I

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

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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.

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 ''Ovarian Cancer Biomarker Research Act of 2009''.

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

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

''SEC. 417G. GRANTS FOR ESTABLISHMENT AND OPERATION OF RESEARCH CENTERS FOR THE STUDY OF OVARIAN CANCER BIOMARKERS.

''(a) IN GENERAL.—The Director of the Institute, in consultation with the directors of other relevant institutes and centers of the National Institutes of Health and the Department of Defense Ovarian Cancer Research Program, shall enter into cooperative agreements with, or make grants to, public or nonprofit entities to establish and operate centers to conduct research on biomarkers for use in risk stratification for, and the early detection and screening of, ovarian cancer, including fallopian tube cancer or primary peritoneal cancer. Each center shall be known as an Ovarian Cancer Biomarker Center of Excellence, and shall focus on translational research of ovarian cancer biomarkers.

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

''(1) The development and characterization of new biomarkers, and the refinement of existing biomarkers, for ovarian cancer.

''(2) The clinical and laboratory validation of such biomarkers, including technical development, standardization of assay methods, sample preparation, reagents, reproducibility, portability, and other refinements.

''(3) The development and implementation of clinical and epidemiological research on the utilization of biomarkers for the early detection and screening of ovarian cancer.

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

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

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

Director of the Institute shall enter into the first cooperative agreement or make the first grant under this section.

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

''(e) REPORT.—Not later than the end of fiscal year 2010, and annually thereafter, the Director of the Institute shall submit a report to the Congress on the cooperative agreements entered into and the grants made under this section.

''(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for each of the fiscal years 2010 through 2013, and such sums as may be necessary for each of the fiscal years 2014 through 2020. Such authorization of appropriations is in addition to any other authorization of appropriations that is available for such purpose.''.

SEC. 3. OVARIAN CANCER BIOMARKER CLINICAL TRIAL COMMITTEE.

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

"SEC. 417H. OVARIAN CANCER BIOMARKER CLINICAL TRIAL COMMITTEE.

''(a) OVARIAN CANCER BIOMARKER RESEARCH COMMITTEE ESTABLISHED.—The Director of the Institute shall establish an Ovarian Cancer Biomarker Clinical Trial Committee (in this section referred to as the 'Committee') to assist the Director to design and implement one or more national clinical trials, in accordance with this section, to determine the utility of using biomarkers validated pursuant to the research conducted under section 417E for risk stratification for, and early detection and screening of, ovarian cancer.

''(b) MEMBERSHIP.—

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

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

medical societies, research societies, and patient advocate organizations, as follows:

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

"(i) Two patient advocates.

"(ii) Two national experts in statistical analysis, clinical trial design, and patient recruitment.

"(iii) Two representatives from the Gynecologic Oncology Group.

"(iv) One representative from the Department of Defense Ovarian Cancer Research Program.

"(v) Four ovarian cancer researchers.

"(B) NONVOTING MEMBERS.—The nonvoting members of the Committee shall include such individuals as the Director of the Institute determines to be appropriate.

"(3) PAY.—Members of the Committee shall serve without pay and those members who are full time officers or employees of the United States shall receive no additional pay by reason of their service on the Committee, except that members of the Committee shall receive travel expenses, including per

diem in lieu of subsistence, in accordance with applicable provisions under chapter I of chapter 57 of title 5, United States Code.

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

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

''(e) CLINICAL TRIAL SPECIFICATIONS.—In designing and implementing the clinical trials under this section, the Director of the Institute shall provide for the following:

''(1) PARTICIPATION IN TRIAL.—To the greatest extent possible, all academic centers, community cancer centers, and individual physician investigators (as defined in subsection (f)) shall have the opportunity to participate in the trials under this section and to enroll women at risk for ovarian cancer in the trials.

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

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

''(4) GUIDELINES FOR MEDICAL COMMUNITY.—Data and statistical analyses of the clinical trials under this section shall be used to establish clinical guidelines to provide the medical community with information regarding the use of biomarkers validated pursuant to the research conducted under section 417E for risk stratification for, and early detection and screening of, ovarian cancer.

''(f) INDIVIDUAL PHYSICIAN INVESTIGATOR DEFINED.—For purposes of subsection (e)(1), the term 'individual physician investigator' means a physician—

''(1) who is a faculty member at an academic institution or who is in a private medical practice; and

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

''(g) REPORT.—Not later than the end of fiscal year 2010, and annually thereafter, the Director of the Institute shall submit a report to the Congress on the activities conducted under this section.

''(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for each of the fiscal years 2010 through 2013, and such sums as may be necessary for each of the fiscal years 2014 through 2020. Such authorization of appropriations is in addition to any other authorization of appropriations that is available for such purpose.''.

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