

110TH CONGRESS  
2D SESSION

# S. 2569

To amend the Public Health Service Act to authorize the Director of the National Cancer Institute to make grants for the discovery and validation of biomarkers for use in risk stratification for, and the early detection and screening of, ovarian cancer.

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## IN THE SENATE OF THE UNITED STATES

JANUARY 29, 2008

Mrs. BOXER (for herself, Mrs. DOLE, Mr. TESTER, Mrs. MURRAY, Mr. WYDEN, Ms. CANTWELL, Ms. STABENOW, and Mr. OBAMA) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Public Health Service Act to authorize the Director of the National Cancer Institute to make grants for the discovery and validation of biomarkers for use in risk stratification for, and the early detection and screening of, ovarian cancer.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Ovarian Cancer Bio-  
5       marker Research Act of 2008”.

1 **SEC. 2. GRANTS FOR ESTABLISHMENT AND OPERATION OF**  
 2 **RESEARCH CENTERS FOR THE STUDY OF**  
 3 **OVARIAN CANCER BIOMARKERS.**

4 Subpart 1 of part C of the Public Health Service Act  
 5 is amended by adding at the end the following new section:

6 **“SEC. 417E. GRANTS FOR ESTABLISHMENT AND OPERATION**  
 7 **OF RESEARCH CENTERS FOR THE STUDY OF**  
 8 **OVARIAN CANCER BIOMARKERS.**

9 “(a) IN GENERAL.—The Director of the Institute, in  
 10 consultation with the directors of other relevant institutes  
 11 and centers of the National Institutes of Health and the  
 12 Department of Defense Ovarian Cancer Research Pro-  
 13 gram, shall enter into cooperative agreements with, or  
 14 make grants to, public or nonprofit entities to establish  
 15 and operate centers to conduct research on biomarkers for  
 16 use in risk stratification for, and the early detection and  
 17 screening of, ovarian cancer, including fallopian tube can-  
 18 cer or primary peritoneal cancer. Each center shall be  
 19 known as an Ovarian Cancer Biomarker Center of Excel-  
 20 lence.

21 “(b) RESEARCH FUNDED.—Federal payments made  
 22 under a cooperative agreement or grant under subsection  
 23 (a) may be used for research on any of the following:

24 “(1) The development and characterization of  
 25 new biomarkers, and the refinement of existing bio-  
 26 markers, for ovarian cancer.

1           “(2) The clinical and laboratory validation of  
2           such biomarkers, including technical development,  
3           standardization of assay methods, sample prepara-  
4           tion, reagents, reproducibility, portability, and other  
5           refinements.

6           “(3) The development and implementation of  
7           clinical and epidemiological research on the utiliza-  
8           tion of biomarkers for the early detection and  
9           screening of ovarian cancer.

10          “(4) The development and implementation of  
11          repositories for new tissue, urine, serum, and other  
12          biological specimens (such as ascites and pleural  
13          fluids).

14          “(c) FIRST AGREEMENT OR GRANT.—Not later than  
15          1 year after the date of the enactment of this section, the  
16          Director of the Institute shall enter into the first coopera-  
17          tive agreement or make the first grant under this section.

18          “(d) AVAILABILITY OF BANKED SPECIMENS.—The  
19          Director of the Institute shall make available for research  
20          conducted under this section banked serum and tissue  
21          specimens from clinical research regarding ovarian cancer  
22          that was funded by the Department of Health and Human  
23          Services.

24          “(e) REPORT.—Not later than the end of fiscal year  
25          2009, and annually thereafter, the Director of the Insti-

1 tute shall submit a report to the Congress on the coopera-  
 2 tive agreements entered into and the grants made under  
 3 this section.

4 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
 5 purpose of carrying out this section, there are authorized  
 6 to be appropriated \$25,000,000 for each of the fiscal years  
 7 2009 through 2012, and such sums as may be necessary  
 8 for each of the fiscal years 2013 through 2019. Such au-  
 9 thorization of appropriations is in addition to any other  
 10 authorization of appropriations that is available for such  
 11 purpose.”.

