American Urological Association

NEWS

EMBARGOED FOR RELEASE UNTIL MONDAY, MAY 21, 2012, 5:00 P.M. EDT

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AUA DISPUTES PANEL'S RECOMMENDATIONS ON PROSTATE CANCER SCREENING

Association urges men to speak with their physicians about their risk for prostate cancer

ATLANTA, GA, May 21, 2012–The American Urological Association (AUA) today released the following statement in response to the U.S. Preventive Services Task Force (USPSTF) recommendations on the use of the prostate-specific antigen (PSA) test. The statement is attributed to AUA President Sushil S. Lacy, MD:

The American Urological Association (AUA) is outraged at the USPSTF's failure to amend its recommendations on prostate cancer testing to more adequately reflect the benefits of the prostate-specific antigen (PSA) test in the diagnosis of prostate cancer. It is inappropriate and irresponsible to issue a blanket statement against PSA testing, particularly for at-risk populations, such as African American men. Men who are in good health and have more than a 10-15 year life expectancy should have the choice to be tested and not discouraged from doing so.

There is strong evidence that PSA testing saves lives. The randomized trials used by the USPSTF do, in fact, show a benefit to patients. The PLCO Trial, imperfect by the pre-screening contamination of the control arm, nonetheless showed that, in a group of young men with no comorbidities, there was a significant reduction of prostate cancer death rates after a median follow-up of seven years (JCO 2011;29:355-361). Additionally, the Göteborg Trial also showed a substantial 44 percent relative risk reduction in prostate cancer mortality occurring in men 50-64 years of age after a median of 14 years. Importantly, the risk reduction occurred in a setting where many of the patients were not aggressively treated for prostate cancer, indicating that the harms of PSA-based screening can, in fact, be minimized by good clinical practice (Lancet Oncol 2010;11:725-732). Furthermore, we have seen a 40 percent reduction in prostate cancer-specific mortality in the United States over the most recent 20 years of PSA-based screening. This has occurred without substantial change in how men with prostate cancer were treated (primarily with surgery and radiation therapy). Models have suggested that more than 50 percent of this reduction is due to early detection (Cancer Cases Control 2008;19:175-181). Additionally, updated data from the European Randomized Study for the Screening of Prostate Cancer (ERSPC) has demonstrated that there is a 21 percent risk reduction in prostate cancer related death associated with screening (up to 29 percent after accounting for non-compliance). The number of cancers that would need to be detected to prevent one death has now dropped to 37.

Rather than instruct primary care physicians to discourage men from having a PSA test, the Task Force should instead focus on how best to educate primary care physicians regarding targeted screening and how to counsel patients about their prostate cancer risk. The PSA test has allowed us to move beyond a time when men presented with high-grade, metastatic disease for which there were little or no treatment options other than palliative care. In its earliest stages, most prostate cancers cause no

Large Urology Group
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LUGPA

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May 21, 2012

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Urologists Outraged over Government Panel's Recommendation to Stop Life-Saving Prostate Cancer Testing

TALLAHASSEE, Fla. – The Large Urology Group Practice Association (LUGPA), representing more than 1,800 urologists, today discredited recommendations by the U.S. Preventive Services Task Force (USPSTF) to stop prostate cancer testing.

USPTSF's final recommendation, released today, instructs physicians to discourage asymptomatic men from having the PSA test. This comes despite overwhelming opposition from urologists, prostate cancer patients, and patient advocacy groups, all who have confirmed the importance of these life-saving measures.

"We are appalled at the USPSTF's recommendation that healthy men should no longer receive prostate-specific antigen (PSA) blood tests as part of routine cancer screening," said Dr. Deepak A. Kapoor, President of LUGPA and Chairman and CEO of Integrated Medical Professionals, PLLC. Kapoor added, "Failing to detect cancer early will create a public health catastrophe in 5-10 years."

The largest study on screening, the European Randomized Study for the Screening of Prostate Cancer (ERSPC) published its updated findings in the March issue of the *New England Journal of Medicine*. This demonstrated a 21 percent survival advantage to PSA screening for all patients, and furthermore, for those with the longest follow-up (over 10 years) this increased to 38 percent. This is consistent with experience in the United States, where death rates from prostate cancer have declined by nearly 40 percent over the last two decades, although the incidence of the disease has been relatively stable.

Dr. Kapoor states, "UPSPTF clearly 'cherry-picked' data to support what can only be viewed as a pre-conceived bias against screening. The task force did not include any physician who treats prostate cancer, and ignored credible studies and epidemiological data demonstrating a significant survival advantage to early detection...we are not detecting more cancer; we are detecting cancer earlier and saving lives."

