

108TH CONGRESS  
2D SESSION

# H. R. 4151

To amend the Public Health Service Act to authorize the Commissioner of Food and Drugs to conduct oversight of any entity engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue or human tissue-based products.

---

## IN THE HOUSE OF REPRESENTATIVES

APRIL 2, 2004

Mr. KLINE (for himself, Mr. KENNEDY of Minnesota, Ms. MCCOLLUM, Mr. RAMSTAD, Mr. PETERSON of Minnesota, Mr. GUTKNECHT, Mr. SABO, Mr. OBERSTAR, Mrs. MUSGRAVE, Mr. MCINNIS, Mr. HEFLEY, and Mr. BEAUPREZ) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

## A BILL

To amend the Public Health Service Act to authorize the Commissioner of Food and Drugs to conduct oversight of any entity engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue or human tissue-based products.

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 “Brian Lykins Human  
5 Tissue Transplant Safety Act of 2004”.

1 **SEC. 2. OVERSIGHT OF ENTITIES ENGAGING IN ACTIVITIES**  
2 **RELATING TO HUMAN CELL, TISSUE, OR CEL-**  
3 **LULAR OR TISSUE-BASED PRODUCTS.**

4 Section 361 of the Public Health Service Act (42  
5 U.S.C. 264) is amended—

6 (1) by striking the section heading and all that  
7 follows through “(a) The” and inserting the fol-  
8 lowing:

9 **“SEC. 361. CONTROL OF COMMUNICABLE DISEASES.**

10 **“(a) PREVENTION OF COMMUNICABLE DISEASES.—**

11 **“(1) IN GENERAL.—The”;**

12 (2) in subsection (b), by striking “(b) Regula-  
13 tions prescribed under this section” and inserting  
14 the following:

15 **“(2) LIMITATION ON PURPOSE.—Regulations**  
16 **prescribed under this subsection”;**

17 (3) in subsection (c), by striking “(c) Except as  
18 provided in subsection (d), regulations prescribed  
19 under this section” and inserting the following:

20 **“(3) LIMITATION ON INDIVIDUALS.—Except as**  
21 **provided in paragraph (4), regulations prescribed**  
22 **under this subsection”;**

23 (4) in subsection (d)—

24 (A) by striking the third sentence and all  
25 that follows through the end and inserting the  
26 following:

1 “(B) DEFINITIONS.—In this paragraph:

2 “(i) QUALIFYING STAGE.—The term  
3 ‘qualifying stage’, with respect to a com-  
4 municable disease, means that such dis-  
5 ease—

6 “(I) is in a communicable stage;

7 or

8 “(II) is in a precommunicable  
9 stage, if the disease would be likely to  
10 cause a public health emergency if  
11 transmitted to other individuals.

12 “(ii) STATE.—The term ‘State’ in-  
13 cludes, in addition to the several States,  
14 only the District of Columbia.”;

15 (B) in paragraph (1), by redesignating  
16 subparagraphs (A) and (B) as clauses (i) and  
17 (ii), respectively; and

18 (C) by striking “(d)(1) Regulations pre-  
19 scribed under this section” and inserting the  
20 following:

21 “(4) CIRCUMSTANCES OF QUARANTINE.—

22 “(A) IN GENERAL.—Regulations pre-  
23 scribed under this subsection”;

24 (5) in subsection (e)—

1 (A) by striking “(e) Nothing in this sec-  
2 tion” and inserting the following:

3 “(5) CONSTRUCTION.—Nothing in this sub-  
4 section”;

5 (B) by striking “such sections” and insert-  
6 ing “this subsection or section 363”; and

7 (C) by striking “under this section” and  
8 inserting “under this subsection”; and

9 (6) by adding at the end the following:

10 “(b) OVERSIGHT OF ENTITIES ENGAGING IN ACTIVI-  
11 TIES RELATING TO HUMAN CELL, TISSUE, OR CELLULAR  
12 OR TISSUE-BASED PRODUCTS.—

13 “(1) DEFINITIONS.—In this subsection:

14 “(A) COMMISSIONER.—The term ‘Commis-  
15 sioner’ means the Commissioner of Food and  
16 Drugs.

17 “(B) COVERED ENTITY.—The term ‘cov-  
18 ered entity’ means any entity or person (as de-  
19 fined in section 201 of the Federal Food, Drug,  
20 and Cosmetic Act (21 U.S.C. 321)) that en-  
21 engages in the recovery, screening or testing (in-  
22 cluding donor eligibility screening or testing),  
23 processing, storage, labeling, packaging, or dis-  
24 tribution of a human cell, tissue, or cellular or

1 tissue-based product in a manner that affects  
2 interstate commerce.

3 “(C) HUMAN CELL, TISSUE, OR CELLULAR  
4 OR TISSUE-BASED PRODUCT.—The term  
5 ‘human cell, tissue, or cellular or tissue-based  
6 product’ means 1 of the articles defined as  
7 ‘human cells, tissues, or cellular or tissue-based  
8 products’ in section 1271.3(d)(2) of title 21,  
9 Code of Federal Regulations.

10 “(2) OVERSIGHT OF ENTITIES.—

11 “(A) IN GENERAL.—No covered entity  
12 shall engage in an activity described in para-  
13 graph (1)(B) unless the entity is in compliance  
14 with this paragraph and the regulations pro-  
15 mulgated under paragraph (3).

16 “(B) REGISTRATION AND LISTING.—Each  
17 covered entity shall submit to the Commissioner  
18 a request for registration and listing and shall  
19 submit, for such registration and listing, such  
20 information relating to the identity and oper-  
21 ations of the covered entity as the Commis-  
22 sioner may require.

