Statement for the Record

House Committee on Energy and Commerce
Subcommittee on Health
November 30, 2016
Hearing: “Examining the United States Preventive Services Task Force”

Submitted by: Men’s Health Network
202-543-6461, ext. 101
publicaffairs@menshealthnetwork.org

Contents

Opening Statement

Men’s Health Network (MHN) appreciates the opportunity to provide comments for the record regarding the U.S. Preventive Services Task Force (USPSTF, often referred to here as the "Task Force") and the current legislation, H.R. 1151, the USPSTF Transparency and Accountability Act of 2016.

MHN believes that the bill makes important changes to the way the USPSTF conducts its work, leading to a more open process that considers a wider array of relevant expertise. These changes are important, as the recommendations made by the USPSTF have wide-ranging implications for the types of preventive services that are available to patients and covered by both private and public insurance.

We appreciate the efforts of the Task Force to address the needs of the medical community, but feel that the changes proposed by this bill would increase the confidence of the public in the recommendations issued. Below, we offer our comments organized by key provisions of the bill as well as additional information that we consider integral to the discussion of improving the function of the USPSTF.

Consulting with Government Agencies

One of the key provisions of the bill, found on page (5), section (4)(A)(iii), addresses the need for required consultation between the USPSTF and relevant government agencies. USPSTF should reach out to all government agencies engaged in research and patient care in the area being reviewed. The enormous research and outcomes information available at agencies like the National Cancer Institute (NCI), the Veterans Administration, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Mental Health (NIMH), and others is invaluable in making decisions about services that can save lives.

As an example, the Centers for Disease Control (CDC) conducts top-level research on the treatment decision-making process of those diagnosed with breast cancer and with prostate cancer, yet the USPSTF does not actively consult with the research teams at CDC. This seems unusual in that ratings are so often based on treatment decisions made by patients in consultation with their providers. Using prostate cancer as an example, there appear to be no harms in the screening test itself, so the current D rating is presumably based on the patient's treatment decision. Not including research on how patients make decisions, and who they trust to advise them, may lead to recommendations that do not reflect the actual experience of patients.

Advisory Board

It is also extremely important that the Task Force consult with patient groups during the process as those groups have a wealth of information on outcomes that may not be found in the limited scope of peer-reviewed journals currently considered by the Task Force.

HR 1151 would establish an Advisory Board composed of patient groups, providers (including specialty physicians), and federal agencies and departments. We see this provision as an important step in ensuring that critical expertise outside the experience of the Task Force members is considered.

The Advisory Committee provided for in the revised bill ensures that the expertise and concern of the patient community, specialty organizations, and federal agencies involved with the rating being considered are actively engaged throughout the process, and are available to help the Task Force make the most informed rating possible, that addresses the needs of the patient.

Representation of Patient Organizations

While the ratings are meant for primary care physicians, the ultimate beneficiary is the patient, and the patient should be the center of concern for all Task Force actions. In order to ensure that patient interests are adequately addressed, patient organizations should be actively involved throughout each rating revision process.

Examples of participation by specialist and patient organizations already exist in federal government. The Congressionally Directed Medical Research Program (CDMRP) at the Department of Defense provides guidance:

> From the CDMRP 2013 report -
>
> Stakeholders Meeting - For new programs, a stakeholders meeting is held to survey the research landscape and identify gaps in the scientific and consumer interest areas. Stakeholders are consumers, scientists, and clinicians. The CDMRP defines consumers as patients, survivors, family members, or caregivers of people living with a disease, injury, or condition and are representatives of consumer advocacy, support, or military organizations. (Additional information about consumers can be found on page 13.) Recommendations from stakeholders meetings are then used to facilitate vision setting.
>
> - and from the CDMRP web site -
>
> http://cdmrp.army.mil/about/2tierRevProcess
>
> All review panels are composed of scientists, clinicians, members of the military as applicable, and consumers from advocacy communities. Consumers serve as full voting members and play a major role in maintaining the focus of the respective program on research that is relevant and has the potential to make a significant impact on the community affected.

