

118TH CONGRESS
2D SESSION

S. 3733

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.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 5, 2024

Mr. PETERS (for himself and Ms. STABENOW) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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:

1 (1) HUMAN CELL AND TISSUE ESTABLISH-
2 MENT.—The term “human cell and tissue establish-
3 ment” means an establishment (as defined in section
4 1271.3(b) of title 21, Code of Federal Regulations
5 (or a successor regulation)) regulated by the Center
6 for Biologics Evaluation and Research under part
7 1271 of title 21, Code of Federal Regulations.

8 (2) HUMAN CELL AND TISSUE PRODUCTS.—
9 The term “human cell and tissue products” has the
10 meaning given the term “human cells, tissues, or
11 cellular or tissue-based products” in section
12 1271.3(d) of title 21, Code of Federal Regulations
13 (or a successor regulation).

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

16 **SEC. 3. HUMAN CELL AND TISSUE PRODUCTS TRANSPLANT**
17 **PUBLIC AWARENESS CAMPAIGN.**

18 (a) IN GENERAL.—The Secretary shall conduct a na-
19 tional, evidence-based education campaign to increase
20 public and health care provider awareness regarding the
21 potential risks and benefits of human cell and tissue prod-
22 ucts transplants.

23 (b) CONSIDERATION OF ADVICE OF STAKEHOLDER
24 EXPERTS.—The Secretary shall develop the education
25 campaign under subsection (a) after taking into consider-

1 ation the advice of stakeholder experts, including the Cen-
2 ters for Disease Control and Prevention and professional
3 associations that represent stakeholders of human cell and
4 tissue establishments that manufacture human cell and
5 tissue products with the highest risk of transmitting infec-
6 tions to their patients.

7 (c) GRANTS.—

8 (1) IN GENERAL.—The Secretary may award
9 grants to nonprofit organizations to carry out activi-
10 ties described in paragraph (2).

11 (2) USE OF FUNDS.—A recipient of a grant
12 under paragraph (1) shall use the grant funds—

13 (A) to increase the knowledge and aware-
14 ness of the public about the potential risks and
15 benefits of human cell and tissue products
16 transplants, including the risks that such trans-
17 plants may lead to infectious diseases, including
18 tuberculosis, latent tuberculosis infection, and
19 sepsis; or

20 (B) to increase the knowledge and aware-
21 ness of health care providers and health care
22 leaders about the potential risks and benefits of
23 human cell and tissue products transplants, in-
24 cluding the risks that such transplants may

1 lead to infectious diseases, including tuber-
2 culosis, latent tuberculosis infection, and sepsis.

3 (d) MEDIA CAMPAIGNS.—

4 (1) IN GENERAL.—In carrying out the edu-
5 cation campaign under subsection (a), the Secretary,
6 after taking into consideration the advice of stake-
7 holder experts, may award grants to, or enter into
8 contracts with, entities to establish national multi-
9 media campaigns to increase public and health care
10 provider awareness regarding the potential risks of
11 human cell and tissue products transplants.

12 (2) INCLUSIONS.—The multimedia campaigns
13 under paragraph (1) may include advertising
14 through television, radio, print media, billboards,
15 posters, all forms of existing and emerging social
16 networking media, other internet media, and any
17 other medium determined appropriate by the Sec-
18 retary.

19 **SEC. 4. CIVIL PENALTIES FOR VIOLATION OF REQUIRE-**
20 **MENTS FOR HUMAN CELL AND TISSUE PROD-**
21 **UCTS.**

22 (a) IN GENERAL.—Any person who violates a re-
23 quirement of section 361 of the Public Health Service Act
24 (42 U.S.C. 264) or part 1271 of title 21, Code of Federal
25 Regulations (or successor regulations) with respect to

1 human cell or tissue products shall be liable to the United
2 States for a civil penalty in an amount not to exceed the
3 sum of—

4 (1)(A) \$20,000 for each violation; or

5 (B) \$20,000 for each day of a continuing viola-
6 tion; and

7 (2) an amount equal to the retail value of the
8 human cell and tissue products that are the subject
9 of the violation.

10 (b) **MAXIMUM PENALTY.**—The total civil penalty
11 under subsection (a) shall not exceed \$10,000,000 for all
12 such violations adjudicated in a single proceeding.

13 **SEC. 5. REPORT TO CONGRESS.**

14 Not later than 2 years after the date of enactment
15 of this Act, the Secretary shall submit to Congress a re-
16 port that describes actions Congress and the Food and
17 Drug Administration could take to improve the safety of
18 human cell and tissue products, including—

19 (1) an examination of existing regulations and
20 guidance relating to human cell and tissue products;

21 (2) documentation of the number of human cell
22 and tissue establishments that have registered with
23 the Food and Drug Administration since 1998;

24 (3) how often the Food and Drug Administra-
25 tion has inspected human cell and tissue establish-

1 ments since 1998, including a comparison of the in-
2 spection rates for blood establishments and Source
3 Plasma establishments with the inspection rates for
4 such human cell and tissue establishments, potential
5 causes of declines in such inspections, if applicable,
6 and recommendations to increase Food and Drug
7 Administration resources, if applicable; and

8 (4) recommendations on potential guidance or
9 regulations that could be issued or promulgated, as
10 applicable, to improve donor screening for human
11 cell and tissue products.

12 **SEC. 6. REVIEW AND UPDATE OF EXISTING GUIDANCE.**

13 The Secretary, acting through the Commissioner of
14 Food and Drugs, shall—

15 (1) not later than 1 year after the date of en-
16 actment of this Act, initiate an internal review of ex-
17 isting guidance for determining eligibility of donors
18 of human cell and tissue products; and

19 (2) not later than 3 years after the date of en-
20 actment of this Act, issue updated guidance for de-
21 termining eligibility of donors of human cell and tis-
22 sue products to comply with part 1271 of title 21,
23 Code of Federal Regulations (or successor regula-
24 tions), including compliance in determining donor
25 eligibility in accordance with subpart C of part 1271

1 of title 21, Code of Federal Regulations (or suc-
2 cessor regulations).

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