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December 13, 2011

Dr. Robert Cosby
c/o USPSTF
540 Gaither Road
Rockville, MD 20850

Re: USPSTF Proposed Recommendation Statement on Screening for Prostate Cancer

Dear Dr. Cosby,

Men's Health Network (MHN) welcomes the opportunity to offer additional comments on the United States Preventive Services Task Force (USPSTF) draft recommendation statement concerning PSA screening for prostate cancer. Please accept the following as our additional comments for the record.

"President Obama is in 'excellent health,' his doctor reports"

Published: Monday, October 31, 2011, 9:32 PM
The Associated Press

"The new report says he was also screened for prostate cancer using a PSA blood test. That's a test that the U.S. Preventive Services Task Force recommended against earlier this month, saying it can do more harm than good in part because many tumors found are too slow-growing to be a threat. The report cites "informed patient request" in giving Obama the screening. His PSA level, or prostate-specific antigen, was found to be low."

"Obama, who turned 50 in August, seems to have improved his health on some fronts since his last physical, which Kuhlman conducted in February 2010."
(*Found at:*
*www.nola.com/politics/index.ssf/2011/10/president_obama_is_in_excellen.html*)

Under the draft recommendation from the USPSTF, men other than the President may be denied the opportunity to receive the welcome news that their "…PSA level, or prostate-specific antigen, was found to be low."

As mentioned in our earlier comments, we oppose a "D" rating for PSA screening for prostate cancer and would suggest a rating that encourages a discussion between a man and his physician about when he should be screened for prostate cancer.

We are also concerned that the USPSTF recommendation process did not involve patient and research organizations at an early stage, groups who are very likely to know about recent discoveries and trends that might affect the final recommendation. We are also concerned that while certain other agencies and organizations are mentioned as

partners in the process, their input is not actively pursued. Some of these partner agencies have important ongoing research programs that are critical to a well-thought-out decision. Partners like:

- Centers for Disease Control and Prevention, which has established an excellent ongoing research program into informed decision making for prostate cancer. (Synopsis presented at the Prostate Cancer Roundtable meeting on November 28, 2011 in Washington, DC.)

- National Institutes of Health (National Cancer Institute), which has determined: "Models suggest between 45% and 70% of the mortality decline (from prostate cancer) observed in the 1990s could be attributed to the stage-shift induced by screening" (A presentation at the 7th Annual African American Prostate Cancer Disparity Summit (Washington, DC, September 2001) by Kathy Cronin Ph.D. MPH and Angela Mariotto Ph.D. of the Surveillance Research Program at the National Cancer Institute.)

- Veteran's Health Administration, which could have provided critical information that men exposed to Agent Orange, and possibly other chemicals, are at significantly high risk for prostate cancer.

- Department of Defense / Military Health System (Congressionally Directed Medical Research Program), which could have provided critical information from the cutting-edge research funded by this program.

- Indian Health Service, which could have provided information about the lack of screening among American Indians / Alaska Natives and the resultant excessively high mortality rate.

The USPSTF process would also have benefited from engaging top researchers such as Dr. Chiledum Ahaghotu of Howard University who presented an excellent critique of the two 'studies" mentioned above at the recent (December 7, 2011) Congressional Men's Health Caucus, Prostate Cancer Task Force briefing "Prostate Cancer Screening: Dangerous or Life Saving?"

We suggest that the USPSTF reopen the recommendation process for use of the PSA to screen for prostate cancer and actively engage other entities in an open discussion of the advisability of placing the health of men in the preliminary results of the two universally criticized "studies" referenced by the USPSTF. (Those studies are the Prostate, Lung, Colorectal and the Ovarian Cancer Screening Trial and European Randomized Study of Screening for Prostate Cancer.)

We also believe that the recent NIH State-of-the-Science Conference: Role of Active Surveillance in the Management of Men With Localized Prostate Cancer revealed important options that should be offered to men who are found to have elevated PSA levels. An elevated, or accelerating PSA need not result in invasive treatment, but careful observation so that proactive treatment can be initiated if and when the cancer becomes aggressive or appears ready to spread to other parts of the body.

The Consensus Statement from the conference echoes what we already know: "Prior to the adoption of PSA screening, the majority of prostate cancer was detected because of symptoms of advanced cancer or a nodule found on digital rectal examination. The symptomatic tumors were usually high grade, advanced, and often lethal. Other tumors were found incidentally at the time of surgery for benign enlargement of the prostate. These were often low grade and localized." (*page 3*)

While acknowledging that "…there are many unanswered questions about active surveillance strategies and prostate cancer," the Statement concludes that "Active surveillance has emerged as a viable option that should be offered to low-risk patients." (*page 18*)

Elaborating on our earlier comments, discouraging use of the PSA puts certain men at needless high risk for early death from prostate cancer:

- *African-American men*: African-American men are 1.6-times as likely as white men to develop prostate cancer, but over 2.4-times as likely to die from prostate cancer. *Found at: http://seer.cancer.gov/statfacts/html/prost.html*

- *Men with a Family History*: The Centers for Disease Control and Prevention (CDC) reports that men with a brother, father, or son who has been diagnosed with prostate cancer are 2- to 3-times more likely to develop prostate cancer. *Found at: http://www.cdc.gov/cancer/prostate/basic_info/risk_factors.htm*

- *Men exposed to Agent Orange*: Giri et al. (2004) found that Vietnam veterans exposed to Agent Orange were more than 2-times as likely to develop prostate cancer and that when diagnosed the cancer was more aggressive.

  > "…twice as many exposed men were diagnosed with prostate cancer (OR=2.19), they developed the disease at a younger age, and they had a more aggressive variant of prostate cancer." *Found at*: *www.atsdr.cdc.gov/toxprofiles/cdds_addendum.pdf*

- *American Indian / Alaska Native men*: Have the lowest incidence rate of prostate cancer, but are twice as likely as Asian/Pacific Islanders (who have a higher incidence rate) to die from it. *Found at: http://seer.cancer.gov/statfacts/html/prost.html*

  This scenario can only be the result of identifying prostate cancer at a later stage, when treatment is minimally effective.

- Men not in any of the above categories who are initially diagnosed with aggressive, life-threatening prostate cancer.

In conclusion, we suggest that the USPSTF scratch its draft recommendation, reopen the process, and start from the beginning in an effort to reach a decision that best serves men and their families.

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