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H. R. 6389

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

SEPTEMBER 29, 2010

Mr. TOWNS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Armed Services and Veterans' Affairs, 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 2010” 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 2009, more than 190,000 new patients
 12 were diagnosed with prostate cancer and more than
 13 27,000 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-
 19 ease, and when prostate cancer appears in early

1 middle age it frequently takes on a more aggressive
2 form.

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

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

13 (7) Urologists may constitute the specialists
14 who diagnose and treat the vast majority of prostate
15 cancer patients.

16 (8) Although much basic and translational re-
17 search has been completed and much is currently
18 known, there are still many unanswered questions.
19 For example, it is not fully understood how much of
20 known disparities are attributable to disease eti-
21 ology, access to care, or education and awareness in
22 the community.

23 (9) Causes of prostate cancer are not known.
24 There is not good information regarding how to dif-
25 ferentiate accurately, early on, between aggressive

1 and indolent forms of the disease. As a result, there
2 is significant overtreatment in prostate cancer.
3 There are no treatments that can durably arrest
4 growth or cure prostate cancer once it has metasta-
5 sized.

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

18 (11) Prostate cancer research and health care
19 programs across Federal agencies should be coordi-
20 nated to improve accountability and actively encour-
21 age the translation of research into practice, to iden-
22 tify and implement best practices, in order to foster
23 an integrated and consistent focus on effective pre-
24 vention, diagnosis, and treatment of this disease.

1 **SEC. 3. PROSTATE CANCER COORDINATION AND EDU-**
2 **CATION.**

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

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

13 (1) develop a summary of advances in prostate
14 cancer research supported or conducted by Federal
15 agencies relevant to the diagnosis, prevention, and
16 treatment of prostate cancer and compile a list of
17 best practices that warrant broader adoption in
18 health care programs;

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

24 (3) share and coordinate information on Fed-
25 eral research and health care program activities, in-
26 cluding activities related to—

1 (A) determining how to improve research
2 and health care programs;

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

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

7 (D) maximizing the effects of Federal ef-
8 forts by identifying opportunities for collabora-
9 tion and leveraging of resources in research and
10 health care programs that serve those suscep-
11 tible to or diagnosed with prostate cancer;

12 (4) develop a comprehensive interagency strat-
13 egy and advise relevant Federal agencies in the solici-
14 tation of proposals for collaborative, multidisci-
15 plinary research and health care programs, including
16 proposals to evaluate factors that may be related to
17 the etiology of prostate cancer, that would—

18 (A) result in innovative approaches to
19 study emerging scientific opportunities or elimi-
20 nate knowledge gaps in research;

21 (B) outline key research questions, meth-
22 odologies, and knowledge gaps;

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

1 (5) develop a coordinated message related to
2 screening and treatment for prostate cancer to be
3 reflected in educational and beneficiary materials for
4 Federal health programs as such documents are up-
5 dated; and

6 (6) not later than two years after the date of
7 the establishment of the Prostate Cancer Task
8 Force, submit to the Secretary of Veterans Affairs
9 recommendations—

10 (A) regarding any appropriate changes to
11 research and health care programs, including
12 recommendations to improve the research port-
13 folio of the Department of Veterans Affairs,
14 Department of Defense, National Institutes of
15 Health, and other Federal agencies to ensure
16 that scientifically based strategic planning is
17 implemented in support of research and health
18 care program priorities;

19 (B) designed to ensure that the research
20 and health care programs and activities of the
21 Department of Veterans Affairs, the Depart-
22 ment of Defense, the Department of Health and
23 Human Services, and other Federal agencies
24 are free of unnecessary duplication;

1 (C) regarding public participation in deci-
2 sions relating to prostate cancer research and
3 health care programs to increase the involve-
4 ment of patient advocates, community organiza-
5 tions, and medical associations representing a
6 broad geographical area;

7 (D) on how to best disseminate informa-
8 tion on prostate cancer research and progress
9 achieved by health care programs;

10 (E) about how to expand partnerships be-
11 tween public entities, including Federal agen-
12 cies, and private entities to encourage collabo-
13 rative, cross-cutting research and health care
14 delivery;

15 (F) assessing any cost savings and effi-
16 ciencies realized through the efforts identified
17 and supported in this Act and recommending
18 expansion of those efforts that have proved
19 most promising while also ensuring against any
20 conflicts in directives from other congressional
21 or statutory mandates or enabling statutes;

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

1 (H) with respect to the level of funding
2 needed by each agency to implement the rec-
3 ommendations contained in the report.

