Statement by
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Before

The Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

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Good morning, Mr. Chairman, Mr. Ranking Member, and distinguished members of the Committee. I am Dr. Otis Brawley, Chief Medical Officer of the American Cancer Society (the Society). On behalf of the millions of cancer patients and survivors in America today, the Society thanks you for your continued leadership in the fight against cancer and your commitment to enacting comprehensive health care reform this year. I appreciate the opportunity to testify today about mammograms and their important role in the fight against breast cancer.

Introduction

Apart from skin cancer, cancer of the breast is the most common malignancy in women.[1] While breast cancer ranks second after lung cancer for the most common cancer death, it causes more lost years of potential life than any other cancer.[2] For a woman of average risk, she has a 1 in 8 chance of developing breast cancer and a 3 percent chance of dying from the disease.[3] Fortunately, breast cancer mortality has been declining significantly in the United States since screening mammography has become the standard of care for most women. The steady drop in the breast cancer death rate means that this year alone, about 15,000 breast cancer deaths were

1 American Cancer Society. Cancer Facts and Figures 2009.
2 Green BB, Taplin SH. Breast cancer screening controversies. J Am Board Fam Pract. 2003 May-Jun;16(3):233-41.
3 American Cancer Society. Breast Cancer Facts and Figures 2009-2010.

avoided that would have occurred had rates not begun to drop due in part to greater access to mammography.[3]

On November 16th, 2009, the U.S. Preventive Services Task Force (USPSTF) announced that it would no longer recommend routine mammograms for women between the ages of 40 and 49, a group that accounts for about 1 out of 6 breast cancers.[4] The USPSTF recommendation has caused a heated public discourse on the benefits, risks and harms of mammograms and breast cancer screening.

Unfortunately, where we might have had an opportunity to further refine our messages about the benefits and limitations of screening, we have had yet another episode of messy and confusing public discourse about an issue that is a leading health concern of women. An unfortunate consequence may be that fewer women will be getting screened, and for those who are unlucky and develop breast cancer, those cancers won't be caught early but rather when they are big enough to feel. That's a step backward we should all be unwilling to take.

In my testimony, I will outline the scientific evidence that supports annual screening for all women age 40 and over. I will also highlight areas of agreement, most notably that all women should have access to this and other evidence-based cancer screenings; mammography remains the best widely-available early detection method for breast cancer available today that has been scientifically proven to reduce deaths from breast cancer; and not enough women in the United States currently get this life-saving test.

American Cancer Society's Review of the Evidence

Mammography is possibly the most intensely scrutinized and debated medical procedure of our time. To help understand the history and the science behind early detection of breast cancer, I will first outline the scope of evidence as analyzed by the nation's leading breast cancer experts who were part of the Society's breast cancer screening guidelines process.

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4 Screening for Breast Cancer, Topic Page. November 2009. U.S. Preventive Services Task Force. Agency for Healthcare Research and Quality, Rockville, MD. *http://www.ahrq.gov/clinic/uspstf/uspsbrca.htm*

Our scientific and medical experts monitor the emerging literature on an ongoing basis to ensure that the Society's guidelines reflect the most current scientific evidence. As such, the Society's guidelines are reviewed and updated regularly. The members of the guidelines committee include breast cancer experts, cancer epidemiologists, gynecologists, primary care physicians, oncologists and radiologists having diverse, extensive research and/or clinical backgrounds in breast cancer screening. The Society's breast cancer screening guidelines were last systematically reviewed and evaluated in 2003 for average-risk women[5] and in 2007 for high-risk women[6]. Our most current recommendations[7] for breast cancer screening are as follows:

- Yearly mammograms are recommended starting at age 40 and continuing for as long as a woman is in good health.
- Clinical breast exam (CBE) should be part of a periodic health exam, about every 3 years for women in their 20s and 30s and every year for women 40 and over.
- Women should know how their breasts normally feel and report any breast change promptly to their health care providers. Breast self-exam (BSE) is an option for women starting in their 20s.
- Women at high risk (greater than 20% lifetime risk) should get an MRI and a mammogram every year. Women at moderately increased risk (15% to 20% lifetime risk) should talk with their doctors about the benefits and limitations of adding MRI screening to their yearly mammogram. Yearly MRI screening is not recommended for women whose lifetime risk of breast cancer is less than 15%.

The Society is not changing its guidelines for breast cancer screening as a result of the USPSTF new recommendations.

5 Smith RA, Saslow D, Sawyer KA, et al. American Cancer Society guidelines for breast cancer screening: update 2003. CA Cancer J Clin. 2003;53:141–169.
6 Saslow D, Boetes C, Burke W, et al. American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. CA Cancer J Clin. 2007;57:75–89.
7 Smith RA, Cokkinides V, Brawley OW. Cancer screening in the United States, 2009: a review of current American Cancer Society guidelines and issues in cancer screening. CA Cancer J Clin. 2009;59:27–41.

