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,

SECTION 1. SHORT TITLE.

- 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.
- "(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.
- "(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).
- 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

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- 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.**
- 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:

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trials.

- 6 "(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
 - "(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 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 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
- 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.".