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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act to ensure the consensual donation and respectful disposition of human bodies and human body parts donated or transferred for education, research, or the advancement of medical, dental, or mortuary science and not for use in human transplantation, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Public Health Service Act to ensure the consensual donation and respectful disposition of human bodies and human body parts donated or transferred for education, research, or the advancement of medical, dental, or mortuary science and not for use in human transplantation, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Consensual Donation
3 and Research Integrity Act of 2023”.

4 **SEC. 2. HUMAN BODIES AND HUMAN BODY PARTS DO-**
5 **NATED OR TRANSFERRED FOR EDUCATION,**
6 **RESEARCH, OR THE ADVANCEMENT OF MED-**
7 **ICAL, DENTAL, OR MORTUARY SCIENCE AND**
8 **NOT FOR USE IN HUMAN TRANSPLANTATION.**

9 (a) IN GENERAL.—Title III of the Public Health
10 Service Act (42 U.S.C. 241 et seq.) is amended by insert-
11 ing after section 373 the following new section:

12 **“SEC. 373A. HUMAN BODIES AND HUMAN BODY PARTS DO-**
13 **NATED OR TRANSFERRED FOR EDUCATION,**
14 **RESEARCH, OR THE ADVANCEMENT OF MED-**
15 **ICAL, DENTAL, OR MORTUARY SCIENCE AND**
16 **NOT FOR USE IN HUMAN TRANSPLANTATION.**

17 “(a) REGISTRATION.—

18 “(1) IN GENERAL.—A person who acquires
19 human bodies and sells for profit a whole human
20 body or human body part in or affecting interstate
21 commerce shall register with the Secretary at such
22 time and in such manner as the Secretary may re-
23 quire.

24 “(2) EXCEPTION.—Paragraph (1) does not
25 apply to the Organ Procurement and Transplan-
26 tation Network under section 372 and any entity

1 that is a member of the Network pursuant to section
2 121.3 of title 42, Code of Federal Regulations (or
3 any successor regulations), funeral service profes-
4 sionals in regard to the preparation, transportation,
5 and final disposition of the human body or body
6 parts, and schools of medicine, dentistry, and mor-
7 tuary science and research, training organizations,
8 and other entities that do not sell for profit a whole
9 body or body part.

10 “(3) CONTENTS OF APPLICATION.—An appli-
11 cant for registration or renewal of registration under
12 this section shall submit an application to the Sec-
13 retary containing such information as the Secretary
14 may by regulation require on the activities to be car-
15 ried out pursuant to the registration. Unless the
16 Secretary specifies otherwise by regulation, an appli-
17 cation shall include—

18 “(A) the name of the applicant, including
19 all trade names under which the applicant con-
20 ducts business;

21 “(B) the date on which the applicant first
22 began or will begin commencing activities de-
23 scribed in paragraph (1);

24 “(C) a list of all addresses at which the
25 applicant conducts business;

1 “(D) a description of the premises and
2 equipment used by the applicant;

3 “(E) a description of the types of service
4 provided by the applicant;

5 “(F) an identification of a representative
6 of the applicant who has attained the age of 18
7 and has the authority to ensure that the appli-
8 cant complies with this section;

9 “(G) an assurance that the Secretary will
10 be permitted to inspect the premises and
11 records of the applicant at the times and in the
12 manners prescribed under subsection (b);

13 “(H) an assurance that the applicant will
14 keep records in accordance with subsection (c);

15 “(I) an assurance that the applicant will
16 label and package all human bodies or human
17 body parts in accordance with subsection (d);
18 and

19 “(J) an assurance that the applicant will
20 limit the use and disclosure of information in
21 accordance with the regulations promulgated
22 pursuant to subsection (e).

23 “(4) FEES.—

24 “(A) AUTHORITY.—The Secretary shall es-
25 tablish a fee for registration under paragraph

1 (1) and renewal under paragraph (5) in an
2 amount in accordance with subparagraph (B).

