

111TH CONGRESS
2^D SESSION

H. R. 4756

To provide for prostate cancer imaging research and education.

IN THE HOUSE OF REPRESENTATIVES

MARCH 4, 2010

Mr. CUMMINGS (for himself, Mr. BURTON of Indiana, Mr. MEEKS of New York, Mr. FRANK of Massachusetts, Mr. SENSENBRENNER, Mrs. CHRISTENSEN, Mr. MCGOVERN, Mr. DOYLE, Mr. EDWARDS of Texas, Mrs. DAVIS of California, Mr. MASSA, Mr. MARSHALL, Mr. GRIJALVA, and Mr. DEFAZIO) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for prostate cancer imaging research and education.

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, Im-
5 aging, and Men’s Education Act of 2010” or the “PRIME
6 Act of 2010”.

7 **SEC. 2. FINDINGS.**

8 Congress makes the following findings:

1 (1) Prostate cancer has reached epidemic pro-
2 portions, particularly among African-American men,
3 and strikes and kills men in numbers comparable to
4 the number of women who lose their lives from
5 breast cancer.

6 (2) Life-saving breakthroughs in screening, di-
7 agnosis, and treatment of breast cancer resulted
8 from the development of advanced imaging tech-
9 nologies led by the Federal Government.

10 (3) Men should have accurate and affordable
11 prostate cancer screening exams and minimally-
12 invasive treatment tools, similar to what women have
13 for breast cancer.

14 (4) While it is important for men to take ad-
15 vantage of current prostate cancer screening tech-
16 niques, a recent NCI-funded study demonstrated
17 that the most common available methods of detect-
18 ing prostate cancer (PSA blood test and physical
19 exams) are not foolproof, causing numerous false
20 alarms and false reassurances.

21 (5) The absence of advanced imaging tech-
22 nologies for prostate cancer causes the lack of accu-
23 rate information critical for clinical decisions, result-
24 ing in missed cancers and lost lives, as well as un-

1 necessary and costly medical procedures, with re-
2 lated complications.

3 (6) With prostate imaging tools, men and their
4 families would face less physical, psychological, fi-
5 nancial and emotional trauma and billions of dollars
6 could be saved in private and public health care sys-
7 tems.

8 **SEC. 3. RESEARCH AND DEVELOPMENT OF PROSTATE CAN-**
9 **CER IMAGING TECHNOLOGIES.**

10 (a) EXPANSION OF RESEARCH.—The Secretary of
11 Health and Human Services (referred to in this Act as
12 the “Secretary”), acting through the Director of the Na-
13 tional Institutes of Health and the Administrator of the
14 Health Resources and Services Administration, and in
15 consultation with the Secretary of Defense, shall carry out
16 a program to expand and intensify research to develop in-
17 novative advanced imaging technologies for prostate can-
18 cer detection, diagnosis, and treatment comparable to
19 state-of-the-art mammography technologies.

20 (b) EARLY STAGE RESEARCH.—In implementing the
21 program under subsection (a), the Secretary, acting
22 through the Administrator of the Health Resources and
23 Services Administration, shall carry out a grant program
24 to encourage the early stages of research in prostate imag-
25 ing to develop and implement new ideas, proof of concepts,

1 and pilot studies for high-risk technologic innovation in
2 prostate cancer imaging that would have a high potential
3 impact for improving patient care, including individualized
4 care, quality of life, and cost-effectiveness.

5 (c) LARGE SCALE LATER STAGE RESEARCH.—In im-
6 plementing the program under subsection (a), the Sec-
7 retary, acting through the Director of the National Insti-
8 tutes of Health, shall utilize the National Institute of Bio-
9 medical Imaging and Bioengineering and the National
10 Cancer Institute for advanced stages of research in pros-
11 tate imaging, including technology development and clin-
12 ical trials for projects determined by the Secretary to have
13 demonstrated promising preliminary results and proof of
14 concept.

15 (d) INTERDISCIPLINARY PRIVATE-PUBLIC PARTNER-
16 SHIPS.—In developing the program under subsection (a),
17 the Secretary, through the Administrator of the Health
18 Resources and Services Administration, shall establish
19 interdisciplinary private-public partnerships to develop
20 and implement research strategies for expedited innova-
21 tion in imaging and image-guided treatment and to con-
22 duct such research.

