

THE WHITE HOUSE  
WASHINGTON

*Health Care -  
Prostate Cancer*

November 7, 1997

**MEMORANDUM FOR THE PRESIDENT**

FROM: Chris Jennings  
SUBJECT: Prostate Cancer and Follow-Up to Beth Kobliner Shaw  
cc: Bruce Reed

Responding to your interest in developments on the prostate cancer front, this memo summarizes our response to the issues Beth Kobliner Shaw raised with you recently and also provides an update on actions the Administration can take to help advance the fight against prostate cancer.

**BACKGROUND**

This year over 210,000 men are expected to be diagnosed with prostate cancer and over 42,000 men are projected to die from this disease (virtually the same number of women who die from breast cancer). Only lung cancer claims more cancer deaths for men.

Prostate cancer does not manifest itself in most men until they have reached traditional retirement age and, when it does, there are great disparities among minorities relative to incidence. In fact, fully 80 percent of those diagnosed with this disease are over age 65. African American men have an incidence rate over 35 percent higher than white men. Interestingly, Asian-Americans have an incidence rate that is less than half of white Americans. (Clinical trials are underway at NIH to determine the causes of these differences.)

**CONCERNS RAISED BY BETH KOBLINER SHAW**

As you may recall, Beth Kobliner Shaw raised concern that: (1) Federal funding for prostate cancer research is inadequate, particularly relative to breast cancer and AIDS, (2) administrative shortcomings have unacceptably delayed the allocation of Defense Department prostate cancer research funds to scientists, and (3) there has been insufficient high level Administration attention paid to this devastating disease (she suggested a White House-sponsored conference). The following responds to the concerns she raised.

**(1) Prostate Cancer Research is Inadequately Funded.** *Response: Probably true, but depends on how you look at the numbers. The overall dollars for funding are low in comparison to some highly-publicized diseases such as breast cancer and AIDS. However, relative to other diseases, prostate cancer has increased significantly since you took office. Moreover, this issue is more complicated than simple dollar comparisons. Overall spending on breast cancer still is more than four times that of prostate cancer research (\$625 million versus over \$140 million).*

According to NIH, this is due in part to limited opportunities for scientifically-sound prostate cancer-specific research. They also argue that there is a great deal of overlap in cancer research, so that the most promising leads in prostate cancer research may in fact result from dollars spent in research for another cancer. It seems clear though that the large amount of public attention to breast cancer has had a major impact on funding.

Notwithstanding the disparity of investments, significant increases in prostate cancer funding have occurred under your Administration and, as will be discussed below, more dollars are likely to be recommended in the very near future. Prostate cancer research has increased about 60 percent since 1993. Such an increase is substantial when compared with other major diseases, such as diabetes (11 percent increase) and heart disease (21 percent increase). Despite these numbers, it does appear that a good case can be made that research funding this type of cancer is inadequate.

**(2) DoD Needs to Allocate Their Prostate Cancer Funding More Quickly.**

*Response: Partially true, but understandable since DoD has never had such funding before.*

In an attempt to address the limitations in research spending imposed by the budget caps, the Appropriations Committees began in the early 1990s to allocate breast cancer research dollars in the Defense budget. Building on the Congress' build-up of breast cancer research at the DoD, Congress appropriated about \$45 million for prostate cancer in FY'97 and again this year.

(Since the DoD believes biomedical research is not their mission, OMB has never suggested using DoD dollars for research in any budget proposal; however, this is something we might want to discuss in this year's budget.)

Although there has been excessive delay in getting these dollars out, DoD did just complete a multi-month consultative process with prostate cancer experts, patients, and advocates to find the best ways to fund top-of-the-line research. They have received over 600 grant proposals and plan to fund as many peer reviewed grants as possible by no later than next April. Beth was quite pleased to learn about this development.

