

**Committee on Energy & Commerce  
U.S. House of Representatives  
Subcommittee on Health**

**“Breast Cancer Screening Recommendations”**

Testimony of  
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Mr. Chairman, Mr. Ranking Member, and Members of the Committee, thank you for the opportunity to testify today about the recent mammography screening recommendations of the U.S. Preventive Services Task Force (USPSTF). My name is Jennifer Luray, and I am President of the Susan G. Komen for the Cure® Advocacy Alliance and Vice President of Government Affairs and Public Policy of Susan G. Komen for the Cure®. On behalf of the breast cancer patients, survivors, families, friends, scientists, clinicians and advocates in the Komen family, thank you for holding this hearing.

More than 190,000 women will be diagnosed with breast cancer in the U.S. this year, and more than 40,000 will die.<sup>1</sup> In the last twenty years, there have been modest declines in the breast cancer mortality rate, attributed to increases in early detection and improvements in breast cancer treatment. When breast cancer is found before it spreads beyond the breast, the 5-year relative survival rate is 98 percent, but declines to 84 percent for regional disease and 23 percent when cancer has metastasized or spread to other parts of the body.<sup>2</sup>

In November, the USPSTF released the following new guidelines for screening mammography:

- For women ages 40-49, the guidelines for screening mammography changed from a B rating (recommended) to a C rating;
- For women ages 50-74, the guidelines for screening mammography remains a B (recommended), but the recommended frequency changed from “every 1-2 years” to biennial (every other year);
- For women ages 75 and over, the guidelines for screening mammography changed from a B (recommended) to an I (insufficient evidence);
- The guideline for teaching regular breast self-examination (BSE) changed from an I (insufficient evidence) to a D (not recommended); and
- A guideline was added, rating digital mammography and magnetic resonance imaging (MRI) over film mammography as an I (insufficient evidence).

These changes have again reignited the controversy over mammography screening, a debate that has raged for a number of years. It is important to remember the following:

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<sup>1</sup> American Cancer Society, “Breast Cancer Facts & Figures, 2009-2010.” Available online at [http://www.cancer.org/downloads/STT/F861009\\_final%209-08-09.pdf](http://www.cancer.org/downloads/STT/F861009_final%209-08-09.pdf).

<sup>2</sup> *Ibid.*

- While there is some disagreement about when mammograms should begin and on what schedule, all agree — including the USPSTF — that mammograms save lives in women 40 to 49, as well as women over 50.
- Susan G. Komen for the Cure continues to recommend annual mammography beginning at age 40 for women of average risk and earlier for women with known risks for breast cancer. We are constantly evaluating our guidelines and would not change them without serious consideration.
- Our real focus, however, should be on the fact that one-third of the women who qualify for screening under today's guidelines are not being screened due to lack of access, education or awareness. That issue needs focus and attention: if we can make progress with screening in vulnerable populations, we could make more progress in the fight against breast cancer.

## **Komen's Response to USPSTF Recommendations**

Susan G. Komen for the Cure®, the world's leading breast cancer advocacy organization, has carefully reviewed the data and new recommendations from the U.S. Preventive Services Task Force (USPSTF) concerning mammography screening.

Komen for the Cure wants to eliminate any impediments to regular mammography screening for women age 40 and older. While there is no question that mammograms save lives for women over 50 and women age 40 to 49, there is enough uncertainty about the age at which mammography should begin and the frequency of screening that we would not want to see a change in policy for screening mammography at this time. As with all screening tests, the decision to perform a mammogram must include an evaluation of the benefits and the risks of the screening tool, as well as a consideration of patient preference. Komen's current screening guidelines can be found at [www.komen.org](http://www.komen.org) and will not be changed at this time.

The recent controversy about mammography should not suggest that there is debate about the most important issues. Most breast cancer experts agree far more than they disagree. For example, there is no debate that mammography reduces the risk of dying from breast cancer. As stated in the new USPSTF recommendations, extensive scientific evidence demonstrates that mammography reduces breast cancer mortality both among women age 50 and older, as well as among women age 40 to 49.