4 (c) MEMBERS OF THE PROSTATE CANCER TASK
5 FORCE.—The Prostate Cancer Task Force described in
6 subsection (a) shall be composed of representatives from
7 such Federal agencies, as each Secretary determines nec-
8 essary, to coordinate a uniform message relating to pros-
9 tate cancer screening and treatment where appropriate,
10 including representatives of the following:

11 (1) The Department of Veterans Affairs, in-
12 cluding representatives of each relevant program
13 areas of the Department of Veterans Affairs.

14 (2) The Prostate Cancer Research Program of
15 the Congressionally Directed Medical Research Pro-
16 gram of the Department of Defense.

17 (3) The Department of Health and Human
18 Services.

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

1 others and individuals with expertise in education and out-
2 reach to underserved populations affected by prostate can-
3 cer.

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

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

11 (g) FEDERAL ADVISORY COMMITTEE ACT.—

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

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

20 **SEC. 4. PROSTATE CANCER RESEARCH.**

21 (a) RESEARCH COORDINATION.—The Secretary of
22 Veterans Affairs, in coordination with the Secretaries of
23 Defense and of Health and Human Services, shall estab-
24 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 life style 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; and

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.

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

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

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

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

18 (3) recognize and address—

19 (A) the racial and ethnic disparities in the
20 incidence and mortality rates of prostate cancer
21 and men with a family history of prostate can-
22 cer;

23 (B) any barriers in access to care and par-
24 ticipation in clinical trials that are specific to
25 racial, ethnic, and other underserved minorities

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

3 (C) needed outreach and educational ef-
4 forts to raise awareness in these communities;
5 and

6 (D) appropriate access and utilization of
7 imaging modalities.

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

9 (a) IN GENERAL.—The Secretary of Veterans Affairs
10 shall establish four-year telehealth pilot projects for the
11 purpose of analyzing the clinical outcomes and cost effec-
12 tiveness associated with telehealth services in a variety of
13 geographic areas that contain high proportions of medi-
14 cally underserved populations, including African-Ameri-
15 cans, Latin-Americans, American Indians, and those in
16 rural areas. Such projects shall promote efficient use of
17 specialist care through better coordination of primary care
18 and physician extender teams in underserved areas and
19 more effectively employ tumor boards to better counsel pa-
20 tients.

21 (b) ELIGIBLE ENTITIES.—

22 (1) IN GENERAL.—The Secretary shall select el-
23 igible entities to participate in the pilot projects
24 under this section.

1 (2) PRIORITY.—In selecting eligible entities to
2 participate in the pilot projects under this section,
3 the Secretary shall give priority to such entities lo-
4 cated in medically underserved areas, particularly
5 those that include African-Americans, Latin-Ameri-
6 cans, and facilities of the Indian Health Service, and
7 those in rural areas.

8 (c) EVALUATION.—The Secretary shall, through the
9 pilot projects, evaluate—

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

16 (2) the effectiveness of improving the capacity
17 of nonmedical providers and nonspecialized medical
18 providers to provide health services for prostate can-
19 cer in medically underserved and tribal areas, in-
20 cluding the exploration of innovative medical home
21 models with collaboration between urologists, other
22 relevant medical specialists, including oncologists,
23 radiologists, and primary care teams and coordina-
24 tion of care through the efficient use of primary care
25 teams and physician extenders; and

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

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

11 **SEC. 6. EDUCATION AND AWARENESS.**

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

19 (b) RACIAL DISPARITIES AND THE POPULATION OF
20 MEN WITH A FAMILY HISTORY OF PROSTATE CANCER.—
21 In developing the national campaign under subsection (a),
22 the Secretary shall ensure that such educational materials
23 and public service announcements are more readily avail-
24 able in communities experiencing racial disparities in the
25 incidence and mortality rates of prostate cancer and by

1 men of any race classification with a family history of
2 prostate cancer.

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

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

8 There is authorized to be appropriated to carry out
9 this Act such sums as may be necessary for each of fiscal
10 years 2011 through 2015.

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