113TH CONGRESS
1ST SESSION

S. 516

To reduce disparities and improve access to effective and cost efficient diagnosis and treatment of prostate cancer through advances in testing, research, and education, including through telehealth, comparative effectiveness research, and identification of best practices in patient education and outreach particularly with respect to underserved racial, ethnic and rural populations and men with a family history of prostate cancer, to establish a directive on what constitutes clinically appropriate prostate cancer imaging, and to create a prostate cancer scientific advisory board for the Office of the Chief Scientist at the Food and Drug Administration to accelerate real-time sharing of the latest research and accelerate movement of new medicines to patients.

IN THE SENATE OF THE UNITED STATES

MARCH 11, 2013

Mr. TESTER (for himself and Mr. BLUNT) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To reduce disparities and improve access to effective and cost efficient diagnosis and treatment of prostate cancer through advances in testing, research, and education, including through telehealth, comparative effectiveness research, and identification of best practices in patient education and outreach particularly with respect to underserved racial, ethnic and rural populations and men with a family history of prostate cancer, to establish a directive on what constitutes clinically appropriate

prostate cancer imaging, and to create a prostate cancer scientific advisory board for the Office of the Chief Scientist at the Food and Drug Administration to accelerate real-time sharing of the latest research and accelerate movement of new medicines to patients.

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 ''Prostate Research, Outreach, Screening, Testing, Access, and Treatment Effectiveness Act of 2013'' or the ''PROSTATE Act''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Prostate cancer is the second leading cause of cancer death among men.

(2) In 2010, more than 217,730 new patients were diagnosed with prostate cancer and more than 32,000 men died from this disease.

(3) Roughly 2,000,000 Americans are living with a diagnosis of prostate cancer and its consequences.

(4) While prostate cancer generally affects older individuals, younger men are also at risk for the disease, and when prostate cancer appears in early middle age it frequently takes on a more aggressive form.

(5) There are significant racial and ethnic disparities that demand attention, namely African-Americans have prostate cancer mortality rates that are more than double those in the White population.

(6) Underserved rural populations have higher rates of mortality compared to their urban counterparts, and innovative and cost-efficient methods to improve rural access to high quality care should take advantage of advances in telehealth to diagnose and treat prostate cancer when appropriate.

(7) Certain veterans populations may have nearly twice the incidence of prostate cancer as the general population of the United States.

(8) Urologists may constitute the specialists who diagnose and treat the vast majority of prostate cancer patients.

(9) Although much basic and translational research has been completed and much is currently known, there are still many unanswered questions. For example, it is not fully understood how much of known disparities are attributable to disease etiology, access to care, or education and awareness in the community.

(10) Causes of prostate cancer are not known. There is not good information regarding how to dif-

ferentiate accurately, early on, between aggressive and indolent forms of the disease. As a result, there is significant overtreatment in prostate cancer. There are no treatments that can durably arrest growth or cure prostate cancer once it has metastasized.

(11) A significant proportion (roughly 23 to 54 percent) of cases may be clinically indolent and ''overdiagnosed'', resulting in significant overtreatment. More accurate tests will allow men and their families to face less physical, psychological, financial, and emotional trauma and billions of dollars could be saved in private and public health care systems in an area that has been identified by the Medicare program as one of eight high volume, high cost areas in the Resource Utilization Report program authorized by Congress under the Medicare Improvements for Patients and Providers Act of 2008.

(12) Prostate cancer research and health care programs across Federal agencies should be coordinated to improve accountability and actively encourage the translation of research into practice, to identify and implement best practices, in order to foster an integrated and consistent focus on effective prevention, diagnosis, and treatment of this disease.

SEC. 3. PROSTATE CANCER COORDINATION AND EDUCATION.

(a) INTERAGENCY PROSTATE CANCER COORDINATION AND EDUCATION TASK FORCE.—Not later than 180 days after the date of the enactment of this section, the Secretary of Veterans Affairs, in cooperation with the Secretary of Defense and the Secretary of Health and Human Services, shall establish an Interagency Prostate Cancer Coordination and Education Task Force (in this section referred to as the ''Prostate Cancer Task Force'').

(b) DUTIES.—The Prostate Cancer Task Force shall—

(1) develop a summary of advances in prostate cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of prostate cancer, including psychosocial impairments related to prostate cancer treatment, and compile a list of best practices that warrant broader adoption in health care programs;

(2) consider establishing, and advocating for, a guidance to enable physicians to allow screening of men who are over age 74, on a case-by-case basis, taking into account quality of life and family history of prostate cancer;

(3) share and coordinate information on Federal research and health care program activities, including activities related to—

(A) determining how to improve research and health care programs, including psychosocial impairments related to prostate cancer treatment;

(B) identifying any gaps in the overall research inventory and in health care programs;

(C) identifying opportunities to promote translation of research into practice; and

(D) maximizing the effects of Federal efforts by identifying opportunities for collaboration and leveraging of resources in research and health care programs that serve those susceptible to or diagnosed with prostate cancer;

