American-Italian Cancer Foundation
Addie Backlund, MBA
Executive Director

Good afternoon. I am Addie Backlund, the Executive Director of the American-Italian Cancer Foundation and a 19-month breast cancer survivor.

Each year, approximately 5,000 women in New York City are diagnosed with breast cancer, and 1,200 will die of the disease. There is no known way to prevent breast cancer at this point in time, so early detection is the best tool we have in reducing the number of deaths. I was fortunate enough to have my breast cancer diagnosed in the earliest stage—Stage I—when it is easily treated and the five-year survival rate is nearly 100%.

Too many women, however, are diagnosed at a later stage because they had not received breast cancer screening on a regular basis. Late stage breast cancer is far more expensive to treat, and the five-year survival rate is only 20%.

The five-year survival rate is even lower in women diagnosed with breast cancer before age 40, and tumors diagnosed in younger women tend to be more aggressive and less responsive to treatment, compared to women diagnosed at a more advanced age. In almost every borough of New York City, 17.6% of all breast cancer diagnoses occur in women age 40 to 49. In Staten Island, that percentage is 19.2%.

The recent report from the United States Preventive Services Task Force has recommended *against* annual mammography screenings for women age 40 to 49, due to the potential harms associated with false positives and the corresponding anxiety women may experience. However, I am quite certain that women in New York City who have been diagnosed with breast cancer at age 40 through 49 will attest to the fact that these potential harms are almost meaningless, in comparison to the harms of a breast cancer diagnosis at an advanced stage. To these women, early detection has often meant the difference between life and death.

Every time a woman gets a mammogram, it is a personal choice. The American-Italian Cancer Foundation believes that it should remain a personal choice. Insurance coverage for mammography services, therefore, should not change; women who choose to get a mammogram should be secure in knowing that this service will be covered by their health insurance or government program. The American-Italian Cancer Foundation's Mobile Mammography Program will continue to cover annual screenings for women age 40 and older, as long as our funders continue to support us, and various cancer advocacy organizations continue to recommend screening for that age group.

I would like to thank the members of the New York City Council for inviting me to speak to you today. I trust you will wish to continue your support of breast cancer screening programs for the women of New York City, with emphasis on those who are age 40 and over, economically disadvantaged, and medically underserved.

Response of The American College of Obstetricians and Gynecologists to New Breast Cancer Screening Recommendations from the U.S. Preventive Services Task Force*

In the November 17 issue of *Annals of Internal Medicine*, the U.S. Preventive Services Task Force (USPSTF) updates its recommendations on screening for breast cancer in the general population (see www.annals.org), including the following:

- The USPSTF recommends against routine screening mammography in women aged 40 to 49 years. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms. (grade C recommendation)
- The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. (grade B recommendation)
- The USPSTF recommends against teaching breast self-examination (BSE). (grade D recommendation)

The American College of Obstetricians and Gynecologists, however, currently continues to recommend the following services:

- Screening mammography every 1-2 years for women aged 40-49 years
- Screening mammography every year for women age 50 or older
- BSE; BSE has the potential to detect palpable breast cancer and can be recommended.

The College is continuing to evaluate in detail the new USPSTF recommendations and the new evidence considered by the USPSTF. Any changes to College guidance will be published in its journal *Obstetrics & Gynecology*.

Why did the USPSTF recommendations change?

Mammography in Women Aged 40-49 Years

In 2002, the USPSTF recommended screening mammography, with or without clinical breast examination, every 1-2 years for women aged 40 and older (grade B recommendation). The new USPSTF recommendations are based on a systematic evidence review by Heidi D. Nelson, MD, MPH, and colleagues and a modeling study by Jeanne S. Mandelblatt, MD, MPH, and colleagues published in the same issue of *Annals of Internal Medicine*.

