

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.

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

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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