**(3) Prostate Cancer Needs a Higher Level Administration Focus.** *Response: We agree with Beth and, in fact, the National Cancer Institute has already convened a high-level panel that will provide recommendations next Spring about new research opportunities and the need for more funding.* This process was pulled together in order to assess how to best move forward on some promising recent break-throughs in prostate cancer made in the last year, including: (1) the discovery of a new hormone therapy which given after radiation therapy can prolong survival of patients with locally advanced prostate cancer; (2) the general location of the first heredity prostate cancer gene; and (3) the identification of hundreds of genes expressed in prostate cancer as the first cancer studied in the recently-launched Cancer Genome Anatomy Project (CGAP) at NIH.

## **NEW ACTIONS ADMINISTRATION COULD TAKE ON PROSTATE CANCER**

### **Announce Recommendations for New Increases in Prostate Cancer Research Funding**

**at an Event at the NCI.** The panel discussed above is scheduled to be completed by March and Dr. Rick Klausner, the NCI Director, fully expects that it will result in greater attention to and more funding of this disease. We are reviewing options to give this work even a higher profile. Preliminary discussions with NCI have led us to conclude that it may be possible for you to announce their Spring recommendations for more funding of prostate cancer research.

### **Send to Hill New Legislation for Medicare Coverage of Cancer Clinical Trials.**

One of the highest priorities by the cancer research advocacy community is enacting a bill that would allow Medicare, for the first time, to cover cancer clinical trials. Having Medicare cover clinical trials would be particularly helpful to those with prostate cancer because: (1) most of the prostate victims are Medicare beneficiaries; (2) the lack of participation of elderly men in trials has undermined clinical research for the treatment, prevention, and screening for this disease; (3) given the promising new findings, NCI expects there will be an increase in clinical trials for prostate cancer, creating a need for even more participants.

We are working with HCFA, NIH, and OMB to develop a workable policy, to cost it out, and to develop Medicare offsets. As of this writing, it appears that the policy we are considering could cost between \$1.5 billion and \$3 billion over 5 years. Even by Medicare standards, this option is a significant investment, particularly for a targeted new benefit. Having said this, it would have the dual benefit of increasing the number of cancer clinical trials and, in so doing, likely push private sector plans to do the same thing. This policy would be widely heralded by the scientific community, cancer patient advocates, and Senators' Mack and Rockefeller. If you decided to endorse this initiative, we would of course have to determine how best to pay for it, whether to include it in your FY'99 budget and when best to announce it.

In the interim, HCFA has the authority to pay for trials on procedures they believe have the potential to no longer be experimental. (This is different than payment for experimental trials, mentioned above, on drugs and devices not yet given FDA approval for certain kinds of treatments.) You recently saw a *USA Today* article referencing possible coverage for a trial on cryotherapy, a treatment that some think has the potential to reduce prostate cancer where the cancer has not yet spread. We have since learned that both HCFA and NIH are skeptical that the procedure merits coverage and may not authorize it. Having said this, it is encouraging that HCFA and NIH are working together to target such procedures for coverage.

**Claim Most of the Revenue from the National Tobacco Legislation for a Major Increase in Research Funding and/or Raise Funds from Other Revenue Sources.** You could call on the Congress to dedicate much of the new revenue from any tobacco legislation to a Trust Fund designed to vastly increase investments in biomedical research, including new increases in prostate cancer research. Today, Senator Kennedy is scheduled to introduce his tobacco legislation bill, which includes provisions to use his assumed and unrealistically high tobacco revenue to be used, in part, to double the NIH budget. Senator Mack and Senator Harkin are also calling for a doubling of the budget. In addition, Donna Shalala's budget submission includes a new insurance premium tax to be used to eventually double the NIH budget. (If you are interested, I can send you a pro/con memo on this proposal.)

The above mentioned actions could be incorporated into a number of events that would visibly associate the Administration with an unprecedented new commitment to cancer research in general, and prostate cancer in particular. We will keep you informed of developments.