The USPSTF's downgrade of prostate cancer screening to a "D" recommendation at this time is irresponsible and inexplicable. It even would deny screening to those at the greatest risk for prostate cancer— African-Americans and those with a family history of prostate cancer. These patients urgently

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AMERICAN ASSOCIATION OF CLINICAL UROLOGISTS REJECT USPSTF RECOMMENDATION

The American Association of Clinical Urologists (AACU), in agreement with the American Urological Association and Large Urology Group Practice Association, strongly rejects the recommendation of the United States Preventive Services Task Force (USPSTF) to downgrade the use of PSA for early detection of prostate cancer to a "D". The key studies used by USPSTF as a basis for this recommendation are severely flawed. Some of the major flaws in the studies include; PSA testing had been performed in many of the "non-screened" control group, there was a relatively short time of follow-up with death from prostate cancer as the endpoint and lastly, no consideration was given to metastatic-free rates as an important outcome. The last point is particularly worrisome because men with metastatic prostate cancer often suffer a protracted painful course before death from the disease.

It is very disappointing that during the comment period to the USPSTF over the past several months, these deficiencies and others, though extensively outlined by experts in urologic oncology, were largely dismissed by the USPSTF.

The panel ALSO overlooked significant progress made in some areas of prostate cancer management. In the United States, prostate cancer is the second leading cause of cancer death in men, but due to PSA testing and cancer awareness campaigns, death from prostate cancer is declining. The 10 year survival from prostate cancer is now over 97%, up from 53% before the PSA era. Prior to PSA testing nearly 25% of men were found to have bone metastases at diagnosis. The number today is less than 5%. The USPSTF wrongly recommends PSA testing only in men presenting with prostate cancer symptoms. Unfortunately for many men this first symptom doesn't occur until late in the course of illness from painful metastatic disease.

The USPSTF contends that screening with PSA leads to unnecessary testing and overtreatment. The task force recommendation against PSA testing blatantly ignores the many studies addressing tumor behavior and patient outcomes which have helped establish appropriate clinical guidelines on prostate cancer management. These studies and guidelines have resulted in the expanded use of appropriate surveillance protocols. After shared doctor-patient decision-making, many men with low risk prostate cancer are appropriately placed on watchful waiting.

The USPSTF recommendations are misleading and harmful. They ignore the nearly 30,000 men who suffer a prolonged course of illness then die from prostate cancer each year. The recommendations do not adequately consider the high risk patients such as those with a family history of prostate cancer and our African American citizens, who as a race are at the highest risk of developing high grade cancer of the prostate. The USPSTF does not include a urologist and ignored the opinions of experts in the field. We must rebuke a recommendation that will place

Prostate Cancer Roundtable

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May 21, 2012

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New PSA Recommendations from U.S. Preventive Services Task Force are a Disservice to Men

"D" Grading ignores benefits of screening in men known to be at high risk

Washington, DC, May 21, 2012– The Prostate Cancer Roundtable expressed deep disappointment today as the U.S. Preventive Services Task Force (USPSTF) issued its final recommendation statement against the use of prostate-specific antigen (PSA) testing in the detection of prostate cancer.

"A "D" grade from the USPSTF will discourage many healthcare providers from using PSA testing at all; will justify non-coverage of PSA testing by many payers; and will also discourage men and their doctors from even beginning conversations about individual risk or the need for the test," explained Scott Williams, Vice President of Men's Health Network.

This decision has been taken despite research by Andrew Vickers, Hans Lilja, et al. published in the *Journal of Clinical Oncology* that shows that even a single PSA test administered between the ages of 44 to 50 can project risk for the future diagnosis of prostate cancer.

Research by the National Cancer Institute's Cancer Modeling Network has also shown that as much as 70 percent of the drop in age-adjusted prostate cancer mortality since 1975 can be attributed to PSA screening. (Quantifying the role of PSA screening in the US prostate cancer mortality decline. Cancer Causes and Control [2007], Volume 19, Number 2, 175-181.)

"The USPSTF continues to ignore the benefits of screening for men known to be at high risk, including African American men, men with a family history, veterans exposed to Agent Orange, and men with an above-average baseline PSA in their 40s" stated Thomas Farrington, President of the Prostate Health Education Network.

Currently Medicare and Medicaid and most insurance companies continue to cover PSA tests. And in 37 U.S. states there are mandates in place that require insurance companies to pay for the test. However, the "D" grade will likely lead many health insurance companies to stop paying for the test, thus cutting off access to many men.

