

Statement for the Record

In support of H.R. 1151,

“USPSTF Transparency and Accountability Act of 2015”

Submitted to the Subcommittee on Health,

House Committee on Energy and Commerce

Wednesday, November 30, 2016

On behalf of the all men and their families, especially those living asymptotically with prostate cancer and those who will develop prostate cancer in the future, ZERO - The End of Prostate Cancer is writing in support of H.R. 1151, The USPSTF Transparency and Accountability Act of 2016.

We are appreciative of Vice Chairwoman Marsha Blackburn's (R-TN) and Representative Bobby Rush's (D-IL) leadership as the sponsors of this legislation that will ensure the current opaque recommendation development process at the U.S. Preventive Services Task Force (USPSTF) is reformed into a more transparent process, inclusive of the expertise of specialists and voices of patients. We thank the House Energy and Commerce Committee and Health Subcommittee for consideration of this bill at an important time for the prostate cancer community, as the USPSTF is currently reviewing its recommendation for Prostate Specific Antigen (PSA)-based screening for prostate cancer.

As the second leading cause of cancer deaths among men, prostate cancer is a serious public health issue in our country, with one in seven men diagnosed in their lifetimes and an estimated more than 26,000 men dying of prostate cancer this year.¹ The PSA-based screening is the primary tool medical professionals use to screen for prostate cancer. PSA screening is critical for catching prostate cancer before it spreads and metastasizes. Prostate cancer has very few symptoms, and if symptoms (such as back pain, problems urinating and erectile dysfunction) present, it is likely that the disease has progressed significantly.

We agree with Congress' premise that Americans should have access to preventive services at no cost. As part of this effort, Congress included Section 2713 of the Patient Protection and Affordable Care Act (ACA), which requires commercial insurers to provide, with no patient copay, coverage of and access to preventive screenings graded with an A

¹ Key Prostate Cancer Statistics. American Cancer Society.
<http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics>

or “B” rating by the USPSTF. As we have seen since the ACA’s implementation, the USPSTF has made several controversial recommendations, including the PSA prostate cancer screening recommendation and recommendations related to a mammography. The USPSTF’s mammography recommendations were so potentially detrimental to women’s health they required Congress to intervene in order to ensure women had access to breast cancer screening recommended by experts. In our experience with the prostate cancer community since the 2012 USPSTF recommendation against PSA screening, we have seen a decline in the availability of free PSA screening services, patient confusion over if they should be screened and when, and data suggesting an increase in the diagnosis of metastatic disease.

We therefore support the USPSTF Transparency and Accountability Act, which uses lessons learned from the Task Force’s controversial work since 2009, to correct the USPSTF’s deficiencies through the codification of an inclusive and transparent recommendation development process.

Inclusion of Specialty Providers and Patients/Patient Representative in the Recommendation Process Ensures Consideration Alternative Perspectives

One of the fundamental objectives of the bill is a change in the composition of the USPSTF to include “specialty care providers” and “patients and health care consumers.”

Additionally, the bill creates the formation of an Advisory Board that includes patient groups like ZERO, clinicians, including specialists, and members of other federal agencies and departments.

Inclusion of specialty care providers in the recommendation process is imperative for ensuring, in the case of prostate cancer, urologists and medical oncologists can provide their unique perspective on interpretation of peer-reviewed research and also communicate real-time developments in standards of care and patient communication. Modern medicine develops faster than the collection data, publication of clinical studies, and the USPSTF review cycle. Data and studies that do not incorporate the latest

developments in advanced testing for prostate cancer fail to capture how a patient and his physician develop a treatment or active surveillance plan using the latest diagnostic technologies' data points. Diagnostic technology developed since the 2012 recommendation allows physicians and patients to understand the aggressiveness of a cancer and its precise location, which improves personalized treatment plans and decreases side effects.

Taken together, these advanced diagnostics are changing the balance of benefit versus harm. However, without specialists involved in the process, consideration of these technologies may not get to the Task Force for years as peer-reviewed data lags clinical practice. Worse, because PSA testing is discouraged, a body of data about the use and impact of new diagnostics technologies with PSA numbers will take longer to develop than if PSA screening was widely practiced. To ensure recommendations include the latest clinical practice developments and the unique perspective of specialists, medical oncologists and urologists must participate in the USPSTF process.

Patient and consumer representation on the Task Force is critical as well. While clinical research data is important in evaluating preventive services, actual clinical practice and patient experience is of equal value. For example, the clinical data pointing to overtreatment does not account for the impact of the suddenness of a cancer diagnosis on a man's treatment decision. Only the patient voice could add this important data point to the evaluation of a screening's harm versus benefit calculation. Or if a man had PSA testing at regular intervals following a baseline screening, a conversation about options following a prostate cancer diagnosis could unfold organically over time between a patient and his doctor, and, knowing his number growth trajectory, a patient may not be as reactive to the diagnosis and risk over-treatment. In other words, a patient's relationship with his doctor, and the various uses of screening in that relationship, is not factored into the outcomes data published in peer-reviewed articles. Patients must have the opportunity to humanize the recommendation process.

