

118TH CONGRESS
2D SESSION

H. R. 7188

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 17 (legislative day, DECEMBER 16), 2024

Received

AN ACT

To require the Secretary of Health and Human Services to conduct a national, evidence-based education campaign to increase public and health care provider awareness regarding the potential risks and benefits of human cell and tissue products transplants, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Shandra Eisenga
5 Human Cell and Tissue Product Safety Act”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

8 (1) HUMAN CELL AND TISSUE PRODUCT.—The
9 terms “human cell and tissue product” and “human
10 cell and tissue products” have the meaning given the
11 term “human cells, tissues, or cellular or tissue-
12 based products” in section 1271.3(d) of title 21,
13 Code of Federal Regulations (or successor regula-
14 tions).

15 (2) SECRETARY.—The term “Secretary” means
16 the Secretary of Health and Human Services.

17 (3) TISSUE REFERENCE GROUP.—The term
18 “Tissue Reference Group” means the Tissue Ref-
19 erence Group of the Food and Drug Administration.

20 **SEC. 3. HUMAN CELL AND TISSUE PRODUCTS TRANSPLANT**
21 **PUBLIC AWARENESS CAMPAIGN.**

22 The Secretary shall support the development and dis-
23 semination of educational materials to inform health care
24 professionals and other appropriate professionals about
25 issues surrounding—

1 (1) organ, tissue, and eye donation, including
2 evidence-based methods to approach patients and
3 their families;

4 (2) the availability of any donor screening tests;
5 and

6 (3) other relevant aspects of donation.

7 **SEC. 4. REVIEW AND UPDATE OF EXISTING GUIDANCE.**

8 The Secretary, acting through the Commissioner of
9 Food and Drugs, shall—

10 (1) not later than 1 year after the date of the
11 enactment of this Act, initiate an internal review of
12 existing guidance for determining eligibility of do-
13 nors of human cell and tissue products;

14 (2) not later than 3 years after the date of the
15 enactment of this Act, if appropriate—

16 (A) update the guidance titled “Eligibility
17 Determination for Donors of Human Cells, Tis-
18 sues, and Cellular and Tissue-Based Products;
19 Guidance for Industry” issued August 2007;
20 and

21 (B) issue or update, as applicable, any
22 guidance for industry of the Food and Drug
23 Administration that includes—

24 (i) recommendations to reduce the
25 risk of transmission of mycobacterium tu-

1 berculosis by human cells, tissues, and cel-
2 lular and tissue-based products (HCT/Ps);
3 or

4 (ii) recommendations to reduce the
5 risk of transmission of disease agents asso-
6 ciated with sepsis for donors of human
7 cells, tissues, and cellular and tissue-based
8 products (HCT/Ps); and

9 (3) if the Secretary determines that issuing or
10 updating guidance as specified in paragraph (2) is
11 not appropriate, provide a written statement of ex-
12 planation of that determination to the Committee on
13 Energy and Commerce of the House of Representa-
14 tives and the Committee on Health, Education,
15 Labor, and Pensions of the Senate.

16 **SEC. 5. CIVIL PENALTIES FOR VIOLATION OF REQUIRE-**
17 **MENTS FOR HUMAN CELL AND TISSUE PROD-**
18 **UCTS.**

19 Section 368 of the Public Health Service Act (42
20 U.S.C. 271) is amended by adding at the end the fol-
21 lowing:

22 “(d)(1) Any person who, on or after the date of the
23 enactment of the Shandra Eisenga Human Cell and Tis-
24 sue Product Safety Act, violates a requirement of subparts
25 C or D of section 1271 of title 21, Code of Federal Regu-

1 lations, (or successor regulations) with respect to human
2 cell or tissue products regulated under section 361 shall
3 be liable to the United States for a civil penalty in an
4 amount not to exceed the sum of—

5 “(A)(i) \$20,000 for each violation; and

6 “(ii) in the case of a violation that continues
7 after the Secretary provides written notice to such
8 person, \$20,000 for each subsequent day on which
9 the violation continues; and

10 “(B) an amount equal to the retail value of the
11 human cell and tissue products that are the subject
12 of the violation.

