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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

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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.

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 ''Brian Lykins Human Tissue Transplant Safety Act of 2004''.

SEC. 2. OVERSIGHT OF ENTITIES ENGAGING IN ACTIVITIES RELATING TO HUMAN CELL, TISSUE, OR CELLULAR OR TISSUE-BASED PRODUCTS.

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

(1) by striking the section heading and all that follows through ''(a) The'' and inserting the following:

''SEC. 361. CONTROL OF COMMUNICABLE DISEASES.

''(a) PREVENTION OF COMMUNICABLE DISEASES.—

''(1) IN GENERAL.—The'';

(2) in subsection (b), by striking ''(b) Regulations prescribed under this section'' and inserting the following:

''(2) LIMITATION ON PURPOSE.—Regulations prescribed under this subsection'';

(3) in subsection (c), by striking ''(c) Except as provided in subsection (d), regulations prescribed under this section'' and inserting the following:

''(3) LIMITATION ON INDIVIDUALS.—Except as provided in paragraph (4), regulations prescribed under this subsection'';

(4) in subsection (d)—

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

''(B) DEFINITIONS.—In this paragraph:

''(i) QUALIFYING STAGE.—The term 'qualifying stage', with respect to a communicable disease, means that such disease—

''(I) is in a communicable stage; or

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

''(ii) STATE.—The term 'State' includes, in addition to the several States, only the District of Columbia.'';

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

(C) by striking ''(d)(1) Regulations prescribed under this section'' and inserting the following:

''(4) CIRCUMSTANCES OF QUARANTINE.—

''(A) IN GENERAL.—Regulations prescribed under this subsection'';

(5) in subsection (e)—

(A) by striking ''(e) Nothing in this section'' and inserting the following:

''(5) CONSTRUCTION.—Nothing in this subsection'';

(B) by striking ''such sections'' and inserting ''this subsection or section 363''; and

(C) by striking ''under this section'' and inserting ''under this subsection''; and

(6) by adding at the end the following:

''(b) OVERSIGHT OF ENTITIES ENGAGING IN ACTIVITIES RELATING TO HUMAN CELL, TISSUE, OR CELLULAR OR TISSUE-BASED PRODUCTS.—

''(1) DEFINITIONS.—In this subsection:

''(A) COMMISSIONER.—The term 'Commissioner' means the Commissioner of Food and Drugs.

''(B) COVERED ENTITY.—The term 'covered entity' means any entity or person (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that engages in the recovery, screening or testing (including donor eligibility screening or testing), processing, storage, labeling, packaging, or distribution of a human cell, tissue, or cellular or

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

''(C) HUMAN CELL, TISSUE, OR CELLULAR OR TISSUE-BASED PRODUCT.—The term 'human cell, tissue, or cellular or tissue-based product' means 1 of the articles defined as 'human cells, tissues, or cellular or tissue-based products' in section 1271.3(d)(2) of title 21, Code of Federal Regulations.

''(2) OVERSIGHT OF ENTITIES.—

''(A) IN GENERAL.—No covered entity shall engage in an activity described in paragraph (1)(B) unless the entity is in compliance with this paragraph and the regulations promulgated under paragraph (3).

''(B) REGISTRATION AND LISTING.—Each covered entity shall submit to the Commissioner a request for registration and listing and shall submit, for such registration and listing, such information relating to the identity and operations of the covered entity as the Commissioner may require.

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

ties as the Commissioner determines are appropriate to evaluate and ensure compliance with—

"(i) this paragraph; and

"(ii) regulations promulgated under paragraph (3).

"(D) ADVERSE REACTIONS.—

"(i) IN GENERAL.—If an adverse reaction (as defined by the Commissioner) relating to a human cell, tissue, or cellular or tissue-based product occurs at the facility of a covered entity and the covered entity receives notification of the adverse reaction, the covered entity shall report the adverse reaction to the Commissioner not later than 15 calendar days after the date on which the covered entity receives the notification.

"(ii) REPORTING MECHANISM; DATABASE.—As soon as practicable, the Commissioner, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop—

"(I) a single, simple reporting mechanism for use in reporting adverse reactions under clause (i); and

''(II) a database for information received in relation to any adverse reaction reported under clause (i).

''(3) REGULATIONS.—

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

''(i) regulations specifying a description of the information required to be submitted for the registration and listing of a covered entity under paragraph (2)(B);

''(ii) regulations specifying a definition of the term 'adverse reaction' for purposes of paragraph (2)(D);

''(iii) regulations specifying procedures for donor eligibility screening and testing, good tissue practices, and procedures for inspection, enforcement, and any other reasonable means to ensure that a human cell, tissue, or cellular or tissue-based product is free from communicable disease and maintains function and integrity during recovery, screening, testing,

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

''(iv) such other regulations relating to the operation of covered entities as the Commissioner determines are necessary.

''(B) ENFORCEMENT.—If the Commissioner determines that a covered entity has violated paragraph (2) or a regulation promulgated under subparagraph (A), the Commissioner (including a designee of the Commissioner) may after providing notice and an opportunity for a hearing—

''(i) issue an order requiring—

''(I) any person that distributed the human cell, tissue, or cellular or tissue-based product involved in the violation to recall or destroy the cell, tissue, or product, as appropriate; and

''(II) any covered entity in possession of the cell, tissue, or product to retain it until—

''(aa) the cell, tissue or product is recalled by the manufacturer or is destroyed or dis-

posed of as specified by the Commissioner; or

"(bb) the safety of the cell, tissue, or product is confirmed by the Commissioner;

"(ii) condemn, and seize or destroy, the cell, tissue, or product;

"(iii) issue an order requiring the covered entity to cease the activity that resulted in the violation so that the covered entity is in compliance with the regulation; or

"(iv) suspend or revoke the registration and listing under this subsection of the covered entity that violated the regulation.

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

"(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary.".

SEC. 3. CONFORMING AMENDMENTS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 801(d)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)(4)) is amended by striking ''section 361'' and inserting ''section 361(a)''.

(b) PUBLIC HEALTH SERVICE ACT.—

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

(2) Section 363 of the Public Health Service Act (42 U.S.C. 266) is amended by striking ''subsection (b) of section 361'' and inserting ''section 361(a)(2)''.

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

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

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