

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 3547

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 HOUSE OF REPRESENTATIVES

NOVEMBER 19, 1993

Mr. WYDEN introduced the following bill; which was referred to the Committee on Energy and Commerce

---

## 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), by  
13 striking “, and (D), and inserting “, (D)” and by in-  
14 serting before the period “, and (E) human tissue in  
15 combination with a drug as described in clause (A),  
16 (B), (C), or (D)”,

17 (2) in paragraph (h), by inserting after “im-  
18 plant,” the following: “human tissue (other than  
19 banked human tissue),”, and

20 (3) by adding at the end the following:

21 “(gg)(1) The term ‘tissue’ means an aggregate of  
22 cells or their intercellular substance that form a structural  
23 material.

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

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

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

8           “(iii) not intended to change tissue structure or  
9           functional characteristics.

10          “(B) Such term does not include—

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

14           “(ii) blood, blood products, bone marrow, repro-  
15           ductive tissue, or human milk, or

16           “(iii) autograft human tissue that is not stored  
17           or processed during a single surgical procedure.”.

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

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

22          Chapter V is amended by adding at the end the fol-  
23          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 PRACTICE.—The Sec-  
16 retary shall by regulation establish good tissue banking  
17 practices by human tissue banks which 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  
3 failures,

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 a Tissue Advisory  
21 Committee, that such an exemption does  
22 not affect the safety and effectiveness of  
23 the operations of such bank, or

24 “(C) the human tissue bank has on file  
25 with the Secretary an application for an exemp-

1           tion from the requirements of subsection (a),  
2           (b), or (c) to investigate new or existing stand-  
3           ards, methods, or uses relating to tissue, such  
4           application is submitted with a proposed sci-  
5           entific protocol for such investigation, and the  
6           Secretary has determined that such investiga-  
7           tion does not affect the safety and effectiveness  
8           of the operations of such bank and that pa-  
9           tients of the bank will be protected by a re-  
10          quirement of adequate informed consent.

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

21          “(3) AMENDMENT.—The Secretary shall allow  
22          a human tissue bank which has a permit issued  
23          under paragraph (2) to amend the permit if under  
24          the amendment the human tissue bank is still in  
25          compliance with paragraph (1).

1           “(4) REVOCATION.—The Secretary shall revoke,  
2           in whole or in part, a permit of a human tissue bank  
3           issued under paragraph (2) if the Secretary deter-  
4           mines that the bank is operating in a manner which  
5           is inconsistent with its permit and which places the  
6           bank out of compliance with paragraph (1).

7           “(e) REGISTRATION.—Each human tissue bank, ex-  
8           cept human tissue banks that operate solely for research  
9           or teaching, shall under regulations of the Secretary be  
10          required to register in accordance with the requirements  
11          of section 510 as made applicable under such regulations.

12          “(f) REGULATIONS.—The Secretary shall promulgate  
13          the regulations required by subsection (a), (b), (c), (d),  
14          and (e) within 5 years of the date of the enactment of  
15          the Human Tissue for Transplantation Act of 1993 and  
16          shall be based on adequate scientific evidence.

17                                 “TISSUE ADVISORY COMMITTEES

18          “SEC. 546. (a) IN GENERAL.—The Secretary shall  
19          establish a national advisory committee to be known as  
20          the Tissue Advisory Committee (hereinafter in this section  
21          referred to as the ‘advisory committee’). The advisory  
22          committee shall be established within one year of the date  
23          of the enactment of the Human Tissue for Transplan-  
24          tation Act of 1993.

25          “(b) COMPOSITION.—The advisory committee shall  
26          be comprised of not fewer than 13 or more than 19 indi-

1 individuals who are not officers or employees of the Federal  
2 Government. The Secretary shall make appointments to  
3 the advisory committee from among physicians, other  
4 health care practitioners, and representatives of human  
5 tissue bank consumers and industry groups whose clinical  
6 practice, research specialization, or expertise include a sig-  
7 nificant focus on tissue transplantation by human tissue  
8 banks.

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

10 “(1) advise the Secretary on appropriate quality  
11 standards and regulations for human tissue banks  
12 under section 545,

13 “(2) report on new developments concerning tis-  
14 sue transplantation,

15 “(3) advise the Secretary on appropriate stand-  
16 ards for the prevention of infectious disease trans-  
17 mission by banked human tissues,

18 “(4) advise the Secretary on appropriate quality  
19 standards for good tissue banking practices under  
20 section 545(b),

21 “(5) advise the Secretary in the development of  
22 regulations to ensure that adequate directions for  
23 use of banked human tissues are provided by human  
24 tissue banks,

1           “(6) make recommendations in the establish-  
2           ment of mechanisms to investigate consumer com-  
3           plaints, and

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

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

9           “(e) CHAIRPERSON.—The Secretary shall appoint the  
10          chairperson of the advisory committee from among mem-  
11          bers of the advisory committee.”.

12          **SEC. 5. ENFORCEMENT.**

13          (a) ADULTERATION.—Section 501 (21 U.S.C. 351)  
14          is amended—

15                 (1) by inserting “, banked human tissue,” after  
16                 “drug” before paragraph (a),

17                 (2) in paragraphs (a)(2)(B) and (d), by insert-  
18                 ing “or banked human tissue” after “drug” each  
19                 place it occurs,

20                 (3) by adding at the end the following:

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

1       “(2) If it is banked human tissue for which an exemp-  
2 tion for investigation use of human tissue has been grant-  
3 ed under section 545(d)(1)(D) and the person granted  
4 such exemption or any investigator fails to comply with  
5 the requirements of such section.”, and

6           (4) in the title to the section, by inserting “OR  
7 BANKED HUMAN TISSUE” after “DRUGS.

