

119TH CONGRESS
1ST SESSION

H. R. 1082

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 HOUSE OF REPRESENTATIVES

FEBRUARY 6, 2025

Mr. MOOLENAAR (for himself and Mrs. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 PRODUCT.—The
2 terms “human cell and tissue product” and “human
3 cell and tissue products” have the meaning given the
4 term “human cells, tissues, or cellular or tissue-
5 based products” in section 1271.3(d) of title 21,
6 Code of Federal Regulations (or successor regula-
7 tions).

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

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

13 **SEC. 3. HUMAN CELL AND TISSUE PRODUCTS TRANSPLANT**
14 **PUBLIC AWARENESS CAMPAIGN.**

15 The Secretary shall support the development and dis-
16 semination of educational materials to inform health care
17 professionals and other appropriate professionals about
18 issues surrounding—

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

22 (2) the availability of any donor screening tests;
23 and

24 (3) other relevant aspects of donation.

1 **SEC. 4. CIVIL PENALTIES FOR VIOLATION OF REQUIRE-**
2 **MENTS FOR HUMAN CELL AND TISSUE PROD-**
3 **UCTS.**

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

7 “(d)(1) Any person who, on or after the date of the
8 enactment of the Shandra Eisenga Human Cell and Tis-
9 sue Product Safety Act, violates a requirement of subparts
10 C or D of section 1271 of title 21, Code of Federal Regu-
11 lations, (or successor regulations) with respect to human
12 cell or tissue products regulated under section 361 shall
13 be liable to the United States for a civil penalty in an
14 amount not to exceed the sum of—

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

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

20 “(B) an amount equal to the retail value of the
21 human cell and tissue products that are the subject
22 of the violation.

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

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

6 **SEC. 5. STREAMLINING REGULATORY OVERSIGHT OF**
7 **HUMAN CELL AND TISSUE PRODUCTS.**

8 (a) INFORMATION ON HUMAN CELL AND TISSUE
9 PRODUCTS.—

10 (1) WEBSITE.—The Secretary, acting through
11 the Commissioner of Food and Drugs, shall publish
12 on the public website of the Food and Drug Admin-
13 istration—

14 (A) educational materials about the Tissue
15 Reference Group; and

16 (B) best practices for obtaining a timely,
17 accurate recommendation regarding human cell
18 and tissue products from the Tissue Reference
19 Group.

20 (2) PUBLIC INFORMATION.—Not later than 1
21 year after the date of the enactment of this Act, and
22 annually for the subsequent 3 years, the Secretary,
23 acting through the Commissioner of Food and
24 Drugs, shall publish on the public website of the
25 Food and Drug Administration—

1 (A) the number of human cell and tissue
2 establishments that registered with the Food
3 and Drug Administration on or after January
4 1, 2019;

5 (B) the number of inspections conducted
6 by the Food and Drug Administration of
7 human cell and tissue establishments on or
8 after January 1, 2019, including a comparison
9 of the number of inspections for blood establish-
10 ments with the number of inspections for such
11 human cell and tissue establishments;

12 (C) the number and type of inquiries to
13 the Tissue Reference Group in the preceding
14 year; and

15 (D) the average response time for submis-
16 sions to the Tissue Reference Group in the pre-
17 ceeding year, including average initial and final
18 response time.

19 (3) EDUCATION.—The Secretary, acting
20 through the Commissioner of Food and Drugs, shall,
21 with respect to the regulation of human cell and tis-
22 sue products—

23 (A) provide information to relevant stake-
24 holders, including industry, tissue establish-

1 ments, academic health centers, biomedical con-
2 sortia, research organizations, and patients; and

3 (B) conduct workshops and other inter-
4 active and educational sessions for such stake-
5 holders to help support regulatory predictability
6 and scientific advancement, as appropriate.

7 (b) HUMAN CELL AND TISSUE PRODUCT SCIENTIFIC
8 AND REGULATORY UPDATES.—Section 3205 of the Food
9 and Drug Omnibus Reform Act of 2022 (title III of divi-
10 sion FF of Public Law 117–328) is amended by striking
11 “best practices” and all that follows through “other cel-
12 lular therapies” and inserting “best practices on gener-
13 ating scientific data necessary to further facilitate the de-
14 velopment of certain human cell-, tissue-, and cellular-
15 based medical products (and the latest scientific informa-
16 tion about such products), namely, stem cell and other cel-
17 lular therapies”.

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

22 (1) the approaches recommended for discussion
23 during the public workshop described in section
24 3205 of the Food and Drug Omnibus Reform Act of

1 2022 (title III of division FF of Public Law 117–
2 328); and

3 (2) modernizing the regulation of human cell
4 and tissue products, including considerations associ-
5 ated with assessing minimal manipulation and ho-
6 mologous use (as such terms are defined in section
7 1271.3 of title 21, Code of Federal Regulations (or
8 successor regulations)) of human cell and tissue
9 products.

10 (d) REPORT TO CONGRESS.—Not later than Sep-
11 tember 30, 2026, the Secretary shall summarize the ap-
12 proaches discussed in the public workshop described in
13 section 3205 of the Food and Drug Omnibus Reform Act
14 of 2022 (title III of division FF of Public Law 117–328)
15 and the public docket described in subsection (c), and de-
16 velop recommendations regarding the regulation of human
17 cell and tissue products, including provisions under sec-
18 tions 1271.10(a) and 1271.3 of title 21, Code of Federal
19 Regulations, taking into account—

20 (1) regulatory burden;

21 (2) scientific developments;

22 (3) access to human cell and tissue products
23 regulated under section 361 of the Public Health
24 Service Act (42 U.S.C. 264); and

1 (4) protecting public health.

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