

113TH CONGRESS
2^D SESSION

H. R. _____

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

Mr. GOSAR introduced the following bill; which was referred to the Committee on _____

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 human tissue specimen;

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

9 (i) labeled with the proper name of
10 the human tissue specimen contained in
11 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) unique donor identifier, tissue
16 type, cause of death, serological test re-
17 sults and any known infectious disease
18 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) labeled “not for transplantation”;
24 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 Health
11 and Human Services shall establish, by rule, require-
12 ments for the approval, suspension, and revocation
13 of non-transplant tissue bank licenses

14 (B) APPROVAL.—The Secretary shall approve a
15 non-transplant tissue bank license application—

16 (i) on the basis of a demonstration that—

17 (I) the human tissue specimen that is
18 the subject of the application is legally do-
19 nated, properly screened for communicable
20 disease agents, properly labeled, trans-
21 ported, stored and used according to the
22 donor's donation authorization; and

23 (II) the facility in which the human
24 tissue specimen is donated, recovered,
25 processed, packed, or held meets standards

1 designed to assure that the human tissue
2 specimen does not pose a communicable
3 disease risk to the general public and/or
4 unknown communicable disease risk to;
5 and

6 (ii) if the applicant (or other appropriate
7 person) consents to the inspection of the facility
8 that is the subject of the application, in accord-
9 ance with subsection (c) of this section.

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

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

20 (c) INSPECTION OF ESTABLISHMENT FOR PROPAGA-
21 TION AND PREPARATION.—

22 (1) IN GENERAL.—Any officer, agent, or em-
23 ployee of the Department of Health and Human
24 Services, authorized by the Secretary for the pur-
25 pose, may during all reasonable hours enter and in-

1 spect any establishment for the propagation or re-
2 covery and preparation of any human tissue speci-
3 men.

4 (2) INSPECTION BY NATIONALLY RECOGNIZED
5 ACCREDITING BODIES.—Any authorized agent of a
6 nationally recognized accrediting body authorized by
7 the Secretary for the purpose, may during all rea-
8 sonable hours enter and inspect any establishment
9 for the propagation or recovery and preparation of
10 any human tissue specimen.

11 (3) RULE OF CONSTRUCTION.—Nothing in this
12 subsection or Act limits any existing authority of the
13 Attorney General, any State Attorney General or
14 local law enforcement to enter and inspect any es-
15 tablishment for the propagation or recovery and
16 preparation of any human tissue.

17 (d) RECALL OF SPECIMEN PRESENTING IMMINENT
18 HAZARD; VIOLATIONS.—

19 (1) RECALL.—Upon a determination that a
20 human tissue specimen or collection of specimens li-
21 censed under this section presents an imminent or
22 substantial hazard to the public health, the Sec-
23 retary shall issue an order immediately ordering the
24 recall of such batch, lot, or other quantity of such

1 product. An order under this paragraph shall be
2 issued in accordance with section 554 of title 5.

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

19 (e) PENALTIES FOR OFFENSES.—Whoever violates
20 any of the provisions of this section shall be imprisoned
21 not more than 1 years, or fined not more than \$500, or
22 both. Section 3571 of title 18, United States Code shall
23 not apply to an offense under this subsection.

24 (f) CONSTRUCTION WITH OTHER LAWS.—Nothing
25 contained in this Act shall be construed as in any way

1 affecting, modifying, repealing, or superseding under any
2 existing provisions under current Federal law.

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