

# Congress of the United States

Washington, DC 20515

June 6, 2023

Michael J. Barry, M.D.  
Chair U.S. Preventive Services Task Force  
c/o USPSTF Senior Project Coordinator  
5600 Fishers Lane Mail Stop 06E53A  
Rockville, MD 20857

Dear Dr. Barry,

We write to express our serious concerns with the United States Preventive Services Task Force's (hereinafter "Task Force") Draft Recommendations for Breast Cancer Screening, published on May 9, 2023. The Task Force now recommends that all women get screened for breast cancer every other year starting at age 40, and failed to recommend that women with dense breasts have additional screening with breast ultrasound or MRI. As such, we are very concerned that the Draft Recommendations miss the mark, creating coverage gaps, generating uncertainty for women and their providers, and exacerbating health disparities.

The Task Force recommendations affect millions of women in the United States and their access to critical preventive screening tools for breast cancer, which, ultimately address entirely preventable deaths through early detection. However, the Draft Recommendations ignore and run counter to the existing body of evidence and national guidelines from leading expert organizations on mammography frequency and the use of supplemental screenings, and instead call for additional research.

It is critical that women are screened for breast cancer without delay. After years of screening declines due to the COVID-19 pandemic, women finally are returning to routine screenings, and the Draft Recommendations jeopardize and inhibit this progress. In their current form, the Draft Recommendations ultimately will lead to the loss of life. We strongly urge you to acknowledge the existing body of data and evidence that recommends women access an annual mammogram beginning at age 40, and women with dense breasts access supplemental screening, and adopt final recommendations that ensure all women will have access to early detection without any barriers to care.

## Women Ages 40 to 74 Years: Biennial Screenings

Breast cancer is the second most common cause of cancer death for women in the United States. The CDC explains that nine percent of all breast cancers in the U.S. are reported in women younger

than age 45. Yet, the Draft Recommendations from the Task Force recommend biennial mammograms for women beginning at age 40, rather than annual screenings. This recommendation creates a discrepancy between the Task Force and the American College of Radiology (ACR), Society of Breast Imaging (SBI), American Cancer Society (ACS), American Medical Association (AMA), American Society of Breast Surgeons (ASBrS), National Comprehensive Cancer Network (NCCN), a majority of oncologists, cancer experts, and patient advocacy organizations who recommend/advocate for annual mammograms. While the recommendation for screening to begin at age 40 does address a necessary change to the age to begin mammography, it is disappointing that American women have waited over a decade for the Task Force to issue incomplete guidance that still runs contrary to the medical community with regard to frequency.

Prevention, awareness, and early detection can be the critical difference between life and death for women with breast cancer. The Draft Recommendations have the potential to create gaps in access to preventive care for younger women, placing additional lives at unnecessary risk. It also will create confusion for providers and their patients during counseling, scheduling of appointments, and navigating follow-up care or additional screenings. The USPSTF's risk-benefit calculation in this regard is off-base, and with hundreds of thousands of new breast cancer diagnoses every year, the Draft Recommendations will result in later-stage detection, and ultimately, preventable deaths. The Draft Recommendations essentially write off many women because this two-year period between screenings will allow many treatable cancers to go unnecessarily undetected. This is particularly problematic for women with dense breasts, where annual screening is known to reduce the rate of symptomatic cancers.

These concerns have been overtly expressed and at issue since 2009, when the Task Force first reversed course on screening age and frequency.<sup>[1]</sup> For that reason, the Task Force's breast cancer screening recommendations have been under a moratorium since the *Protecting Access to Lifesaving Screenings Act (PALS)* was passed in 2015,<sup>[2]</sup> and subsequently extended in the Labor, Health and Human Services, and Education appropriations bills.<sup>[3]</sup>

### Women with Dense Breasts

The Draft Recommendations further place women's lives at risk because of the Task Force's continued failure to recognize the significant body of evidence<sup>[4]</sup> supporting additional breast cancer screenings with MRIs or ultrasound following a mammogram for women with dense breasts. The Draft Recommendations concludes that "current evidence is insufficient to assess the balance of benefits and harms of supplemental screening," instead calling for additional research in this regard and labeling this recommendation with an "Inadequate" grade. For women with dense breasts, additional screening is vital, and these recommendations unfortunately will further exacerbate the inability of women to receive adequate screening and could lead to later stage diagnoses, more harmful treatments and time lost from work, and increased mortality.

