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116TH CONGRESS
1ST SESSION

H. R. 1966

To direct the Comptroller General of the United States to complete a study on barriers to participation in federally funded cancer clinical trials by populations that have been traditionally underrepresented in such trials.

IN THE HOUSE OF REPRESENTATIVES

MARCH 28, 2019

Mr. CUMMINGS (for himself, Mr. SARBANES, and Mr. RUPPERSBERGER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Armed Services, and Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To direct the Comptroller General of the United States to complete a study on barriers to participation in federally funded cancer clinical trials by populations that have been traditionally underrepresented in such trials.

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 ''Henrietta Lacks Enhancing Cancer Research Act of 2019''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Only a small percent of patients participate in cancer clinical trials, even though most express an interest in clinical research. There are several obstacles that restrict individuals from participating including lack of available local trials, restrictive eligibility criteria, transportation to trial sites, taking time off from work, and potentially increased medical and nonmedical costs. Ultimately, about 1 in 5 cancer clinical trials fail because of lack of patient enrollment.

(2) Groups that are generally underrepresented in clinical trials include racial and ethnic minorities and older, rural, and lower-income individuals.

(3) Henrietta Lacks, an African-American woman, was diagnosed with cervical cancer at the age of 31, and despite receiving painful radium treatments, passed away on October 4, 1951.

(4) Medical researchers took samples of Henrietta Lacks' tumor during her treatment and the HeLa cell line from her tumor proved remarkably resilient.

(5) HeLa cells were the first immortal line of human cells. Henrietta Lacks' cells were unique, growing by the millions, commercialized and distrib-

uted worldwide to researchers, resulting in advances in medicine.

(6) Henrietta Lacks' prolific cells continue to grow and contribute to remarkable advances in medicine, including the development of the polio vaccine, as well as drugs for treating the effects of cancer, HIV/AIDS, hemophilia, leukemia, and Parkinson's disease. These cells have been used in research that has contributed to our understanding of the effects of radiation and zero gravity on human cells. These immortal cells have informed research on chromosomal conditions, cancer, gene mapping, and precision medicine.

(7) Henrietta Lacks and her immortal cells have made a significant contribution to global health, scientific research, quality of life, and patient rights.

(8) For more than 20 years, the advances made possible by Henrietta Lacks' cells were without her or her family's consent, and the revenues they generated were not known to or shared with her family.

(9) Henrietta Lacks and her family's experience is fundamental to modern and future bioethics policies and informed consent laws that benefit patients nationwide by building patient trust; promoting eth-

ical research that benefits all individuals, including traditionally underrepresented populations; and protecting research participants.

SEC. 3. GAO STUDY ON BARRIERS TO PARTICIPATION IN FEDERALLY FUNDED CANCER CLINICAL TRIALS BY POPULATIONS THAT HAVE BEEN TRADITIONALLY UNDERREPRESENTED IN SUCH TRIALS.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall—

(1) complete a study that—

(A) reviews what actions Federal agencies have taken to help to address barriers to participation in federally funded cancer clinical trials by populations that have been traditionally underrepresented in such trials, and identifies challenges, if any, in implementing such actions; and

(B) identifies additional actions that can be taken by Federal agencies to address barriers to participation in federally funded cancer clinical trials by populations that have been traditionally underrepresented in such trials; and

(2) submit a report to the Congress on the results of such study, including recommendations on potential changes in practices and policies to improve participation in such trials by such populations.

(b) INCLUSION OF CLINICAL TRIALS.—The study under subsection (a)(1) should include review of cancer clinical trials that are largely funded by Federal agencies, including the National Institutes of Health, the Department of Defense, the Department of Veterans Affairs, the Agency for Health Research and Quality, the Food and Drug Administration, and such other Federal agencies as the Comptroller General of the United States may identify.

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