(4) develop a comprehensive interagency strategy and advise relevant Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research and health care programs, including proposals to evaluate factors that may be related to the etiology of prostate cancer, that would—

(A) result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the

prostate cancer research portfolio of the Federal Government;

(B) outline key research questions, methodologies, and knowledge gaps; and

(C) ensure consistent action, as outlined by section 402(b) of the Public Health Service Act;

(5) develop a coordinated message related to screening and treatment for prostate cancer to be reflected in educational and beneficiary materials for Federal health programs as such documents are updated; and

(6) not later than two years after the date of the establishment of the Prostate Cancer Task Force, submit to the Expert Advisory Panel to be reviewed and returned within 30 days, and then within 90 days submitted to Congress recommendations—

(A) regarding any appropriate changes to research and health care programs, including recommendations to improve the research portfolio of the Department of Veterans Affairs, Department of Defense, National Institutes of Health, and other Federal agencies to ensure that scientifically based strategic planning is implemented in support of research and health care program priorities;

(B) designed to ensure that the research and health care programs and activities of the Department of Veterans Affairs, the Department of Defense, the Department of Health and Human Services, and other Federal agencies are free of unnecessary duplication;

(C) regarding public participation in decisions relating to prostate cancer research and health care programs to increase the involvement of patient advocates, community organizations, and medical associations representing a broad geographical area;

(D) on how to best disseminate information on prostate cancer research and progress achieved by health care programs;

(E) about how to expand partnerships between public entities, including Federal agencies, and private entities to encourage collaborative, cross-cutting research and health care delivery;

(F) assessing any cost savings and efficiencies realized through the efforts identified and supported in this Act and recommending expansion of those efforts that have proved most promising while also ensuring against any

conflicts in directives from other congressional or statutory mandates or enabling statutes;

(G) identifying key priority action items from among the recommendations; and

(H) with respect to the level of funding needed by each agency to implement the recommendations contained in the report.

(c) MEMBERS OF THE PROSTATE CANCER TASK FORCE.—The Prostate Cancer Task Force described in subsection (a) shall be composed of representatives from such Federal agencies, as each Secretary determines necessary, to coordinate a uniform message relating to prostate cancer screening and treatment where appropriate, including representatives of the following:

(1) The Department of Veterans Affairs, including representatives of each relevant program areas of the Department of Veterans Affairs.

(2) The Prostate Cancer Research Program of the Congressionally Directed Medical Research Program of the Department of Defense.

(3) The Department of Health and Human Services, including at a minimum representatives of the following:

(A) The National Institutes of Health.

(B) National research institutes and centers, including the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the Office of Minority Health.

(C) The Centers for Medicare & Medicaid Services.

(D) The Food and Drug Administration.

(E) The Centers for Disease Control and Prevention.

(F) The Agency for Healthcare Research and Quality.

(G) The Health Resources and Services Administration.

(d) APPOINTING EXPERT ADVISORY PANELS.—The Prostate Cancer Task Force shall appoint expert advisory panels, as determined appropriate, to provide input and concurrence from individuals and organizations from the medical, prostate cancer patient and advocate, research, and delivery communities with expertise in prostate cancer diagnosis, treatment, and research, including practicing urologists, primary care providers, and others and individuals with expertise in education and outreach to underserved populations affected by prostate cancer.

(e) MEETINGS.—The Prostate Cancer Task Force shall convene not less than twice a year, or more frequently as the Secretary determines to be appropriate.

(f) SUBMITTAL OF RECOMMENDATIONS TO CONGRESS.—The Secretary of Veterans Affairs shall submit to Congress any recommendations submitted to the Secretary under subsection (b)(5).

(g) FEDERAL ADVISORY COMMITTEE ACT.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Prostate Cancer Task Force.

(2) EXCEPTION.—Section 14(a)(2)(B) of such Act (relating to the termination of advisory committees) shall not apply to the Prostate Cancer Task Force.

(h) SUNSET DATE.—The Prostate Cancer Task Force shall terminate at the end of fiscal year 2016.

SEC. 4. PROSTATE CANCER RESEARCH.

(a) RESEARCH COORDINATION.—The Secretary of Veterans Affairs, in coordination with the Secretaries of Defense and of Health and Human Services, shall establish and carry out a program to coordinate and intensify prostate cancer research as needed. Specifically, such research program shall—

(1) develop advances in diagnostic and prognostic methods and tests, including biomarkers and an improved prostate cancer screening blood test, including improvements or alternatives to the prostate specific antigen test and additional tests to distinguish indolent from aggressive disease;

(2) better understand the etiology of the disease (including an analysis of life style factors proven to be involved in higher rates of prostate cancer, such as obesity and diet, and in different ethnic, racial, and socioeconomic groups, such as the African-American, Latin American, and American Indian populations and men with a family history of prostate cancer) to improve prevention efforts;

(3) expand basic research into prostate cancer, including studies of fundamental molecular and cellular mechanisms;

(4) identify and provide clinical testing of novel agents for the prevention and treatment of prostate cancer;

(5) establish clinical registries for prostate cancer;

(6) use the National Institute of Biomedical Imaging and Bioengineering and the National Can-

cer Institute for assessment of appropriate imaging modalities; and

(7) address such other matters relating to prostate cancer research as may be identified by the Federal agencies participating in the program under this section.