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veteranshealth.org

Vietnam Veterans of America's Veterans Health Council

Statement on the USPSTF final recommendation on the use of prostate-specific antigen (PSA) testing in the early detection of prostate cancer

Vietnam Veterans of America's Veterans Health Council strongly opposes the U.S. Preventive Services Task Force (USPSTF) final recommendation on the use of prostate-specific antigen (PSA) testing in the early detection of prostate cancer. Some three million veterans served in Southeast Asia, and no one knows for sure how many of these veterans were exposed to Agent Orange. In November 1996 then-Secretary Jesse Brown of the Department of Veterans' Affairs (VA) issued the final rule recognizing prostate cancer as a service-connected presumptive disease associated with exposure to Agent Orange and other phenoxy herbicides during military service. Furthermore, in 2008, University of California - Davis Cancer Center physicians released results of research showing that Vietnam veterans exposed to Agent Orange have greatly increased risks of prostate cancer and even greater risks of getting the most aggressive form of the disease as compared to those who were not exposed. The research was also the first to utilize a large population of men in their 60s and the prostate-specific antigen (PSA) test to screen for the disease. More than 13,000 Vietnam veterans enrolled in the VA Northern California Health Care System were stratified into two groups — exposed or not exposed to Agent Orange between 1962 and 1971. Based on medical evaluations conducted between 1998 and 2006, the study revealed that:

- twice as many Agent Orange-exposed men were identified with prostate cancer than non-exposed;
- Agent Orange-exposed men were diagnosed two-and-a-half years younger than non-exposed; and
- Agent Orange-exposed men were nearly four times more likely to present with metastatic disease than non-exposed.

Other prostate cancer risk factors — race, body-mass index and smoking — were not statistically different between the two groups.

Further buttressing this link, in April 2009, a study of 1,495 veterans in five cities who underwent radical prostatectomy to remove their cancerous prostates showed that 206 exposed to Agent Orange had nearly a 50 percent increased risk of their cancer recurring, despite the fact that their cancer seemed relatively nonaggressive at the time of surgery. And their cancer came back with a vengeance: the time it took the prostate specific antigen, or PSA, level to double – an indicator of aggressiveness – was eight months versus more than 18 months in non-exposed veterans.

- Thus, veterans exposed to Agent Orange are at least twice as likely to develop prostate cancer, their recurrence rates are higher, and recurring cancers are more aggressive.

If allowed to stand, USPSTF clearly abrogates its responsibility for the health and well-being of America's Vietnam veterans.

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May 21, 2012

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GOVERNMENT ELIMINATES EARLY DETECTION FOR PROSTATE CANCER, FAILS AMERICAN MEN

Washington, DC – The United States Preventive Services Task Force has issued its final recommendation for early detection of prostate cancer, effectively eliminating the PSA test and leaving American men without a defense in the fight against prostate cancer.

"We are greatly disappointed by the decision to give the PSA test a "D" rating by United States Preventive Services Task Force," said Skip Lockwood, CEO of ZERO – The Project to End Prostate Cancer. "We believe that the decision, which eliminates men's access to potentially lifesaving information provided by a PSA test, should not be made by a government panel that doesn't include a medical oncologist or urologist."

The USPSTF rated PSA testing "D," saying there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. This decision contradicts prostate cancer testing recommendations from medical and professional organizations, including the National Comprehensive Cancer Network and American Urological Association.

Since the decision by the USPSTF in 2009 to change prostate cancer testing recommendations for men over the age of 75, no new research has been cited that would call for a drastic change in prostate cancer testing recommendations for all men.

Recent research confirms that the PSA test saves lives. The results of the Göteborg Randomized Population-based Prostate Cancer Screening Trial, released in July 2010, showed a 44 percent decline in prostate cancer deaths as a result of PSA testing. In this Swedish study, partially funded by the National Cancer Institute, an analysis of some 20,000 men was conducted during a 14-year period.

The PSA test and advances in treatment have led to a 40 percent reduction in prostate cancer deaths since the mid-1990s, and 90 percent of all prostate cancers are now discovered before they spread outside the gland. The five-year survival rate is nearly 100 percent when prostate cancer is detected early, while the tumor is still localized and hasn't spread.

The decision on how best to test and treat for prostate cancer must be made between a man and his doctor and ZERO encourages men to continue to educate themselves and be active participants in their health care. In the absence of an improved test for the disease, ZERO believes that all men, especially those with risk factors, need to consider testing for prostate cancer in order to have the most information possible and make the best health decisions.

For more information on prostate cancer risk, testing and diagnosis, and treatment options, visit www.ZeroCancer.org.

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May 21, 2012

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Men's Health Network and Veterans Health Council Oppose Final USPSTF Recommendation Against Prostate Cancer Screening

Deeply flawed process produces a dangerous and life-threatening recommendation

Washington, DC, May 21, 2012- Men's Health Network (MHN) and the Veterans Health Council are strongly opposing the U.S. Preventive Services Task Force (USPSTF) final recommendation against the use of prostate-specific antigen (PSA) testing in the early detection of prostate cancer. The PSA test, used with a DRE (digital rectal exam), is the only method currently available for the early detection of prostate cancer.

