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June 6, 2023

Michael J. Barry, M.D.
Chair
United States Preventive Services Task Force
540 Gaither Road
Rockville, MD 20850

Re: Screening for Breast Cancer: Draft Recommendation Statement

Dear Dr. Barry:

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is writing in response to the United State Preventive Services Task Force (USPSTF) draft recommendation statement on breast cancer screening. Medical imaging technologies play a key role in breast cancer screening, and diagnosis, which leads to early and more effective treatment, saving lives.

Breast cancer is the second most common cancer among women in the United States.¹ Screening for breast cancer is essential to reduce breast cancer mortality and improve outcomes for patients.² As part of the Healthy People 2030 initiative, the Centers for Disease Control and Prevention established screening targets and objectives for the US population. We are still falling short of meeting these targets, and we must do more to promote access and adherence to screening exams:

| | Baseline | Target |
|---|-----------------|---------------|
| Females who get screened for breast cancer ³ | 76.4% (2019) | 80.5% |

We believe the Task Force has made a step forward by recommending that average risk women begin screening at age 40 instead of 50. However, we believe the draft recommendation statement is inadequate in other areas that must be addressed to provide screening access consistent with clinical best practice.

¹ American Cancer Society. How Common Is Breast Cancer? Jan. 2020. Available at: <https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html>

² Dibden A, Offman J, Duffy SW, Gabe R. Worldwide Review and Meta-Analysis of Cohort Studies Measuring the Effect of Mammography Screening Programmes on Incidence-Based Breast Cancer Mortality. *Cancers (Basel)*. 2020;12(4):976. Published 2020 Apr 15. doi:10.3390/cancers12040976

³ <https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-proportion-females-who-get-screened-breast-cancer-c-05>

Specifically, we believe the recommendations need to reflect: 1) annual screening, 2) screening beyond the age of 74, and 3) supplemental imaging for women with dense breasts.

Annual screening

The evidence demonstrates that increasing the frequency of breast cancer screenings in average risk women increases early detection and improves overall mortality. Biennial screening is linked to diagnosis of later stage breast cancer and allows for missed cancers to grow. It is imperative that the Task Force revise the recommendation on frequency to annual screenings, aligned with the frequency recommendation of leading professional organizations.

Screening of women over age 74

The Task Force's finding of insufficient evidence to screen women over the age of 74 is inconsistent with guidelines including those of the American Cancer Society (ACS), American College of Obstetricians and Gynecologists (ACOG), American College of Radiology (ACR), National Comprehensive Care Network (NCCN) and Women's Preventive Services Initiative (WPSI). Current guidelines state no upper limit in screening age. Breast cancer incidence increases with age,⁴ further supporting screening for women over the age of 74.

Breast Density

The evidence of breast density as a risk factor for cancer is well established. Further, women with dense breasts (as defined by BI-RADS categories C and D) risk mammographic screening missing their cancer due to the "masking" effect of dense breast tissue. In the context of FDA mandated reporting of density in mammography results, shared decision-making about additional testing is hindered as it occurs in the absence of consensus on guidelines. USPSTF should recognize the risk of breast density and recommend supplementary and diagnostic breast imaging options such as MRI with contrast, ultrasound, and contrasted enhanced mammography (CEM) in assessing women with dense breasts. The role of these technologies is discussed in the recently released ACR guidelines for screening women at high-risk for breast cancer.⁵

As USPSTF finalizes this recommendation statement, we urge review of the guidelines of other expert groups—and the underlying evidence those groups relied upon to publish their guidelines. The current inconsistency between USPSTF guidance and those of relevant clinical professional societies hinders the consistent practice of evidence-based care and shared decision-making between women and their clinicians.

Examples of breast cancer screening guidelines from professional societies and public health organizations include:

- **The American College of Radiology (ACR)** recommends annual mammographic screening beginning at age 40 for women of average risk. Higher-risk women should start mammographic screening earlier and may benefit from supplemental screening modalities.⁶
- **The National Comprehensive Care Network (NCCN)** recommends "annual mammographic screening for average-risk women beginning at age 40 years."⁷
- **The American Cancer Society (ACS)** recommends that "women with an average risk of breast cancer should undergo regular screening mammography starting at age 45 years (strong

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7822071/>

⁵ <https://www.acr.org/Media-Center/ACR-News-Releases/2023/New-ACR-Breast-Cancer-Screening-Guidelines-call-for-earlier-screening-for-high-risk-women>

⁶ <https://www.acr.org/Media-Center/ACR-News-Releases/2023/New-ACR-Breast-Cancer-Screening-Guidelines-call-for-earlier-screening-for-high-risk-women>

⁷ <https://pubmed.ncbi.nlm.nih.gov/30442736/>

recommendation). Women aged 45 to 54 years should be screened annually (qualified recommendation). Women 55 years and older should transition to biennial screening or have the opportunity to continue screening annually (qualified recommendation). Women should have the opportunity to begin annual screening between the ages of 40 and 44 years (qualified recommendation). Women should continue screening mammography as long as their overall health is good and they have a life expectancy of 10 years or longer (qualified recommendation).⁸⁸

- **The American College of Obstetricians and Gynecologists (ACOG)** recommends that women at average risk of breast cancer “should be offered screening mammography starting at age 40 years” and “should have screening mammography every 1 or 2 years based on an informed, shared decision-making process...”⁸⁹

It is also our position that USPSTF should adopt open and transparent research methodologies for its assessment of breast cancer screening, as well as for other preventive services in the future. The modeling used by USPSTF should be much clearer to interested parties, including a full explication of the models being used, the data being input to the models, and how the data are being manipulated. Further, the Task Force should also be open to other types or levels of evidence in its assessment, including well designed observational studies and real-world evidence. This will ensure that a holistic assessment of available data is being conducted.

Finally, we suggest that USPSTF reduce its review cycles for preventive services, including for breast cancer screening. The clinical evidence is rapidly evolving, and differing recommendations are being issued by the public health community (some from organizations with shorter review cycles) and USPSTF must keep pace.

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⁸⁸ <https://jamanetwork.com/journals/jama/fullarticle/2463262>

⁸⁹ <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2017/07/breast-cancer-risk-assessment-and-screening-in-average-risk-women>

Please contact Peter Weems, Senior Director, Policy & Strategic Operations, at pweems@medicalimaging.org or (703) 841-3238 if MITA can be of any assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick Hope". The signature is fluid and cursive, with a large initial "P" and a long horizontal stroke at the end.

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.