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CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 1487

Introduced by Assembly Member Hill
(Coauthor: Senator Leno)

February 27, 2009

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, as amended, 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 lymphotropic 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 lymphotropic viruses.

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

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

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

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

3 1635. (a) “Donor” means an individual, living or deceased,
4 from whom tissue is removed.

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

8 (c) “Tissue” means a human cell, group of cells, ~~tissue or organ~~
9 including the cornea, sclera, or vitreous humor and other segments
10 of, or the whole eye, bones, skin, arteries, sperm, blood, other
11 fluids, and any other portion of a human body.

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

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

18 (f) “Department” means the State Department of Public Health.

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

21 1644. (a) For purposes of this chapter, “donor,” “person,”
22 “tissue,” “transplantation,” and “department” shall have the
23 meaning as defined for those terms in Section 1635.

24 (b) For purposes of this chapter, “HIV” shall mean human
25 immunodeficiency virus.

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

28 1644.5. (a) ~~No tissues—~~*Except as provided in subdivision (c)*
29 *or (d), no tissues* shall be transferred into the body of another
30 person by means of transplantation, unless the donor of the tissues
31 has been screened and found nonreactive by laboratory tests for
32 evidence of infection with human immunodeficiency virus (HIV),
33 agents of viral hepatitis (HBV and HCV), ~~human T-lymphotrophic~~
34 ~~virus (HTLV), and syphilis, except as provided in subdivision (e).~~
35 *syphilis. For tissues that are rich in viable leukocytes, the tissue*
36 *shall be tested for evidence of infection with human T*
37 *lymphotrophic virus (HTLV) and found nonreactive. The*
38 department may adopt regulations requiring additional screening

1 tests of donors of tissues when, in the opinion of the department,
2 the action is necessary for the protection of the public, donors, or
3 recipients.

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

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

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

14 (2) A recipient of sperm may consent to therapeutic insemination
15 of sperm or use of sperm in other advanced reproductive
16 technologies even if the sperm donor is found reactive for hepatitis
17 B, hepatitis C, syphilis, HIV or HTLV if the sperm donor is the
18 spouse of, partner of, or designated donor for that recipient. The
19 physician providing insemination or advanced reproductive
20 technology services shall advise the donor and recipient of the
21 potential medical risks associated with receiving sperm from a
22 reactive donor. The donor and the recipient shall sign a document
23 affirming that each comprehends the potential medical risks of
24 using sperm from a reactive donor for the proposed procedure and
25 that each consents to it. Copies of the document shall be placed in
26 the medical records of the donor and the recipient.

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

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

1 (ii) Not later than January 1, 2014, the department shall adopt
2 regulations regulating facilities that perform sperm processing,
3 pursuant to this subparagraph, that prescribe standards for the
4 handling and storage of sperm samples of carriers of HIV, HTLV,
5 or any other virus as deemed appropriate by the department. The
6 department may propose to adopt, as initial regulations, the
7 recommendations made within the “Guidelines for Reducing Risk
8 of Viral Transmission During Fertility Treatment” as published
9 by the American Society for Reproductive Medicine. Notice of
10 the department’s proposed adoption of the regulations shall be
11 posted on the department’s Internet Web site for at least 45 days.
12 Public comment shall be accepted by the department for at least
13 30 days after the conclusion of the 45-day posting period. If a
14 member of the public requests a public hearing during the 30-day
15 comment period, the hearing shall be held prior to the adoption of
16 the regulations. If no member of the public requests a public
17 hearing, the regulations shall be deemed adopted at the conclusion
18 of the 30-day comment period. Comments received shall be
19 considered prior to the adoption of the final initial regulations. The
20 department may modify any guidance published by the American
21 Society for Reproductive Medicine. Adoption of initial regulations
22 by the department pursuant to this subdivision shall not be subject
23 to the rulemaking requirements of Chapter 3.5 (commencing with
24 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
25 Code and written responses to public comments shall not be
26 required. Updates to the regulations shall be adopted pursuant to
27 the same process. Until the department adopts these regulations,
28 facilities that perform sperm processing pursuant to this section
29 shall follow facility and sperm processing guidelines for the
30 reduction of viral transmission developed by the American Society
31 for Reproductive Medicine. Nothing in this section shall prevent
32 the department from monitoring and inspecting facilities that
33 process sperm to ensure adherence to the regulations, or, until
34 regulations are adopted, to the guidelines set forth by the American
35 Society for Reproductive Medicine.

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

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

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

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

10 (IV) The recommendations made within the “Guidelines for
11 Reducing the Risk of Viral Transmission During Fertility
12 Treatment” published by the American Society for Reproductive
13 Medicine regarding followup testing for HIV and HTLV after use
14 of sperm from an HIV or HTLV reactive donor and have the
15 recommendations regarding followup testing be documented in
16 the recipient’s medical record.

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

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

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

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

36 (d) Subdivision (a) shall not apply to the transplantation of tissue
37 from a donor who has not been tested or, with the exception of
38 HIV and HTLV, has been found reactive for the infectious diseases
39 listed in subdivision (a) or for which the department has, by

1 regulation, required additional screening tests, if both of the
2 following conditions are satisfied:

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

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

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

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

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

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

23 ~~SEC. 2.~~

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

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