AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 7188

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Shandra Eisenga Human Cell and Tissue Product Safety Act''.

SEC. 2. DEFINITIONS.

In this Act:

(1) HUMAN CELL AND TISSUE PRODUCT.—The 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 a successor regulation).

(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. HUMAN CELL AND TISSUE PRODUCTS TRANSPLANT PUBLIC AWARENESS CAMPAIGN.

The Secretary, in coordination with the Organ Procurement and Transplantation Network and other appropriate organizations, shall support the development and dissemination of educational materials to inform health care professionals and other appropriate professionals about issues surrounding—

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

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

(3) other relevant aspects of organ donation.

SEC. 4. REVIEW AND UPDATE OF EXISTING GUIDANCE.

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

(1) not later than 1 year after the date of the enactment of this Act, initiate an internal review of existing guidance for determining eligibility of donors of human cell and tissue products;

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

(A) update the guidance titled ''Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products;

Guidance for Industry'' issued August 2007; and

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

(i) recommendations to reduce the risk of transmission of mycobacterium tuberculosis by human cells, tissues, and cellular and tissue-based products (HCT/Ps); or

(ii) recommendations to reduce the risk of transmission of disease agents associated with sepsis for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps); and

(3) if the Secretary determines that issuing or updating guidance as specified in paragraph (2) is not appropriate, provide a written statement of explanation of that determination to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

SEC. 5. 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 internet 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.

(2) EDUCATION.—The Secretary, acting through the Commissioner of Food and Drugs, shall, with respect to the regulation of human cell and tissue products—

(A) provide information to relevant stakeholders, including industry, tissue establishments, academic health centers, biomedical consortia, research organizations, and patients; and

(B) conduct workshops and other interactive and educational sessions for such stakeholders to help support regulatory predictability and scientific advancement, as appropriate.

(b) HUMAN CELL AND TISSUE PRODUCT SCIENTIFIC AND REGULATORY UPDATES.—Section 3205 of the Food and Drug Omnibus Reform Act of 2022 (title III of division FF of Public Law 117–328) is amended by striking ''best practices'' and all that follows through ''other cellular therapies'' and inserting ''best practices on generating scientific data necessary to further facilitate the development of certain human cell-, tissue-, and cellular-based medical products (and the latest scientific information about such products) that are regulated as human cell and tissue products under section 361 of the Public Health Service Act (42 U.S.C. 264), drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), namely, stem cell and other cellular therapies''.

(c) PUBLIC DOCKET.—Not later than 60 days after the date of enactment of this Act, the Secretary shall establish a public docket to receive written comments related to—

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

(2) the definition of the term ''minimal manipulation'' under section 1271.3 of title 21, Code of Federal Regulations, including—

(A) previous and current interpretations of such term;

(B) the landscape of products which have been identified by the Food and Drug Administration as meeting—

(i) such definition of ''minimal manipulation'';

(ii) the definition of ''more than minimally manipulated'' as used in the guidance of the Food and Drug Administration titled ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use'' issued July 2020 (or any successor guidance); or

(iii) neither of the definitions referred to in clause (i) or (ii);

(C) the approximate scope of use of such products; and

(D) any changes to the interpretation of ''minimal manipulation'' that may be necessary to meet the risk benefit of such products; and

(3) considerations in assessing homologous use of human cell and tissue products, and the character and function of human cell and tissue products, including—

(A) previous and current considerations of such use, character, and function; and

(B) potential such considerations with respect to products described in paragraph (2)(B).

(d) REPORT TO CONGRESS.—Not later than September 30, 2026, the Secretary shall summarize the approaches discussed in the public workshop described in section 3205 of the Food and Drug Omnibus Reform Act of 2022 (title III of division FF of Public Law 117–328) and the public docket described in subsection (c), and develop and publish recommendations for modernizing considerations for homologous use of human cell and tissue products and the other criteria described in section 1271.10(a) of title 21, Code of Federal Regulations, and minimal manipulation under section 1271.3 of such title 21, taking into account—

(1) regulatory burden;

(2) scientific development;

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

(4) protecting public health.

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