

# H. R. 3563

To provide for prostate cancer imaging research and education.

## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2007

Mr. CUMMINGS (for himself, Mr. WYNN, Mrs. CAPPs, Ms. EDDIE BERNICE JOHNSON of Texas, Mrs. CHRISTENSEN, Mr. BURTON of Indiana, Mr. HOLDEN, Ms. JACKSON-LEE of Texas, Mr. JEFFERSON, and Mr. MEEKS of New York) 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.

*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, Imaging, and Men’s Education Act of 2007” or the “PRIME 6 Act of 2007”.

### SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Prostate cancer has reached epidemic proportions, particularly among African-American men, and strikes and kills

men in numbers comparable to the number of women who lose their lives from 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 unnecessary and costly medical procedures, with related complications.

(6) With prostate imaging tools, men and their families would face less physical, psychological, financial and emotional trauma and billions of dollars could be saved in private and public health care systems.

### **SEC. 3. RESEARCH AND DEVELOPMENT OF PROSTATE CANCER IMAGING TECHNOLOGIES.**

(a) EXPANSION OF RESEARCH – The Secretary of

Health and Human Services (referred to in this Act as the “Secretary”), acting through the Director of the National Institutes of Health and the Administrator of the Health Resources and Services Administration, and in consultation with the Secretary of Defense, shall carry out a program to expand and intensify research to develop innovative advanced imaging technologies for prostate cancer detection, diagnosis, and treatment comparable to state-of-the-art mammography technologies.

(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 imaging to develop and implement new ideas, proof of concepts, 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.

(c) LARGE SCALE LATER STAGE RESEARCH.—In implementing the program under subsection (a), the Secretary, acting through the Director of the National Institutes of Health, shall utilize the National Institute of Biomedical Imaging and Bioengineering and the National Cancer Institute for advanced stages of research in prostate imaging, including technology development and clinical trials for projects determined by the Secretary to have demonstrated

promising preliminary results and proof of concept.

(d) **INTERDISCIPLINARY PRIVATE-PUBLIC PARTNERSHIPS.** – In developing the program under subsection (a), the Secretary, through the Administrator of the Health Resources and Services Administration, shall establish interdisciplinary private-public partnerships to develop and implement research strategies for expedited innovation in imaging and image-guided treatment and to conduct such research.

(e) **RACIAL DISPARITIES.** – In developing the program under subsection (a), the Secretary shall recognize and address—

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

(2) any barriers in access to care and participation in clinical trials that are specific to racial minorities.

(f) **AUTHORIZATION OF APPROPRIATIONS.**—

(1) **IN GENERAL.**—Subject to paragraph (2), there is authorized to be appropriated to carry out 10 this section, \$100,000,000 for each of the fiscal 11 years 2008 through 2012.

(2) **SPECIFIC ALLOCATIONS.**—Of the amount authorized to be appropriated under paragraph (1) for each of the fiscal years described in such paragraph—

(A) no less than 10 percent may be appropriated to carry out the grant program under subsection (b); and

(B) no more than 1 percent may be appropriated to carry out subsection (d).

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

(a) NATIONAL CAMPAIGN.—The Secretary shall carry out a national campaign to increase the awareness and knowledge of Americans with respect to the need for prostate cancer screening and for improved detection technologies.

(b) REQUIREMENTS.—The national campaign conducted under subsection (a) shall include—

(1) roles for the Health Resources Services Administration, the Office on Minority Health of the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the Office of Minority Health of the Centers for Disease Control and Prevention; and

(2) the development and distribution of written educational materials, and the development and placing of public service announcements, that are intended to encourage men to seek prostate cancer screening and to create awareness of the need for improved imaging technologies for prostate cancer screening and diagnosis, including in vitro blood testing and imaging technologies.

(c) RACIAL DISPARITIES.—In developing the national campaign under subsection (a), the Secretary shall recognize and address—

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

(2) any barriers in access to care and participation in clinical trials that are specific to racial minorities.

(d) GRANTS.—The Secretary shall establish a program to award grants to nonprofit private entities to enable such entities to test alternative outreach and education strategies to increase the awareness and knowledge of Americans with respect to the need for prostate cancer screening and improved imaging technologies.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, \$10,000,000 for each of the fiscal years 2008 through 2012.

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

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

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, \$20,000,000 for each of fiscal years 2008 through 2012.

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

(a) REPORT AND STRATEGY.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report that details the strategy of the Secretary for implementing the requirements of this Act and the status of such efforts.

(b) FULL COMPLIANCE.—Not later than 1 year after the date of the enactment of this Act, and annually thereafter, the Secretary shall submit to Congress a report that—

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

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

(3) provides evidence that the Secretary recognizes and addresses any barriers in access to care and participation in clinical trials that are specific to racial minorities in the implementation of this Act;

(4) contains assurances that the all other provisions of this Act are fully implemented; and

(5) certifies compliance with the provisions of this Act, or in the case of a Federal agency that has not complied with any of such provisions, an explanation as to such failure to comply.