The 2009 USPSTF judged that, although women in their 40s and women in their 50s benefit equally from routine screening mammography, women in their 40s experience greater harms from screening than women in their 50s. The harms assessed by the USPSTF were radiation exposure, false-positive and false-negative results, overdiagnosis, pain during procedures, and anxiety, distress, and other

psychologic responses. Therefore, the USPSTF recommended routine screening for women aged 50-74 but recommended against *routine* screening for women in their 40s.

Breast Self-Examination

In 2002, the USPSTF judged that evidence was inadequate to make a recommendation on teaching or performing BSE. The new USPSTF recommendations are based on a systematic evidence review by Heidi D. Nelson, MD, MPH, and colleagues published in the same issue of *Annals of Internal Medicine*. This systematic evidence review identified two studies published since the 2002 recommendations. These studies found that teaching BSE did not reduce breast cancer mortality but resulted in additional imaging procedures and biopsies. Therefore, the USPSTF recommended against teaching BSE on the grounds that it has no benefit for women but places them at risk of harm.

What Should Fellows Do?

At this time, The American College of Obstetricians and Gynecologists recommends that Fellows continue to follow current College guidelines for breast cancer screening. Evaluation of the new USPSTF recommendations is under way. Should the College update its guidelines in the future, Fellows would be alerted and such revised guidelines would be published in *Obstetrics & Gynecology*.

The College continues to recommend that Fellows advise mammography screening for their patients aged 40 and older and that they counsel their patients that BSE has the potential to detect palpable breast cancer and can be performed. Fellows should be aware that the new USPSTF recommendation against routine screening mammography for women aged 40-49 (a grade C recommendation) has implications for insurance coverage, as some insurers will cover only preventive services rated as an "A" or a "B" by the USPSTF. Fellows should counsel their patients that insurance coverage for "routine screening" mammography may become variable and that patients should address this question with their insurers. These recommendations do not apply to high-risk women or patients with clinical findings, and they should be managed accordingly.

* For additional information, see "Interpreting the USPSTF Breast Cancer Screening Recommendations for the General Population," available at: http://www.acog.org/from_home/Misc/uspstfinterpretation.cfm

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

Interpreting the U.S. Preventive Services Task Force Breast Cancer Screening Recommendations for the General Population

What are the new recommendations from the U.S. Preventive Services Task Force (USPSTF)?

The following recommendations for the general population appear in the November 17, 2009, issue of *Annals of Internal Medicine* (see www.annals.org):

- The USPSTF recommends against routine screening mammography in women aged 40 to 49 years. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms. (grade C recommendation)
- The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. (grade B recommendation)
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older. (grade I statement)
- The USPSTF recommends against teaching breast self-examination (BSE). (grade D recommendation)
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older (grade I statement)

What were the previous (2002) USPSTF recommendations?

- The USPSTF recommended screening mammography, with or without CBE, every 1-2 years for women aged 40 and older. (grade B recommendation)
- The USPSTF concluded that the evidence was insufficient to recommend for or against routine CBE alone to screen for breast cancer. (grade I statement)
- The USPSTF concluded that the evidence was insufficient to recommend for or against teaching or performing BSE. (grade I statement)

What do the USPSTF letter grades mean?

The USPSTF's recommendations are based on its assessment of *net benefit*—identified benefits minus identified harms. The USPSTF will only make a recommendation if it judges the available evidence to be of high enough quality that it can have high or moderate certainty as to the magnitude of the net benefit.

Interventions that are deemed to have substantial net benefit receive an A grade; interventions with moderate to substantial net benefit receive a B grade; interventions with small net benefit receive a C grade; interventions that have no net benefit (have harms that exceed the benefits) receive a D grade. If the evidence does not meet USPSTF standards, an "I statement" is issued.

Each letter grade is accompanied by a suggestion for practice. For A and B recommendations, the suggestion is to "offer/provide this service." For C recommendations, the suggestion is to "offer/provide this service only if other considerations support offering or providing the service in an individual patient."

For D recommendations, the suggestion is to "discourage the use of this service." For I statements, the suggestion is to "read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms."