Because breast cancer false positive results are more common in women under 50, some argue for a different screening approach in women 40 to 49 than in those over 50. The USPSTF suggests that women 40 to 49 consider their individual risk of developing breast cancer before making a decision about screening mammography. They further suggest that those women at increased risk should strongly consider regular mammography screening. Women at lower risk, who wish to initiate screening in their 40s should recognize that the benefits of screening are less than in older women.

As to the timing of mammography, the USPSTF also suggests that screening every other year is likely to be as effective as annual screening, and that this approach would decrease false positives. Biennial screening is already practiced in many countries. Different organizations, based on a review of the same data, may recommend either yearly or every other year screening for women at average risk of breast cancer between the ages of 40 and 75. We believe that the timing of assessment is best left to a woman and her health care provider. It is our view, however, that the exact timing of assessments is less important than guaranteeing access to screening. We call upon third party payers to fund annual mammography if a woman and her health care provider opt for this approach. There are no studies that directly address the role of mammography in women over the age of 75. Thus, we recommend that older women, particularly those in excellent health, discuss the role of ongoing screening with their health care provider.

As a breast cancer community, we must all recognize that both breast cancer screening and breast cancer treatment are moving targets. As treatment continues to evolve in the years ahead, these changes may have an impact on the optimal approaches to screening as well. In the meantime, honest differences in opinion can and do exist, and such differences represent attempts on the part of individuals and/or organizations to provide the best possible care to women of all ages and to minimize mortality and suffering from breast cancer.

It is important to note that the USPSTF analysis is based on studies of conventional mammography, and some have noted that digital mammography may offer better results and may alter recommendations in the future.

We encourage women to be aware of their breast health, understand their risks, and continue to follow existing recommendations for routine screenings including mammography beginning at age 40. Additionally, women with unresolved questions about breast cancer screening should engage in discussion with their health care providers.

## **Public Reaction to the USPSTF Recommendations**

Since the announcement of the new USPSTF guidelines, our offices have been inundated with worried and outraged women, expressing deep concern that this change could create impediments to mammography. Many comments have come from breast cancer survivors who were diagnosed before the age of 50.

Here is a sample of the reaction we have received:

“If a woman is diagnosed at a later age because she couldn’t get a mammogram and the cancer got a head start, then time was lost in her chance to win the fight.”

“I am a breast cancer thriver and a yearly visitor at my Komen Center in Peoria, Illinois, where they biopsied and diagnosed my breast cancer at age 44. I know far too many younger women who either died because they did not receive proper treatment and diagnosis early, or whose lives were saved due to early detection.”

“I am shocked and saddened... They clearly have not spoken to the thousands of women who have fought breast cancer. I was 44 when I was diagnosed, and yes, I found the lump myself. Not only that, I have heard numerous stories of much younger women than myself who have battled breast cancer ~ even pregnant women and new mothers. How sad that the USPSTF would put this generation at further risk by taking away the very test that can detect the disease.”

“As a breast cancer survivor, I am outraged by the guidelines that recently were announced. I was 46 years old when I went in for my annual mammogram. Like so many other women, there is no history of breast cancer in my family. The lump was so deep that neither myself nor my doctor felt the lump that had been growing for months. I was in stage 2 when it was discovered and if not for the mammogram, it would have been very advanced if I had to follow the guidelines that are now in discussion. ... My daughter, younger sister, and thousands of women are at risk and with policies such as this, insurance companies will have the ability to reject early screenings. I will do whatever is necessary to help make the changes that will save lives and raise awareness.”

Clearly, these comments illustrate the concern many women have about the USPSTF recommendations. We continue to emphasize the points of agreement, as opposed to the points of disagreement. We have known for some time that mammography is an imperfect tool. However, we are concerned that the current debate about screening will be taken by many women to be an indictment of mammography, and that the fear and confusion will drive women away from screening, which we know was not the intent of the USPSTF.