Mammograms for Women Age 40-49

The primary evidence[5] supporting the recommendation for periodic screening for breast cancer with mammography derives from nine randomized clinical trials (RCTs). These RCTs were the same trials used in the USPSTF analysis. Two of the trials took place in North America, two in the United Kingdom, one in Scotland, and four in Sweden. These RCTs were the same trials used in the USPSTF analysis. The Society also included in its analysis several recent population-based studies of modern mammography which show much stronger benefits from screening as compared to the more limited data examined by USPSTF. The Society found that while variation exists in the observed mortality reductions, a meta-analysis of all the studies' results showed a 24 percent mortality reduction associated with screening. Furthermore, although the trials vary somewhat in their design, the results are uniformly consistent with respect to the relationships between the stage shift at diagnosis and a reduction in mortality.

Modern population studies have shown much greater mortality reductions for women ages 40-49 and 50-69 than are estimated with USPSTF's meta-analyses of all randomized trial data. These mortality reductions also are very similar due to the fact that modern screening programs tailor the screening interval to screen younger women at a shorter interval. Let me cite just one example. In a report published in 2003 in the Lancet, an international team of researchers compared deaths from breast cancer diagnosed in the 20 years before screening was introduced in two large Swedish counties with those with those from breast cancer diagnosed in the 20 years after the introduction of screening.[8] This was a study involving over 200,000 women. In the analysis, data were stratified into age-groups invited for screening (40-49, and 40-69) and not invited (20–39 years), and by whether or not the women had actually received a screening mammogram in the post screening epoch. After adjustment for age, self-selection bias, and changes in breast-cancer incidence in the 40–69 years age-group, breast-cancer mortality was reduced in women who were screened by 44%, but only 16% in women who were not screened. In the 40-49 age group, there was a 48% reduction in deaths in the women who were screened, but only 19% fewer deaths in women who were not screened. While this study was not a

[8] Tabar L, Yen MF, Vitak B, Chen HH, Smith RA, Duffy SW. Mammography service screening and mortality in breast cancer patients: 20-year follow-up before and after introduction of screening.Lancet. 2003 Apr 26;361(9367):1405-10.

randomized trial, it applies statistical adjustments derived from what was learned in the trials, represents 40 years of data from a health system with impeccable record keeping and very high rates of adherence to screening in the mammography program. It shows that modern mammography screening is achieving mortality reductions as good as or better than those observed in the individual trials that showed the strongest benefits. Unfortunately, this study was not included for consideration by the USPSTF.

While we commend the USPSTF for their legacy of evidence-based guidelines for preventive health, we do have some fundamental concerns about the conclusions that were drawn in this update of breast cancer screening guidelines based on the evidence it considered. Unlike the USPSTF, the Society believes that achieving even a 15 percent reduction in mortality (and we believe this estimate of benefit is artificially low), associated stage-shifts, and improvements in quality of life due to less invasive treatment warrant a recommendation of annual screening in the 40-49 population. The Society, along with numerous other medical groups, believes that the available evidence supports the conclusion that screening mammography offers an identifiable and important survival benefit to women in this age group.

Furthermore, since the studies included in the USPSTF analysis were published, we have seen a number of advancements that have increased the effectiveness of mammograms in the 40-49 population. For example, we have seen improvements in the quality of mammograms resulting from passage of the Mammography Quality Standards Act (MQSA); a shift to using digital mammograms over film mammograms, which research shows may be more sensitive in younger women and women with denser breasts; and finally, new technology has been introduced, including breast Magnetic Resonance Imaging (MRI) that has proven to be an effective screening tool in high-risk women.

While we believe the efficacy of mammography has been demonstrated, we also acknowledge that it is not a perfect test. As such, we must strive to improve these tests and address issues of adverse consequences for women who undergo screening. For example, women often must undergo additional studies for suspicious lesions. Some women have biopsies that ultimately do not show breast cancer. We know that mammography screening comes with limitations, and the

Society is committed to finding better tests. In the meantime, it is equally important to acknowledge that beginning in 1990, breast cancer deaths declined 2.3 percent annually for all women and 3.3 percent per year for women aged 40-50 years. That may not seem like much from year to year, but when you consider the total over 19 years, the impact translates to a 20 percent drop in mortality for women less than 50. This is particularly significant when taking into consideration that the death rate was absolutely stable for the preceding six decades. There is no dispute that screening mammograms and better treatments are responsible for that success. Based on our review of the USPSTF analysis, we see no reason to change a strategy that has proven effective in reducing the death rates for breast cancer in all recommended age groups, including those women ages 40-49.

