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H. R. 2159

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 HOUSE OF REPRESENTATIVES

JUNE 14, 2011

Mr. TOWNS (for himself, Mr. BROUN of Georgia, Ms. FUDGE, Ms. RICHARDSON, Mr. GERLACH, Ms. MOORE, Mr. MCINTYRE, Mr. RANGEL, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. WILSON of Florida, Ms. NORTON, Mr. THOMPSON of Mississippi, Mr. CARSON of Indiana, Ms. LEE of California, Mr. ISRAEL, and Mr. KING of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Veterans' Affairs and Armed Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Prostate Research,
5 Outreach, Screening, Testing, Access, and Treatment Ef-
6 fectiveness Act of 2011” or the “PROSTATE Act”.

7 **SEC. 2. FINDINGS.**

8 Congress makes the following findings:

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

11 (2) In 2010, more than 217,730 new patients
12 were diagnosed with prostate cancer and more than
13 32,000 men died from this disease.

14 (3) Roughly 2,000,000 Americans are living
15 with a diagnosis of prostate cancer and its con-
16 sequences.

17 (4) While prostate cancer generally affects older
18 individuals, younger men are also at risk for the dis-

1 ease, and when prostate cancer appears in early
2 middle age it frequently takes on a more aggressive
3 form.

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

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

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

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

20 (9) Although much basic and translational re-
21 search has been completed and much is currently
22 known, there are still many unanswered questions.
23 For example, it is not fully understood how much of
24 known disparities are attributable to disease eti-

1 ology, access to care, or education and awareness in
2 the community.

3 (10) Causes of prostate cancer are not known.
4 There is not good information regarding how to dif-
5 ferentiate accurately, early on, between aggressive
6 and indolent forms of the disease. As a result, there
7 is significant overtreatment in prostate cancer.
8 There are no treatments that can durably arrest
9 growth or cure prostate cancer once it has metasta-
10 sized.

11 (11) A significant proportion (roughly 23 to 54
12 percent) of cases may be clinically indolent and
13 “overdiagnosed”, resulting in significant overtreat-
14 ment. More accurate tests will allow men and their
15 families to face less physical, psychological, financial,
16 and emotional trauma and billions of dollars could
17 be saved in private and public health care systems
18 in an area that has been identified by the Medicare
19 program as one of eight high volume, high cost areas
20 in the Resource Utilization Report program author-
21 ized by Congress under the Medicare Improvements
22 for Patients and Providers Act of 2008.

23 (12) Prostate cancer research and health care
24 programs across Federal agencies should be coordi-
25 nated to improve accountability and actively encour-

1 age the translation of research into practice, to iden-
2 tify and implement best practices, in order to foster
3 an integrated and consistent focus on effective pre-
4 vention, diagnosis, and treatment of this disease.

5 **SEC. 3. PROSTATE CANCER COORDINATION AND EDU-**
6 **CATION.**

7 (a) INTERAGENCY PROSTATE CANCER COORDINA-
8 TION AND EDUCATION TASK FORCE.—Not later than 180
9 days after the date of the enactment of this section, the
10 Secretary of Veterans Affairs, in cooperation with the Sec-
11 retary of Defense and the Secretary of Health and Human
12 Services, shall establish an Interagency Prostate Cancer
13 Coordination and Education Task Force (in this section
14 referred to as the “Prostate Cancer Task Force”).

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

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

24 (2) consider establishing, and advocating for, a
25 guidance to enable physicians to allow screening of

1 men who are over age 74, on a case-by-case basis,
2 taking into account quality of life and family history
3 of prostate cancer;

4 (3) share and coordinate information on Fed-
5 eral research and health care program activities, in-
6 cluding activities related to—

7 (A) determining how to improve research
8 and health care programs, including psycho-
9 social impairments related to prostate cancer
10 treatment;

11 (B) identifying any gaps in the overall re-
12 search inventory and in health care programs;

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

15 (D) maximizing the effects of Federal ef-
16 forts by identifying opportunities for collabora-
17 tion and leveraging of resources in research and
18 health care programs that serve those suscep-
19 tible to or diagnosed with prostate cancer;

20 (4) develop a comprehensive interagency strat-
21 egy and advise relevant Federal agencies in the solici-
22 tation of proposals for collaborative, multidisci-
23 plinary research and health care programs, including
24 proposals to evaluate factors that may be related to
25 the etiology of prostate cancer, that would—

1 (A) result in innovative approaches to
2 study emerging scientific opportunities or elimi-
3 nate knowledge gaps in research to improve the
4 prostate cancer research portfolio of the Fed-
5 eral Government;