(b) PROSTATE CANCER ADVISORY BOARD.—There is established in the Office of the Chief Scientist of the Food and Drug Administration a Prostate Cancer Scientific Advisory Board. Such board shall be responsible for accelerating real-time sharing of the latest research data and accelerating movement of new medicines to patients.

(c) UNDERSERVED MINORITY GRANT PROGRAM.—In carrying out such program, the Secretary shall—

(1) award grants to eligible entities to carry out components of the research outlined in subsection (a);

(2) integrate and build upon existing knowledge gained from comparative effectiveness research; and

(3) recognize and address—

(A) the racial and ethnic disparities in the incidence and mortality rates of prostate cancer and men with a family history of prostate cancer;

(B) any barriers in access to care and participation in clinical trials that are specific to racial, ethnic, and other underserved minorities and men with a family history of prostate cancer;

(C) needed outreach and educational efforts to raise awareness in these communities; and

(D) appropriate access and utilization of imaging modalities.

SEC. 5. TELEHEALTH AND RURAL ACCESS PILOT PROJECT.

(a) IN GENERAL.—The Secretary of Veterans Affairs, the Secretary of Defense, and the Secretary of Health and Human Services (in this section referred to as the ''Secretaries'') shall establish 4-year telehealth pilot projects for the purpose of analyzing the clinical outcomes and cost effectiveness associated with telehealth services in a variety of geographic areas that contain high proportions of medically underserved populations, including African-Americans, Latin Americans, American Indians, and those in rural areas. Such projects shall promote efficient use of specialist care through better coordination of primary care and physician extender teams in underserved areas and more effectively employ tumor boards to better counsel patients.

(b) ELIGIBLE ENTITIES.—

(1) IN GENERAL.—The Secretaries shall select eligible entities to participate in the pilot projects under this section.

(2) PRIORITY.—In selecting eligible entities to participate in the pilot projects under this section, the Secretaries shall give priority to such entities located in medically underserved areas, particularly those that include African-Americans, Latin Americans, and facilities of the Indian Health Service, and those in rural areas.

(c) EVALUATION.—The Secretaries shall, through the pilot projects, evaluate—

(1) the effective and economic delivery of care in diagnosing and treating prostate cancer with the use of telehealth services in medically underserved and tribal areas including collaborative uses of health professionals and integration of the range of telehealth and other technologies;

(2) the effectiveness of improving the capacity of nonmedical providers and nonspecialized medical providers to provide health services for prostate cancer in medically underserved and tribal areas, including the exploration of innovative medical home models with collaboration between urologists, other

relevant medical specialists, including oncologists, radiologists, and primary care teams and coordination of care through the efficient use of primary care teams and physician extenders; and

(3) the effectiveness of using telehealth services to provide prostate cancer treatment in medically underserved areas, including the use of tumor boards to facilitate better patient counseling.

(d) REPORT.—Not later than 12 months after the completion of the pilot projects under this subsection, the Secretaries shall submit to Congress a report describing the outcomes of such pilot projects, including any cost savings and efficiencies realized, and providing recommendations, if any, for expanding the use of telehealth services.

SEC. 6. EDUCATION AND AWARENESS.

(a) IN GENERAL.—The Secretary of Veterans Affairs shall develop a national education campaign for prostate cancer. Such campaign shall involve the use of written educational materials and public service announcements consistent with the findings of the Prostate Cancer Task Force under section 3, that are intended to encourage men to seek prostate cancer screening when appropriate.

(b) RACIAL DISPARITIES AND THE POPULATION OF MEN WITH A FAMILY HISTORY OF PROSTATE CANCER.—In developing the national campaign under subsection (a),

the Secretary shall ensure that such educational materials and public service announcements are more readily available in communities experiencing racial disparities in the incidence and mortality rates of prostate cancer and by men of any race classification with a family history of prostate cancer.

(c) GRANTS.—In carrying out the national campaign under this section, the Secretary shall award grants to nonprofit private entities to enable such entities to test alternative outreach and education strategies.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There is authorized to be appropriated to carry out this Act for the period of fiscal years 2014 through 2018 an amount equal to the savings described in subsection (b).

(b) CORRESPONDING REDUCTION.—The amount authorized to be appropriated by provisions of law other than this Act for the period of fiscal years 2014 through 2018 for Federal research and health care program activities related to prostate cancer is reduced by the amount of Federal savings projected to be achieved over such period by implementation of section 3(b)(3) of this Act.

○