tested positive.

(C) The symptoms from the infectious disease for which the donor has tested positive will most likely not appear during the intended recipient's likely lifespan after transplantation with the tissue or may be treated prophylactically if they do appear.

(2) Consent for the use of the tissue has been obtained from the recipient, if possible, or if not possible, from a member of the recipient's family, or the recipient's legal guardian. For purposes of this section, "family" shall mean spouse, adult son or daughter, either parent, adult brother or sister, or grandparent.

(e) Human breast milk from donors who test reactive for agents of viral hepatitis (HBV and HCV), HTLV, HIV, or syphilis shall not be used for deposit into a milk bank for human ingestion in California.

SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

To help prevent the spread of HIV, at the earliest possible time, it is necessary that this legislation take immediate effect.

Approved _____, 2010

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Governor