The active involvement of these stakeholders has led to extraordinarily high patient confidence in the decisions on research reached by that panel, supported by the openness of the process.

Representation of Specialists

Specialty representation on the Task Force should be expanded to provide a greater degree of relevant expertise in decisions at all stages of the recommendation process. The recommendations issued by the Task Force have implications that reach far beyond the offices of primary care physicians, and specialty providers have insight on the benefits and risks of preventive services that should be formally considered by the Task Force.

Despite concerns from some that specialist representation on the Task Force may lead to conflicts of interest, most of the present members of the Task Force are engaged in specialist professions and could conceivably benefit from a positive (“A” or “B”) screening recommendation. Task Force membership presently consists of four family medicine physicians, four internal medicine physicians, three pediatricians, two obstetrician/gynecologists, two psychologists, and 1 nurse midwife.

As we can see from some of the screening recommendations mentioned below, the Task Force could only benefit from the expertise of specialists and the collective experience of patient organizations, and a standing Preventive Services Advisory Board.

Gender

Gender is not listed among the considerations in the revised HR 1131, (Section (a)(4(A)(ii) – currently as seen at the top of page (5), but should be included.

The Task Force should address gender in all recommendations that are not limited to one gender (ovarian cancer, testicular cancer, etc.). Women's organizations, like the Society for Women's Health Research, have made gender identification a necessary part of research, as has our organization, Men's Health Network. In the development of Healthy People 2010 by the Department of Health and Human Services, gender was specifically noted as a necessary consideration in the elimination of health disparities, the focus of which was prevention.

We appreciate that the Task Force often points out deficiencies in research (including a lack of gender-specific data) which make it more difficult to reach a decision on ratings, but considering gender in screening recommendations, where pertinent, would best meet the needs of the medical and patient communities.

D Ratings and Secretary's Authority

The Secretary of HHS should have no right to "veto" a law passed by Congress, but was given the power to deny coverage in Medicare for any service that receives a D rating by the Task Force.

The bill before the Committee removes that power from the Secretary, and MHN supports this provision.

While we understand that an act of Congress gave the Secretary this unusual power, we also understand, as much discussed and commented on, that the Affordable Care Act passed Congress without the benefit of a conference committee and that some parts in the bill that passed were meant as bargaining tools, as is typical in the regular order. We trust that this unusual power granted the Secretary would not have been included in a final bill had the regular order been followed.

> (Bold emphasis added.)
>
> Legislative Council - 111TH CONGRESS
> 2d Session PRINT 111–1
> COMPILATION OF PATIENT PROTECTION AND AFFORDABLE CARE ACT
> [As Amended Through May 1, 2010]
> INCLUDING PATIENT PROTECTION AND AFFORDABLE CARE ACT

HEALTH-RELATED PORTIONS OF THE HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010

Page 484 -

SEC. 4105. EVIDENCE-BASED COVERAGE OF PREVENTIVE SERVICES IN MEDICARE.
(a) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is

‘‘(n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010, **if the Secretary determines appropriate, the Secretary may—**
‘‘(1) modify—
‘‘(A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and
‘‘(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and
‘‘(2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.’’.
(b) CONSTRUCTION.—

Transparency

Created in the mid-1980s to establish preventive recommendations for the medical community, and now, in practice, coverage decisions for insurance companies, the USPSTF is no longer an obscure semi-government entity, staffed by AHRQ, but an extraordinarily powerful panel that now has significant influence over the preventive measures every person in the country may receive.

In spite of this relatively new position in the health care delivery system, the Task Force appears to the public to be an insular entity with little accountability to the people affected by its recommendations and few requirements to engage with relevant outside audiences. While we understand that this is not the intent of the Task Force, we feel that the changes proposed in the bill would allow the Task Force to interact more openly with the public while still performing its core responsibilities.