23 (e) RACIAL DISPARITIES.—In developing the pro-
24 gram under subsection (a), the Secretary shall recognize
25 and address—

1 (1) the racial disparities in the incidences of
2 prostate cancer and mortality rates with respect to
3 such disease; and

4 (2) any barriers in access to care and participa-
5 tion in clinical trials that are specific to racial mi-
6 norities.

7 (f) AUTHORIZATION OF APPROPRIATIONS.—

8 (1) IN GENERAL.—Subject to paragraph (2),
9 there is authorized to be appropriated to carry out
10 this section, \$100,000,000 for each of the fiscal
11 years 2012 through 2016.

12 (2) SPECIFIC ALLOCATIONS.—Of the amount
13 authorized to be appropriated under paragraph (1)
14 for each of the fiscal years described in such para-
15 graph—

16 (A) no less than 10 percent may be appro-
17 priated to carry out the grant program under
18 subsection (b); and

19 (B) no more than 1 percent may be appro-
20 priated to carry out subsection (d).

21 **SEC. 4. PUBLIC AWARENESS AND EDUCATION CAMPAIGN.**

22 (a) NATIONAL CAMPAIGN.—The Secretary shall carry
23 out a national campaign to increase the awareness and
24 knowledge of Americans with respect to the need for pros-

1 tate cancer screening and for improved detection tech-
2 nologies.

3 (b) REQUIREMENTS.—The national campaign con-
4 ducted under subsection (a) shall include—

5 (1) roles for the Health Resources Services Ad-
6 ministration, the Office on Minority Health of the
7 Department of Health and Human Services, the
8 Centers for Disease Control and Prevention, and the
9 Office of Minority Health of the Centers for Disease
10 Control and Prevention; and

11 (2) the development and distribution of written
12 educational materials, and the development and
13 placing of public service announcements, that are in-
14 tended to encourage men to seek prostate cancer
15 screening and to create awareness of the need for
16 improved imaging technologies for prostate cancer
17 screening and diagnosis, including in vitro blood
18 testing and imaging technologies.

19 (c) RACIAL DISPARITIES.—In developing the national
20 campaign under subsection (a), the Secretary shall recog-
21 nize and address—

22 (1) the racial disparities in the incidences of
23 prostate cancer and mortality rates with respect to
24 such disease; and

1 (2) any barriers in access to care and participa-
2 tion in clinical trials that are specific to racial mi-
3 norities.

4 (d) GRANTS.—The Secretary shall establish a pro-
5 gram to award grants to nonprofit private entities to en-
6 able such entities to test alternative outreach and edu-
7 cation strategies to increase the awareness and knowledge
8 of Americans with respect to the need for prostate cancer
9 screening and improved imaging technologies.

10 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
11 authorized to be appropriated to carry out this section,
12 \$10,000,000 for each of the fiscal years 2012 through
13 2016.

14 **SEC. 5. IMPROVING PROSTATE CANCER SCREENING BLOOD**
15 **TESTS.**

16 (a) IN GENERAL.—The Secretary, in coordination
17 with the Secretary of Defense, shall carry out research to
18 develop an improved prostate cancer screening blood test
19 using in-vitro detection.

20 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
21 authorized to be appropriated to carry out this section,
22 \$20,000,000 for each of fiscal years 2012 through 2016.

23 **SEC. 6. REPORTING AND COMPLIANCE.**

24 (a) REPORT AND STRATEGY.—Not later than 12
25 months after the date of the enactment of this Act, the

1 Secretary shall submit to Congress a report that details
2 the strategy of the Secretary for implementing the require-
3 ments of this Act and the status of such efforts.

4 (b) FULL COMPLIANCE.—Not later than 36 months
5 after the date of the enactment of this Act, and annually
6 thereafter, the Secretary shall submit to Congress a report
7 that—

8 (1) describes the research and development and
9 public awareness and education campaigns funded
10 under this Act;

11 (2) provides evidence that projects involving
12 high-risk, high impact technologic innovation, proof
13 of concept, and pilot studies are prioritized;

14 (3) provides evidence that the Secretary recog-
15 nizes and addresses any barriers in access to care
16 and participation in clinical trials that are specific to
17 racial minorities in the implementation of this Act;

18 (4) contains assurances that the all other provi-
19 sions of this Act are fully implemented; and

20 (5) certifies compliance with the provisions of
21 this Act, or in the case of a Federal agency that has
22 not complied with any of such provisions, an expla-
23 nation as to such failure to comply.

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