"*Early detection saves lives*," said MHN VP Scott Williams, "*and this recommendation essentially eliminates access for patients and their healthcare providers to the only test available for early detection of prostate cancer.*"

The final recommendation, relying on an inadequate and deeply flawed decision-making process, downgrades PSA testing to "D", recommending against the use of PSA testing in healthy men that "do not have symptoms that are highly suspicious for prostate cancer." This in the face of strong evidence that use of the PSA test saves lives.

A "D" grade is defined as "moderate or high certainty that the service has no net benefit, or that the harms outweigh the benefits". This means that the USPSTF believes men should only be tested for prostate cancer using the PSA after they display symptoms of possible prostate cancer, meaning the cancer has spread and the prospects for a cure are remote.

There are repercussions beyond an individual's decision to be screened. The USPSTF is empowered by the Affordable Care Act to determine which screenings Americans receive. A "D" rating means Medicare, Medicaid and/or private insurers could choose not to cover PSA test for tens of thousands of men nationwide.

USPSTF placed heavy emphasis on the PLCO (Prostate, Lung, Colorectal and Ovarian) study, whose prostate arm was critically flawed. Approximately 50% of the control (non-screened) group received PSA testing one or more times as part of their routine care,

while 15% of the screening group were never screened. In addition, African-American men, a group at highest risk of developing prostate cancer, constituted only 4% of the study. The USPSTF also failed to consider past and present data available at CDC, NCI, NIH, VA, CMS, and other agencies

In stark contrast to PLCO, the European Randomized Study of Screening for Prostate Cancer (ERSPC) has followed 182,000 men for 11 years. The latest data from ERSPC, released while the USPSTF was still considering the PSA, indicates a reduction in prostate cancer specific mortality of 29% at 11 years follow-up, a significant life-saving benefit. ERSPC is a much larger study than PLCO and compliance has been greater from the beginning of the study.

Also not considered is a study which 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.

"*If allowed to stand, USPSTF clearly abrogates its responsibility for the health and well-being of America's Vietnam veterans*," stated Thomas Berger, PhD, Executive Director, Veterans Health Council.

The USPSTF decision-making process shoulders the blame for this decision:

> The decision is reached without consultation with other federal agencies, such as the National Cancer Institute, Veterans Administration, other NIH agencies, or the Centers for Disease Control and Prevention – each of which can provide information and research that are critical to an informed recommendation.
>
> Medical specialists (i.e. urologists, oncologists, etc.) are excluded from membership on the USPSTF, eliminating the experts who know most about an issue.
>
> Patient organizations, with their vast patient resources and experience, are excluded from the process, allowed only to provide comments to a draft decision.

MHN pointed out these and other flaws in the decision-making process in an April 23, 2012 letter to HHS Secretary Sebelius, found at:
http://www.menshealthnetwork.org/library/USPSTFMHNtoSecSebelius042312.pdf

For example, not consulted was CDC which has found that men with a family history are 2- to 3-times more likely to develop prostate cancer.
http://www.cdc.gov/cancer/prostate/basic_info/risk_factors.htm

Also not consulted was NCI, whose recent modeling studies "suggest that between 45% - 70% of the mortality decline…can be attributed to that stage-shift induced by screening." (presentation at the 7th Annual African American Prostate Cancer Disparity Summit, September 2011)

"The recommendation against PSA testing puts men's lives in jeopardy as they will be

discouraged from getting screened for prostate cancer. This especially affects African-American men, men exposed to Agent Orange, and men with a family history, all of whom are at greatest risk of developing prostate cancer and dying from the disease. In the US alone, 30,000 men die from prostate cancer annually, a staggering number. Early detection is key and PSA testing is the best available tool, reducing prostate cancer mortality by 40% since its inception," commented Ana Fadich, MPH, CHES, Director of Programs and Health Promotion at MHN.

MHN recognizes that a better test for the early detection of prostate cancer is desperately needed, however, the PSA is the best screening tool available today. Until a new test is found, the USPSTF should withdraw its current recommendation and initiate a new study that actively engages all relevant stakeholders, including federal agencies, professional organizations that advise patients and treat prostate cancer; and patient representatives.

About Men's Health Network

MHN is a national non-profit organization whose mission is to reach men and their families where they live, work, play, and pray with health prevention messages and tools, screening programs, educational materials, advocacy opportunities and patient navigation. For more information, please visit www.menshealthnetwork.org .

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