111TH CONGRESS 2D 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.
 - (2) Life-saving breakthroughs in screening, diagnosis, and treatment of breast cancer resulted from the development of advanced imaging technologies led by the Federal Government.
 - (3) Men should have accurate and affordable prostate cancer screening exams and minimally-invasive treatment tools, similar to what women have for breast cancer.
 - (4) While it is important for men to take advantage of current prostate cancer screening techniques, a recent NCI-funded study demonstrated that the most common available methods of detecting prostate cancer (PSA blood test and physical exams) are not foolproof, causing numerous false alarms and false reassurances.
 - (5) The absence of advanced imaging technologies for prostate cancer causes the lack of accurate information critical for clinical decisions, resulting in missed cancers and lost lives, as well as un-

- necessary and costly medical procedures, with related 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.
- (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
- placing of public service announcements, that are in-
- tended to encourage men to seek prostate cancer
- screening and to create awareness of the need for
- improved imaging technologies for prostate cancer
- 17 screening and diagnosis, including in vitro blood
- 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
- prostate cancer and mortality rates with respect to
- 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
- of concept, and pilot studies are prioritized;
- 14 (3) provides evidence that the Secretary recog-
- nizes and addresses any barriers in access to care
- 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-
- 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.