Similarly, the change in recommendation for breast self-examinations has caused confusion and led some women to believe that they should not examine themselves or raise any concerns they have to their health care provider. In fact, the USPSTF recommendation on breast self-examinations did not change substantially, and it is in line with the recommendations of Komen for the Cure and other major cancer organizations. Instead, we recommend breast self-awareness – knowing your risk, getting screened, knowing what is normal for you, and making healthy lifestyle choices. While the evidence shows that a regular, routine monthly self-exam does not reduce mortality, it is never wrong for women to be familiar with their bodies, to know the look and feel of what is normal for her and to report any changes to her health care provider.

## **Need for Better Technology**

Mammography is not perfect, but is still our best tool for early detection and successful treatment of this disease. We must close the technology gap in breast cancer screening. New screening approaches and more individualized recommendations for breast cancer screening are urgently needed. Komen for the Cure is currently funding research initiatives designed to improve screening, and we believe that it is imperative that this research move forward rapidly. But we can't do it alone. We need to work together — government, private industry, the public health community and patient advocates — to develop and deliver technology that is more predictive, available and personalized, but less expensive.

That is why, in 2010, Susan G. Komen for the Cure will host a Technology Summit where the top leaders from the public health, scientific, governmental, and advocacy communities will identify specific ways to close this gap.

We also ask the President and Congress to report to the American people on investments they've made in screening technology and to commit to us that they will redouble their efforts to create a technology that is more specific, has a higher level of sensitivity and is more accessible (that is, more affordable and more portable).

As Dr. Eric Winer, Komen for the Cure's Chief Scientific Advisor and director of the Breast Oncology Program at the Dana-Farber Cancer Institute, and Dr. Ann Partridge, Clinical Director of the Breast Oncology Program at the Dana-Farber Cancer Institute, recently commented in the *New England Journal of Medicine*, "Our understanding of the molecular basis of breast cancer continues to evolve, and we now view it as a family of distinct disease subtypes — which may well require their own screening tools. Moreover, the evolution of breast-cancer treatment is likely to have a profound effect on the way we conceptualize screening. There may be room for debate about the optimal age at which to begin screening and the optimal frequency of screening, but there is no debate that technical advances will make these controversies fade. Although we must optimize what is available today, we must also promote far better approaches for tomorrow."<sup>3</sup>

In addition to better screening technology, we need to identify the causes and ways to prevent breast cancer. Early detection, while important, is not the same as prevention. That is why Komen for the Cure invested \$20 million this year alone toward prevention research through our Promise Grants.

## **Ensuring Access to Screening for Underserved Women**

When it comes to screening, our primary focus should be on the one-third of women — some 23 million women — who are not receiving regular recommended screenings due to lack of access,

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<sup>3</sup> Ann H. Partridge and Eric P. Winer, "On Mammography — More Agreement than Disagreement," *New England Journal of Medicine*, November 25, 2009, published online at <http://content.nejm.org/cgi/content/full/NEJMp0911288>.

education or awareness.<sup>4</sup> Many women in the U.S. are getting their first mammogram later than recommended, not having mammograms at recommended intervals or not receiving appropriate and timely follow-up of positive screening results, which leads to advanced tumor sizes, later stage at diagnosis and lower survival rates.<sup>5</sup>

The Komen Advocacy Alliance believes there should be no impediments to screening for these women. Unfortunately, such barriers do exist.

**Breast Cancer Screening and Health Insurance Status.** Women who are uninsured or underinsured are more likely to skip potentially life-saving cancer screenings. In 2008, 46.3 million Americans lacked health insurance, and that number is climbing.<sup>6</sup> Some estimates suggest rising unemployment over the past year has added an additional 4 million people to the ranks of the uninsured.<sup>7</sup> Further, many Americans are just a pink slip, unexpected life event or major medical diagnosis away from losing their health insurance. Lack of adequate health insurance means lower screening rates, more advanced cancer at diagnosis and lower chances of survival. Patients with private insurance are more likely to be diagnosed at earlier stages, and are more likely to survive at all stages of diagnosis than the uninsured. Cancer patients who are uninsured (and those who were Medicaid-insured at time of diagnosis) are 60 percent more likely to die in 5 years than those with private insurance.<sup>8</sup>

