

115TH CONGRESS
1ST SESSION

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To ensure certain safety measures are utilized in the interest of public health security with respect to labeling and transporting human tissue specimen or collection of specimens into interstate commerce.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2017

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

A BILL

To ensure certain safety measures are utilized in the interest of public health security with respect to labeling and transporting human tissue specimen or collection of specimens into interstate commerce.

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 “Label and Transport
5 Tissues Safely Act of 2017” or as the “LATTS Act of
6 2017”.

7 **SEC. 2. IN GENERAL.**

8 (a) NON-TRANSPLANT TISSUE BANK LICENSE.—

1 (1) PROHIBITION.—No person may introduce or
2 deliver for introduction into interstate commerce any
3 human tissue specimen for medical research or edu-
4 cation unless—

5 (A) a non-transplant tissue bank license is
6 in effect for the entity introducing the human
7 tissue specimen into interstate commerce;

8 (B) each package of the human tissue
9 specimen is labeled with—

10 (i) the proper name of the human tis-
11 sue specimen contained in the package;

12 (ii) the name, address, and applicable
13 license number of the source tissue bank of
14 the human tissue specimen;

15 (iii) a unique donor identifier, the tis-
16 sue type, the cause of death, serological
17 test results, and any known infectious dis-
18 ease agents;

19 (iv) a statement about the mandatory
20 use of personal protective equipment and
21 universal precautions when handling
22 human tissue; and

23 (v) the statement “not for transplan-
24 tation”; and

1 (C) each package of the human tissue
2 specimen is wrapped and packaged in a manner
3 that—

4 (i) mitigates potential contamination
5 and cross contamination;

6 (ii) mitigates potential safety hazards;

7 (iii) is sealed to prevent leakage; and

8 (iv) ensures the integrity of the tissue.

9 (2) PROCEDURES ESTABLISHED.—

10 (A) IN GENERAL.—The Secretary of
11 Health and Human Services shall establish, by
12 rule, requirements for the approval, suspension,
13 and revocation of non-transplant tissue bank li-
14 censes.

15 (B) APPROVAL.—The Secretary shall ap-
16 prove a non-transplant tissue bank license ap-
17 plication—

18 (i) on the basis of a demonstration
19 that—

20 (I) the human tissue specimens
21 of the applicant are legally donated,
22 properly screened for communicable
23 disease agents, properly labeled,
24 transported, and stored, and used ac-

1 cording to the donor's donation au-
2 thorization;

3 (II) each facility in which the
4 human tissue specimens of the appli-
5 cant are donated, recovered, proc-
6 essed, packed, or held meets stand-
7 ards designed to ensure that the
8 human tissue specimens do not pose a
9 communicable disease risk to the gen-
10 eral public; and

11 (III) the applicant creates, com-
12 piles, and maintains a complete record
13 on each donor from which it recovers
14 a human body or human tissue speci-
15 men for educational or research pur-
16 poses, which record shall include, at a
17 minimum—

18 (aa) documentation dem-
19 onstrating that the donor or the
20 agent making the donation on
21 the donor's behalf has knowingly
22 consented to the anatomical do-
23 nation for educational or re-
24 search purposes;

1 (bb) documentation showing
2 that the donor or the agent mak-
3 ing the donation on the donor's
4 behalf has been informed as to
5 whether the body or human tis-
6 sue specimens shall be returned
7 to a relative or personal rep-
8 resentative or whether the appli-
9 cant shall arrange and carry out
10 the disposition of the human
11 body or human tissue specimens;

12 (cc) documentation of the
13 identity and address of each enti-
14 ty which has been in possession
15 of the human body or human tis-
16 sue specimen before the applicant
17 took possession, such as a fu-
18 neral home, coroner, hospital,
19 organ procurement organization,
20 or tissue bank; and

21 (dd) documentation on the
22 use and disposition of each
23 human body or human tissue
24 specimen, including the name
25 and address of each person or en-

1 tity that receives the human body
2 or human tissue specimen di-
3 rectly from the applicant; and

4 (ii) only if the applicant (or other ap-
5 propriate person) consents to the inspec-
6 tion of the facility that is the subject of the
7 application, in accordance with subsection
8 (c).

9 (3) REQUIREMENTS FOR EXEMPTION.—The
10 Secretary shall prescribe requirements under which
11 a human tissue specimen shall be exempt from the
12 requirements of paragraph (1).

