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118TH CONGRESS
2D SESSION

H. R. 8251

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

IN THE HOUSE OF REPRESENTATIVES

MAY 6, 2024

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''The HCT/P Modernization Act of 2024''.

SEC. 2. STREAMLINING REGULATORY OVERSIGHT OF HUMAN CELL AND TISSUE PRODUCTS.

(a) REGULATORY CLASSIFICATION INQUIRIES.—

(1) INQUIRY DESCRIBED.—An inquiry described in this paragraph is an inquiry—

(A) made by the manufacturer or sponsor of a human cell and tissue product;

(B) to the Tissue Reference Group; and

(C) for information regarding the regulatory classification of whether such product is subject to regulation solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and part 1271 or title 21, Code of Federal Regulations (or successor regulations).

(2) RESPONSE BY SECRETARY.—Not later than 70 days after receipt of a written inquiry described in subsection (a) from a manufacturer or sponsor of a human cell and tissue product, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall provide such manufacturer or sponsor—

(A) a nonbinding, written statement on whether such product is subject to regulation solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and part 1271 or title 21, Code of Federal Regulations (or successor regulations); or

(B) a notification that the manufacturer or sponsor must resubmit the inquiry with additional information.

(3) REQUEST TO MEET WITH TISSUE REFERENCE GROUP.—

(A) REQUEST.—Upon receipt of a statement under paragraph (2)(A), the manufacturer or sponsor of a human cell and tissue product may request a meeting with the Tissue Reference Group to discuss the decision in such statement regarding the product's regulatory classification.

(B) MEETING REQUIRED.—Upon receipt of a request under subparagraph (A), the Tissue Reference Group shall hold a meeting with the requesting manufacturer or sponsor.

(b) PUBLIC MEETING.—Not later than 90 days after the date of enactment of this Act, the Secretary shall publish in the Federal Register a notice to convene a public meeting to discuss and obtain input and recommendations from relevant stakeholders, including industry, tissue establishments, academic health centers, biomedical consortia, research organizations, and patients, regarding—

(1) 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 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'' (dated July 2020) (or any successor guidance); or

(iii) neither the definition 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

(2) 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 (1)(B).

(c) UPDATES TO REGULATIONS AND GUIDANCE.—

(1) IN GENERAL.—Not later than 12 months after the date of enactment of this Act, the Secretary shall update the criteria for homologous use and the other criteria under section 1271.10(a) of title 21, Code of Federal Regulations, and the definition of minimal manipulation under section 1271.3 of such title 21, with the goals of—

(A) minimizing regulatory burden;

(B) protecting public health; and

(C) maintaining the existence of the current pathways by which certain human cell and tissue products are marketed under section 361 of the Public Health Service Act (42 U.S.C. 264), certain biological products are licensed under section 351 of the Public Health Service

Act (42 U.S.C. 351), and certain drugs are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(2) TECHNICAL ASSISTANCE; EDUCATION.—The Secretary shall, with respect to the regulation of human cell and tissue products, including the updates under paragraph (1)—

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

(B) at least every six months, initiate and conduct workshops and other interactive and educational sessions for such stakeholders.

(d) REPORTS TO CONGRESS.—

(1) REPORT ON MEETING.—Not later than 12 months after the date of enactment of this Act, the Secretary shall submit a report to the Congress on the results of the meeting under subsection (b).

(2) ANNUAL REPORT.—Not later than March 1, 2025, and March 1 of each calendar year thereafter, the Secretary shall, with respect to the previous calendar year, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and

the Committee on Energy and Commerce of the House of Representatives, and publish on the internet website of the Department of Health and Human Services, a report on—

(A) the number and type of inquiries received by the Tissue Reference Group;

(B) the average response time for inquiries received by the Tissue Reference Group, including the average response times for initial and final responses; and

(C) with respect to final decisions issued by the Tissue Reference Group, the number of human cell and tissue products determined to be regulated under each regulatory category.

(e) DEFINITIONS.—In this section:

(1) The term ''human cell and tissue product''—

(A) means a ''human cells, tissues, or cellular or tissue based product'' as such term is defined in section 1271.3 of title 21, Code of Federal Regulations (or successor regulations); and

(B) includes any such product regardless of whether it is approved for marketing, ap-

proved for investigational use, or merely proposed.

(2) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

(3) The term ''Tissue Reference Group'' means the Tissue Reference Group of the Food and Drug Administration.

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