- In the U.S., the lowest prevalence (33.2 percent) of mammography screening in the past two years occurred among women who do not have health insurance.<sup>9</sup>
- For women who are uninsured and underinsured, cost is a significant barrier to getting preventive care — only 67 percent of underinsured women over the age of 50 received a mammogram in the past two years, compared with 85 percent of adequately insured women.<sup>10</sup>
- For women with health insurance or Medicare, even a relatively small co-payment can significantly reduce mammography rates, particularly for underserved populations.<sup>11</sup>

The Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) was created to protect low-income women without health insurance; yet the program is dangerously underfunded. In fact, a recent study by the Government Accountability Office (GAO) reveals that the NBCCEDP, which serves low-income, uninsured and underinsured women, only screens about 15 percent of eligible women.

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<sup>4</sup> American Cancer Society, "Breast Cancer Facts and Figures 2009-2010." From the National Health Interview Survey, which is conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics, with the help of the U.S. Census Bureau.

<sup>5</sup> American Cancer Society, "Cancer Prevention and Early Detection Facts and Figures 2009." Available online at [http://www.cancer.org/downloads/STT/CPED\\_2009.pdf](http://www.cancer.org/downloads/STT/CPED_2009.pdf).

<sup>6</sup> U.S. Census Bureau, "Income, Poverty, and Health Insurance Coverage in the United States: 2008," September 2009. Available online: <http://www.census.gov/prod/2009pubs/p60-236.pdf>.

<sup>7</sup> "One-Two Punch: Unemployed and Uninsured," Families USA, October 1009. Available online at <http://www.familiesusa.org/assets/pdfs/one-two-punch.pdf>.

<sup>8</sup> Elizabeth Ward, et al., "Association of Insurance with Cancer Care Utilization and Outcomes," *CA: A Cancer Journal for Clinicians*, Vol. 58, No. 1, January/February 2008, p.9-31.

<sup>9</sup> American Cancer Society, "Cancer Prevention and Early Detection Facts and Figures 2009."

<sup>10</sup> Sheila Rustgi, et al., "Women at Risk: Why Many Women are Forgoing Needed Health Care," *The Commonwealth Fund*, Issue Brief, May 2009. (Available online: <http://www.commonwealthfund.org/content/publications/issue-briefs/2009/may/women-at-risk.aspx>.)

<sup>11</sup> Amal N. Trivedi, et al., "Effect of Cost Sharing on Screening Mammography in Medicare Health Plans," *The New England Journal of Medicine*, Vol. 358, January 24, 2008, pp. 375-383. (Available online: <http://content.nejm.org/cgi/content/full/358/4/375>). The study examined 174 Medicare managed-care plans from 2001 through 2004, which included 550,082 individual-level observations for 366,475 women between the ages of 65 and 69 years.

About 26 percent of eligible women are screened by other providers, such as free clinics and mobile vans, some of which are funded by Komen Affiliates. (Komen Affiliates advocate for state funding and in FY09 provide more than \$30 million in grants to state and local NBCCEDP programs.) Yet, the GAO noted these resources are limited and often not available in rural or other underserved areas — shockingly, 60 percent of eligible women do not receive recommended breast cancer screening from any provider — a disturbing revelation that is much higher than previously understood and underscores the need for access to affordable insurance.

If we can improve access to high quality care among vulnerable populations, we could make more progress in the fight against breast cancer.

