



October 12, 2013

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Dear Dr. Cosby and esteemed USPSTF panel members:

I am contacting you regarding the USPSTF draft guidelines on Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer. USPSTF guidelines have significant implications for high-risk patient access to preventive care, particularly because they are referenced by the Patient Protection and Affordable Care Act (PPACA); requiring insurers to cover preventive services outlined under the guidelines without co-pay or deductible.

Facing Our Risk of Cancer Empowered (FORCE) is most concerned about two particular aspects of these guidelines:

- Limiting the patient population covered by the guidelines to women who have not been diagnosed with breast or ovarian cancer but who have affected family members with unknown BRCA status omits significant populations from receiving preventive services coverage under the PPACA.
- Omitting letter grades for specific prevention and screening options available for women with a BRCA mutation fails to establish provision of these preventive services under the Affordable Care Act, thereby limiting patient access to these services.

Below is an outline of our concerns and suggestions for changes to these guidelines, which we believe will provide consistency in the application of evidence-based criteria to determine appropriate patient access to preventive services.

- **Expand the patient population included in the guidelines**
Based on the level of evidence available, we urge the USPSTF to extend the population covered under the guidelines to include:

- 1. Undiagnosed women with a known mutation in the family**

As written, the USPSTF acknowledges that women who have a relative with a known BRCA mutation should receive genetic counseling and consideration for testing. However, exclusion of this population in the “Patient Population Under Consideration” section implies that the Grade B recommendation for genetic counseling and testing does not extend to those with a known mutation in the family.



From a preventive perspective, access to genetic counseling and testing in women with a known mutation in the family is evidenced as strongly—if not more strongly—as evidence for genetic risk assessment in women who are covered under the current draft who have a family history of cancer and no known familial mutation. Further, testing women with a known mutation in the family is least likely to return an uninformative test result. Single-site testing, which is usually appropriate for these women, is also less expensive than the full-sequence testing required when there is no known mutation in the family.

We request that the USPSTF review the evidence for genetic counseling and testing in women with a known mutation in the family, and based on the strength of the evidence, clearly state that these women are included in the patient population covered under the guidelines and the “B” letter grade. As written, PPACA provisions do not extend to this population; this can impact access to care for these individuals.

2. Women who have been diagnosed with breast or ovarian cancer who meet criteria for genetic counseling and testing due to personal and family history of cancer

With many more women surviving breast cancer, there is a need in this population for access to preventive services for unrelated conditions.

A diagnosis of cancer does not in itself exempt women from risk for other unrelated diseases, and this population is not excluded from other USPSTF guidelines, such as “Screening for Lipid Disorders in Adults” or “Cervical Cancer Screening.”

Women with BRCA mutations and a cancer diagnosis are at high risk for a second primary cancer. In this regard, their risks for a new cancer are similar to the risks of BRCA carriers who have never been diagnosed with cancer. Strong research evidence supports genetic risk assessment for preventive purposes in women who have been diagnosed with breast cancer and meet national guidelines; this evidence warrants a literature review and consideration by the task force. Assuming that these women would not benefit from further preventive services to address their risk for a new cancer is neither reasonable nor evidence-based. Recommended cancer screening and preventive services for women who carry a BRCA mutation, including cancer survivors, differs significantly from the recommendations for the general population and those affected by sporadic cancer. Omission of survivors from these guidelines will negatively impact their access to care and coverage for preventive services under the PPACA.

Further, genetic risk assessment is most likely to yield informative results when the family testing process begins with an individual who has already been diagnosed with cancer. Once a mutation is identified in the family, then other family members can be screened for that mutation. This cascade approach to



genetic testing increases the likelihood of informative testing and minimizes wasted health care dollars on inconclusive tests. As written, the USPSTF draft guidelines favor testing within a family, beginning with an undiagnosed member. Initially testing a family member who is most likely to test positive, including an individual who is a cancer survivor, is a scientifically sound approach that is backed by evidence, fits the definition of preventive services and will be more productive than omitting survivors from these guidelines, which may lead to more uninformative tests and higher health care costs.

We request that the USPSTF review the evidence for genetic counseling and testing in women with a diagnosis of breast cancer and history (both personal and family) that is suggestive of a mutation, and based on the strength of the evidence, include these women in the patient population under guidelines and the “B” letter grade.

- **Assign a letter grade to specific screening and preventive services for people with BRCA mutations**

Under the draft guidelines, BRCA counseling and testing are assigned a “B” letter grade. Awarding a grade to both services acknowledges their clinical utility. The clinical value of genetic counseling and testing for BRCA with regard to preventive medicine, however, lies in a high-risk individual’s access to appropriate evidence-based screening and prevention services that lower the risk for breast or ovarian cancer or detect these cancers at an early stage. Without an assigned grade, these preventive services are exempt from the PPACA, which limits patient access. In contrast, breast cancer screenings for average risk women are covered under the PPACA because they carry a “B” grade in published USPSTF guidelines. National expert guidelines such as NCCN guidelines recommend different screening and prevention for breast cancer in women with BRCA mutations. The USPSTF is inconsistent if fails to outline and provide letter grades for breast screening and preventive services for high-risk women, while it provides letter grades for the same services in women of average risk.

We request that the USPSTF review the evidence for risk-management services, including annual screening with breast MRI and mammogram for women found to have a BRCA mutation, and based on the strength of this evidence, provide a letter grade to these preventive services.

Primary care clinicians, health systems, private insurers, and others look to the USPSTF for guidance regarding who should receive genetic counseling and testing. Leaving these important gaps in the Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer statement—and not providing a Grade A or B recommendation—affects patient access to preventive care.

Unfortunately, FORCE is finding that some payors are denying any coverage of preventive services that have not been assigned a letter grade within USPSTF guidelines, and for individuals



who fall outside of the patient population covered; this is despite the fact that these individuals meet national standard of care guidelines as outlined by NCCN, ASCO, American Cancer Society, and other professional agencies. Some patients report that their insurance companies are specifically citing lack of letter grade by USPSTF as reason for denial, even in situations where genetic testing or risk-management strategies are clearly appropriate and evidence-based.

We implore the USPSTF to review the evidence for extending the population and preventive services included in these guidelines to address these inconsistencies and gaps. Should the task force reject these suggestions or decide that further review and extension of the guidelines to the above-mentioned areas falls outside its scope, I respectfully request a written response to that effect, which clearly outlines the reasoning and rationale for these decisions.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sue Friedman", is positioned below the closing.

Sue Friedman
Executive Director