

113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5318

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.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 31, 2014

Mr. GOSAR (for himself and Mr. FRANKS of Arizona) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 2014” or as the “LATTS Act of  
6       2014”.

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 tissue bank license is in effect for  
6 the entity introducing the human tissue speci-  
7 men into interstate commerce;

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

10           (i) labeled with the proper name of  
11 the human tissue specimen contained in  
12 the package;

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

16           (iii) unique donor identifier, tissue  
17 type, cause of death, serological test re-  
18 sults and any known infectious disease  
19 agents;

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

24           (v) labeled “not for transplantation”;  
25 and

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

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

6 (ii) mitigates potential safety hazards;

7 (iii) 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 specimen  
21 that is the subject of the application  
22 is legally donated, properly screened  
23 for communicable disease agents,  
24 properly labeled, transported, stored

1 and used according to the donor's do-  
2 nation authorization; and

3 (II) the facility in which the  
4 human tissue specimen is donated, re-  
5 covered, processed, packed, or held  
6 meets standards designed to assure  
7 that the human tissue specimen does  
8 not pose a communicable disease risk  
9 to the general public and/or unknown  
10 communicable disease risk to; and

11 (ii) if the applicant (or other appro-  
12 priate person) consents to the inspection of  
13 the facility that is the subject of the appli-  
14 cation, in accordance with subsection (c) of  
15 this section.

16 (3) REQUIREMENTS FOR EXEMPTION.—The  
17 Secretary shall prescribe requirements under which  
18 a human tissue specimen shall be exempt from the  
19 requirements of paragraph (1).

20 (b) FALSELY LABELING OR MARKING PACKAGE OR  
21 CONTAINER; ALTERING LABEL OR MARK.—No person  
22 shall falsely label or mark any package or container of  
23 any human tissue specimen or alter any label or mark on  
24 the package or container of the biological product so as  
25 to falsify the label or mark.

1 (c) INSPECTION OF ESTABLISHMENT FOR PROPAGA-  
2 TION AND PREPARATION.—

3 (1) IN GENERAL.—Any officer, agent, or em-  
4 ployee of the Department of Health and Human  
5 Services, authorized by the Secretary for the pur-  
6 pose, may during all reasonable hours enter and in-  
7 spect any establishment for the propagation or re-  
8 covery and preparation of any human tissue speci-  
9 men.

10 (2) INSPECTION BY NATIONALLY RECOGNIZED  
11 ACCREDITING BODIES.—Any authorized agent of a  
12 nationally recognized accrediting body authorized by  
13 the Secretary for the purpose, may during all rea-  
14 sonable hours enter and inspect any establishment  
15 for the propagation or recovery and preparation of  
16 any human tissue specimen.

17 (3) RULE OF CONSTRUCTION.—Nothing in this  
18 subsection or Act limits any existing authority of the  
19 Attorney General, any State Attorney General or  
20 local law enforcement to enter and inspect any es-  
21 tablishment for the propagation or recovery and  
22 preparation of any human tissue.

23 (d) RECALL OF SPECIMEN PRESENTING IMMINENT  
24 HAZARD; VIOLATIONS.—

1           (1) RECALL.—Upon a determination that a  
2 human tissue specimen or collection of specimens li-  
3 censed under this section presents an imminent or  
4 substantial hazard to the public health, the Sec-  
5 retary shall issue an order immediately ordering the  
6 recall of such batch, lot, or other quantity of such  
7 product. An order under this paragraph shall be  
8 issued in accordance with section 554 of title 5.

9           (2) VIOLATIONS.—Any violation of paragraph  
10 (1) shall subject the violator to a civil penalty of up  
11 to \$10,000 per day of violation. The amount of a  
12 civil penalty under this paragraph shall, effective  
13 December 1 of each year beginning 1 year after the  
14 effective date of this paragraph, be increased by the  
15 percent change in the Consumer Price Index for the  
16 base quarter of such year over the Consumer Price  
17 Index for the base quarter of the preceding year, ad-  
18 justed to the nearest  $\frac{1}{10}$  of 1 percent. For purposes  
19 of this paragraph, the term “base quarter”, as used  
20 with respect to a year, means the calendar quarter  
21 ending on September 30 of such year and the price  
22 index for a base quarter is the arithmetical mean of  
23 such index for the 3 months comprising such quar-  
24 ter.

1           (e) PENALTIES FOR OFFENSES.—Whoever violates  
2 any of the provisions of this section shall be imprisoned  
3 not more than 1 year, or fined not more than \$500, or  
4 both. Section 3571 of title 18, United States Code shall  
5 not apply to an offense under this subsection.

6           (f) CONSTRUCTION WITH OTHER LAWS.—Nothing  
7 contained in this Act shall be construed as in any way  
8 affecting, modifying, repealing, or superseding under any  
9 existing provisions under current Federal law.

10          (g) HUMAN TISSUE SPECIMEN DEFINED.—In this  
11 section, the term “non-transplant tissue specimen” means  
12 legally donated anatomical segments, cells, collection of  
13 cells, bodily fluids, or the complete body that are recovered  
14 for medical research and education. The term does not in-  
15 clude anything that would qualify as a biological product  
16 under the Public Health Service Act.

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