8       (b) MISBRANDING.—Section 502 (21 U.S.C. 352) is  
9 amended—

10           (1) by inserting “, banked human tissue,” after  
11 “drug” before paragraph (a),

12           (2) in paragraph (f), the first sentence of para-  
13 graph (h), and (i), by inserting “or banked human  
14 tissue” after “drug” each place it occurs

15           (3) in paragraph (o), by inserting “or if an ap-  
16 plication or other information respecting it was not  
17 provided as required by section 545(d),” after  
18 “510(e)”,

19           (4) by adding at the end the following:

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

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

1 (5) in the title to the section, by inserting “OR  
2 BANKED HUMAN TISSUE” after “DRUGS.

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

5 (1) in paragraphs (a), (b), (c), (g), (h), (k), and  
6 (l), by inserting “, banked human tissue” after  
7 “drug” each place it occurs,

8 (2) in paragraph (d), by striking “404 or 505”  
9 and inserting “404, 505, or 545”,

10 (3) in paragraph (j), by inserting “, 545” after  
11 “520”,

12 (4) in paragraph (p), by striking “510,” and in-  
13 serting “510 or 545(e),”, and

14 (5) in paragraphs (q)(2) and (r), by inserting  
15 “or banked human tissue” after “device”.

16 (d) PENALTIES.—Section 303(f) (21 U.S.C. 333(f))  
17 is amended by inserting “or banked human tissues” after  
18 “devices”.

19 (e) SEIZURES.—Section 304 (21 U.S.C. 334) is  
20 amended—

21 (1) in subsections (a)(1) and (d)(1), by insert-  
22 ing “, banked human tissue” after “drug”,

23 (2) in subsection (a)(1), by striking “, and (D)”  
24 and inserting “(D) Any adulterated or misbranded  
25 banked human tissue, and (E)”, and

1           (3) in subsection (g)(1), by striking “or a vehi-  
2           cle, a device” and inserting “, a vehicle, a device, or  
3           banked human tissue” and by inserting after each  
4           other occurrence of “device” the following: “or  
5           banked human tissue”.

6           (f) INVESTIGATIONS.—Section 702 (21 U.S.C. 372)  
7 is amended—

8           (1) in subsection (b), by inserting “, banked  
9           human tissue” after “drug”, and

10           (2) in subsection (d), by inserting “or banked  
11           human tissues” after “drugs”.

12           (g) RECORDS OF INTERSTATE SHIPMENT.—Section  
13 703 (21 U.S.C. 373) is amended—

14           (1) by inserting “or banked human tissues”  
15           after “drugs” each place it occurs, and

16           (2) by inserting “or banked human tissue”  
17           after “drug” each place it occurs.

18           (h) INSPECTIONS.—Section 704 (21 U.S.C. 374) is  
19 amended—

20           (1) in subsection (a)(1)(A), by inserting “,  
21           banked human tissues” after “drugs” each place it  
22           occurs,

23           (2) in subsection (a)(1)(B), by inserting “,  
24           banked human tissues” after “prescription drugs”  
25           each place it occurs, and

1           (3) in subsection (b), by inserting “, banked  
2 human tissue” after “drug”.

3           (i) PUBLICITY.—Section 705(b) (21 U.S.C. 375(b))  
4 is amended by inserting “, banked human tissues” after  
5 “drugs”.

6           (j) INTERSTATE COMMERCE PRESUMPTION.—Sec-  
7 tion 709 (21 U.S.C. 379a) is amended by inserting “or  
8 banked human tissue” after “device”.

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

11           (1) in the first sentence of subsection (a), by in-  
12 serting “, banked human tissues” and “drugs”,

13           (2) in subsection (a)(3), by inserting “or 545”  
14 after “505”, and

15           (3) in subsections (b) and (e)(1), by inserting  
16 “, banked human tissue” after “drug”.

17 **SEC. 6. FUNDING.**

18           (a) IMPOSITION.—Each human tissue bank—

19           (1) which has a permit issued under section  
20 545(d) shall pay a fee for such permit, and

21           (2) which is registered under section 545(e)  
22 shall pay a fee for such registration.

23 The fees imposed under this subsection are imposed to  
24 cover the costs of the Secretary in the implementation of  
25 sections 545 and 546.

1 (b) FEE AMOUNT.—The Secretary shall determine  
2 the amount of the fees imposed by subsection (a) on the  
3 basis of the gross revenue of the human tissue bank pay-  
4 ing the fee which relates to the procurement, processing,  
5 storage, and distribution of human tissue.

6 (c) CREDITING AND AVAILABILITY OF FEES.—

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

13 (2) COLLECTIONS.—The fees imposed under  
14 subsection (a)—

15 (A) shall be collected in each fiscal year in  
16 an amount equal to the amount specified in ap-  
17 propriation Acts for such fiscal year, and

18 (B) shall only be collected and available to  
19 defray the costs of implementing sections 545  
20 and 546.

21 (d) EFFECTIVE DATE.—The fee authorized by sub-  
22 section (a)(1) shall take effect 4 years after the date of  
23 the enactment of the Human Tissue for Transplantation  
24 Act of 1993 and the fee authorized by subsection (a)(2)  
25 shall take effect one year after the date of the enactment.

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 issued June 26, 1991 (56  
9 FR 29177), acting through the Food and Drug Adminis-  
10 tration, that human heart valves are replacement heart  
11 valves subject to premarket approval under section 515  
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 360e) shall have no legal force and effect.