Senate Bill No. 443

Passed the Senate August 27, 2007

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Secretary of the Senate

Passed the Assembly July 12, 2007

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Chief Clerk of the Assembly

This bill was received by the Governor this _____ day of _____, 2007, at _____ o'clock ___M.

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Private Secretary of the Governor

CHAPTER _____

An act to amend Section 1644.5 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 443, Migden. Tissue donors: sperm donors.

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 HIV, agents of viral hepatitis (HBV and HCV), human T lymphotrophic virus-1 (HTLV-1), and syphilis.

Existing law provides an exception to this prohibition for therapeutic insemination of sperm or use of sperm in other advanced reproductive technologies if the sperm donor is found reactive for hepatitis B, hepatitis C, or syphilis if the sperm donor is the spouse of, partner of, or designated donor for that recipient.

This bill would expand the exception to that prohibition for therapeutic insemination of sperm or use of sperm in other advanced reproductive technologies if the sperm donor is found reactive for HIV or HTLV-1.

The bill would authorize the use of sperm whose donor has tested reactive for HIV or HTLV-1 for the purposes of insemination or advanced reproductive technology 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. The bill would require the State Department of Public Health to adopt regulations by January 1, 2010, regulating facilities that perform sperm processing pursuant to those provisions.

The bill would require a physician providing insemination or advanced reproductive technologies to, among other things, provide, as appropriate, prophylactic treatments, including, but not limited to, antiretroviral treatments, to the recipient to reduce the risk of acquiring infection during and subsequent to insemination, and to perform appropriate followup testing of the

recipient for HIV or HTLV-1 following the insemination or other advanced reproductive technology.

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

SECTION 1. Section 1644.5 of the Health and Safety Code is amended to read:

1644.5. (a) 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 HIV, agents of viral hepatitis (HBV and HCV), human T lymphotrophic virus-1 (HTLV-1), and syphilis, except as provided in subdivision (c). 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 1601) 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-1 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 medical repercussions 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-1 may be used for the purposes of insemination or advanced reproductive technology for a recipient testing negative for HIV or HTLV-1 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) The department shall adopt regulations by January 1, 2010, 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-1, or any other virus as deemed appropriate by the department. Until the department adopts these regulations, facilities that perform sperm processing shall follow facility and sperm processing guidelines developed by the American Society of Reproductive Medicine.

(iii) Prior to insemination or other advanced reproductive technology services, the physician shall inform the recipient of sperm from a donor who has tested reactive for HIV or HTLV-1 that sperm processing may not eliminate all risks of HIV or HTLV-1 transmission, and that the sperm may be tested to determine whether or not it is free of HIV or HTLV-1. The physician shall also inform the recipient of potential adverse effects the testing may have on the processed sperm.

(iv) The physician providing insemination or advanced reproductive technology services shall provide, as appropriate, prophylactic treatments, including, but not limited to, antiretroviral treatments, to the recipient to reduce the risk of acquiring infection during, and subsequent to, insemination or advanced reproductive technology. The physician shall also treat, as appropriate, the donor of sperm that tests reactive for HIV or HTLV-1 with antiretroviral treatments prior to insemination or advanced reproductive technology services. The physician shall perform appropriate followup testing of the recipient for HIV or HTLV-1 following the insemination or other advanced reproductive technology, and

recommend ongoing monitoring by a physician during treatment and pregnancy. The physician shall also recommend in the sperm recipient's medical record that the recipient be monitored during treatment and pregnancy.

(v) In the event that the recipient tests reactive for HIV or HTLV-1 following insemination or other advanced reproductive technology, the physician shall inform the recipient of appropriate treatments during and after pregnancy, and of treatments or procedures that may reduce the risk of transmission to the offspring.

(vi) Sperm whose donor has tested reactive for HIV or HTLV-1 may be used for the purposes of insemination or advanced reproductive technology if the recipient already has been previously documented with HIV or HTLV-1 infection, and where informed and mutual consent has occurred.

(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-1, 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), human T lymphotrophic virus-1 (HTLV-1), HIV, or syphilis shall not be used for deposit into a milk bank for human ingestion in California.

Approved _____, 2007

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Governor