3 “(B) AMOUNT.—The Secretary shall deter-
4 mine the amount of the fees authorized by sub-
5 paragraph (A) on an annual basis based on the
6 projected cost of implementing and enforcing
7 this section, including the cost of inspections
8 under subsection (b).

9 “(C) COLLECTIONS AND APPROPRIATIONS
10 ACTS.—The fees authorized by subparagraph
11 (A) shall be available for obligation only to the
12 extent and in the amounts provided in advance
13 in appropriations Acts.

14 “(5) REGISTRATION RENEWAL.—The Secretary
15 shall require that the registration of a registrant be
16 renewed by such registrant at such intervals as the
17 Secretary determines appropriate.

18 “(6) CHANGE OF INFORMATION.—Not later
19 than 30 days after any change of any information
20 listed in paragraph (3), an applicant or registrant
21 shall notify the Secretary of such change in writing
22 as prescribed by regulation by the Secretary.

23 “(b) INSPECTIONS.—The Secretary shall inspect at
24 regular intervals (to be prescribed by the Secretary) the
25 premises described in subsection (a)(3)(D).

1 “(c) RECORD KEEPING.—

2 “(1) IN GENERAL.—A registrant shall maintain
3 a record for each case in which the registrant ac-
4 quires a human body or human body part.

5 “(2) RECORD REQUIREMENTS.—A record under
6 paragraph (1) shall contain such information as the
7 Secretary may by regulation require. Unless the Sec-
8 retary specifies otherwise by regulation, a record
9 under paragraph (1) shall include the following:

10 “(A) Documentation that the donor has
11 knowingly consented to the transfer of the
12 human body or human body part (not for use
13 in transplantation) involved for education, re-
14 search, or the advancement of medical, dental,
15 or mortuary science in accordance with all ap-
16 plicable laws pertaining to the disposition of
17 human remains.

18 “(B) Documentation that the donor has
19 been informed of the obligation of the reg-
20 istrant under subsection (e) to dispose of the
21 human body or human body part.

22 “(C) The date and time of the donation or
23 transfer from the donor.

24 “(D) The name of the person, including
25 any trade or business name, who transferred

1 the human body or human body part to the reg-
2 istrant, if applicable.

3 “(E) The full name and most recent ad-
4 dress of the donor.

5 “(F) A description of the human body or
6 human body part being acquired or transferred.

7 “(G) The medical history of the donor, in-
8 cluding the autopsy report if an autopsy was
9 conducted.

10 “(H) The identity and address of each per-
11 son that has been in possession of the human
12 body or human body part prior to the reg-
13 istrant, including any funeral home, coroner,
14 hospital, organ procurement organization, or
15 tissue bank.

16 “(I) Documentation of the use and dispo-
17 sition of each human body or human body part
18 by the registrant.

19 “(J) Documentation of the name and ad-
20 dress of each person to whom the registrant
21 transfers such human body or human body
22 part.

23 “(d) LABELING AND PACKAGING.—

24 “(1) IN GENERAL.—A registrant shall ensure
25 that all human bodies and human body parts in the

1 possession of, or transferred by, a registrant are la-
2 beled and packaged in accordance with paragraphs
3 (2) and (3) and that a proper chain of custody is
4 maintained.

5 “(2) LABELING REQUIREMENTS.—

6 “(A) PLACEMENT.—The labeling required
7 by paragraph (1) shall be affixed beneath the
8 outer packaging.

9 “(B) CONTENTS.—The labeling required
10 by paragraph (1) shall contain such information
11 as the Secretary may by regulation require con-
12 sistent with any applicable Federal privacy pro-
13 visions. Unless the Secretary specifies otherwise
14 by regulation, a label under paragraph (1) shall
15 include the following:

16 “(i) The proper name of the donor.

17 “(ii) A description of the contents of
18 the packaging, indicating whether it is a
19 human body or human body parts, includ-
20 ing a list of all such parts.

21 “(iii) The name, address, and any ap-
22 plicable license or registration number of
23 the person transferring the human body or
24 human body part.

1 “(iv) The tissue types of the human
2 body or human body part.

3 “(v) The cause of death of the donor,
4 if applicable and known.