Access to additional screening means the opportunity for cancer to be found early, when the 5-year survival rate is 99%.<sup>[5]</sup> In contrast, a delayed diagnosis, when cancer is found when no longer early stage, results in a 5-year survival rate of 30%. A call for additional research essentially delays what is already known: women with dense breasts require additional screenings beyond a

mammogram. It is unfortunate that the Task Force concluded they have insufficient evidence to balance benefits and “harms” of supplemental screening, regardless of breast density. The harms of missing breast cancer in a young woman outweigh the harms outlined in the Task Force’s findings, and access to advanced imaging would address these misguided concerns.

We are very concerned that the continued “Inadequate” grade stems from the Task Force’s own value judgments on the benefits and risks of additional screening, which are not based on science. These judgments are eroding women and their health care provider’s ability to make an informed decision about a woman’s preventive care needs. We submit that it would be beneficial, before the recommendation is finalized, for the Task Force to receive input from health care providers who are experienced in reviewing breast imaging utilizing all forms of technologies including mammography, ultrasound, and MRI.

In response to the Task Force’s repeated failure to recommend additional screenings for women at higher risk of breast cancer, including women with dense breasts, legislation, including the *Find It Early Act*, has been introduced. *Find it Early* would ensure there is no cost-sharing for additional breast screenings for these women at great risk for breast cancer. However, the Task Force has the ability to ensure these critical supplemental screenings are covered in a more timely manner.

This is critically important as the Food and Drug Administration (FDA) plans to fully implement a nationwide breast density reporting standard, effective September 10, 2024, which was required through the Fiscal Year 2019 Omnibus because Congress sought to ensure women understand the implications of breast density. With this new nationwide reporting standard, all women will be told that dense tissue makes it hard to find cancer on a mammogram and also raises the risk of developing cancer. Women with dense breasts will receive a standardized report advising that other imaging in addition to a mammogram may help find cancer. Unfortunately, if the Draft Recommendations are finalized as is, women with dense breasts will be forced to pay out of pocket for lifesaving secondary screenings.

The Task Force states that it does not consider the cost of care when making determinations, nevertheless most private insurance plans are required to cover preventive services that receive a grade of “A” or “B” from the Task Force without a copay. Several states already have adopted legislation that require state-regulated health insurance plans to utilize national guidelines from the NCCN and ACR, which recommend women at higher risk of breast cancer receive an annual MRI (or ultrasound if an MRI is not possible). But, importantly, for all other health plans, including employer-sponsored coverage, Medicare, and Medicaid, coverage is entirely reliant on the Task Force’s recommendations. Thus, because most health insurance coverage for additional breast imaging is virtually reliant on the Task Force’s recommendations, the “Inadequate” grade will continue to exacerbate coverage disparities by making additional imaging only accessible to those who can afford to pay substantial out-of-pocket costs. It is our view that the Task Force should be considering the tremendous power its grades have on insurance coverage of benefits and women’s access to screening.

## Women of Color and Women at Higher Risk

The Draft Recommendations acknowledge that Black women are forty percent more likely to die of breast cancer than white women.<sup>[6]</sup> A recent study (that used the most recent and largest nationwide cancer mortality data available in the United States) found that if breast cancer screening starts at the age of 40 for the entire female population, as the draft recommendations recommend, then black women should begin to be screened at the age of 34.<sup>[7]</sup> The ACS's 2022 breast cancer statistics show that Black women have the highest incidence rate of breast cancer before the age of 40.<sup>[8]</sup> More recently, the ACR<sup>[9]</sup> and the NCCN<sup>[10]</sup> have recommended for high-risk women, including Black women and Ashkenazi Jewish women that risk assessments for breast cancer begin at the age of 25 through the age of 40. Both NCCN and ACR recommend women at higher risk of breast cancer, including women with dense breasts, should consider supplemental screening with an MRI or an ultrasound, as a 2D mammogram is not sufficient to detect cancer.

We suggest the Task Force consider if breast cancer screenings for Black women and women at high risk merit their own grades to ensure health care providers are aware of the special attention that should be given to Black women, Ashkenazi Jewish women, and other groups who are at higher risk of breast cancer that may require screening earlier than 40. This could be as simple as recommending shared decision making with risk assessment starting at age 25.

## Digital Mammography

The Task Force's Draft Recommendations also miss the mark by not recommending, nor providing any guidance, on the use of digital modalities for mammography. Digital Breast Tomosynthesis (DBT), or 3D mammography, for breast cancer screening was approved by the FDA in 2011, and Medicare began coverage of digital mammography in 2015. It offers clinical benefits to women with dense breasts, detects more invasive cancers, improves accuracy, reduces patient recalls for additional testing, and provides rapid and reliable results and storage of images. Review of the literature clearly demonstrates that all women benefit from having a tomosynthesis mammogram, rather than or in addition to 2D mammography, in terms of recall rate being lower and increased invasive cancer detection.

