119TH CONGRESS
2D SESSION

S. _____

To increase utilization of breast cancer risk assessment tools, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. KELLY (for himself and Mrs. CAPITO) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To increase utilization of breast cancer risk assessment tools, 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 ''Know Your Risk Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) According to the Centers for Disease Control and Prevention, 288,494 new breast cancers were reported in women in the United States in 2023.

(2) According to the American Cancer Society, in 2026, in the United States, an estimated 324,600 individuals will be diagnosed with, and 42,670 individuals will die from, breast cancer.

(3) Rates of breast cancer in women under age 45 have been increasing across racial and ethnic groups.

(4) When breast cancer is diagnosed early at a localized stage, the 5-year relative survival rate is approximately 99 percent.

(5) Breast cancer risk assessment tools help clinicians estimate a patient's risk of developing invasive breast cancer over a specific time period, allowing for more personalized breast health care based on a patient's personal and family health history.

(6) Breast cancer risk assessment tools use different combinations of personal, reproductive, and family history information to estimate breast cancer risk.

(7) The Tyrer-Cruzick model, the Breast Cancer Risk Assessment Tool (BCRAT) of the National Cancer Institute, and the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Al-

gorithm (BOADICEA) are examples of such scientifically-validated breast cancer risk assessment tools.

(8) Model performance varies across populations, demonstrating the need for continuous improvement of breast cancer risk assessment tools.

(9) Improving the accuracy and awareness of breast cancer risk assessment tools can aid in the earlier detection of breast cancers and save lives.

SEC. 3. INCREASING UTILIZATION OF BREAST CANCER RISK ASSESSMENT TOOLS.

Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following:

"SEC. 417H. INCREASING UTILIZATION OF BREAST CANCER RISK ASSESSMENT TOOLS.

''(a) INTERAGENCY TASK FORCE.—

''(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Know Your Risk Act, the Secretary shall establish a task force, to be known as the Interagency Task Force to Increase Utilization of Breast Cancer Risk Assessment Tools (referred to in this section as the 'Task Force'), for purposes of increasing use of evidence-based breast cancer risk assessment tools.

''(2) DUTIES.—The Task Force shall—

"(A) develop strategies to improve access to, evaluation of, and awareness of, evidence-based breast cancer risk assessment tools to guide personalized breast health care, including strategies to improve access to guideline-recommended genetic counseling and testing services or other testing services that may be needed prior to using such tools;

"(B) provide guidance on the appropriate use of such tools with consideration of population demographics including age, racial or ethnic background, personal and family health history, known genetic information, reproductive history, and breast density;

"(C) evaluate barriers to adoption of such tools in clinical settings;

"(D) recommend updates to address known limitations in the predictive accuracy of such tools; and

"(E) recommend appropriate strategies to increase access to, and utilization of, medically necessary interventions following assessment findings, including enhanced surveillance through supplemental imaging, genetic counseling and testing, and adoption of risk-reduc-

ing medication, as appropriate and in accordance with guidelines of the National Comprehensive Cancer Network.

''(3) MEMBERSHIP.—

''(A) IN GENERAL.—The Task Force shall be composed of members appointed by the Secretary, including 1 or more of each of the following:

''(i) Representatives of the Department of Health and Human Services, including the National Institutes of Health, the Office on Women's Health, and the Centers for Disease Control and Prevention.

''(ii) Representatives of nonprofit organizations with expertise related to breast cancer.

''(iii) Individuals with relevant medical and scientific expertise on breast cancer, family or internal medicine, gynecology, and known inherited genetic risk of cancer.

''(iv) Representatives of organizations that provide relevant clinical guidelines.

"(v) Individuals who have, are at an increased risk of having, or have previously had, breast cancer.

"(B) COMPOSITION.—The members described in clauses (ii), (iii), (iv), and (v) of subparagraph (A) shall compose, collectively, not more than one half and not less than one third of the total membership of the Task Force.

"(C) CHAIR.—The Secretary shall appoint a chair of the Task Force from among the members representing the National Institutes of Health appointed under subparagraph (A)(i).

"(4) REPORT.—

"(A) IN GENERAL.—The Task Force shall 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 an annual report describing its work related to the duties described in paragraph (2).

"(B) PUBLIC ACCESS.—Each report described in subparagraph (A) shall be made available to the public in an easily accessible online format.

''(b) RESEARCH, EVALUATION, AND MODEL IMPROVEMENT.—

''(1) IN GENERAL.—The Secretary, acting through the Director of NIH, shall support ongoing research on breast cancer risk assessment tools, for purposes of refining such tools through improvements with respect to—

''(A) the risk assessment for patient populations for whom the existing tools are inaccurate;

''(B) data limitations, in order to develop more accurate, representative risk models; and

''(C) the utilization of artificial intelligence.

''(2) REPORTING.—Not later than 1 year after the date of enactment of the Know Your Risk Act, the Secretary shall submit a report on progress and findings of the research under paragraph (1), and recommendations based on such research to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives.

''(c) PUBLIC EDUCATION AND CLINICAL INTEGRATION.—The Director of the Institute shall, not later than 1 year after the date of enactment of the Know Your Risk Act, and every 2 years thereafter—

''(1) update and expand publicly available educational materials relating to recommendations of the Task Force, including clear explanations of the capabilities and limitations of breast cancer risk assessment tools, evidence-based guidance on clinical use of the tools, and materials for populations whose risk is unrepresented or inaccurately estimated by existing such tools; and

''(2) collaborate with national medical professional societies, physician organizations, nursing organizations, and other relevant clinical organizations to update and disseminate educational and training materials related to the use of such tools.''.