23 “(C) INSPECTION.—The Commissioner  
24 may conduct such inspections of covered enti-

1           ties as the Commissioner determines are appro-  
2           priate to evaluate and ensure compliance with—

3                   “(i) this paragraph; and

4                   “(ii) regulations promulgated under  
5           paragraph (3).

6           “(D) ADVERSE REACTIONS.—

7                   “(i) IN GENERAL.—If an adverse re-  
8           action (as defined by the Commissioner)  
9           relating to a human cell, tissue, or cellular  
10          or tissue-based product occurs at the facil-  
11          ity of a covered entity and the covered en-  
12          tity receives notification of the adverse re-  
13          action, the covered entity shall report the  
14          adverse reaction to the Commissioner not  
15          later than 15 calendar days after the date  
16          on which the covered entity receives the  
17          notification.

18                   “(ii) REPORTING MECHANISM; DATA-  
19          BASE.—As soon as practicable, the Com-  
20          missioner, in consultation with the Direc-  
21          tor of the Centers for Disease Control and  
22          Prevention, shall develop—

23                   “(I) a single, simple reporting  
24          mechanism for use in reporting ad-  
25          verse reactions under clause (i); and

1                   “(II) a database for information  
2                   received in relation to any adverse re-  
3                   action reported under clause (i).

4                   “(3) REGULATIONS.—

5                   “(A) IN GENERAL.—Not later than 90  
6                   days after the date of enactment of the Human  
7                   Tissue Transplant Safety Act of 2003, the  
8                   Commissioner shall promulgate regulations to  
9                   carry out this subsection, including—

10                   “(i) regulations specifying a descrip-  
11                   tion of the information required to be sub-  
12                   mitted for the registration and listing of a  
13                   covered entity under paragraph (2)(B);

14                   “(ii) regulations specifying a defini-  
15                   tion of the term ‘adverse reaction’ for pur-  
16                   poses of paragraph (2)(D);

17                   “(iii) regulations specifying proce-  
18                   dures for donor eligibility screening and  
19                   testing, good tissue practices, and proce-  
20                   dures for inspection, enforcement, and any  
21                   other reasonable means to ensure that a  
22                   human cell, tissue, or cellular or tissue-  
23                   based product is free from communicable  
24                   disease and maintains function and integ-  
25                   rity during recovery, screening, testing,

1 processing, storage, labeling, packaging,  
2 and distribution to a patient; and

3 “(iv) such other regulations relating  
4 to the operation of covered entities as the  
5 Commissioner determines are necessary.

6 “(B) ENFORCEMENT.—If the Commis-  
7 sioner determines that a covered entity has vio-  
8 lated paragraph (2) or a regulation promul-  
9 gated under subparagraph (A), the Commis-  
10 sioner (including a designee of the Commis-  
11 sioner) may after providing notice and an op-  
12 portunity for a hearing—

13 “(i) issue an order requiring—

14 “(I) any person that distributed  
15 the human cell, tissue, or cellular or  
16 tissue-based product involved in the  
17 violation to recall or destroy the cell,  
18 tissue, or product, as appropriate; and

19 “(II) any covered entity in pos-  
20 session of the cell, tissue, or product  
21 to retain it until—

22 “(aa) the cell, tissue or  
23 product is recalled by the manu-  
24 facturer or is destroyed or dis-

1 posed of as specified by the Com-  
2 missioner; or

3 “(bb) the safety of the cell,  
4 tissue, or product is confirmed by  
5 the Commissioner;

6 “(ii) condemn, and seize or destroy,  
7 the cell, tissue, or product;

8 “(iii) issue an order requiring the cov-  
9 ered entity to cease the activity that re-  
10 sulted in the violation so that the covered  
11 entity is in compliance with the regulation;  
12 or

13 “(iv) suspend or revoke the registra-  
14 tion and listing under this subsection of  
15 the covered entity that violated the regula-  
16 tion.

17 “(4) APPLICABILITY.—Nothing in this sub-  
18 section shall be construed to affect the regulation of  
19 human cell, tissue, or cellular or tissue-based prod-  
20 ucts as biological products under section 351 or  
21 drugs or devices under the Federal Food, Drug, and  
22 Cosmetic Act (21 U.S.C. 301 et seq.).

23 “(5) AUTHORIZATION OF APPROPRIATIONS.—  
24 There are authorized to be appropriated to carry out  
25 this subsection such sums as may be necessary.”.

1 **SEC. 3. CONFORMING AMENDMENTS.**

2 (a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—  
3 Section 801(d)(4) of the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 381(d)(4)) is amended by striking  
5 “section 361” and inserting “section 361(a)”.

6 (b) PUBLIC HEALTH SERVICE ACT.—

7 (1) Section 2(f) of the Public Health Service  
8 Act (42 U.S.C. 201(f)) is amended by striking  
9 “361(d),” and inserting “361(a)(4),”.

10 (2) Section 363 of the Public Health Service  
11 Act (42 U.S.C. 266) is amended by striking “sub-  
12 section (b) of section 361” and inserting “section  
13 361(a)(2)”.

14 (3) Section 368 of the Public Health Service  
15 Act (42 U.S.C. 271) is amended by striking “361”  
16 and inserting “361(a)”.

17 (c) TITLE 49, UNITED STATES CODE.—Section  
18 24301(m)(2) of title 49, United States Code is amended  
19 by striking “Section 361” and inserting “Section 361(a)”.

○