Increased Transparency and Accountability Surrounding the Recommendation Development Process Will Lead to Better Overall Recommendations

As the bills title suggests, the second achievement of this legislation is its codification of a transparent recommendation process. Subjecting the process to the Federal Advisory Committee Act (FACA) ensures public awareness and participation in the recommendation development process no matter who is leading USPSTF, the Agency for Healthcare Research and Quality (AHRQ), or the Department of Health and Human Services (HHS). While the current leadership has made some strides to be more transparent and public facing with its recommendation process, this bill ensures those gains survive any leadership changes.

We applaud the language in the bill that provides a process for public participation, inspection and commenting on Task Force appointments, draft research plans, draft evidence reports, and draft recommendations. The codification of the recommendation development process and the transparency of the steps in that process ensure that the public has ample opportunity to communicate with the USPSTF and that public comment is acknowledged and considered. Transparency and accountability surrounding the process should lead to recommendations informed by broad perspectives that avoid some of the controversies we have seen from the USPSTF's myopic consideration of data from one perspective.

Coordination Between Federal Agencies Improves Recommendations Through Sharing of Science

The bill also codifies a requirement for the USPSTF to consult with other Federal agencies and departments on its research plans. ZERO is aware that groundbreaking prostate cancer research has occurred and continues in various areas of our government, including the National Cancer Institute and Department of Defense. To ensure that research plans include the latest research, which may not have made it into peer-reviewed journals, we support the language that directs AHRQ to facilitate USPSTF's interaction with other agencies. Through such interaction, USPSTF may include more research in its

recommendations for specific cancers and possibly broaden research that applies to different subpopulations through consultation with agencies like the National Institute on Minority Health and Health Disparities.

Prostate cancer mortality in African American men is double that of white men. Yet, the studies USPSTF used in the 2012 PSA recommendation included mostly of white men. The USPSTF recommendation acknowledges greater prostate cancer risk for African Americans (and for those with a family history), but simply concludes it has no reason to believe the benefit outweighs the harm for African Americans based on its review of the limited data. If the USPSTF had consulted the National Institute on Minority Health and Health Disparities, it may have come to a different conclusion, or, at least determined a better, more sensitive way to communicate its recommendation to the African American community.

In these ways, the legislative directive to consult with other departments and agencies ensures that we leverage all of the resources within our federal government that are working toward the health of our country.

Revision of HHS Secretary’s Discretion to Remove Coverage for D Rated Preventive Services Protects Medicare Beneficiaries

The legislation also maintains Medicare coverage for PSA screening until the USPSTF can review the screening under the new process. Under current law, the Secretary has the power to eliminate USPSTF “D” rated preventive services, like the PSA. Eliminating this authority will ensure the Medicare beneficiaries have certainty that they can continue to access PSA screening. The legislation allows the Secretary to remove payment for “D” rated preventive services once the new process has vetted the service. This provision ensures uninterrupted care and certainty for Medicare beneficiaries as the new USPSTF is constituted and the PSA screening is reviewed.

ZERO Believes the Passage USPSTF Transparency and Accountability Act will Improve Access to Preventive Screenings

In conclusion, ZERO supports this legislation's effort to ensure that screening recommendations tied to insurance coverage and primary care provider practices include broader perspectives, including those of specialists, patients, and other agencies. Additionally, a transparent process will provide the public with more confidence about the recommendation process, leading to less controversy and ultimately more patient and provider certainty about when to conduct preventive services. On behalf of all men, who deserve to know their PSA numbers through a simple screening blood test, we urge Congress to pass this legislation that improves upon a good idea and makes it a more inclusive process with broader perspectives and greater resources. We appreciate your consideration of our comments.

Respectfully submitted,

Drew Saelens

Vice President of Government Affairs & Patient Advocacy

ZERO - The End of Prostate Cancer

ZERO – The End of Prostate Cancer is the leading national nonprofit organization with the mission to end prostate cancer. ZERO advances research, encourages action, and provides education and support to men and their families through our patient-centric programs. ZERO's premier activities include the ZERO Prostate Cancer Run/Walk, America's largest men's health event series. We are a 501(c)(3) philanthropic organization recognized with four out of four stars by Charity Navigator in 2014 and 2015, accredited by the Better Business Bureau, and 94 cents of every dollar donated goes to research and programs.