As an example, while information available on the USPSTF web site has improved, including information on procedures, and while the Task Force has expressed a willingness to send a speaker to conferences, and sometimes does, those public relations appearances do not provide the same level of interaction and eventual understanding and acceptance that a series of ongoing meetings with Task Force personnel would provide. Coupled with the lack of continuing patient input, the result is

an unintended lack of trust in the Task Force system, and a feeling of alienation from the process, which leads to a reluctance to accept Task Force recommendations that are not A or B, and ongoing concern about the future of those that are A or B.

In addition to the provisions addressed by the bill and mentioned above, we would like to propose that after finalizing recommendations on preventive services, the Task Force should meet with and develop plans to actively engage patient and medical groups (physician, nursing, physician assistants, etc.) in the dissemination of Task Force ratings so that they are better understood.

We also believe that in order to accurately demonstrate the value (or lack thereof) for a preventive service to the patient, The Task Force should implement procedures that will assess the results of not being screened for these conditions, which is, often, death or permanent disability.

Conclusion

Where the powers granted to the Task Force by the Affordable Care Act survive the new Congress and a new president, the Task Force will continue to set standards that are followed by insurance companies and some medical associations as we move forward. It is imperative that the issues addressed in these comments be resolved so that patients can be best served.

We have addended this statement with excerpts from a blog by actor Ben Stiller, a man with no family history of the cancer, wherein he explains his journey through diagnosis and treatment of prostate cancer, attributing his survival to early detection through regular screening. We can assume he had some anxiety along the way, waiting for test results and worrying about elevated PSAs, but without those tests he would not be listed as a “survivor.”

USPSTF screening recommendations referenced above –

Breast Cancer –
Like many breast cancer organizations, Men’s Health Network is perplexed by the 2009 Task Force “D” rating for breast cancer self-exams, and the decision not to update that recommendation in the most recent review of breast cancer screening, “The USPSTF did not update its 2009 recommendation on teaching breast self-examination….”

Additionally, we do not find any reference to breast cancer in men, which has approximately the same mortality rate as that in women, nor a caution to the medical community that what appears to be a sports or work injury might be breast cancer.

Depression –
While we applaud the rating on screening for depression, the Task Force did not address the need for a depression tool specifically for males, understanding that existing tools work best for identifying depression in women, but often do not work for

identifying depression in men. The result is, in part, a significantly higher suicide rate in men than in women (4 times higher). In its recent revision of the depression screening rating, the Task Force was made aware (by Men's Health Network) of this deficiency in the screening tools presently used, but did not address the need in its final recommendation. See Depression in Adults: Screening (January 2016) (https://www.uspreventiveservicestaskforce.org) and Screening for Depression in Adults: US Preventive Services Task Force Recommendation Statement (JAMA January 26, 2016 Volume 315, Number 4).

Osteoporosis –
We applaud that there are separate osteoporosis ratings for males and for females, but are concerned that the need for a different screening test for males is not addressed, nor is the need for bone mass screening in males that are undergoing hormone treatment for prostate cancer, a treatment that almost immediately places them in a menopause-like condition and at high risk for broken bones.

Testicular Cancer –
The "D" recommendation for testicular cancer screening in "adolescent or adult men" (Testicular Cancer: Screening [April 2011]) is particularly perplexing. This "D" rating, as in the case of the prostate cancer rating, would result in some cancers being caught in advanced stages when they might have been detected earlier, when treatment is more likely to be effective. There may be worry and anxiety associated with early detection, but at that stage the cancer can be successfully treated, if treatment is necessary. As an example in the testicular cancer recommendation (https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/testicular-cancer-screening) – (emphasis added):

