November 8, 2011

Virginia Moyer, MD, MPH
Chair
U.S. Preventative Services Task Force
c/o Dr. Robert Cosby
540 Gaither Road
Rockville, MD 20850

Dear Dr. Moyer:

The American Association of Clinical Urologists (AACU), AACU State Society Network and undersigned urologic professional societies respectfully submit these comments on the U.S. Preventative Services Task Force (USPSTF) Recommendation Statement on Screening for Prostate Cancer.

The AACU is a professional organization representing the interests of more than 3,000 urologists across the United States, as well as urologic societies engaged as advocacy affiliates. The AACU and undersigned urologic societies believe the proposed Grade D recommendation against prostate-specific antigen (PSA)-based screening for prostate cancer regardless of age, race or family history will severely undermine the great progress we have made in the detection and management of this complex disease.

The serum PSA test is the best currently-approved biomarker for prostate gland abnormalities. Reports of an elevated PSA measurement lead a man to careful, deliberate and informed decisions based on his values and preferences. If further tests confirm a cancer diagnosis, the disease is found to be at its earliest stage 90% of the time, up from 35% when PSA-based screening was not available. Early detection of prostate cancer made possible by the PSA test affords men the opportunity to consider myriad disease management options. We therefore maintain that the beneficial impact of PSA-based screening on the early detection of prostate cancer outweighs the harms identified by the USPSTF and that the test must not be classified as a Grade D recommendation.

The USPSTF bases its wholesale rejection of PSA-testing on studies that the authors of the evidence review admit are "poor quality", "flawed" and "contradictory".[1] Although the Prostate, Lung, Colorectal, and Ovarian Cancer Screening (PLCO) trial was very large, the design features a fundamental flaw. Observers did not compare "screening" against "no screening", but rather "screening" to "usual treatment". This definition resulted in data contamination of the control group because over 50% of patients received PSA screening. The USPSTF accepts at face value that this flaw was corrected, yet discounts the reduction in prostate cancer mortality in the European Randomized Study

[1] Chou R, Croswell JM, Dana T, Bougatsos C, Blazina I, et al. Screening for prostate cancer: a review of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med. 2011 Oct 7. Chou, Roger. U.S. Preventative Services Task Force briefing call. 2011 Oct 14.

of Screening for Prostate Cancer (ESRPC) trial because the control group definition varied in each country.

The studies considered by reviewers and the USPSTF also fail to exclude patients based upon limited life expectancy or elevated co-morbidities. Physicians generally advise against prostate cancer screening, including PSA tests, for these patients. A recent PLCO subgroup analysis evaluating healthy men under 65-years old finds a significant reduction in the prostate-cancer specific mortality for these patients.[2] This report was not cited in the evidence review, nor referenced by the USPSTF. The broad USPSTF recommendation against PSA-based screening for prostate cancer is thus not supported by sufficient and consistent evidence.

The USPSTF Recommendation Statement on Screening for Prostate Cancer has been delayed innumerable times since 2009, yet over the last two years, the Task Force did not convene an independent group of statisticians to review their pending findings, nor consider new data. Instead, the data was reconsidered by the same researchers who, not surprisingly, agreed with their earlier work. Even more problematic, the USPSTF chose not to address the connection it makes between PSA-based screening and treatment-related harms with the physicians who fight this disease daily - urologists and oncologists. Urologists could have reassured the USPSTF that modern management of prostate cancer is rooted in patient education and shared decision making. Neither physicians nor patients rush to treatment with surgery, radiation or androgen deprivation therapy, despite "adequate" evidence suggesting otherwise. Indeed, when interpreted correctly and administered in combination with digital rectal examinations, PSA measurements inform physicians' assessments of cancer risk, expected disease progression and recommendations that will promote positive outcomes and the highest quality of life.

The AACU and undersigned urologic societies urge the USPSTF to withdraw the Grade D recommendation for PSA-based screening for prostate cancer. We believe the current evidence does not support a broad recommendation against PSA-based screening for all asymptomatic men, irrespective of age, family history and race. The limitations of the insufficient and conflicting evidence may instead be consistent with a reaffirmed Grade I Statement.[3]

More than two million men are alive today because of early detection and improved management of prostate cancer. We must continue to encourage physicians to speak freely to their patients about PSA-based screening for prostate cancer and endorse informed decision making. The USPSTF draft Recommendation will stifle these conversations, discourage men from taking an active role in health promotion and ultimately subject high-risk populations to increased incidence of advanced prostate cancer.

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[2] Crawford ED, et al. J Clin Oncol. 2011; 29:355-61.

[3] Neither the AACU, nor supporting urologic societies, specifically endorse a Grade I recommendation. These comments simply point out that insufficient and contradictory evidence are characteristics of that classification as defined by the USPSTF.

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Sincerely,

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