

**MEMORANDUM**

To: Mr. William V. Corr, Prof. John T. Monahan  
From: Dr. Fay Shtern, AdMeTech Foundation  
Date: December 19, 2008  
Re: Ending the Prostate Cancer Epidemic

As you requested, we are providing a short memo outlining our coalition's proposal to end the prostate cancer crisis through an HHS-led funding initiative to develop, test and implement improved prostate cancer diagnostics, which are critical for early detection and cure.

**PROPOSAL: Starting with the Fiscal Year 2010 Budget Request, the Obama Administration should recognize prostate cancer as a national priority and initiate a public-private effort led by HHS to develop life-saving tools for early diagnosis and treatment of prostate cancer, including in vitro testing (e.g., blood or urinary analysis) and imaging technology to guide biopsy and treatment.**

**RATIONALE:** In spite of the magnitude of prostate cancer as a socio-economic problem and as an epidemic which has become even more common than breast cancer in women, men do not have accurate and affordable tools comparable to mammograms. Indeed, a "blue ribbon" panel convened by HHS last year reviewed scientific evidence and concluded that current prostate cancer diagnostics cause more harm than good in men older than 75 and questioned their value in younger men. The lack of accurate and affordable diagnostics has led to a crisis in patient care, including failed treatments and widespread unnecessary procedures, which cause life-altering complications in millions of men and cost billions of dollars to our nation's health care system.

**OUR COALITION:** Leaders of medicine, philanthropy, industry (GE, Siemens, Philips, Medical Imaging and Technology Alliance) and advocacy groups (National Prostate Cancer Coalition/ZERO, UsTOO, Men's Health Network, Prostate Health Education Network) have been working together for several years to support all stages of technologic innovation and its transfer to patients, from stimulating new ideas to large-scale implementation. We have been working with supporters on Capitol Hill and the Executive Branch, leading to the recent passage of House Resolution 353 (calling for increased federal support for prostate imaging research). In April, 2008, we had a productive meeting with NIH Director Zerhouni and in November, 2008 with OMB Director Nussle.

**PROBLEM:** Prostate cancer threatens every man and is the most common major cancer in the U.S., with 1 in 6 men diagnosed, compared to the 1 in 7 women diagnosed with breast cancer. While prostate cancer can be cured if detected early, it is the second most lethal cancer in men and it does not have diagnostic tools comparable to life-saving mammograms. *And yet, NIH and other government agencies have not recognized prostate cancer as a national priority comparable to breast cancer. They have failed to provide comparable funding and support.* The lack of accurate and affordable diagnostics causes prostate cancer to become both a patient care crisis and a socio-economic problem, which compromises the quality of life and survival for millions of American men and adds billions of dollars to our nation's health care costs:

- Over 2 million American men currently live with prostate cancer.
- Around 30,000 men die and 230,000 men are diagnosed with prostate cancer each year. A man is diagnosed with prostate cancer every 2.5 minutes. A man dies from it every 19 minutes.
- The PSA blood test - the main diagnostic tool today - causes frequent false alarms and false assurances: (1) when the PSA test is abnormal, up to 88% of men (over 1 million each year) have biopsies that do not show prostate cancer but cost over \$2 billion to our health care system annually; and (2) when the PSA test is "normal," 15% of men have prostate cancer.
- Without accurate imaging for guidance, blind biopsy techniques miss cancer in at least 20% of men and underestimate the extent and aggressiveness of prostate cancer in at least 20-30% of men. The



underdiagnosis leads to return and/or progression of prostate cancer in as many as 1 in 2 men undergoing treatment (over 70,000 men each year).

- Current diagnostics cannot distinguish the aggressive type of prostate cancer that requires treatment from the non-aggressive disease which needs only careful monitoring. The overdiagnosis results in up to 54% of men undergoing treatment which is unnecessary, causes incontinence and/or impotence in about 50-80% of patients, and inflates health care costs.

**SOLUTION:** The Obama Administration should initiate a public-private effort led by HHS to develop reliable tools for early diagnosis of prostate cancer, including improved in vitro testing (e.g., blood or urinary analysis) and imaging technology to guide biopsy and treatment. This effort will be modeled after federal investment in the development of breast cancer imaging that improved early detection, saved lives, replaced radical mastectomy with minimally-invasive lumpectomy and reduced the impact of breast cancer epidemic on women, our health care system, and our society. Improved diagnostic tools will save thousands of lives, eliminate unnecessary pain and suffering in millions of men, and save billions of dollars each year. For example, improved diagnostic tools will:

- Improve early detection and save American men from being lost to prostate cancer.
- Improve the quality of life for millions of American men.
- Enable physicians to select the most effective and the least invasive treatment that will be performed in an outpatient setting and will cause minimal discomfort, complications and costs.
- Eliminate unnecessary biopsies and treatment and save at least \$5 billion annually.

This federal investment should track what was done for breast cancer research in general and imaging specifically, should take the shape of the PRIME Act legislation introduced by Congressman Elijah Cummings and Senator Barbara Boxer and their many bipartisan cosponsors, and should involve HRSA, the National Institutes of Health (particularly NCI and NIBIB), and CDC. We believe that in the first year, \$50 million should be specifically allocated for this research initiative.

**SUMMARY/JUSTIFICATION:** This proposal is for the U.S. Government to replicate for prostate cancer - the most common major cancer in the U.S. and the second most lethal cancer in men today - what the Clinton Administration successfully did during the 1990's to support breast imaging technologies, which led to life-saving breakthroughs in detection, diagnosis and treatment of breast cancer and improved quality of life for millions of women. This research effort will more than pay for itself, since accurate and affordable diagnosis of prostate cancer could reduce health care costs by over \$5 billion per year through elimination of unnecessary biopsies and treatment.

**Neither HHS nor DOD devote substantial resources to improve screening and early detection of prostate cancer, including prostate imaging research; per public records, they invest primarily in the development of drugs and other treatment for advanced prostate cancer when it is frequently too late.** According to top HHS officials, in a recent budget year, out of \$350 million for prostate cancer research, NIH spent \$29 million on prostate cancer imaging, but aimed less than \$10 million at using imaging for detection/prevention of prostate cancer.

There is substantial support in Congress for increasing federal funding for prostate imaging research, as evidenced by unanimous passage of House Resolution 353 (100 cosponsors), cosponsorship of the PRIME Act bills (35 House Members, 7 Senators), and inclusion of language urging prioritization of this kind of research in the FY09 Labor, HHS, Education Appropriations Committee reports.

The recent HHS "blue ribbon" panel reviewed scientific evidence and concluded that current prostate diagnostics cause "more harm than good" in men older than 75 and questioned their value in younger men. This underscores the urgent need for federal investment in improved prostate cancer diagnostics, which will end the fear, pain, suffering and costs that prostate cancer causes men, their families and our society.