

103^D CONGRESS
1ST SESSION

S. 1702

To amend the Federal Food, Drug, and Cosmetic Act to ensure that human tissue intended for transplantation is safe and effective, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 19 (legislative day, NOVEMBER 2), 1993

Mr. SIMON introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that human tissue intended for transplantation is safe and effective, 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 (a) SHORT TITLE.—This Act may be cited as the
5 “Human Tissue for Transplantation Act of 1993”.

6 (b) REFERENCE.—Whenever in this Act an amend-
7 ment or repeal is expressed in terms of an amendment
8 to, or repeal of, a section or other provision, the reference

1 shall be considered to be made to a section or other provi-
2 sion of the Federal Food, Drug, and Cosmetic Act.

3 **SEC. 2. FINDINGS.**

4 The Congress finds that reasonable assurance of the
5 safety and effectiveness of human tissue for transplan-
6 tation through regulatory oversight is necessary to protect
7 the public health against the transmission of infectious
8 disease or the conduct of medical therapy with human tis-
9 sue unfit for use.

10 **SEC. 3. DEFINITIONS.**

11 Section 201 (21 U.S.C. 321) is amended—

12 (1) in the first sentence of paragraph (g)(1)—

13 (A) by striking “; and (D), and inserting
14 “; (D)”;

15 (B) by inserting before the period “; and
16 (E) human tissue in combination with a drug
17 as described in clause (A), (B), (C), or (D)”;

18 (2) in paragraph (h), by striking “implant,”
19 and inserting “implant, human tissue (other than
20 banked human tissue),”;

21 (3) by adding at the end the following new
22 paragraph:

23 “(ff)(1) The term ‘tissue’ means an aggregate of cells
24 or their intercellular substance that form a structural ma-
25 terial.

1 “(2)(A) The term ‘banked human tissue’ means any
2 tissue—

3 “(i) derived from a human body that is in-
4 tended for administration to a human for the diag-
5 nosis, cure, mitigation, treatment, or prevention of
6 any condition or disease;

7 “(ii) procured, processed, stored, or distributed
8 by methods to prevent the transmission of infectious
9 disease and to preserve clinical usefulness; and

10 “(iii) not intended to change tissue structure or
11 functional characteristics.

12 “(B) Such term does not include—

13 “(i) whole organs, including hearts, kidneys, liv-
14 ers, lungs, pancreases, or any other organ containing
15 vasculature that carries blood after transplantation;

16 “(ii) blood, blood products, bone marrow, repro-
17 ductive tissue, or human milk; or

18 “(iii) autograft human tissue that is not stored
19 or processed during a single surgical procedure.

20 “(3) The term ‘human tissue bank’ means a person
21 that procures, processes, stores, or distributes banked
22 human tissue.”.

23 **SEC. 4. REGULATION OF HUMAN TISSUE BANKS.**

24 Chapter V is amended by adding at the end the fol-
25 lowing:

1 “SUBCHAPTER D—HUMAN TISSUE BANKS

2 “REGULATION OF HUMAN TISSUE BANKS

3 “SEC. 545. (a) PREVENTION OF DISEASE TRANS-
4 MISSION.—To prevent the transmission of infectious dis-
5 ease by the use of banked human tissue, the Secretary
6 may by regulation require—

7 “ (1) the screening of donors of tissue;

8 “ (2) the testing of donors of tissue and tissue
9 donated; and

10 “ (3) recordkeeping by human tissue banks, in-
11 cluding records that provide a method to track tis-
12 sue from a donor to a recipient and from a recipient
13 to a donor, taking into account the privacy interest
14 of donors, donor families, and recipients.

15 “ (b) GOOD TISSUE BANKING PRACTICES.—The Sec-
16 retary shall by regulation establish good tissue banking
17 practices, by human tissue banks, that may require—

18 “ (1) ascertainment of donor suitability;

19 “ (2) recovery of cadaveric or living donor tis-
20 sue;

21 “ (3) tissue screening and acceptance;

22 “ (4) validation of the manufacturing, equip-
23 ment, and facilities used for banked human tissue;

24 “ (5) finished tissue inspection and control;

25 “ (6) inspection for quality control;

1 “(7) investigation of failures involving banked
2 human tissue and files of complaints about such fail-
3 ures;

4 “(8) recordkeeping;

5 “(9) assurance of the quality of banked human
6 tissue;

7 “(10) personnel requirements, including a re-
8 quirement for a medical director who is a physician
9 licensed to practice medicine in the State in which
10 the bank is located; and

11 “(11) special practices for specific tissues.

