FORCE
Facing Our Risk of Cancer Empowered
Fighting Hereditary Breast and Ovarian Cancer

May 18, 2015

USPSTF Chair
540 Gaither Road
Rockville, MD 20850

Dear Chair, USPSTF:

Facing Our Risk of Cancer Empowered (FORCE), the only national nonprofit organization devoted to people and families affected by hereditary breast and ovarian cancer, is committed to providing information, education, and advocacy to empower women to make informed decisions about their health, including decisions about cancer screening. Our organization and the undersigned members of our Scientific Advisory Board and community oppose many aspects of the proposed Draft Breast Cancer Screening Guidelines because we believe they will worsen existing disparities, lead to confusion, and cost the lives of women in the community that FORCE serves.

The proposed guidelines state: "The USPSTF is committed to improving the health of **all** Americans. To achieve this, the USPSTF assesses evidence on specific populations and makes specific evidence-based recommendations for specific populations." The panel wields considerable power over consumer access to preventive health care services—primary care clinicians and health systems follow its guidelines. And importantly, the guidelines are incorporated into the Patient Protection and Affordable Care Act (PPACA), which states that health plans must provide benefits without imposing cost-sharing (i.e., without a deductible or co-pay) for services that have a Task Force rating of "A" or "B." As such, any omissions or gaps in the populations under consideration for a given service can limit access and worsen disparity in access to care.

Our concerns are as follows:

The guidelines will disproportionately harm women with Hereditary Breast and Ovarian Cancer (HBOC) and women with a BRCA mutation:
The USPSTF recommendations specifically apply to women of average risk, but these guidelines detrimentally affect members of the high-risk community we serve, for whom breast cancer before age 50 is particularly common. Because genetics experts and risk-assessment tools are underutilized, many high-risk women with an inherited predisposition to cancer learn about their high-risk status only AFTER THEY ARE DIAGNOSED with breast cancer that has been detected by mammography. For this population, access to surveillance is important and can

lower the risk of breast cancer mortality. Giving a "C" grade to mammography in women ages 40-49 creates significant barriers to them having access to care and misses an opportunity to diagnose breast cancer in high-risk women at earlier stages.

The guidelines discriminate against high-risk women:
The guidelines create a gap in screening recommendations and access to preventive services for women at high risk for breast cancer, thus discriminating against this vulnerable group. Although the USPSTF is committed to improving the health of all Americans, women who are most at risk for breast cancer are omitted from screening guidelines.

In 2013, the USPSTF published guidelines that assigned a letter grade of "B" for identification of women at high risk for breast and ovarian cancer through genetic counseling and BRCA testing. However, the clinical utility of genetic counseling and testing for BRCA lies in the high-risk individual accessing preventive services to lower their risk for breast or ovarian cancer or to detect these cancers at an earlier stage. During the review phase of the draft guidelines in 2013, FORCE urged the USPSTF to review the evidence and assign a letter grade to expert-recommended interventions for high-risk women, including risk-reducing salpingo-oophorectomy and breast MRI. The USPSTF did not implement these suggestions. Without a letter grade assigned to screening and prevention interventions, these preventive services are not covered under the PPACA, giving high-risk women less access to recommended interventions than average risk women.

The USPSTF also notes that women in their 40s who have a mother, sister, or daughter with breast cancer may benefit more than average-risk women by initial breast cancer screening before age 50. The proposed breast cancer screening guidelines, however, assign this service a grade "C" recommendation, which will make insurance reimbursement for screening mammography before age 50 difficult for millions of women who have increased risk for breast cancer due to family history.

Having dense breast tissue is linked to an increased risk of breast cancer. Mammography is less effective in screening dense breasts for cancer, so other screening tools such as MRI or ultrasound may provide crucial early detection for these women. Several states have laws requiring that women be informed if they have dense breasts. Unfortunately, without a USPSTF grade "A" or "B" recommendation, insurers are not required to pay for supplemental screenings in these high-risk women. This may place an unnecessary financial burden on this population.

The guidelines miss an opportunity to find aggressive breast cancers and cancers in younger women:

The task force acknowledges that screening mammography is likely to save lives, but that it saves fewer lives for women ages 40-49 than older women. Nevertheless, we must apply every and all means at our disposal to save as many lives as possible. By delaying screening mammography until age 50 we miss opportunities to identify breast cancers in high-risk women. Limiting mammography after age 50 to biennial screenings means many aggressive, quicker developing, interval breast cancers (cancers that develop between screenings) will go undetected until they are advanced and much harder to treat. These recommendations may also disproportionately burden and increase disparities for African American women, who are more likely to develop aggressive triple-negative breast cancer, and who are more likely to die of their breast cancer than women of other races. We are concerned that if implemented, these recommendations will cost lives.

The guidelines emphasize risks for overdiagnosis and treatment, while minimizing risks of misdiagnosis, and ignoring clinical tools that can help minimize overdiagnosis:

According to the draft guidelines, "All women undergoing regular screening mammography are at risk for the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to her health, or even apparent, during her lifetime (known as "overdiagnosis"). This risk is predicted to be increased when beginning regular mammography before age 50 years."

The guidelines do not acknowledge the existence of decision-support tools such as Oncotype DX and Mammaprint, technologies that can help prevent overtreatment by determining which early-stage cancers, when found, are more likely to behave aggressively and thus avoid overtreatment.

Conclusion

The task force review of risk and the cost/benefit ratio for breast cancer screening highlights the need for:

- more effective breast cancer screening,
- better utilization of risk-assessment tools, and
- more research on breast cancer risk factors, screening, and outcomes.

To make breast cancer preventive services accessible to all Americans we must provide guidelines for breast cancer screening that take into account high-risk women, as well as women at average risk. and assure coverage for preventive services without cost-sharing for people at increased risk for breast cancer by reviewing the evidence and providing a letter

grade for recommended services such as risk-reducing salpingo-oophorectomy for women with a BRCA mutation and breast MRI for women at high risk for breast cancer due to inherited risk factors. At a time when our elected leaders are focusing on personalized and precision medicine, we should strive to replace sweeping one-size-fits-all recommendations with more appropriate guidelines that support individualized risk assessment and screening. Until risk assessment becomes an exact science, *all* women should have access to credible and balanced information, and with guidance from their physician, be allowed to decide and have insurance coverage for the breast screening that makes sense for them.

Respectfully yours,

Sue Friedman, DVM
Executive Director
Facing Our Risk of Cancer Empowered