Screening Intervals

The goal of screening is to reduce the incidence rate of advanced disease. Therefore, the routine screening interval should be set to help ensure adherence that is likely to result in the detection of the majority of cancers while still localized. Data from randomized clinical trials (RCTs) and inferential evidence have provided persuasive evidence that women likely will benefit more from annual screening compared with screening at two-year intervals. Both the Society and the USPSTF reached this conclusion in 2002. Further, data from the RCTs have shown that progressively shorter screening intervals result in detection of tumors at smaller sizes and a decrease in mortality rates. The American College of Radiology estimates that providing mammography only every other year in women 50-74 would miss 19 to 33 percent of cancers that could be detected by annual screening.[9] As a result, the breast cancer experts involved with review of the Society's guidelines concluded that "given the prognostic value of smaller tumors, and the findings that annual screening results in more favorable tumor characteristics in both pre- and postmenopausal women, annual screening may offer advantages over biennial screening for all women."[5]

9 American College of Radiology. Joint Statement from the American College of Radiology and Society of Breast Imaging. USPSTF Mammography Recommendations Should Be Specifically Excluded From Health Care Reform Legislation.

Breast Self Examination (BSE)

Breast self-examination (BSE) is a monthly step-by-step approach that involves women examining her breasts in a systematic pattern while in front of a mirror, lying on her back, and/or in a shower. Part of the controversy on the net impact of BSE is that the actual definition and what is involved for effective BSE is not clear. BSE is different than breast awareness, which is where women are knowledgeable about how their breasts normally look and feel and are able to recognize any changes. The Society's guideline recommends that: "Women should know how their breasts normally feel and report any breast change promptly to their health care providers." BSE, a formal monthly-exam of the breast, is still viewed as an option for women starting in their 20s. However, the Society wants to be clear that the current evidence based on two new randomized trials have shown that breast awareness alone has the same mortality reduction as monthly BSE. [5]

Even when provided with the evidence, some women feel very comfortable doing BSE regularly and may benefit from the routine examination of the breast. Other women are more comfortable simply feeling their breasts in a less systematic approach, such as while showering or getting dressed or doing an occasional thorough exam. Sometimes, women are so concerned about "doing it right" that they become stressed over the technique. Doing BSE regularly is only one way for women to know how their breasts normally look and feel and to notice any changes. It is okay for women to choose not to do BSE or not to do it on a regular schedule such as once every month. We must work harder to get a responsible message out to all women that checking their breasts in a way they feel comfortable with is absolutely vital for protecting their breast health. Furthermore, it is critical if a woman feels or sees a change in her breast, she should be able to access a health care provider to undergo further evaluation.

Improving Breast Cancer Screening and the Messages about it

The real travesty today is that approximately 30 to 40 percent of American women aged 40 and over fail to have regular screening mammograms.[10] The inability of millions of women to access proven life-saving services such as mammograms is a failure of our health care system. We also

10 American Cancer Society. Cancer Prevention and Early Detection Facts and Figures 2009.

know that lack of adequate health insurance coverage can be deadly. Only one in four women without health insurance had a regular mammogram in the past year.[11] Furthermore, a recent study by the Society found that uninsured breast cancer patients are more likely to be diagnosed at a later stage and have lower survival rates than women who are privately insured.[12] Without access to these tools, far too many women are at risk of being diagnosed at later stages of the disease after the cancer has spread, when treatment is more difficult, more expensive, and less likely to save lives.

Mammography screening is not perfect. Women deserve a better test, but in the meantime, we must stop sending messages that a screening and early detection test is of little or no value. We need to encourage women to get this test because it has shown to save lives.

Throughout the country, women are forced to choose between health care and more routine things, such as paying for food, housing, utilities or even the health of their kids and spouses, especially in hard economic times. The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the Society, conducted a national survey in April 2009 to understand how Americans are dealing with health care costs in the current economic environment and found that 1 in 5 women said that they or a family member in their home put off getting a cancer screening test in the past year. Furthermore, nearly one-third of Americans with household incomes less than $35,000 said they put off potentially lifesaving screenings such as mammograms.[13]

We should be particularly concerned about how these guidelines will influence the perceptions of medically underserved women, such as minority women and those who lack health insurance. Evidence shows that African Americans and Ashkenazi Jewish women get breast cancer at an earlier age, and may have a greater benefit from starting screening sooner. We all have a duty to ensure that progress made in breast cancer does not get reversed as a result of these new recommendations or confusion about what they mean. It is our collective job to strive to do

11 Ibid.

12 Halpern MT, Ward EM, Pavluck AL, Schrag NM, Bian J, Chen AY. Association of insurance status and ethnicity with cancer stage at diagnosis for 12 cancer sites: a retrospective analysis. Lancet Oncol. 2008;9(3):222-31

13 The American Cancer Society Cancer Action Network (ACS CAN). The Need for Health Care Reform through the Eyes of Cancer Patients: A National Poll. http://acscan.org/pdf/healthcare/reports/healthcare-cancerpoll.pdf

better in providing clear and understandable information about the benefits of evidence-based prevention and early detection, particularly for populations most in need to help decrease disparities in health care and improve health outcomes.

