

119TH CONGRESS
1ST SESSION

H. R. 340

To direct the Secretary of Health and Human Services carry out activities to streamline regulatory oversight of human cell and tissue products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 13, 2025

Mr. CRENSHAW (for himself and Ms. BARRAGÁN) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To direct the Secretary of Health and Human Services carry out activities to streamline regulatory oversight of human cell and tissue products, 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 “The HCT/P Mod-
5 ernization Act of 2025”.

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

cell and tissue products” have the meaning given the term “human cells, tissues, or cellular or tissue-based products” in section 1271.3(d) of title 21, Code of Federal Regulations (or successor regulations).

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

(3) TISSUE REFERENCE GROUP.—The term “Tissue Reference Group” means the Tissue Reference Group of the Food and Drug Administration.

**SEC. 3. STREAMLINING REGULATORY OVERSIGHT OF
HUMAN CELL AND TISSUE PRODUCTS.**

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

(1) WEBSITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publish on the public website of the Food and Drug Administration—

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

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

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

7 (A) the number of human cell and tissue
8 establishments that registered with the Food
9 and Drug Administration on or after January
10 1, 2019;

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

18 (C) the number and type of inquiries to
19 the Tissue Reference Group in the preceding
20 year; and

21 (D) the average response time for submis-
22 sions to the Tissue Reference Group in the pre-
23 ceding year, including average initial and final
24 response time.

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

5 (A) provide information to relevant stake-
6 holders, including industry, tissue establish-
7 ments, academic health centers, biomedical con-
8 sortia, research organizations, and patients; and

9 (B) conduct workshops and other inter-
10 active and educational sessions for such stake-
11 holders to help support regulatory predictability
12 and scientific advancement, as appropriate.

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

24 (c) PUBLIC DOCKET.—Not later than 60 days after
25 the date of the enactment of this Act, the Secretary shall

1 establish a public docket to receive written comments re-
2 lated to—

3 (1) the approaches recommended for discussion
4 during the public workshop described in section
5 3205 of the Food and Drug Omnibus Reform Act of
6 2022 (title III of division FF of Public Law 117–
7 328); and

8 (2) modernizing the regulation of human cell
9 and tissue products, including considerations associ-
10 ated with assessing minimal manipulation and ho-
11 mologous use (as such terms are defined in section
12 1271.3 of title 21, Code of Federal Regulations (or
13 successor regulations)) of human cell and tissue
14 products.

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

25 (1) regulatory burden;

- 1 (2) scientific developments;
- 2 (3) access to human cell and tissue products
- 3 regulated under section 361 of the Public Health
- 4 Service Act (42 U.S.C. 264); and
- 5 (4) protecting public health.

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