ACR and SBI: Draft USPSTF Breast Cancer Screening Recommendations Would Cost Thousands of Lives and Could Eliminate Mammography Insurance Coverage for Millions of Women

Lack of Transparency and Adherence to IOM Methodology Standards Renders USPSTF Recommendations "Untrustworthy"

Washington, DC (April 20, 2014) – Adoption of draft United States Preventive Services Task Force (USPSTF) breast cancer screening recommendation would result in thousands of additional and unnecessary breast cancer deaths each year. Thousands more women would experience more extensive and expensive treatments than if their cancers were found early by a regular mammogram. Adoption of these USPSTF recommendations could also strip millions of women 40-and-older of private insurance coverage with no copay for mammograms at the time of their choosing previously guaranteed by the Affordable Care Act (ACA).

The ACA requires private insurers to cover exams or procedures given a grade of "B" or higher by the USPSTF. The Task Force gave routine screening of women ages 40-49 a grade of "C" and gave a "B" grade only to biennial (every other year) screening for women 50-74. This would indicate that women ages 40-49 who choose routine screening and those 50-74 who want to be screened annually would not be guaranteed coverage. This may particularly impact underserved and rural areas.

"We believe that the Secretary of the Department of Health and Human Services (HHS) can clarify now whether adoption of the USPSTF recommendations would mean that private insurers no longer have to cover mammograms for millions of women 40-49 who, together with their doctor, choose to have regular mammograms and those 50-74 who choose to be screened annually. We call on her to affirm that coverage will not be affected," said Bibb Allen, MD, FACR, chair of the American College of Radiology Board of Chancellors.

According to National Cancer Institute <u>data</u>, since mammography screening became widespread in the mid-1980s, the U.S. breast cancer death rate has dropped 35 percent. Insurance coverage has enabled this dramatic reduction in breast cancer deaths. Published analysis (<u>Hendrick and Helvie</u>), using the task force's 2009 methodology, showed that if women ages 40-49 go unscreened, and those 50-74 are screened biennially, approximately 6,500 additional women each year in the U.S. would die from breast cancer.

<u>A 2014 study</u> published in the *JAMA Internal Medicine* shows that patients experience short term anxiety regarding test results that rapidly declines over time with no measurable effect to women's health from a false-positive exam. Past research indicates that nearly all women who experience a false-positive exam support screening and want to know their status. The USPSTF made a value judgement – not a scientific judgement – that, based on the link between USPSTF recommendations and insurance coverage, effectively takes away women's right to choose when or if to be screened for the nation's second leading cause of cancer death in women.

"The USPSTF limited its consideration to studies that underestimate the lifesaving benefit of regular screening and greatly inflate overdiagnosis claims. They ignored more modern studies that have shown much greater benefit. These limitations result in the misrepresentation of the real trade-offs that women and health care providers need to know about in order to make good decisions about screening. They also ignored the demonstrated views of American women on screening. Unfortunately, these recommendations will only add to confusion that is placing women at risk," **said Barbara Monsees, MD, FACR, chair of the American College of Radiology Breast Imaging Commission.**

The USPSTF does not comply with Institute of Medicine (IOM) recommendations for guideline development – widely regarded as the medical standard. The methods used by the USPSTF do not meet the IOM thresholds to be considered "trustworthy guidelines". No breast cancer experts sit on the task force that created these recommendations. The USPSTF did not allow participation of breast cancer or breast screening experts at meetings where evidence was reviewed. The lack of transparency does not meet the IOM standard. These recommendations should be regarded as suspect until experts recognized by major organizations in this area of medicine are included in a meaningful way in their creation.

"These USPSTF draft recommendations are based on a curiously selective analysis that does not foster a great deal of trust. Their recommendation creation process does not comply with IOM standards for trustworthy guideline creation that most major medical organizations are working to meet. This lack of transparency, lack of breast cancer expertise, and exclusion of studies that would support screening effectiveness and lower overdiagnosis estimates may result in unnecessary lives lost," said Murray Rebner, MD, FSBI, president of the Society of Breast Imaging (SBI).

The ACR and SBI back the USPSTF Transparency and Accountability Act of 2015 (<u>H.R. 1151</u>), recently introduced in the House of Representatives by Reps. Marsha Blackburn (R-TN) and Bobby L. Rush (D-IL).

The bill seeks greater USPSTF transparency regarding the public comment process, adherence to the Administrative Procedure Act, engaging stakeholder experts and patients in a meaningful way and public access to deliberations and supporting materials.

For more information regarding the proven effectiveness of regular mammography screening at reducing breast cancer deaths, please visit <u>MammographySavesLives.org</u>.

Contact Shawn Farley at 703-648-8936 or <u>PR@acr.org</u> to arrange an interview with an ACR spokesperson.

Contact <u>Joy</u> Burwell at 202-263-2971 or jburwell@amplifypublicaffairs.net to arrange an interview with an SBI spokesperson.