5 “(vi) Serological test results, if any
6 such results exist.

7 “(vii) Record of the presence of radio-
8 active materials or implants.

9 “(viii) Any known infectious disease
10 agents of such human body or human body
11 part.

12 “(ix) A statement about the use of
13 personal protective equipment and uni-
14 versal precautions when handling a human
15 body or human body part as required by
16 law.

17 “(x) The statement ‘not for transplan-
18 tation’.

19 “(3) PACKAGING REQUIREMENTS.—Each
20 human body or human body part described in para-
21 graph (1) shall be wrapped and packaged in such
22 manner as the Secretary may by regulation require.
23 Unless the Secretary specifies otherwise by regula-
24 tion, each such human body or human body part
25 shall be wrapped and packaged in a manner that—

1 “(A) mitigates potential contamination and
2 cross contamination;

3 “(B) mitigates potential safety hazards;

4 “(C) is sealed to prevent leakage; and

5 “(D) ensures the integrity of the human
6 body or human body part.

7 “(e) LIMITATIONS ON USE AND DISCLOSURE OF IN-
8 FORMATION.—Individually identifiable information relat-
9 ing to the donor of a human body or human body part
10 acquired or transferred pursuant to a registration under
11 this section shall be used and disclosed only for such pur-
12 poses (including the return of remains for burial) as the
13 Secretary may explicitly authorize by regulation.

14 “(f) DISPOSITION.—The registrant shall ensure the
15 proper disposition of a human body or human body part,
16 in accordance with applicable Federal and State law, by—

17 “(1) returning the human body or human body
18 part to a relative or personal representative of the
19 donor or carrying out the disposition of such human
20 body or human body part in accordance with the
21 written instructions of the person or persons with
22 the right to control the disposition of the human
23 body or body parts; or

24 “(2) if the registrant is transferring the human
25 body or human body part to another person, con-

1 tracting with such person to assume the obligation
2 described in paragraph (1).

3 “(g) VIOLATIONS.—

4 “(1) IN GENERAL.—Any person who violates a
5 requirement of this section shall be fined in accord-
6 ance with title 18, United States Code.

7 “(2) REVOCATION OF REGISTRATION.—The
8 Secretary may suspend or revoke the registration of
9 any registrant found to be in violation of this sec-
10 tion.

11 “(3) ALTERATION OR FALSIFICATION OF
12 LABEL.—It shall be a violation of this section for
13 any person to alter or falsify any information in a
14 label required by subsection (d).

15 “(h) DEFINITIONS.—In this section:

16 “(1) DONOR.—The term ‘donor’ means a per-
17 son who has knowingly consented in accordance with
18 applicable law to the transfer of such person’s de-
19 ceased body or deceased or living body part (not for
20 use in transplantation) for education, research, or
21 the advancement of medical, dental, or mortuary
22 science.

23 “(2) EDUCATION.—The term ‘education’ means
24 the use of a human body or body parts for teaching
25 or training individuals, including medical, dental, or

1 mortuary science students or professionals, with re-
2 gard to the anatomy and characteristics of the
3 human body, disease detection, and such other uses
4 as may be specified by the Secretary by regulation.

5 “(3) HUMAN BODY.—The term ‘human body’
6 means a deceased human body.

7 “(4) HUMAN BODY PART.—The terms ‘human
8 body part’ or ‘body part’ mean an organ, tissue, eye,
9 bone, blood vessel or any other portion of a deceased
10 or living human body that is subject to an anatom-
11 ical gift or other transfer made pursuant to State
12 law, but do not include—

13 “(A) blood drawn for medical purposes; or

14 “(B) a growing cell line.

15 “(5) RESEARCH.—The term ‘research’ does not
16 include an autopsy or examination, conducted as
17 part of a criminal investigation.”.

18 (b) RULE OF APPLICABILITY.—The amendments
19 made by this section shall apply with respect to any acqui-
20 sition or transfer of a human body or human body parts
21 after the date that is 2 years after the date of the enact-
22 ment of this Act.