12 **SEC. 3. OVARIAN CANCER BIOMARKER CLINICAL TRIAL**  
 13 **COMMITTEE.**

14 Subpart 1 of part C of the Public Health Service Act,  
 15 as amended by section 2, is further amended by adding  
 16 at the end the following new section:

17 **“SEC. 417F. OVARIAN CANCER BIOMARKER CLINICAL TRIAL**  
 18 **COMMITTEE.**

19 “(a) OVARIAN CANCER BIOMARKER RESEARCH COM-  
 20 MITTEE ESTABLISHED.—The Director of the Institute  
 21 shall establish an Ovarian Cancer Biomarker Clinical  
 22 Trial Committee (in this section referred to as the ‘Com-  
 23 mittee’) to assist the Director to design and implement  
 24 one or more national clinical trials, in accordance with this  
 25 section, to determine the utility of using biomarkers vali-

1 dated pursuant to the research conducted under section  
2 417E for risk stratification for, and early detection and  
3 screening of, ovarian cancer. Such Committee shall be es-  
4 tablished and operate in consultation with the Gynecologic  
5 Oncology Group (as funded by the National Cancer Insti-  
6 tute).

7 “(b) MEMBERSHIP.—

8 “(1) IN GENERAL.—The Committee shall con-  
9 sist of the following types of members, to be ap-  
10 pointed by the Director of the Institute, in consulta-  
11 tion with appropriate national medical and research  
12 societies and patient advocate groups:

13 “(A) National experts in statistical anal-  
14 ysis, clinical trial design, and patient recruit-  
15 ment.

16 “(B) National experts in ovarian cancer re-  
17 search.

18 “(C) Patient advocates.

19 “(D) Representatives of Federal Govern-  
20 ment agencies that currently fund ovarian can-  
21 cer research.

22 “(E) Nonvoting members that the Director  
23 of the Institute determines to be appropriate.

24 “(2) PAY.—Members of the Committee shall  
25 serve without pay and those members who are full

1       time officers or employees of the United States shall  
2       receive no additional pay by reason of their service  
3       on the Committee, except that members of the Com-  
4       mittee shall receive travel expenses, including per  
5       diem in lieu of subsistence, in accordance with appli-  
6       cable provisions under chapter I of chapter 57 of  
7       title 5, United States Code.

8       “(c) MEETINGS.—The Committee shall meet at the  
9       call of the chairperson or upon the request of the Director  
10      of the Institute, but at least four times each year.

11      “(d) CLINICAL TRIAL SPECIFICATIONS.—In design-  
12      ing and implementing the clinical trials under this section,  
13      the Director of the Institute shall provide for the fol-  
14      lowing:

15           “(1) PARTICIPATION IN TRIAL.—To the great-  
16      est extent possible, all academic centers, community  
17      cancer centers, and individual physician investigators  
18      (as defined in subsection (e)) shall have the oppor-  
19      tunity to participate in the trials under this section  
20      and to enroll women at risk for ovarian cancer in the  
21      trials.

22           “(2) COSTS FOR ENROLLMENTS.—Subject to  
23      the availability of appropriations, all the costs to the  
24      centers and offices described in paragraph (1) for

1 enrolling women in the trials under this section shall  
 2 be reimbursed by the Institute.

3 “(3) NATIONAL DATA CENTER.—A national  
 4 data center shall be established in and supported by  
 5 the Institute to conduct statistical analyses of the  
 6 data derived from the trials under this section and  
 7 to store such analyses and data.

8 “(4) GUIDELINES FOR MEDICAL COMMUNITY.—  
 9 Data and statistical analyses of the clinical trials  
 10 under this section shall be used to establish clinical  
 11 guidelines to provide the medical community with in-  
 12 formation regarding the use of biomarkers validated  
 13 pursuant to the research conducted under section  
 14 417E for risk stratification for, and early detection  
 15 and screening of, ovarian cancer.

16 “(e) INDIVIDUAL PHYSICIAN INVESTIGATOR DE-  
 17 FINED.—For purposes of subsection (d)(1), the term ‘indi-  
 18 vidual physician investigator’ means a physician—

19 “(1) who is a faculty member at an academic  
 20 institution or who is in a private medical practice;  
 21 and

22 “(2) who provides health care services to  
 23 women at risk for ovarian cancer.

24 “(f) REPORT.—Not later than the end of fiscal year  
 25 2009, and annually thereafter, the Director of the Insti-

1 tute shall submit a report to the Congress on the activities  
2 conducted under this section.

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—For the  
4 purpose of carrying out this section, there are authorized  
5 to be appropriated \$5,000,000 for each of the fiscal years  
6 2009 through 2012, and such sums as may be necessary  
7 for each of the fiscal years 2013 through 2019. Such au-  
8 thorization of appropriations is in addition to any other  
9 authorization of appropriations that is available for such  
10 purpose.”.

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