

110TH CONGRESS
1ST SESSION

H. R. 3689

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

SEPTEMBER 27, 2007

Mr. BERMAN (for himself, Mr. HALL of Texas, Mr. BURTON of Indiana, Mr. ISSA, Mrs. JO ANN DAVIS of Virginia, Mr. RADANOVICH, Mr. WOLF, Ms. LEE, Mr. McDERMOTT, Mr. McNULTY, Mrs. TAUSCHER, Mrs. MCCARTHY of New York, Ms. DELAURO, Mr. FARR, Mr. CLEAVER, Mr. WEINER, Mr. HONDA, Mr. PATRICK J. MURPHY of Pennsylvania, Mr. RUSH, Mr. GENE GREEN of Texas, Mr. ISRAEL, and Mr. KING of New York) 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 2007”.

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. 417E. GRANTS FOR ESTABLISHMENT AND OPERATION**
10 **OF RESEARCH CENTERS FOR THE STUDY OF**
11 **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.

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

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

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

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

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

17 “(c) FIRST AGREEMENT OR GRANT.—Not later than
18 1 year after the date of the enactment of this section, the
19 Director of the Institute shall enter into the first coopera-
20 tive agreement or make the first grant under this section.

21 “(d) AVAILABILITY OF BANKED SPECIMENS.—The
22 Director of the Institute shall make available for research
23 conducted under this section banked serum and tissue
24 specimens from clinical research regarding ovarian cancer

1 that was funded by the Department of Health and Human
2 Services.

3 “(e) REPORT.—Not later than the end of fiscal year
4 2009, and annually thereafter, the Director of the Insti-
5 tute shall submit a report to the Congress on the coopera-
6 tive agreements entered into and the grants made under
7 this section.

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

16 **SEC. 3. OVARIAN CANCER BIOMARKER CLINICAL TRIAL**
17 **COMMITTEE.**

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

21 **“SEC. 417F. OVARIAN CANCER BIOMARKER CLINICAL TRIAL**
22 **COMMITTEE.**

23 “(a) OVARIAN CANCER BIOMARKER RESEARCH COM-
24 MITTEE ESTABLISHED.—The Director of the Institute
25 shall establish an Ovarian Cancer Biomarker Clinical

1 Trial Committee (in this section referred to as the ‘Com-
2 mittee’) to assist the Director to design and implement
3 one or more national clinical trials, in accordance with this
4 section, to determine the utility of using biomarkers vali-
5 dated pursuant to the research conducted under section
6 417E for risk stratification for, and early detection and
7 screening of, ovarian cancer.

8 “(b) MEMBERSHIP.—

9 “(1) NUMBER.—The Committee shall consist of
10 11 voting members and such number of nonvoting
11 members as the Director of the Institute determines
12 appropriate.

13 “(2) APPOINTMENT.—The members of the
14 Committee shall be appointed by the Director of the
15 Institute, in consultation with appropriate national
16 medical societies, research societies, and patient ad-
17 vocate organizations, as follows:

18 “(A) VOTING MEMBERS.—The voting
19 members of the Committee shall be appointed
20 by the Director of the Institute as follows:

21 “(i) Two patient advocates.

22 “(ii) Two national experts in statis-
23 tical analysis, clinical trial design, and pa-
24 tient recruitment.

1 “(iii) Two representatives from the
2 Gynecologic Oncology Group.

3 “(iv) One representative from the De-
4 partment of Defense Ovarian Cancer Re-
5 search Program.

6 “(v) Four ovarian cancer researchers.

7 “(B) NONVOTING MEMBERS.—The non-
8 voting members of the Committee shall include
9 such individuals as the Director of the Institute
10 determines to be appropriate.

11 “(3) PAY.—Members of the Committee shall
12 serve without pay and those members who are full
13 time officers or employees of the United States shall
14 receive no additional pay by reason of their service
15 on the Committee, except that members of the Com-
16 mittee shall receive travel expenses, including per
17 diem in lieu of subsistence, in accordance with appli-
18 cable provisions under chapter I of chapter 57 of
19 title 5, United States Code.

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

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

1 “(e) CLINICAL TRIAL SPECIFICATIONS.—In design-
2 ing and implementing the clinical trials under this section,
3 the Director of the Institute shall provide for the fol-
4 lowing:

5 “(1) PARTICIPATION IN TRIAL.—To the great-
6 est extent possible, all academic centers, community
7 cancer centers, and individual physician investigators
8 (as defined in subsection (f)) shall have the oppor-
9 tunity to participate in the trials under this section
10 and to enroll women at risk for ovarian cancer in the
11 trials.

12 “(2) COSTS FOR ENROLLMENTS.—Subject to
13 the availability of appropriations, all the costs to the
14 centers and offices described in paragraph (1) for
15 enrolling women in the trials under this section shall
16 be reimbursed by the Institute.

17 “(3) NATIONAL DATA CENTER.—A national
18 data center shall be established in and supported by
19 the Institute to conduct statistical analyses of the
20 data derived from the trials under this section and
21 to store such analyses and data.

22 “(4) GUIDELINES FOR MEDICAL COMMUNITY.—
23 Data and statistical analyses of the clinical trials
24 under this section shall be used to establish clinical
25 guidelines to provide the medical community with in-

1 formation regarding the use of biomarkers validated
2 pursuant to the research conducted under section
3 417E for risk stratification for, and early detection
4 and screening of, ovarian cancer.

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

8 “(1) who is a faculty member at an academic
9 institution or who is in a private medical practice;
10 and

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

13 “(g) REPORT.—Not later than the end of fiscal year
14 2009, and annually thereafter, the Director of the Insti-
15 tute shall submit a report to the Congress on the activities
16 conducted under this section.

17 “(h) AUTHORIZATION OF APPROPRIATIONS.—For the
18 purpose of carrying out this section, there are authorized
19 to be appropriated \$5,000,000 for each of the fiscal years
20 2009 through 2012, and such sums as may be necessary
21 for each of the fiscal years 2013 through 2019. Such au-
22 thorization of appropriations is in addition to any other
23 authorization of appropriations that is available for such
24 purpose.”.

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