12 “(c) LABELING, ADVERTISING, AND PROMOTION.—
13 The Secretary may by regulation prescribe requirements
14 for the labeling, advertising, and promotion of banked
15 human tissue by human tissue banks. Such requirements
16 shall include—

17 “(1) requirements for adequate direction for
18 use; and

19 “(2) information about results from the use of
20 banked human tissue according to directions or
21 under customary and usual conditions.

22 “(d) OPERATING PERMITS.—

23 “(1) IN GENERAL.—The Secretary shall by reg-
24 ulation require human tissue banks to acquire a per-

1 mit for operation. Such a permit may be acquired by
2 a human tissue bank if—

3 “(A) the human tissue bank has on file
4 with the Secretary an application for such per-
5 mit which demonstrates, through supporting
6 documentation, that the bank is in compliance
7 with the requirements of subsections (a), (b),
8 and (c);

9 “(B) the human tissue bank has on file
10 with the Secretary an application for an exemp-
11 tion from the requirements of subsection (a),
12 (b), or (c) and the Secretary has approved such
13 application based upon—

14 “(i) data from well controlled sci-
15 entific studies designed to provide reason-
16 able assurance that an exemption from
17 such requirements is safe and does not re-
18 duce clinical utility; or

19 “(ii) a determination by the Secretary,
20 after consultation with the Tissue Advisory
21 Committee under section 546, that such an
22 exemption does not affect the safety and
23 effectiveness of the operations of such
24 bank; or

1 “(C)(i) the human tissue bank has on file
2 with the Secretary an application for an exemp-
3 tion from the requirements of subsection (a),
4 (b), or (c) in order to conduct an investigation
5 of new or existing standards, methods, or uses
6 relating to tissue;

7 “(ii) such application is submitted with a
8 proposed scientific protocol for such investiga-
9 tion; and

10 “(iii) the Secretary has determined that
11 such investigation does not affect the safety and
12 effectiveness of the operations of such bank and
13 that patients of the bank will be protected by
14 a requirement of adequate informed consent.

15 “(2) PERMITS.—The Secretary shall issue an
16 operating permit to a human tissue bank if the Sec-
17 retary determines the bank meets the requirements
18 of paragraph (1). Such a permit shall identify the
19 tissues banked by the bank and the methods of pro-
20 curement, processing, storage, and distribution of
21 such tissue which the Secretary had determined to
22 be safe and effective. A permit shall be valid for
23 such period as specified by the Secretary but not for
24 more than 3 years.

1 committee shall be established within 1 year of the date
2 of the enactment of the Human Tissue for Transplan-
3 tation Act of 1993.

4 “(b) COMPOSITION.—The advisory committee shall
5 be comprised of not fewer than 13 or more than 19 indi-
6 viduals who are not officers or employees of the Federal
7 Government. The Secretary shall make appointments to
8 the advisory committee from among physicians, other
9 health care practitioners, and representatives of human
10 tissue bank consumers and industry groups whose clinical
11 practice, research specialization, or expertise include a sig-
12 nificant focus on tissue transplantation by human tissue
13 banks.

14 “(c) FUNCTIONS.—The advisory committee shall—

15 “(1) advise the Secretary on appropriate quality
16 standards and regulations for human tissue banks
17 under section 545;

18 “(2) report on new developments concerning tis-
19 sue transplantation;

20 “(3) advise the Secretary on appropriate stand-
21 ards for the prevention of infectious disease trans-
22 mission by banked human tissues;

23 “(4) advise the Secretary on appropriate quality
24 standards for good tissue banking practices under
25 section 545(b);

1 “(5) advise the Secretary in the development of
2 regulations to ensure that adequate directions for
3 use of banked human tissues are provided by human
4 tissue banks;

5 “(6) make recommendations in the establish-
6 ment of mechanisms to investigate consumer com-
7 plaints; and

8 “(7) perform such other activities as the Sec-
9 retary may require.

10 “(d) MEETINGS.—The advisory committee shall meet
11 not less often than quarterly during the first 3 years of
12 its operation.

13 “(e) CHAIRPERSON.—The Secretary shall appoint the
14 chairperson of the advisory committee from among mem-
15 bers of the advisory committee.”.

16 “(f) PERSONNEL MATTERS.—

17 “(1) MEMBERS.—

18 “(A) COMPENSATION.—Each member of
19 the advisory committee shall be compensated at
20 a rate equal to the daily equivalent of the an-
21 nual rate of basic pay prescribed for level IV of
22 the Executive Schedule under section 5315 of
23 title 5, United States Code, for each pay (in-
24 cluding travel time) during which such member

1 is engaged in the performance of the duties of
2 the advisory committee.

3 “(B) TRAVEL.—The members of the advi-
4 sory committee shall be allowed travel expenses,
5 including per diem in lieu of subsistence, at
6 rates authorized for employees of agencies
7 under subchapter I of chapter 57 of title 5,
8 United States Code, while away from their
9 homes or regular places of business in the per-
10 formance of services for the advisory committee.