The Implications for Health Care Reform

On behalf of the Society and ACS CAN, we applaud you for your work on HR 3962, the Affordable Health Care for America Act, which has the potential to take our country's fight against cancer to a new level.

The legislation presents an exceptional opportunity to advance the Society's mission of reducing suffering and death related to cancer and the potential to transform our nation's health care system in a fundamental way that begins the process of making adequate and affordable health care accessible to all Americans.

The House bill takes a number of steps to improve health care for cancer patients and their families by refocusing the system to emphasize prevention, ending the practice of denying coverage because of pre-existing conditions, limiting the cost burden on families by providing care that covers more and costs less and emphasizing patients' quality of life.

The Society and ACS CAN believe more than 60 percent of all cancer deaths could be avoided through more effective use of existing scientific knowledge. The House bill proposes a significant investment in cancer prevention and early detection by requiring coverage for preventive programs in both public and private plans at little or no cost to patients. HR 3962 also calls for an investment of $34 billion over five years in a new Public Health Investment Fund for community health centers, primary care training and prevention and wellness research.

We thank you and the members of Congress who have worked so hard to pass meaningful health care reform and we are strongly supportive of the changes which you made to the operation of USPSTF in the legislation. These changes are particularly important given that the legislation stipulates that both public and private insurance entities would be required to cover all preventive services receiving an "A" or "B" rating from USPSTF. However, we remain concerned that due

to USPSTF's November 16th recommendation, coverage for mammography services for certain women could be reduced or eliminated. ACS CAN strongly believes that an essential benefits package cover more than what receives a USPSTF grade of 'A' or 'B', and USPSTF recommendations should constitute a floor, not a ceiling, for coverage. We support the committee's report language to the House-passed reform bill that advises the Secretary to consider the USPSTF guidelines a floor for prevention benefits, and strongly urge that this provision be includes in the final conference statutory language.

For the record, ACS CAN has been advocating for the following changes to the function and composition of the USPSTF:

- Membership -- USPSTF membership should include experts in clinical and community medicine, specialists in the technology under consideration, health delivery, public health, and health data, as well as patient representation and representatives experienced in minority health and health disparities.
- Transparency -- USPSTF meetings should be open to the public, and the methodologies used to establish priorities should be made available to the public through forums and drafts that are subject to public review and comment before being made final.
- Representation -- USPSTF advisory panels should include a cross-section of interests, including patient representatives, experts in health care delivery and health care providers.
- Outside sources -- The Secretary of Health and Human Services should be empowered to recognize other sources and interpretations of scientific evidence in determining recommendations for preventive services.

Accordingly, the Society and ACS CAN commend the members of the House, especially on this Committee, for including provisions in HR 3962 that will ensure that USPSTF will be transformed and the process for making these recommendations will incorporate the perspectives and interpretations of outside individuals and groups. These constructive changes will lead to a more transparent and inclusive process for the task force to perform its important work. We look forward to working with you and members of the Senate to ensure that all Americans have

access to credible information and coverage that allows them to make meaningful decisions on what preventive services are the most-effective and best choice for them.

Conclusion

We all value the lives of American women and want to eradicate this deadly disease. This year alone in the United States, over 192,370 women will be diagnosed with breast cancer and approximately 40,170 women will die from the disease.[3] The USPSTF, with its new recommendations, is telling women that mammography saves lives -- just not enough of them to recommend that all women over 40 get screened. The Society disagrees with the USPSTF new recommendation and urges all women age 40 and older to get a mammogram every year. We will continue to provide information designed to inform the public about the benefits and limitations of mammography screening. We are confident that, armed with information, women and their health care providers will continue to see mammography as the best current strategy to reduce death from this disease.

We have made so much progress in the last 30 years. The decline in breast cancer deaths adds up to more than 130,000 grandmothers, mothers, wives, sisters and daughters who were alive, perhaps to celebrate another birthday, and even to go on to live a full, rich life. Let's make sure we do not reverse the course of our progress. Thank you again for the opportunity to testify before this committee today, we look forward to working with you to help ensure that we continue to make progress in the war against cancer.