**Breast Cancer Screening and Racial/Ethnic Disparities.** Unfortunately, there are also racial and ethnic differences in access to screening services. In the U.S., white women age 40 and older were more likely to report a mammogram in the past two years (68 percent) than any other racial or ethnic group. Screening rates were 66.6 percent for American Indian/Alaska native, 64.9 percent in African American, 59.6 percent in Hispanic and 54.2 percent in Asian women.<sup>12</sup>

Disparities in access and utilization of breast cancer screening contributes to disparities in breast cancer survival rates: African American women have a 37 percent higher rate of mortality from breast cancer than white women, despite having an overall lower level of incidence of breast cancer.<sup>13</sup> Some geographic areas are worse than others. Komen's work with the Metropolitan Chicago Breast Cancer Task Force, which was formed in response to the growing disparity in breast cancer mortality rates between African-Americans and whites in Chicago, revealed that the mortality rate for African American women in Chicago is 68 percent higher than for white women.<sup>14</sup>

## **USPSTF Recommendations and Health Care Reform**

The Komen Advocacy Alliance believes all cancer patients deserve access to affordable, high-quality health care. Unfortunately, in today's health care system, not every patient is able to get the care they need.

We applaud this committee for considering the needs and challenges facing cancer patients and survivors as you developed proposals to reform the nation's health care system. The Komen Advocacy Alliance supports valuable patient protections in H.R. 3962, the "Affordable Health Care for America Act," that would increase access to affordable health insurance for all, prevent insurance companies from denying coverage due to pre-existing conditions such as cancer, protect patients from high out-of-pocket costs, and increase access to early detection services. We also hope that health care reform legislation will ensure that women, including women ages 40 to 49, have access to affordable screening mammography.

H.R. 3962 calls for "preventive services, including those services recommended with a grade of A or B by the Task Force on Clinical Preventive Services" to be included in a new minimum benefit package and for those services to be offered with no co-pay or cost sharing requirements. This will increase access to mammography, Pap smears and other preventive services for the millions of women who do not currently have access to screening services in the current health care system. Evidence shows that even a relatively small co-payment significantly reduces mammography rates, particularly for women with low incomes.

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<sup>12</sup> American Cancer Society, "Cancer Prevention and Early Detection Facts and Figures 2009."

<sup>13</sup> *Ibid.*

<sup>14</sup> Hirschman J, Whitman S, Ansell D. "The Black:White disparity in breast cancer mortality: The example of Chicago." *Cancer Causes Control* 2007; Vol. 18, pages 323-333.

In light of the new recommendations by the USPSTF, we must ensure that women ages 40 to 49 will have access to the same coverage and cost-sharing benefits as women age 50 and older. We understand that the Task Force on Clinical Preventive Services is a new entity, and that current USPSTF guidelines are not necessarily binding on the new committee. We also understand that the current language does not necessarily *exclude* from the minimum benefits package services that are not rated A or B.

However, I urge you to ensure mammography services for women ages 40 to 49 are included in the essential benefit package and that cost sharing is waived for such services. While some women in the 40 to 49 age group may, after consulting with their doctor and weighing the evidence, respond to the task force recommendations by choosing to forgo a mammogram, women who choose to have a mammogram should still have access to such screenings on the same terms as women age 50 and older.

The Komen Advocacy Alliance appreciates that HR 3962 newly includes patient representatives as advisors to the Task Force on Clinical Preventive Services. As we have emphasized in the last several weeks, we strongly believe that patients have a unique and valuable perspective that should be better used to develop and disseminate appropriate messages about prevention and screening. We also appreciate that the Task Force must consider disparities in care when developing its recommendations.

## **About Susan G. Komen for the Cure and the Komen Advocacy Alliance**

Susan G. Komen for the Cure began with a promise from Ambassador Nancy G. Brinker to her dying sister Suzy that she would do everything in her power to end breast cancer forever. In 1982, that promise became Susan G. Komen for the Cure and launched the global breast cancer movement.

Today, Komen for the Cure is the world's largest grassroots network of breast cancer survivors and activists fighting to save lives, empower people, ensure quality care for all and energize science to find the cures. Thanks to events like the Susan G. Komen Race for the Cure® Series, in our first 27 years, Komen has invested almost \$1.5 billion to fulfill our promise, becoming the largest source of nonprofit funds dedicated to the fight against breast cancer in the world. To continue this progress, Komen will invest another \$2 billion over the next decade into cutting-edge research and community programs.

