

109TH CONGRESS
2D SESSION

S. _____

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

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe Tissue Act”.

5 **SEC. 2. DEFINITIONS.**

6 In this Act:

7 (1) ESTABLISHMENT.—The term “establish-
8 ment” has the meaning given such term in section
9 1271.3 of title 21, Code of Federal Regulations (or
10 any successor regulation).

1 (2) HUMAN CELLS, TISSUES, OR CELLULAR OR
2 TISSUE-BASED PRODUCTS.—The term “human cells,
3 tissues, or cellular or tissue-based products” has the
4 meaning given such term is section 1271.3 of title
5 21, Code of Federal Regulations (or any successor
6 regulation).

7 (3) SECRETARY.—The term “Secretary” means
8 the Secretary of Health and Human Services.

9 **SEC. 3. INSPECTIONS AND AUDITS BY THE FOOD AND DRUG**
10 **ADMINISTRATION.**

11 (a) INSPECTIONS OF TISSUE BANKS.—

12 (1) IN GENERAL.—Notwithstanding section
13 1271.400(b) of title 21, Code of Federal Regula-
14 tions, the Food and Drug Administration shall in-
15 spect each establishment regulated by such section
16 not less than once every 2 years.

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

22 (b) AUDITS OF TISSUE BANKS.—The Food and Drug
23 Administration shall conduct periodic audits of all docu-
24 mentation submitted by each establishment under part
25 1271 of title 21, Code of Federal Regulations, to deter-

1 mine compliance with all applicable requirements, includ-
2 ing those requirements related to ensuring—

3 (1) that human cells, tissues, or cellular or tis-
4 sue-based products are obtained by the establish-
5 ment legally;

6 (2) that donor eligibility and donor medical his-
7 tory interviews are based on accurate information
8 that was not provided or obtained in a fraudulent
9 manner; and

10 (3) current good tissue practice.

11 **SEC. 4. DEVELOPMENT OF MODEL CONSENT FORM.**

12 (a) IN GENERAL.—The Secretary shall publish in the
13 Federal Register a model form containing minimum re-
14 quirements for establishments to use in obtaining consent
15 from a potential donor, or the legally authorized represent-
16 ative of a potential donor, of human cells, tissues, or cel-
17 lular or tissue-based products.

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

20 (1) requirements for obtaining consent from a
21 potential donor, or the legally authorized representa-
22 tive of a potential donor, regarding—

23 (A) the type of human cells, tissues, or cel-
24 lular or tissue-based product to be donated;

1 (B) the purpose for which such human
2 cells, tissues, or cellular or tissue-based prod-
3 ucts shall be used, such as transplantation for
4 medical purposes, transplantation for cosmetic
5 purposes, therapy, research, or medical edu-
6 cation; and

7 (C) other matters as determined appro-
8 priate by the Secretary;

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

15 (3) a requirement that an establishment—

16 (A) provide, upon request, to the potential
17 donor, or the legally authorized representative
18 of a potential donor, a description of the recov-
19 ery process for human cells, tissues, or cellular
20 or tissue-based products;

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

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

1 the regulations promulgated by the Secretary
2 pursuant to section 5.

3 (c) USE OF MODEL FORM.—The Secretary shall pro-
4 mulgate regulations requiring that establishments provide
5 and obtain no less information than that specified in the
6 model form under subsection (a) prior to accepting a do-
7 nation of human cells, tissues, or cellular or tissue-based
8 products.

9 (d) ENFORCEMENT.—

10 (1) FAILURE TO COMPLY WITH REQUIRE-
11 MENTS.—An establishment, or an individual em-
12 ployed by an establishment, that fails to comply with
13 the requirements of the model form under subsection
14 (a) shall be subject to a civil penalty of not more
15 than \$5,000.

16 (2) USE OF FRAUDULENT INFORMATION.—An
17 establishment, or an individual employed by an es-
18 tablishment, that knowingly uses fraudulent infor-
19 mation for, or fraudulent means of, obtaining the
20 consent described under the model form under sub-
21 section (a) shall be—

22 (A) fined not more than \$10,000, or im-
23 prisoned for not more than 6 months, or both,
24 for the first such violation; and

1 (B) fined not more than \$250,000, or im-
2 prisoned for not more than 10 years, or both,
3 for the second and any subsequent such viola-
4 tion.

5 (e) PREEMPTION.—The model form regulations pro-
6 mulgated under subsection (c) shall supercede any provi-
7 sions of the law with respect to obtaining consent from
8 a potential donor, or legally authorized representative of
9 a potential donor, of human cells, tissues, or cellular or
10 tissue-based products, of the State in which an establish-
11 ment operates to the extent such law is less stringent than
12 the requirements imposed under such subsection.

13 **SEC. 5. ACCREDITATION OF ESTABLISHMENTS AND PER-**
14 **SONNEL.**

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

17 (1) establishments; and

18 (2) the personnel of establishments who partici-
19 pate in the recovery, processing, storage, labeling,
20 packaging, or distribution of human cells, tissues, or
21 cellular or tissue-based products.

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

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

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

7 **SEC. 6. DETERMINATION OF REASONABLE PAYMENTS.**

8 The Secretary shall promulgate regulations defining
9 “reasonable payments” for the purposes of section
10 301(c)(2) of the National Organ Transplant Act (42
11 U.S.C. 274e(c)(2)), as such section relates to human tis-
12 sue and tissue-based products regulated under part 1271
13 of title 21, United States Code.