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118TH CONGRESS
2D SESSION

H. R. 7188

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 1, 2024

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

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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.

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 ''Shandra Eisenga Human Cell and Tissue Product Safety Act''.

SEC. 2. DEFINITIONS.

In this Act:

(1) HUMAN CELL AND TISSUE ESTABLISHMENT.—The term ''human cell and tissue establishment'' means an establishment (as defined in section 1271.3(b) of title 21, Code of Federal Regulations (or a successor regulation)) regulated by the Center for Biologics Evaluation and Research under part 1271 of title 21, Code of Federal Regulations.

(2) HUMAN CELL AND TISSUE PRODUCTS.—The term ''human cell and tissue products'' has 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).

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

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

(a) IN GENERAL.—The Secretary shall 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.

(b) CONSIDERATION OF ADVICE OF STAKEHOLDER EXPERTS.—The Secretary shall develop the education campaign under subsection (a) after taking into consider-

ation the advice of stakeholder experts, including the Centers for Disease Control and Prevention and professional associations that represent stakeholders of human cell and tissue establishments that manufacture human cell and tissue products with the highest risk of transmitting infections to their patients.

(c) GRANTS.—

(1) IN GENERAL.—The Secretary may award grants to nonprofit organizations to carry out activities described in paragraph (2).

(2) USE OF FUNDS.—A recipient of a grant under paragraph (1) shall use the grant funds—

(A) to increase the knowledge and awareness of the public about the potential risks and benefits of human cell and tissue products transplants, including the risks that such transplants may lead to infectious diseases, including tuberculosis, latent tuberculosis infection, and sepsis; or

(B) to increase the knowledge and awareness of health care providers and health care leaders about the potential risks and benefits of human cell and tissue products transplants, including the risks that such transplants may

lead to infectious diseases, including tuberculosis, latent tuberculosis infection, and sepsis.

(d) MEDIA CAMPAIGNS.—

(1) IN GENERAL.—In carrying out the education campaign under subsection (a), the Secretary, after taking into consideration the advice of stakeholder experts, may award grants to, or enter into contracts with, entities to establish national multimedia campaigns to increase public and health care provider awareness regarding the potential risks of human cell and tissue products transplants.

(2) INCLUSIONS.—The multimedia campaigns under paragraph (1) may include advertising through television, radio, print media, billboards, posters, all forms of existing and emerging social networking media, other internet media, and any other medium determined appropriate by the Secretary.

SEC. 4. CIVIL PENALTIES FOR VIOLATION OF REQUIREMENTS FOR HUMAN CELL AND TISSUE PRODUCTS.

(a) IN GENERAL.—Any person who violates a requirement of section 361 of the Public Health Service Act (42 U.S.C. 264) or part 1271 of title 21, Code of Federal Regulations (or successor regulations) with respect to

human cell or tissue products shall be liable to the United States for a civil penalty in an amount not to exceed the sum of—

(1)(A) $20,000 for each violation; or

(B) $20,000 for each day of a continuing violation; and

(2) an amount equal to the retail value of the human cell and tissue products that are the subject of the violation.

(b) MAXIMUM PENALTY.—The total civil penalty under subsection (a) shall not exceed $10,000,000 for all such violations adjudicated in a single proceeding.

SEC. 5. REPORT TO CONGRESS.

Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report that describes actions Congress and the Food and Drug Administration could take to improve the safety of human cell and tissue products, including—

(1) an examination of existing regulations and guidance relating to human cell and tissue products;

(2) documentation of the number of human cell and tissue establishments that have registered with the Food and Drug Administration since 1998;

(3) how often the Food and Drug Administration has inspected human cell and tissue establish-

ments since 1998, including a comparison of the inspection rates for blood establishments and Source Plasma establishments with the inspection rates for such human cell and tissue establishments, potential causes of declines in such inspections, if applicable, and recommendations to increase Food and Drug Administration resources, if applicable; and

(4) recommendations on potential guidance or regulations that could be issued or promulgated, as applicable, to improve donor screening for human cell and tissue products.

SEC. 6. 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 enactment of this Act, initiate an internal review of existing guidance for determining eligibility of donors of human cell and tissue products; and

(2) not later than 3 years after the date of enactment of this Act, issue updated guidance for determining eligibility of donors of human cell and tissue products to comply with part 1271 of title 21, Code of Federal Regulations (or successor regulations), including compliance in determining donor eligibility in accordance with subpart C of part 1271

of title 21, Code of Federal Regulations (or successor regulations).

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