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on behalf of the

American Urological Association

Before the House Energy and Commerce Health Subcommittee

Hearing Titled

"Examining the United States Preventive Services Task Force"

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Chairman Pitts, Ranking Member Green, members of the Energy and Commerce Health Subcommittee, and honored guests, my name is Dr. John Lynch, and I am testifying today as a member of the American Urological Association and as a practicing urologist, prostate cancer researcher and Professor and Chairman of the Department of Urology at MedStar Georgetown University Hospital. I also appear before you today as a prostate cancer survivor who fears that if the U.S. Preventive Services Task Force (USPSTF) recommendations were in existence when I was diagnosed, my prostate cancer might have been missed. Early detection saved my life, which is why this hearing today is of utmost importance.

The AUA would like to thank the House Energy and Commerce Subcommittee on Health for taking an in-depth look at H.R. 1151, the "USPSTF Transparency and Accountability Act." As you are aware, this critical legislation, spearheaded by Representatives Marsha Blackburn and Bobby Rush, would make much-needed reforms to the USPSTF. Namely, it would enhance

transparency and accountability for the Task Force activities by requiring four key reforms. First, it would ensure that representation on the Task Force is balanced to include practicing specialty care providers. Second, the bill requires an accountable and transparent process for comments and consideration related to research plans and recommendations. Third, a key reform includes establishment of an advisory board to ensure regular input from interested stakeholders, including Federal agencies and payors likely to be impacted by Task Force recommendations. Finally, it would require a process to request review of previous recommendations when additional peer-reviewed scientific evidence is available.

For your reference, the AUA was founded in 1902 and is the premier professional association for the advancement of urologic patient care. The AUA works to ensure that its more than 22,000 members are current on the latest research and practices in urology. The AUA also pursues its mission of fostering the highest standards of urologic care by providing a wide range of services—including publications, research, an annual scientific meeting, clinical practice guidelines, continuing medical education (CME) and the formulation of health policy.

The USPSTF was created in 1984 but did not receive Congressional authorization under the Agency for Healthcare Research and Quality (AHRQ) until over a decade later – in 1998. During the critical initial authorization of AHRQ, the agency's authority was updated to provide a greater focus on quality and update statutory authority for activities the agency was no longer engaged in, such as practice guideline development. Therefore, as you seek to revise the statute, I hope that you will remain focused on the appropriate goals and not allow the Task Force to

devolve into practice guideline development – something Congress altered in the initial AHRQ authorization.

The Affordable Care Act (ACA) requires coverage without co-payment, co-insurance, or deductible, when provided by an in-network provider for certain age-appropriate preventive health services. Those services include recommendations with a grade "A" or "B" by the USPSTF. By making this change, the law shifted the USPSTF's role from a scientific advisory body to a body with the authority to influence federal benefit and coverage requirements. However, due to a lack of inclusion of the specialists who treat the diseases for which the USPSTF makes recommendations, the long-term impacts of its guidance aren't always clear. The stakes are high.

As a urologist, I will focus my comments on our experience with the 2012 USPSTF recommendation against routine prostate-specific antigen (PSA)-based prostate cancer screening for healthy men, regardless of risk factors such as age, race and family history. The experience with PSA screening is not the only one where providers and patients alike were left confused by or disagreed with recommendations. There has been controversy related to a number of recommendations including those related to mammography, colonoscopy and skin cancer screening.

Earlier this year, the USPSTF published a final research plan to update the PSA screening recommendation. That's a good thing, and something urologists and many patients have been urging for the past several years. However, since the release of the 2012 recommendation,

providers faced conflicting recommendations, and patients did not know where to turn to determine what was best for their individual needs. More accountability and transparency in the Task Force process will help identify evidence that should be reviewed and identify any potential issues earlier in the process. Likewise, it would be helpful to acknowledge the other recommendations or practice guidelines in the medical and patient communities, as well as those issued by federal agencies.

In November 2015, JAMA -the Journal of the American Medical Association- published two peer-reviewed studies, which documented that fewer men are being screened for prostate cancer, and fewer early-stage cases are being detected. These studies highlighted that the number of cases has dropped not because the disease is becoming less common but because there is less effort to find it.

