

119TH CONGRESS
1ST SESSION

H. R. 1082

IN THE SENATE OF THE UNITED STATES

JUNE 24, 2025

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

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,*

1 **SECTION 1. SHORT TITLE.**

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

4 **SEC. 2. DEFINITIONS.**

5 In this Act:

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

13 (2) **SECRETARY.**—The term “Secretary” means
14 the Secretary of Health and Human Services.

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

18 **SEC. 3. HUMAN CELL AND TISSUE PRODUCTS TRANSPLANT**
19 **PUBLIC AWARENESS CAMPAIGN.**

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

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

- 1 (2) the availability of any donor screening tests;
2 and
3 (3) other relevant aspects of donation.

4 **SEC. 4. CIVIL PENALTIES FOR VIOLATION OF REQUIRE-**
5 **MENTS FOR HUMAN CELL AND TISSUE PROD-**
6 **UCTS.**

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

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

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

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

23 “(B) an amount equal to the retail value of the
24 human cell and tissue products that are the subject
25 of the violation.

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

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

9 **SEC. 5. STREAMLINING REGULATORY OVERSIGHT OF**
10 **HUMAN CELL AND TISSUE PRODUCTS.**

11 (a) INFORMATION ON HUMAN CELL AND TISSUE
12 PRODUCTS.—

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

17 (A) educational materials about the Tissue
18 Reference Group; and

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

23 (2) PUBLIC INFORMATION.—Not later than 1
24 year after the date of the enactment of this Act, and
25 annually for the subsequent 3 years, the Secretary,

1 acting through the Commissioner of Food and
2 Drugs, shall publish on the public website of the
3 Food and Drug Administration—

4 (A) the number of human cell and tissue
5 establishments that registered with the Food
6 and Drug Administration on or after January
7 1, 2019;

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

15 (C) the number and type of inquiries to
16 the Tissue Reference Group in the preceding
17 year; and

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

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

1 (A) provide information to relevant stake-
2 holders, including industry, tissue establish-
3 ments, academic health centers, biomedical con-
4 sortia, research organizations, and patients; and

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

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

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

24 (1) the approaches recommended for discussion
25 during the public workshop described in section

1 3205 of the Food and Drug Omnibus Reform Act of
2 2022 (title III of division FF of Public Law 117–
3 328); and

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

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

21 (1) regulatory burden;

22 (2) scientific developments;

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

1 (4) protecting public health.

Passed the House of Representatives June 23, 2025.

Attest: KEVIN F. MCCUMBER,
Clerk.