6 (B) outline key research questions, meth-
7 odologies, and knowledge gaps; and

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

10 (5) develop a coordinated message related to
11 screening and treatment for prostate cancer to be
12 reflected in educational and beneficiary materials for
13 Federal health programs as such documents are up-
14 dated; and

15 (6) not later than two years after the date of
16 the establishment of the Prostate Cancer Task
17 Force, submit to the Expert Advisory Panel to be re-
18 viewed and returned within 30 days, and then within
19 90 days submitted to Congress recommendations—

20 (A) regarding any appropriate changes to
21 research and health care programs, including
22 recommendations to improve the research port-
23 folio of the Department of Veterans Affairs,
24 Department of Defense, National Institutes of
25 Health, and other Federal agencies to ensure

1 that scientifically based strategic planning is
2 implemented in support of research and health
3 care program priorities;

4 (B) designed to ensure that the research
5 and health care programs and activities of the
6 Department of Veterans Affairs, the Depart-
7 ment of Defense, the Department of Health and
8 Human Services, and other Federal agencies
9 are free of unnecessary duplication;

10 (C) regarding public participation in deci-
11 sions relating to prostate cancer research and
12 health care programs to increase the involve-
13 ment of patient advocates, community organiza-
14 tions, and medical associations representing a
15 broad geographical area;

16 (D) on how to best disseminate informa-
17 tion on prostate cancer research and progress
18 achieved by health care programs;

19 (E) about how to expand partnerships be-
20 tween public entities, including Federal agen-
21 cies, and private entities to encourage collabo-
22 rative, cross-cutting research and health care
23 delivery;

24 (F) assessing any cost savings and effi-
25 ciencies realized through the efforts identified

1 and supported in this Act and recommending
2 expansion of those efforts that have proved
3 most promising while also ensuring against any
4 conflicts in directives from other congressional
5 or statutory mandates or enabling statutes;

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

8 (H) with respect to the level of funding
9 needed by each agency to implement the rec-
10 ommendations contained in the report.

11 (c) MEMBERS OF THE PROSTATE CANCER TASK
12 FORCE.—The Prostate Cancer Task Force described in
13 subsection (a) shall be composed of representatives from
14 such Federal agencies, as each Secretary determines nec-
15 essary, to coordinate a uniform message relating to pros-
16 tate cancer screening and treatment where appropriate,
17 including representatives of the following:

18 (1) The Department of Veterans Affairs, in-
19 cluding representatives of each relevant program
20 areas of the Department of Veterans Affairs.

21 (2) The Prostate Cancer Research Program of
22 the Congressionally Directed Medical Research Pro-
23 gram of the Department of Defense.

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

4 (A) The National Institutes of Health.

5 (B) National research institutes and cen-
6 ters, including the National Cancer Institute,
7 the National Institute of Allergy and Infectious
8 Diseases, and the Office of Minority Health.

9 (C) The Centers for Medicare & Medicaid
10 Services.

11 (D) The Food and Drug Administration.

12 (E) The Centers for Disease Control and
13 Prevention.

14 (F) The Agency for Healthcare Research
15 and Quality.

16 (G) The Health Resources and Services
17 Administration.

18 (d) APPOINTING EXPERT ADVISORY PANELS.—The
19 Prostate Cancer Task Force shall appoint expert advisory
20 panels, as determined appropriate, to provide input and
21 concurrence from individuals and organizations from the
22 medical, prostate cancer patient and advocate, research,
23 and delivery communities with expertise in prostate cancer
24 diagnosis, treatment, and research, including practicing
25 urologists, primary care providers, and others and individ-

1 uals with expertise in education and outreach to under-
2 served populations affected by prostate cancer.

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

6 (f) SUBMITTAL OF RECOMMENDATIONS TO CON-
7 GRESS.—The Secretary of Veterans Affairs shall submit
8 to Congress any recommendations submitted to the Sec-
9 retary under subsection (b)(5).

10 (g) FEDERAL ADVISORY COMMITTEE ACT.—

11 (1) IN GENERAL.—Except as provided in para-
12 graph (2), the Federal Advisory Committee Act (5
13 U.S.C. App.) shall apply to the Prostate Cancer
14 Task Force.

15 (2) EXCEPTION.—Section 14(a)(2)(B) of such
16 Act (relating to the termination of advisory commit-
17 tees) shall not apply to the Prostate Cancer Task
18 Force.