11 “(2) OTHER PERSONNEL.—

12 “(A) IN GENERAL.—The Chairperson of
13 the advisory committee may, without regard to
14 the civil service laws and regulations, appoint
15 and terminate such other additional personnel
16 as may be necessary to enable the advisory
17 committee to perform its duties.

18 “(B) COMPENSATION.—The Chairperson
19 of the advisory committee may fix the com-
20 pensation of personnel described in subpara-
21 graph (A) without regard to provisions of chap-
22 ter 51 and subchapter III of chapter 53 of title
23 5, United States Code, relating to classification
24 of positions and General Schedule pay rates, ex-
25 cept that the rate of pay for such personnel

1 may not exceed the rate payable for level V of
2 the Executive Schedule under section 5316 of
3 such title.”.

4 **SEC. 5. ENFORCEMENT.**

5 (a) ADULTERATION.—Section 501 (21 U.S.C. 351)
6 is amended—

7 (1) in the matter preceding subsection (a), by
8 striking “drug” and inserting “drug, banked human
9 tissue,”;

10 (2) in subsection (a)(2)(B), by striking “drug”
11 each place such term appears and inserting “drug or
12 banked human tissue”;

13 (3) in subsection (d), by striking “drug” and
14 inserting “drug or banked human tissue”; and

15 (4) by adding at the end thereof the following
16 new subsection:

17 “(j)(1) If it is a banked human tissue and the mate-
18 rials, facilities, or controls used for its procurement, proc-
19 essing, storage, or distribution are not in conformity with
20 the requirements of section 545(b).

21 “(2) If it is a banked human tissue for which an ex-
22 emption has been granted under section 545(d)(1)(C) to
23 permit investigation use of human tissue and the person
24 granted such exemption or any investigator fails to comply
25 with the requirements of such section.”; and

1 (5) in the title of the section, by striking
2 “DRUGS” and inserting “DRUGS OR BANKED HUMAN
3 TISSUE”.

4 (b) MISBRANDING.—Section 502 (21 U.S.C. 352) is
5 amended—

6 (1) in paragraph (f), by striking “drug” each
7 place such term appears and inserting “drug,
8 banked human tissue,”;

9 (2) in the first sentence of paragraph (h), by
10 striking “drug” and inserting “drug or banked
11 human tissue”;

12 (3) in paragraph (i), by striking “drug” each
13 place such term appears and inserting “drug or
14 banked human tissue”;

15 (4) in paragraph (o) by striking “510(e)” and
16 inserting “510(e) or if an application or other infor-
17 mation respecting it was not provided as required by
18 section 545(d),”;

19 (5) by adding at the end the following new
20 paragraph:

21 “(u)(1) If it is banked human tissue subject to regu-
22 lation under section 545(c) unless it bears such labeling
23 as may be required.

1 “(2) If it is a banked human tissue distributed or
2 offered for sale in any State and its promotion or advertis-
3 ing is false or misleading in any particular.”; and

4 (6) in the title of the section, by striking
5 “DRUGS” and inserting “DRUGS, BANKED HUMAN
6 TISSUE,”.

7 (c) PROHIBITED ACTS.—Section 301 (21 U.S.C.
8 331) is amended—

9 (1) in paragraphs (a), (b), (c), (g), (h), (k), and
10 (l), by striking “drug,” each place such term ap-
11 pears and inserting “drug, banked human tissue,”;

12 (2) in paragraph (d), by striking “404 or 505”
13 and inserting “404, 505, or 545”;

14 (3) in paragraph (j), by striking “520,” and in-
15 sserting “520, 545,”;

16 (4) in paragraph (p), by striking “510,” and in-
17 sserting “510 or 545(e),”;

18 (5) in paragraphs (q)(2), by striking “device”
19 and inserting “device or banked human tissue”; and

20 (6) in paragraph (r), by striking “device” each
21 place such term appears and inserting “device or
22 banked human tissue”.

23 (d) PENALTIES.—Section 303(g) (21 U.S.C. 333(g))
24 is amended by striking “devices” and inserting “devices
25 or banked human tissues”.

1 (e) SEIZURES.—Section 304 (21 U.S.C. 334) is
2 amended—

3 (1) in subsections (a)(1) and (d)(1), by striking
4 “drug,” and inserting “drug, banked human tis-
5 sue,”;

6 (2) in subsection (a)(2), by striking “and (D)”
7 and inserting “(D) Any adulterated or misbranded
8 banked human tissue, and (E)”; and

9 (3) in subsection (g)(1)—

10 (A) by striking “or a vehicle, a device” and
11 inserting “or a vehicle, a device or banked
12 human tissue”; and

13 (B) by striking “device” each place such
14 term appears and inserting “device or banked
15 human tissue”.

