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116TH CONGRESS
2D SESSION

H. R. 8168

To require the guidance of the Food and Drug Administration on reducing the risk of human immunodeficiency virus (HIV), hepatitis A, and hepatitis B transmission by blood and blood products (including the donor history questionnaire) to be based on an individual risk assessment of sexual behaviors upon which all donors are evaluated equally, without regard to sexual orientation or gender identity, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 4, 2020

Mrs. DEMINGS (for herself and Mr. QUIGLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the guidance of the Food and Drug Administration on reducing the risk of human immunodeficiency virus (HIV), hepatitis A, and hepatitis B transmission by blood and blood products (including the donor history questionnaire) to be based on an individual risk assessment of sexual behaviors upon which all donors are evaluated equally, without regard to sexual orientation or gender identity, 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 ''Science in Blood Donation Act of 2020''.

SEC. 2. REQUIRING GUIDANCE ON REDUCING RISK OF HIV, HEPATITIS A, AND HEPATITIS B TRANSMISSION BY BLOOD PRODUCTS TO BE BASED ON AN INDIVIDUAL RISK ASSESSMENT.

(a) IN GENERAL.—The Secretary of Health and Human Services acting through the Commissioner of Food and Drugs (in this section referred to as the ''Secretary'') shall—

(1) not later than 45 days after the date of enactment of this Act, revise and publish the guidance of the Food and Drug Administration on reducing the risk of human immunodeficiency virus, hepatitis A, and hepatitis B transmission by blood and blood products so as to eliminate—

(A) the recommendation to defer for 3 months from the most recent sexual contact, a man who has had sex with another man during the past 3 months; and

(B) the recommendation to defer for 3 months from the most recent sexual contact, a female who has had sex during the past 3 months with a man who has had sex with another man in the past 3 months;

(2) not later than 45 days after the date of enactment of this Act, initiate a process—

(A) to update such guidance—

(i) in conformity with paragraph (1); and

(ii) so as to ensure that such guidance, including the corresponding donor deferral recommendations, are based on an individual risk assessment of sexual behaviors upon which all donors are evaluated equally, without regard to sexual orientation or gender identity; and

(B) to update the donor history questionnaire consistent with the updates under subparagraph (A); and

(3) not later than 18 months after the date of enactment of this Act—

(A) complete the process initiated pursuant to paragraph (2); and

(B) publish the updated guidance and donor history questionnaire.

(b) SPECIAL RULE.—Throughout the period during which the Secretary is revising guidance pursuant to subsection (a)(1), the recommendations described in subpara-

graphs (A) and (B) of subsections (a)(1) are deemed to be eliminated with respect to any individual who—

(1) is a human subject in research;

(2) is being routinely tested for human immunodeficiency virus, hepatitis A, and hepatitis B as part of such research; and

(3) is not found, pursuant to such testing, to be positive for human immunodeficiency virus, hepatitis A, or hepatitis B.

(c) PROGRESS REPORT.—The Secretary shall—

(1) not later than each of 6 and 12 months after the date of enactment of this Act, submit a report to the appropriate congressional committees on the progress made pursuant to the process under subsection (a)(2); and

(2) not later than 18 months after the date of enactment of this Act, submit a final report to the appropriate congressional committees on the updated guidance and donor history questionnaire.

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