13 “(2) The total civil penalty under paragraph (1) may
14 not exceed \$10,000,000 for all such violations adjudicated
15 in a single proceeding.

16 “(3) In this subsection, the term ‘human cell and tis-
17 sue products’ has the meaning given the term ‘human
18 cells, tissues, or cellular or tissue-based products’ in sec-
19 tion 1271.3(d) of title 21, Code of Federal Regulations
20 (or successor regulations).”.

21 **SEC. 6. STREAMLINING REGULATORY OVERSIGHT OF**
22 **HUMAN CELL AND TISSUE PRODUCTS.**

23 (a) INFORMATION ON HUMAN CELL AND TISSUE
24 PRODUCTS.—

1 (1) WEBSITE.—The Secretary, acting through
2 the Commissioner of Food and Drugs, shall publish
3 on the public website of the Food and Drug Admin-
4 istration—

5 (A) educational materials about the Tissue
6 Reference Group; and

7 (B) best practices for obtaining a timely,
8 accurate recommendation regarding human cell
9 and tissue products from the Tissue Reference
10 Group.

11 (2) PUBLIC INFORMATION.—Not later than 1
12 year after the date of the enactment of this Act, and
13 annually for the subsequent 3 years, the Secretary,
14 acting through the Commissioner of Food and
15 Drugs, shall publish on the public website of the
16 Food and Drug Administration—

17 (A) the number of human cell and tissue
18 establishments that registered with the Food
19 and Drug Administration on or after January
20 1, 2019;

21 (B) the number of inspections conducted
22 by the Food and Drug Administration of
23 human cell and tissue establishments on or
24 after January 1, 2019, including a comparison
25 of the number of inspections for blood establish-

1 ments with the number of inspections for such
2 human cell and tissue establishments;

3 (C) the number and type of inquiries to
4 the Tissue Reference Group in the preceding
5 year; and

6 (D) the average response time for submis-
7 sions to the Tissue Reference Group in the pre-
8 ceding year, including average initial and final
9 response time.

10 (3) EDUCATION.—The Secretary, acting
11 through the Commissioner of Food and Drugs, shall,
12 with respect to the regulation of human cell and tis-
13 sue products—

14 (A) provide information to relevant stake-
15 holders, including industry, tissue establish-
16 ments, academic health centers, biomedical con-
17 sortia, research organizations, and patients; and

18 (B) conduct workshops and other inter-
19 active and educational sessions for such stake-
20 holders to help support regulatory predictability
21 and scientific advancement, as appropriate.

22 (b) HUMAN CELL AND TISSUE PRODUCT SCIENTIFIC
23 AND REGULATORY UPDATES.—Section 3205 of the Food
24 and Drug Omnibus Reform Act of 2022 (title III of divi-
25 sion FF of Public Law 117–328) is amended by striking

1 “best practices” and all that follows through “other cel-
2 lular therapies” and inserting “best practices on gener-
3 ating scientific data necessary to further facilitate the de-
4 velopment of certain human cell-, tissue-, and cellular-
5 based medical products (and the latest scientific informa-
6 tion about such products), namely, stem cell and other cel-
7 lular therapies”.

8 (c) PUBLIC DOCKET.—Not later than 60 days after
9 the date of the enactment of this Act, the Secretary shall
10 establish a public docket to receive written comments re-
11 lated to—

12 (1) the approaches recommended for discussion
13 during the public workshop described in section
14 3205 of the Food and Drug Omnibus Reform Act of
15 2022 (title III of division FF of Public Law 117–
16 328); and

17 (2) modernizing the regulation of human cell
18 and tissue products, including considerations associ-
19 ated with assessing minimal manipulation and ho-
20 mologous use (as such terms are defined in section
21 1271.3 of title 21, Code of Federal Regulations (or
22 successor regulations)) of human cell and tissue
23 products.

24 (d) REPORT TO CONGRESS.—Not later than Sep-
25 tember 30, 2026, the Secretary shall summarize the ap-

10 (2) scientific developments;

14 (4) protecting public health.

Attest: KEVIN F. MCCUMBER,
Clerk.