Over 95% of mammography units in the United States are already full field digital as digital mammography has demonstrated clear clinical benefits as compared to film screen mammography. While some states require insurance plans to cover tomosynthesis with no co-pay, many do not, which exacerbates health disparities. If 3D mammograms are not covered by insurance, a patient may face hundreds of dollars in out-of-pocket costs for screening and the possible additional testing. Insurance coverage of "all modalities," including 3D mammography, is vital to ensure that women have access to the recommended screenings.

## USPSTF Shortcomings

The Task Force is an independent panel of medical experts that makes recommendations about the frequency and methods of clinical preventive services, such as screenings, counseling, and preventive medication. The Task Force's recommendations are vital for younger women because the Affordable Care Act requires most private health insurers to cover the services they

recommend, including annual mammograms, with no cost sharing, making them free to patients. However, over the last decade, the Task Force has unfortunately made several concerning recommendations that use outdated research with non-diverse samples, often running counter to the general consensus from medical experts and researchers.

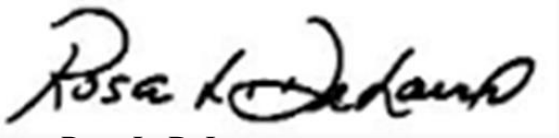
As such, we reiterate the Congress' deep concerns<sup>[11]</sup> about significant deficiencies in the process and structure of the Task Force, clearly illustrated by the last several rounds of recommendations concerning screening mammography. It is vital to ensure the Task Force's recommendations further public health for all Americans and address health inequities, not create additional gaps to accessing care. The Task Force's process must provide timely recommendations, ensure transparency, afford ample opportunity for public comment, make such comments publicly available, and provide meaningful responses to and engage with commenters. Moreover, the Task Force's methodologies should be firmly grounded in evidence that most accurately represents the nation's racial and ethnic subpopulations; this evidence must include high quality, real-world data sets and longitudinal or observational studies and not just randomized controlled trials.

### Conclusion

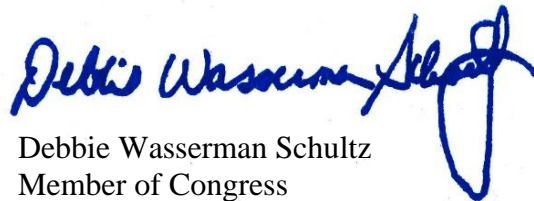
The Task Force works to improve the health of people nationwide by making evidence-based recommendations on effective ways to prevent disease, promote health, and prolong life. For women with breast cancer, the Task Force's Draft Recommendations fall well short in addressing this mission. We strongly encourage the Task Force to revise its Draft Recommendations and recommend: (i) annual screenings beginning at age 40; (ii) for women with dense breasts, coverage of supplemental screenings; (iii) for women of color and women at higher risk, coverage for counseling and screenings before age 40; and (iv) coverage of digital modalities, such as DBT.

To save lives, we must make sure that every woman has access to the screenings she needs when she needs them.

