

110TH CONGRESS  
1ST SESSION

# H. R. 3563

To provide for prostate cancer imaging research and education.

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## 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

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## 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 2007” or the “PRIME  
6       Act of 2007”.

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 2008 through 2012.

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 2008 through  
13          2012.

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 2008 through 2012.

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

24          (a) REPORT AND STRATEGY.—Not later than 6  
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 1 year after  
5 the date of the enactment of this Act, and annually there-  
6 after, 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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