

107TH CONGRESS  
2D SESSION

# S. 2531

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.

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## IN THE SENATE OF THE UNITED STATES

MAY 17, 2002

Ms. COLLINS introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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.

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 “Human Tissue Trans-  
5       plant Safety Act of 2002”.

1 **SEC. 2. OVERSIGHT OF ENTITIES ENGAGING IN ACTIVITIES**  
 2 **RELATING TO HUMAN TISSUE AND TISSUE-**  
 3 **BASED PRODUCTS.**

4 Part G of the Public Health Service Act (42 U.S.C.  
 5 361 et seq.) is amended by adding at the end the fol-  
 6 lowing:

7 **“SEC. 369A. OVERSIGHT OF ENTITIES ENGAGING IN ACTIVI-**  
 8 **TIES RELATING TO HUMAN TISSUE AND TIS-**  
 9 **SUE-BASED PRODUCTS.**

10 “(a) DEFINITIONS.—In this section:

11 “(1) COMMISSIONER.—The term ‘Commis-  
 12 sioner’ means the Commissioner of Food and Drugs.

13 “(2) COVERED ENTITY.—The term ‘covered en-  
 14 tity’ means any entity located in the United States  
 15 that engages in the recovery, screening, testing,  
 16 processing, storage, or distribution of human tissue  
 17 or a tissue-based product.

18 “(3) HUMAN TISSUE OR A TISSUE-BASED PROD-  
 19 UCT.—The term ‘human tissue or a tissue-based  
 20 product’ has the meaning given the term ‘human  
 21 cells, tissues, or cellular tissue-based products’ in  
 22 section 1271.3(d)(2) of title 21, Code of Federal  
 23 Regulations.

24 “(b) OVERSIGHT OF ENTITIES.—

25 “(1) REGISTRATION.—As a condition of con-  
 26 ducting business in the United States, each covered

entity shall submit to the Commissioner a request for registration that includes such information relating to the identity and operations of the covered entity as the Commissioner may require.

“(2) INSPECTION.—The Commissioner may conduct such inspections of entities as the Commissioner determines are appropriate to evaluate and ensure compliance with—

“(A) this section; and

“(B) regulations promulgated under subsection (c).

“(3) ADVERSE INCIDENTS.—

“(A) IN GENERAL.—If an adverse incident relating to human tissue or a tissue-based product (as defined by the Commissioner) occurs at a covered entity, the covered entity shall report the adverse incident to the Commissioner not later than 15 days after the occurrence of the adverse incident.

“(B) REPORTING MECHANISM; DATABASE.—As soon as practicable after the date of enactment of this section, the Commissioner, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop—

1 “(i) a single, simple reporting mecha-  
 2 nism for use in reporting adverse incidents  
 3 under subparagraph (A); and

4 “(ii) a database for information re-  
 5 ceived in relation to any adverse incident  
 6 reported under subparagraph (A).

7 “(c) REGULATIONS.—

8 “(1) IN GENERAL.—As soon as practicable  
 9 after the date of enactment of this section, the Com-  
 10 missioner shall promulgate regulations to carry out  
 11 this section, including—

12 “(A) a description of the information re-  
 13 quired to be submitted for the registration of a  
 14 covered entity under subsection (b)(1);

15 “(B) a definition of the term ‘adverse inci-  
 16 dent’ for purposes of subsection (b)(3); and

17 “(C) such other regulations relating to the  
 18 operation of covered entities as the Commis-  
 19 sioner determines are necessary.

20 “(2) ENFORCEMENT.—If the Commissioner de-  
 21 termines that a covered entity has violated a regula-  
 22 tion promulgated under paragraph (1), the Commis-  
 23 sioner may suspend or revoke the registration of the  
 24 covered entity.”.

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