> *Detection*
> **Most cases of testicular cancer are discovered accidentally by patients or their partners.** There is inadequate evidence that screening by clinician examination or patient self-examination has a higher yield or greater accuracy for detecting testicular cancer at earlier (and more curable) stages.
>
> (Men's Health Network comment, "…discovered accidentally by patients or their partners" is a self-exam. More on this is found below.)
>
> *Benefits of Detection and Early Intervention*
> Based on the low incidence of this condition **and favorable outcomes of treatment, even in cases of advanced disease**, there is adequate evidence that the benefits of screening for testicular cancer are small to none.
>
> *Harms of Detection and Early Intervention*
> **Potential harms** associated with screening for testicular cancer **include false-positive results, anxiety, and harms from diagnostic tests or procedures.** The USPSTF found no new evidence on potential harms of screening and concluded that these harms are no greater than small.

USPSTF Assessment
The USPSTF concludes that there is moderate certainty that screening for testicular cancer has no net benefit.

It is hard to determine how that series of statements leads to a "D" rating, which means that for testicular exams, including self-exams, "There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits." (USPSTF definition of a D grade). An "I" rating might be appropriate in this instance.

As to self-exams, all testicular cancer patient organizations, including Men's Health Network, recommend regular self-exams. The American Cancer Society addresses testicular cancer screening, including self-exam, in this manner:

www.cancer.org/cancer/testicularcancer/detailedguide/testicular-cancer-detection

Most doctors agree that examining a man's testicles should be part of a general physical exam. The American Cancer Society (ACS) recommends a testicular exam as part of a routine cancer-related checkup.

The ACS advises men to be aware of testicular cancer and to see a doctor right away if they find a lump in a testicle. Because regular testicular self-exams have not been studied enough to show they reduce the death rate from this cancer, the ACS does not have a recommendation on regular testicular self-exams for all men. However, some doctors recommend that all men examine their testicles monthly after puberty.

Prostate Cancer Survivor (blog) – Ben Stiller (actor)

"Taking the PSA test saved my life." – Ben Stiller[1]

The Prostate Cancer Test That Saved My Life

By Ben Stiller – 10-4-16

"So, yeah, it's cancer."….

I got diagnosed with prostate cancer Friday, June 13th, 2014. ….

Taking the PSA test saved my life. Literally. … The bottom line for me: I was lucky enough to have a doctor who gave me what they call a "baseline" PSA test when I was about 46. I have no history of prostate cancer in my family and I am not in the high-risk group, being neither—to the best of my knowledge—of African or Scandinavian ancestry. I had no symptoms.

[1] Complete blog found at https://medium.com/@RedHourBen/the-prostate-cancer-test-that-saved-my-life-613feb3f7c00#.kl82vescg

What I had—and I'm healthy today because of it—was a thoughtful internist who felt like I was around the age to start checking my PSA level, and discussed it with me.
….
So. What is the deal with this PSA test and why the controversy?

It is a simple, painless blood test. It is not dangerous in itself in any way. If the PSA (Prostate Specific Antigen) value is elevated in the blood, or levels rise sharply over time, it could indicate the presence of prostate cancer. It is definitely not foolproof.
….
But without this PSA test itself, or any screening procedure at all, how are doctors going to detect asymptomatic cases like mine, before the cancer has spread and metastasized throughout one's body rendering it incurable? Or what about the men who are most at risk, those of African ancestry, and men who have a history of prostate cancer in their family? Should we, as the USPSTF suggests, not screen them at all? There is growing evidence that these guidelines have led to increased cases of prostate cancers that get detected too late for the patient to survive the disease.

…I think men over the age of 40 should have the opportunity to discuss the test with their doctor and learn about it, so they can have the chance to be screened. After that an informed patient can make responsible choices as to how to proceed.

I count my blessings that I had a doctor who presented me with these options. After I chose to take the test, he directed me to doctors who worked at centers of excellence in this field to determine the next steps. This is a complicated issue, and an evolving one. But in this imperfect world, I believe the best way to determine a course of action for the most treatable, yet deadly cancer, is to detect it early.

# # #