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

21 **SEC. 4. PROSTATE CANCER RESEARCH.**

22 (a) RESEARCH COORDINATION.—The Secretary of
23 Veterans Affairs, in coordination with the Secretaries of
24 Defense and of Health and Human Services, shall estab-
25 lish and carry out a program to coordinate and intensify

1 prostate cancer research as needed. Specifically, such re-
2 search program shall—

3 (1) develop advances in diagnostic and prog-
4 nostic methods and tests, including biomarkers and
5 an improved prostate cancer screening blood test, in-
6 cluding improvements or alternatives to the prostate
7 specific antigen test and additional tests to distin-
8 guish indolent from aggressive disease;

9 (2) better understand the etiology of the disease
10 (including an analysis of lifestyle factors proven to
11 be involved in higher rates of prostate cancer, such
12 as obesity and diet, and in different ethnic, racial,
13 and socioeconomic groups, such as the African-
14 American, Latin-American, and American Indian
15 populations and men with a family history of pros-
16 tate cancer) to improve prevention efforts;

17 (3) expand basic research into prostate cancer,
18 including studies of fundamental molecular and cel-
19 lular mechanisms;

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

23 (5) establish clinical registries for prostate can-
24 cer;

1 (6) use the National Institute of Biomedical
2 Imaging and Bioengineering and the National Can-
3 cer Institute for assessment of appropriate imaging
4 modalities; and

5 (7) address such other matters relating to pros-
6 tate cancer research as may be identified by the
7 Federal agencies participating in the program under
8 this section.

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

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

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

19 (a);

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

22 (3) recognize and address—

23 (A) the racial and ethnic disparities in the
24 incidence and mortality rates of prostate cancer

1 and men with a family history of prostate can-
2 cer;

3 (B) any barriers in access to care and par-
4 ticipation in clinical trials that are specific to
5 racial, ethnic, and other underserved minorities
6 and men with a family history of prostate can-
7 cer;

8 (C) needed outreach and educational ef-
9 forts to raise awareness in these communities;
10 and

11 (D) appropriate access and utilization of
12 imaging modalities.

13 **SEC. 5. TELEHEALTH AND RURAL ACCESS PILOT PROJECT.**

14 (a) IN GENERAL.—The Secretary of Veterans Af-
15 fairs, the Secretary of Defense, and the Secretary of
16 Health and Human Services (in this section referred to
17 as the “Secretaries”) shall establish 4-year telehealth pilot
18 projects for the purpose of analyzing the clinical outcomes
19 and cost effectiveness associated with telehealth services
20 in a variety of geographic areas that contain high propor-
21 tions of medically underserved populations, including Afri-
22 can-Americans, Latin-Americans, American Indians, and
23 those in rural areas. Such projects shall promote efficient
24 use of specialist care through better coordination of pri-
25 mary care and physician extender teams in underserved

1 areas and more effectively employ tumor boards to better
2 counsel patients.

3 (b) ELIGIBLE ENTITIES.—

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

7 (2) PRIORITY.—In selecting eligible entities to
8 participate in the pilot projects under this section,
9 the Secretaries shall give priority to such entities lo-
10 cated in medically underserved areas, particularly
11 those that include African-Americans, Latin-Ameri-
12 cans, and facilities of the Indian Health Service, and
13 those in rural areas.

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

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

22 (2) the effectiveness of improving the capacity
23 of nonmedical providers and nonspecialized medical
24 providers to provide health services for prostate can-
25 cer in medically underserved and tribal areas, in-

1 including the exploration of innovative medical home
2 models with collaboration between urologists, other
3 relevant medical specialists, including oncologists,
4 radiologists, and primary care teams and coordina-
5 tion of care through the efficient use of primary care
6 teams and physician extenders; and

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

11 (d) REPORT.—Not later than 12 months after the
12 completion of the pilot projects under this subsection, the
13 Secretaries shall submit to Congress a report describing
14 the outcomes of such pilot projects, including any cost sav-
15 ings and efficiencies realized, and providing recommenda-
16 tions, if any, for expanding the use of telehealth services.

17 **SEC. 6. EDUCATION AND AWARENESS.**

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

1 (b) RACIAL DISPARITIES AND THE POPULATION OF
2 MEN WITH A FAMILY HISTORY OF PROSTATE CANCER.—

3 In developing the national campaign under subsection (a),
4 the Secretary shall ensure that such educational materials
5 and public service announcements are more readily avail-
6 able in communities experiencing racial disparities in the
7 incidence and mortality rates of prostate cancer and by
8 men of any race classification with a family history of
9 prostate cancer.

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

14 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

15 (a) IN GENERAL.—There is authorized to be appro-
16 priated to carry out this Act for the period of fiscal years
17 2012 through 2016 an amount equal to the savings de-
18 scribed in subsection (b).

19 (b) CORRESPONDING REDUCTION.—The amount au-
20 thorized to be appropriated by provisions of law other than
21 this Act for the period of fiscal years 2012 through 2016
22 for Federal research and health care program activities
23 related to prostate cancer is reduced by the amount of

- 1 Federal savings projected to be achieved over such period
- 2 by implementation of section 3(b)(3) of this Act.

○