

111TH CONGRESS
1ST SESSION

H. R. 1816

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 HOUSE OF REPRESENTATIVES

MARCH 31, 2009

Mr. BERMAN (for himself, Mr. HALL of Texas, Ms. BORDALLO, Ms. LEE of California, Mr. VAN HOLLEN, Mr. MCGOVERN, Mr. MCDERMOTT, Mr. BOUCHER, Mr. KING of New York, Mr. GENE GREEN of Texas, Mr. WOLF, Ms. KILROY, Mr. BURTON of Indiana, Mr. ISRAEL, Mr. HINCHEY, Mr. SESTAK, Ms. DELAURO, Ms. SHEA-PORTER, Mrs. MALONEY, Mr. MCMAHON, Ms. WASSERMAN SCHULTZ, Mrs. CAPPS, Mr. SERRANO, Mr. FARR, and Ms. EDWARDS of Maryland) introduced the following bill; which was referred to the Committee on Energy and Commerce

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Ovarian Cancer Bio-
3 marker Research Act of 2009”.

4 **SEC. 2. GRANTS FOR ESTABLISHMENT AND OPERATION OF**
5 **RESEARCH CENTERS FOR THE STUDY OF**
6 **OVARIAN CANCER BIOMARKERS.**

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

9 **“SEC. 417G. GRANTS FOR ESTABLISHMENT AND OPER-**
10 **ATION OF RESEARCH CENTERS FOR THE**
11 **STUDY OF OVARIAN CANCER BIOMARKERS.**

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

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

4 “(1) The development and characterization of
5 new biomarkers, and the refinement of existing bio-
6 markers, for ovarian cancer.

7 “(2) The clinical and laboratory validation of
8 such biomarkers, including technical development,
9 standardization of assay methods, sample prepara-
10 tion, reagents, reproducibility, portability, and other
11 refinements.

12 “(3) The development and implementation of
13 clinical and epidemiological research on the utiliza-
14 tion of biomarkers for the early detection and
15 screening of ovarian cancer.

16 “(4) The development and implementation of
17 repositories for new tissue, urine, serum, and other
18 biological specimens (such as ascites and pleural
19 fluids).

20 “(5) Genetics, proteomics, and pathways of
21 ovarian cancer as they relate to the discovery and
22 development of biomarkers.

23 “(c) FIRST AGREEMENT OR GRANT.—Not later than
24 1 year after the date of the enactment of this section, the

1 Director of the Institute shall enter into the first coopera-
2 tive agreement or make the first grant under this section.

3 “(d) AVAILABILITY OF BANKED SPECIMENS.—The
4 Director of the Institute shall make available for research
5 conducted under this section banked serum and tissue
6 specimens from clinical research regarding ovarian cancer
7 that was funded by the Department of Health and Human
8 Services.

9 “(e) REPORT.—Not later than the end of fiscal year
10 2010, and annually thereafter, the Director of the Insti-
11 tute shall submit a report to the Congress on the coopera-
12 tive agreements entered into and the grants made under
13 this section.

14 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
15 purpose of carrying out this section, there are authorized
16 to be appropriated \$25,000,000 for each of the fiscal years
17 2010 through 2013, and such sums as may be necessary
18 for each of the fiscal years 2014 through 2020. Such au-
19 thorization of appropriations is in addition to any other
20 authorization of appropriations that is available for such
21 purpose.”.

1 **SEC. 3. OVARIAN CANCER BIOMARKER CLINICAL TRIAL**
2 **COMMITTEE.**

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

6 **“SEC. 417H. OVARIAN CANCER BIOMARKER CLINICAL**
7 **TRIAL COMMITTEE.**

8 “(a) OVARIAN CANCER BIOMARKER RESEARCH COM-
9 MITTEE ESTABLISHED.—The Director of the Institute
10 shall establish an Ovarian Cancer Biomarker Clinical
11 Trial Committee (in this section referred to as the ‘Com-
12 mittee’) to assist the Director to design and implement
13 one or more national clinical trials, in accordance with this
14 section, to determine the utility of using biomarkers vali-
15 dated pursuant to the research conducted under section
16 417E for risk stratification for, and early detection and
17 screening of, ovarian cancer.

18 “(b) MEMBERSHIP.—

19 “(1) NUMBER.—The Committee shall consist of
20 11 voting members and such number of nonvoting
21 members as the Director of the Institute determines
22 appropriate.

23 “(2) APPOINTMENT.—The members of the
24 Committee shall be appointed by the Director of the
25 Institute, in consultation with appropriate national

1 medical societies, research societies, and patient ad-
2 vocate organizations, as follows:

3 “(A) VOTING MEMBERS.—The voting
4 members of the Committee shall be appointed
5 by the Director of the Institute as follows:

6 “(i) Two patient advocates.

7 “(ii) Two national experts in statis-
8 tical analysis, clinical trial design, and pa-
9 tient recruitment.

10 “(iii) Two representatives from the
11 Gynecologic Oncology Group.

12 “(iv) One representative from the De-
13 partment of Defense Ovarian Cancer Re-
14 search Program.

15 “(v) Four ovarian cancer researchers.

16 “(B) NONVOTING MEMBERS.—The non-
17 voting members of the Committee shall include
18 such individuals as the Director of the Institute
19 determines to be appropriate.

20 “(3) PAY.—Members of the Committee shall
21 serve without pay and those members who are full
22 time officers or employees of the United States shall
23 receive no additional pay by reason of their service
24 on the Committee, except that members of the Com-
25 mittee shall receive travel expenses, including per

1 diem in lieu of subsistence, in accordance with appli-
2 cable provisions under chapter I of chapter 57 of
3 title 5, United States Code.

4 “(c) CHAIRPERSON.—The voting members of the
5 Committee appointed under subsection (b)(2) shall select
6 a chairperson from among such members.

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

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

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

21 “(2) COSTS FOR ENROLLMENTS.—Subject to
22 the availability of appropriations, all the costs to the
23 centers and offices described in paragraph (1) for
24 enrolling women in the trials under this section shall
25 be reimbursed by the Institute.

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

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

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

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

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

22 “(g) REPORT.—Not later than the end of fiscal year
23 2010, and annually thereafter, the Director of the Insti-
24 tute shall submit a report to the Congress on the activities
25 conducted under this section.

1 “(h) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated \$5,000,000 for each of the fiscal years
4 2010 through 2013, and such sums as may be necessary
5 for each of the fiscal years 2014 through 2020. Such au-
6 thorization of appropriations is in addition to any other
7 authorization of appropriations that is available for such
8 purpose.”.

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