Sincerely,



Rosa L. DeLauro  
Member of Congress



Debbie Wasserman Schultz  
Member of Congress

- <sup>[1]</sup> See U.S. Preventive Services Task Force (USPSTF), Breast Cancer: Screening, 2002 (Sept. 03, 2022), available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening-2002>; USPSTF, Breast Cancer: Screening, 2009 (Dec. 15, 2009) available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening-2009>; USPSTF, Breast Cancer: Screening, 2016 (Jan. 11, 2016), available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening>.
- <sup>[2]</sup> Originally enacted in 2015, the Protecting Access to Lifesaving Screening (PALS) Act places a moratorium on the U.S. Preventive Services Task Force (USPSTF) recommendation that breast screening for women ages 40-49 should only be performed selectively, while women ages 50-74 should have mammograms bi-annually. See Public Law No: 114-113, Sec. 229.
- <sup>[3]</sup> See Fiscal Year (FY) 23 Labor, Health and Human Services, Education Appropriations bill Sec. 222, available at: <https://docs.house.gov/meetings/AP/AP00/20220630/114968/BILLS-117-FC-AP-FY2023-AP00-LHHS.pdf>.
- <sup>[4]</sup> See Johanna O.P Wanders, et al., *Volumetric breast density affects performance of digital screening mammography*, 162(1) Breast Cancer Research and Treatment 95–103 (2017), available at <https://doi.org/10.1007/s10549-016-4090-7>; Stamatia Destounis, et al., *Using Volumetric Breast Density to Quantify the Potential Masking Risk of Mammographic Density*, 208(1) Am. J. Roentgenology 222-227 (2017), available at <https://www.ajronline.org/doi/10.2214/AJR.16.16489>; Karla Kerlikowske, et al. *Identifying women with dense breasts at high risk for interval cancer: a cohort study*, 162(10) Ann. Intern. Med. 673–681 (2015), available at <https://doi.org/10.7326/M14-1465>; Daniëlle van der Waal, et al., *Breast cancer screening effect across breast density strata: A case-control study*, 140(1) Int. J. Cancer 41–49 (2017), available at <https://doi.org/10.1002/ijc.30430>; Veronica Irvin, et al., *Comparison of Mortality Among Participants of Women's Health Initiative Trials With Screening-Detected Breast Cancers vs Interval Breast Cancers*, 3(6) JAMA Netw. Open e207227 (2020), available at <https://doi.org/10.1001/jamanetworkopen.2020.7227>; Emily B. Ambinder, et al, *Interval Breast Cancers Versus Screen Detected Breast Cancers: A Retrospective Cohort Study*, Academic Radiology S1076-6332(23)00020-X (2023), available at <https://doi.org/10.1016/j.acra.2023.01.007>; Narumi Harada-Shoji, et al, *Evaluation of Adjunctive Ultrasonography for Breast Cancer Detection Among Women Aged 40-49 Years With Varying Breast Density Undergoing Screening Mammography: A Secondary Analysis of a Randomized Clinical Trial*, 4(8) JAMA Netw. Open e2121505 (2021), available at <https://doi.org/10.1001/jamanetworkopen.2021.21505>; Wendie A Berg, MD, PhD & Athina Vourtsis, MD, PhD, *Screening Breast Ultrasound Using Handheld or Automated Technique in Women with Dense Breasts*, 1(4) J. Breast Imaging 283–296 (2019), available at <https://doi.org/10.1093/jbi/wbz055>; Stefanie G. A. Veenhuizen, et al. *Supplemental Breast MRI for Women with Extremely Dense Breasts: Results of the Second Screening Round of the DENSE Trial*, 299(2) Radiol. 278–286 (2021), available at <https://doi.org/10.1148/radiol.2021203633>; Min Sun Bae, et al, *Survival Outcomes of Screening with Breast MRI in Women at Elevated Risk of Breast Cancer*, 2(1) J. Breast Imaging 29–35 (2020), available at <https://doi.org/10.1093/jbi/wbz083>; Christiane K. Kuhl, et al, *Supplemental Breast MR Imaging Screening of Women with Average Risk of Breast Cancer*, 283(2) Radiology 361–370 (2017), available at <https://doi.org/10.1148/radiol.2016161444>; Hebba Hussein, *Supplemental Breast Cancer Screening in Women with Dense Breasts and Negative Mammography: A Systematic Review and Meta-Analysis*, 306(3) Radiol. e221785 (2023), available at <https://doi.org/10.1148/radiol.221785>; Suneela Vegunta, et al., *Supplemental Cancer Screening for Women With Dense Breasts: Guidance for Health Care Professionals*, 96(11) Mayo Clinic Proceedings 2891–2904 (2021), available at <https://doi.org/10.1016/j.mayocp.2021.06.001>.
- <sup>[5]</sup> See U.S. Dep't of Health and Human Servs., Office of Women's Health, "99 Percent Survival Rate for Breast Cancer Caught Early," (Oct. 6, 2022), available at <https://www.womenshealth.gov/blog/99-percent-survival-rate-breast-cancer-caught-early>.
- <sup>[6]</sup> Amer. Cancer Soc., *Breast Cancer Facts & Figures 2019-2020* (2019), available at <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf>.
- <sup>[7]</sup> Tianhui Chen, et al., *Race and Ethnicity-Adjusted Age Recommendation for Initiating Breast Cancer Screening*, 6(4) JAMA Netw. Open e238893 (2023), available at <https://doi.org/10.1001/jamanetworkopen.2023.8893>.
- <sup>[8]</sup> Angela N. Giaquinto, et al., *Breast Cancer Statistics, 2022*, 72 CA A Cancer J. Clin. 524-541 (2022), available at <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21754>.
- <sup>[9]</sup> Debra L. Monticciolo, et al., *Breast Cancer Screening for Women at Higher-than-Average Risk: Updated Recommendations from the ACR*, J. Am. Coll. Radiol. S1546-1440(23)00334-4 (2023), available at <https://doi.org/10.1016/j.jacr.2023.04.002>.
- <sup>[10]</sup> See National Comprehensive Cancer Network, *NCCN Guidelines for Patients: Breast Cancer Screening and Diagnosis* (2022), available at <https://www.nccn.org/patients/guidelines/content/PDF/breastcancerscreening-patient.pdf>.
- <sup>[11]</sup> See H. Rept. 117–403, at 178 (2022).