The decrease in testing is almost certainly a result of a recommendation against screening made in 2012 by the USPSTF. The Task Force found that risks outweighed the benefits of routine blood tests for prostate-specific antigen, or PSA, a protein associated with prostate cancer.

Because prostate cancer often grows slowly, the task force said, screening finds many tumors that might never have harmed the patient, resulting in potential overtreatment for some patients. As a result, it concluded, testing saves few lives and leads too many men into unneeded surgery or radiation, which potentially leaves them impotent and incontinent.

I, and many other urologists, strongly disagree with the Task Force's assessment. Rather than issuing a blanket recommendation against screening, it would be better to "screen smarter" by testing most men at individualized intervals (not every year) and adding additional focus to how we screen men at a higher risk for disease. These decisions are best made between the physician and patient, taking into consideration their individual risk factors and family history.

Further, that underlying philosophy is captured in the AUA policy statement on early detection of prostate cancer, based on the AUA's 2013 guideline, which emphasizes the importance of shared decision making as well as consideration of risk factors.

> *The American Urological Association (AUA) and the Urology Care Foundation believe that the decision to perform early detection for prostate cancer should be made in the context of a detailed conversation between an asymptomatic man and his physician, and recommend that men ages 55 to 69 at average risk for prostate cancer should talk with their doctors about being tested. Screening for men outside this age range is not recommended as a routine; however, those men with significant risk factors (family history, race) should discuss early detection with their physicians. (AUA Policy Statement 2013)*

I believe the disconnect between practicing physicians and the Task Force is related to the disparate composition of the group. While the USPSTF is composed of independent, national experts in prevention and evidence-based medicine, representation by urology or other medical specialties is noticeably absent when recommendations or research plans are under

review. By including, in some manner, those that treat the condition for which recommendations are being made, the USPSTF will ensure appropriate interpretation of currently available literature, and can benefit from added expert input into diagnosis and treatment of a disease or condition, as well as ensure the appropriateness and relevance of recommendations in the clinical setting. I understand that every specialty provider cannot be represented full-time on the Task Force, but having a specialty voice for individual recommendations can improve the outreach and review process. Likewise, an advisory board to allow more formal input can allow improved engagement of interested stakeholders, including the medical specialists and patients related to the recommendation under review. It is a disservice to patients to issue recommendations on the primary method used to diagnose prostate cancer or other conditions without consulting with those physicians who work with such patients every day. As such, we continue to urge the USPSTF to seek further input from the practicing medical specialty community as recommendations are developed or revisited. This request is in line with American Medical Association House of Delegates Resolution 225 adopted November 16, 2015, which advocates for the inclusion of relevant specialty societies and their members in guideline and performance measure development, including in technical expert panels.

Since the legislation was first introduced, the USPSTF has improved its outreach to the public and stakeholders, but more needs to be done. For example, they now publish draft research plans and solicit public comment. However, the transparency of this process would be greatly enhanced by requiring that these communications are published in the Federal Register and provide adequate time for public comment, are reviewed by external subject matter experts, that public comments are made publicly available, and that a summary of comments received

and recommendations of other Federal agencies or organizations relating to the topic are included.

We hope that Congress will enact the "USPSTF Transparency and Accountability Act" so that key improvements in transparency and accountability for the Task Force's process for determining coverage and access will assist patients in receiving appropriate preventive care.

The AUA is a member of the Alliance of Specialty Medicine, a coalition of national medical specialty societies representing more than 100,000 physicians and surgeons, as well as the Urology Policy Forum. Both organizations support passage of H.R. 1151.

Thank you for your commitment and leadership on this important issue to urologists, my colleagues in medicine, and our patients whom are concerned their cancer or other conditions may go undiagnosed. It is important to urologists and to the medical profession, and it is important to all patients that they have appropriate access to prostate cancer screening tests and other key preventive health measures. To help ensure that access, I urge you to enact into law the "USPSTF Transparency and Accountability Act." I am happy to answer any questions or follow up with additional information about this critical issue.