16 (f) INVESTIGATIONS.—Section 702 (21 U.S.C. 372)
17 is amended—

18 (1) in subsection (b), by striking “drug,” and
19 inserting “drug, banked human tissue,”; and

20 (2) in subsection (d), by striking “drugs” and
21 inserting “drugs, or banked human tissues”.

22 (g) RECORDS OF INTERSTATE SHIPMENT.—Section
23 703 (21 U.S.C. 373) is amended—

1 (1) by striking “drugs,” each place such term
2 appears and inserting “drugs, banked human tis-
3 sues,”; and

4 (2) by striking “drug,” each place such term
5 appears and inserting “drug, banked human tis-
6 sue,”.

7 (h) INSPECTIONS.—Section 704 (21 U.S.C. 374) is
8 amended—

9 (1) in subsection (a)(1)(A), by striking
10 “drugs,” each place such term appears and inserting
11 “drugs, banked human tissues,”;

12 (2) in the first sentence after paragraph (1)(B)
13 of subsection (a), by striking “prescription drugs”
14 each place such term appears and inserting “pre-
15 scription drugs, banked human tissues,”; and

16 (3) in subsection (b), by striking “drug,” and
17 inserting “drug, banked human tissue,”.

18 (i) PUBLICITY.—Section 705(b) (21 U.S.C. 375(b))
19 is amended by striking “drugs,” and inserting “drugs,
20 banked human tissues,”.

21 (j) INTERSTATE COMMERCE PRESUMPTION.—Sec-
22 tion 709 (21 U.S.C. 379a) is amended by striking “de-
23 vice” and inserting “device or banked human tissue”.

24 (k) IMPORTS AND EXPORTS.—Section 801 (21 U.S.C.
25 381) is amended—

1 (1) in the first sentence of subsection (a), by
2 striking “drugs,” and inserting “drugs, banked
3 human tissues,”;

4 (2) in subsection (a)(3), by striking “505” and
5 inserting “505 or 545”; and

6 (3) in subsections (b) and (e)(1), by striking
7 “drug,” and inserting “drug, banked human tis-
8 sue,”.

9 **SEC. 6. FUNDING.**

10 (a) IMPOSITION.—

11 (1) IN GENERAL.—Each human tissue bank—

12 (A) that has a permit issued under section
13 545(d) of the Federal Food, Drug, and Cos-
14 metic Act shall pay a fee for such permit; and

15 (B) that is registered under section 545(e)
16 of such Act shall pay a fee for such registra-
17 tion.

18 (2) USE OF FEES.—The fees imposed under
19 this subsection are imposed to cover the costs of the
20 Secretary in the implementation of sections 545 and
21 546 of the Federal Food, Drug, and Cosmetic Act.

22 (b) FEE AMOUNT.—The Secretary of Health and
23 Human Services shall determine the amount of the fees
24 imposed by subsection (a) on the basis of the gross reve-
25 nue of the human tissue bank paying the fee that relates

1 to the procurement, processing, storage, and distribution
2 of human tissue.

3 (c) CREDITING AND AVAILABILITY OF FEES.—

4 (1) IN GENERAL.—Fees collected for a fiscal
5 year pursuant to subsection (a) shall be credited to
6 the appropriation account for salaries and expenses
7 of the Secretary of Health and Human Services and
8 shall be available in accordance with appropriation
9 Acts until expended without fiscal year limitation.

10 (2) COLLECTIONS.—The fees imposed under
11 subsection (a)—

12 (A) shall be collected in each fiscal year in
13 an amount equal to the amount specified in ap-
14 propriation Acts for such fiscal year; and

15 (B) shall only be collected and available to
16 defray the costs of implementing sections 545
17 and 546 of the Federal Food, Drug, and Cos-
18 metic Act.

19 (d) EFFECTIVE DATE.—The fee authorized by sub-
20 section (a)(1) shall take effect 4 years after the date of
21 the enactment of this Act and the fee authorized by sub-
22 section (a)(2) shall take effect 1 year after the date of
23 the enactment of this Act.

1 **SEC. 7. HUMAN HEART VALVES.**

2 (a) ENFORCEMENT.—The Secretary of Health and
3 Human Services may not enforce the Secretary's regula-
4 tion, promulgated on May 13, 1987, and published at page
5 18162 of 52 Federal Register, insofar as such regulation
6 applies to human heart valves.

7 (b) PREMARKET APPROVAL DETERMINATION.—The
8 determination of the Secretary of Health and Human
9 Services issued June 26, 1991 (56 FR 29177), acting
10 through the Food and Drug Administration, that human
11 heart valves are replacement heart valves subject to pre-
12 market approval under section 515 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 360e) shall have no
14 legal force and effect.

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