110TH CONGRESS
1ST SESSION

S. 1479

To improve the oversight and regulation of tissue banks and the tissue donation process, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 24, 2007

Mr. SCHUMER (for himself and Mr. LEAHY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To improve the oversight and regulation of tissue banks and the tissue donation process, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safe Tissue Act''.

SEC. 2. DEFINITIONS.

In this Act:

(1) ESTABLISHMENT.—The term ''establishment'' has the meaning given such term in section 1271.3 of title 21, Code of Federal Regulations (or any successor regulation).

(2) HUMAN CELLS, TISSUES, OR CELLULAR OR TISSUE-BASED PRODUCTS.—The term ''human cells, tissues, or cellular or tissue-based products'' has the meaning given such term in section 1271.3 of title 21, Code of Federal Regulations (or any successor regulation).

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 3. INSPECTIONS AND AUDITS BY THE FOOD AND DRUG ADMINISTRATION.

(a) INSPECTIONS OF TISSUE BANKS.—

(1) IN GENERAL.—Notwithstanding section 1271.400(b) of title 21, Code of Federal Regulations, the Food and Drug Administration shall inspect each establishment regulated by such section not less than once every 2 years.

(2) USER FEES.—The Secretary may establish a user fee program applicable to each establishment under part 1271 of title 21, Code of Federal Regulations, to fund the inspections required by paragraph (1).

(b) AUDITS OF TISSUE BANKS.—The Food and Drug Administration shall conduct periodic audits of all documentation submitted by each establishment under part 1271 of title 21, Code of Federal Regulations, to deter-

mine compliance with all applicable requirements, including those requirements related to ensuring—

(1) that human cells, tissues, or cellular or tissue-based products are obtained by the establishment legally;

(2) that donor eligibility and donor medical history interviews are based on accurate information that was not provided or obtained in a fraudulent manner; and

(3) current good tissue practice.

SEC. 4. DEVELOPMENT OF MODEL CONSENT FORM.

(a) IN GENERAL.—The Secretary shall publish in the Federal Register a model form containing minimum requirements for establishments to use in obtaining consent from a potential donor, or the legally authorized representative of a potential donor, of human cells, tissues, or cellular or tissue-based products.

(b) CONTENT.—The model form under subsection (a) shall include—

(1) requirements for obtaining consent from a potential donor, or the legally authorized representative of a potential donor, regarding—

(A) the type of human cells, tissues, or cellular or tissue-based product to be donated;

(B) the purpose for which such human cells, tissues, or cellular or tissue-based products shall be used, such as transplantation for medical purposes, transplantation for cosmetic purposes, therapy, research, or medical education; and

(C) other matters as determined appropriate by the Secretary;

(2) a requirement that an establishment provide assurance to the Secretary and a potential donor, or the legally authorized representative of a potential donor, that such an establishment will only obtain consent directly from such donor or representative; and

(3) a requirement that an establishment—

(A) provide, upon request, to the potential donor, or the legally authorized representative of a potential donor, a description of the recovery process for human cells, tissues, or cellular or tissue-based products;

(B) inform such donor or representative of the right to receive such a description; and

(C) inform such donor or representative of whether the establishment is accredited under

the regulations promulgated by the Secretary pursuant to section 5.

(c) USE OF MODEL FORM.—The Secretary shall promulgate regulations requiring that establishments provide and obtain no less information than that specified in the model form under subsection (a) prior to accepting a donation of human cells, tissues, or cellular or tissue-based products.

(d) ENFORCEMENT.—

(1) FAILURE TO COMPLY WITH REQUIREMENTS.—An establishment, or an individual employed by an establishment, that fails to comply with the requirements of the model form under subsection (a) shall be subject to a civil penalty of not more than $5,000.

(2) USE OF FRAUDULENT INFORMATION.—An establishment, or an individual employed by an establishment, that knowingly uses fraudulent information for, or fraudulent means of, obtaining the consent described under the model form under subsection (a) shall be—

(A) fined not more than $10,000, or imprisoned for not more than 6 months, or both, for the first such violation; and

(B) fined not more than $250,000, or imprisoned for not more than 10 years, or both, for the second and any subsequent such violation.

(e) PREEMPTION.—The model form regulations promulgated under subsection (c) shall supercede any provisions of the law with respect to obtaining consent from a potential donor, or legally authorized representative of a potential donor, of human cells, tissues, or cellular or tissue-based products, of the State in which an establishment operates to the extent such law is less stringent than the requirements imposed under such subsection.

SEC. 5. ACCREDITATION OF ESTABLISHMENTS AND PERSONNEL.

(a) IN GENERAL.—The Secretary shall promulgate regulations to accredit—

(1) establishments; and

(2) the personnel of establishments who participate in the recovery, processing, storage, labeling, packaging, or distribution of human cells, tissues, or cellular or tissue-based products.

(b) AUTHORITY OF SECRETARY.—In promulgating the regulations under subsection (a), the Secretary shall—

(1) establish an accreditation process modeled after the Joint Commission on Accreditation of Healthcare Organizations; or

(2) adopt an accreditation process established by a private entity that is in effect as of the date of enactment of this Act.

SEC. 6. DETERMINATION OF REASONABLE PAYMENTS.

The Secretary shall promulgate regulations defining ''reasonable payments'' for the purposes of section 301(c)(2) of the National Organ Transplant Act (42 U.S.C. 274e(c)(2)), as such section relates to human tissue and tissue-based products regulated under part 1271 of title 21, United States Code.

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