13 (b) FALSELY LABELING OR MARKING PACKAGE OR
14 CONTAINER; ALTERING LABEL OR MARK.—No person
15 shall falsely label or mark any package or container of
16 any human tissue specimen or alter any label or mark on
17 the package or container of the human tissue specimen
18 so as to falsify the label or mark.

19 (c) INSPECTION OF FACILITIES.—

20 (1) IN GENERAL.—Any officer, agent, or em-
21 ployee of the Department of Health and Human
22 Services, authorized by the Secretary for the pur-
23 pose, may during all reasonable hours enter and in-
24 spect any facility that is subject to a non-transplant
25 tissue bank license under this section.

1 (2) INSPECTION BY NATIONALLY RECOGNIZED
2 ACCREDITING BODIES.—Any authorized agent of a
3 nationally recognized accrediting body authorized by
4 the Secretary for the purpose, may during all rea-
5 sonable hours enter and inspect any such facility.

6 (3) RULE OF CONSTRUCTION.—Nothing in this
7 Act limits any existing authority of the Attorney
8 General, any State Attorney General, or local law
9 enforcement to enter and inspect any such facility.

10 (d) RECALL OF SPECIMEN PRESENTING IMMINENT
11 HAZARD; VIOLATIONS.—

12 (1) RECALL.—Upon a determination that a
13 human tissue specimen or collection of specimens of
14 a tissue bank licensed under this section presents an
15 imminent or substantial hazard to the public health,
16 the Secretary shall issue an order immediately order-
17 ing the recall of such batch, lot, or other quantity
18 of such product. An order under this paragraph
19 shall be issued in accordance with section 554 of
20 title 5, United State Code.

21 (2) VIOLATIONS.—Any violation of a recall
22 order under paragraph (1) shall subject the violator
23 to a civil penalty of up to \$10,000 per day of viola-
24 tion. The amount of a civil penalty under this para-
25 graph shall, effective December 1 of each calendar

1 year beginning 1 year or more after the effective
2 date of this paragraph, be increased by the percent
3 change in the Consumer Price Index for the base
4 quarter of such year over the Consumer Price Index
5 for the base quarter of the preceding year, adjusted
6 to the nearest $\frac{1}{10}$ of 1 percent. For purposes of this
7 paragraph, the term “base quarter”, as used with
8 respect to a year, means the calendar quarter ending
9 on September 30 of such year, and the price index
10 for a base quarter is the arithmetical mean of such
11 index for the 3 months comprising such quarter.

12 (e) PROHIBITIONS OF SALES AND PURCHASES OF
13 HUMAN TISSUE SPECIMEN.—It shall be unlawful for any
14 person to knowingly sell, acquire, receive, or otherwise
15 transfer any human tissue specimen for valuable consider-
16 ation if the transfer affects interstate commerce.

17 (f) PENALTIES FOR OFFENSES.—Whoever violates
18 any of the provisions of this section shall be imprisoned
19 not more than 1 year, or fined not more than \$10,000,
20 or both. Section 3571 of title 18, United States Code, shall
21 not apply to an offense under this section.

22 (g) CONSTRUCTION WITH OTHER LAWS.—Nothing
23 in this Act (other than subsection (f)) shall be construed
24 as in any way affecting, modifying, repealing, or super-
25 seding any other provision of Federal law.

1 (h) DEFINITIONS.—For the purposes of this section:

2 (1) Unless the context indicates otherwise, the
3 term “agent” means the person who is expressly au-
4 thorized to make an anatomical donation on the do-
5 nor’s behalf under State law.

6 (2) The term “donor” means a person whose
7 body or whose human tissue specimen is the subject
8 of an anatomical donation.

9 (3) The term “human tissue specimen”—

10 (A) means legally donated anatomical seg-
11 ments, cells, or body fluids (including a com-
12 plete body) that are recovered for medical re-
13 search or education; and

14 (B) does not include a biological product
15 (as defined in section 351 of the Public Health
16 Services Act (42 U.S.C. 262)).

17 (4) The term “valuable consideration” means
18 something of value, but does not include the reason-
19 able payments associated with the removal, transpor-
20 tation, processing, preservation, quality control, stor-
21 age, and lawful disposition of human tissue speci-
22 mens.

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