The Komen Advocacy Alliance, a sister organization to Susan G. Komen for the Cure, is the nonpartisan voice for more than 2.5 million breast cancer survivors and the people who love them. The Alliance's mission is to translate the Komen promise to end breast cancer forever into action at all levels of government to discover and deliver the cures for cancer. With a network of more than 250,000 advocates, the Komen Advocacy Alliance promotes increased funding for cancer research and expanded access to cancer care services for all women.

Komen's goal is to reduce and one day eliminate suffering and death from cancer. To realize this goal, Komen promotes education and awareness to empower women to be advocates for their own health, and we invest in the tools to make it possible. Our investments span the entire continuum of cancer care — from cancer research about the biology of breast cancer to early detection to treatment to survivorship. We make significant grants to fund innovative community services, and advocate for improved access to high-quality cancer care and an increased commitment to the fight against breast cancer by the public and private sectors. We believe it is this three-pronged approach — research, community programs, and advocacy — that will make the biggest impact and the most progress toward our promise to end breast cancer forever.

**Cancer Research.** When Komen advocates for breast cancer research funding, it is as a full partner in the effort to discover and deliver the cures. Neither the federal government nor the private sector can accomplish this goal alone. Over the past three years alone, Komen for the Cure funded \$237

million in research grants to the best minds in cancer science all over the world, to take advantage of new breakthroughs and accelerate treatments for women with aggressive breast cancers that do not respond to current therapies. In fact, a Komen grant has touched every major breast cancer breakthrough in the past 25 years, including the basic discoveries in genetics and biology that have evolved into less invasive, personalized treatments for what was once a “one-treatment-fits-all” approach. In addition, Komen grants helped make possible:

- Discovery of the first breast cancer susceptibility gene (BRCA1), and a test for women to learn about their inherited risk. This has led to very early detection of breast cancer in some women and prevention in others.
- Understanding that breast cancer is not one disease – it is a collection of diseases, each with different characteristics that allow doctors to deliver tailored treatments that are more effective and involve fewer side effects.
- Insight into the role of hormonal factors in breast cancer risk, development and progression, leading to understanding of tamoxifen resistance, tools to identify women who are more likely to develop resistance, and development of new hormonal therapies such as aromatase inhibitors.
- Understanding the role of angiogenesis in providing the blood supply that allows cancer cells to continue to grow and leading to discovery of drugs like Avastin that kill cancer cells by starving them of their blood supply.
- Discovery of signaling pathways ‘turned on’ by the over-expression of HER2 receptors in some types of very aggressive breast cancers and the role of kinase inhibitors as potential therapeutic agents with fewer adverse effects than Herceptin.

**Community Investment.** Komen Affiliates operate in more than 120 communities across the country, and this year alone invested nearly \$160 million in their local communities to provide underserved populations with access to breast cancer education, screening and treatment. This includes \$93 million in community grants to more than 1,900 organizations that provide free or low-cost mammograms, as well as physical, emotional and financial support for breast cancer patients and survivors. Many Affiliates also fund treatment assistance programs that help breast cancer patients with day-to-day chores and provide monetary assistance with rent, utilities, and co-pays. This year alone, Komen has funded education/awareness programs reaching more than 3 million women; and has funded programs providing breast screenings to more than 500,000 women and men in under-served populations. This is part of our \$900 million investment in community programs since inception.

**Public Policy and Advocacy.** The Komen Advocacy Alliance directly engages policymakers and opinion leaders at the state and federal levels. This year, we opened a new office in Washington, DC and have expanded our presence in the nation’s capital. Across the country, our Affiliates work to increase funding for state breast and cervical screening programs, expand access to Medicaid treatment for uninsured women diagnosed with breast and cervical cancer, require insurance companies to cover routine care costs for clinical trials, and require parity in the coverage of oral chemotherapy drugs, compared with intravenous therapy, among other legislative successes.