Grade C recommendations highlight the need for individualized decision making that considers the patient's own assessment of benefits and harms. The American College of Obstetricians and Gynecologists strongly supports shared decision making, and in the case of screening for breast cancer it is essential. Surveys have shown that women are more concerned about their risk of breast cancer than heart disease, which is more common. *Many women, after weighing the benefits and risks for their own particular situation, will choose to have screening mammography.*

What are the current recommendations from The American College of Obstetricians and Gynecologists?

The American College of Obstetricians and Gynecologists continues to recommend the following services:

- Screening mammography every 1-2 years for women aged 40-49 years
- Screening mammography every year for women aged 50 years or older.
- BSE; BSE has the potential to detect palpable breast cancer and can be recommended.
- CBE every year for women aged 19 or older

What is the College doing in response to the new recommendations?

The College, as a partner organization of the USPSTF, reviewed the draft recommendation statement and expressed concern regarding the implications of recommending against routine screening mammography for women in their 40s.

The College is continuing to evaluate in detail the new USPSTF recommendations and the new evidence considered by the USPSTF. The new recommendations and the evidence on which they were based will be reviewed by College committees that make recommendations on screening for breast cancer. Should the College update its guidelines in the future, Fellows would be alerted and such revised guidelines would be published in *Obstetrics & Gynecology*.

Why did the USPSTF recommend against routine mammography for women in their 40s?

The new USPSTF recommendations are based on a systematic evidence review by Heidi D. Nelson, MD, MPH, and colleagues and a modeling study by Jeanne S. Mandelblatt, MD, MPH, and colleagues that were published in the same issue of *Annals of Internal Medicine* as the recommendation statement. Based on these analyses, the 2009 USPSTF judged that although women in their 40s and women in their 50s benefit equally from routine screening mammography, women in their 40s experience greater harms from screening than do women in their 50s. Therefore, the USPSTF recommended routine screening for women aged 50-74 years but recommended against *routine* screening for women in their 40s.

The USPSTF's evaluation of the evidence found that *the benefit to women in their 40s was virtually the same as the benefit to women in their 50s*. The relative risk of breast cancer mortality for women randomly assigned to mammography screening was 0.85 in women aged 39-49 years and 0.86 in women aged 50-59.

Rather than benefit from screening, women without cancer who undergo mammography, additional imaging, and biopsies may incur harm. These outcomes were more common in women in their 40s (see Table). In addition, because the prevalence of breast cancer is higher in women in their 50s and because younger women are more likely to have dense breasts that may be difficult to assess on mammography,

women in their 40s had more false-positive mammograms and underwent more additional imaging than women in their 50s.

Table. Age-Specific Screening Results from the Breast Cancer Surveillance Consortium

Age Group (Y)	No. of procedures to diagnose one case of invasive breast cancer*		
	Mammography	Additional Imaging	Biopsy
40-49	556	47	5
50-59	294	22	3

*Data are from a single screening round in regularly screened women. Because the Breast Cancer Surveillance Consortium incompletely captures additional imaging and biopsies, these rates may be underestimates.

Data from: Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, Humphrey L. Screening for breast cancer: an update for the U.S. Preventive Services Task Force. Ann Intern Med 2009;151:727-37.

The number needed to invite for screening (over several rounds of screening and at least 11 years of follow-up) to prevent one breast cancer death in women aged 39-49 was 1,904, compared with 1,339 in women aged 50-59.

The USPSTF also considered pain and psychologic responses as harms. The USPSTF notes that "anxiety, distress, and other psychosocial effects. . . fortunately are usually transient, and some research suggests that these effects are not a barrier to screening. . . Other potential harms, such as pain caused by the procedure, exist but are thought to have little effect on mammography use."

The Mandelblatt modeling study assessed six separate models of the effects of screening mammography using the National Cancer Institute's Cancer Intervention and Surveillance Modeling Network (CISNET). It states: "If the goal of a national screening program is to reduce mortality in the most efficient manner, then programs that screen biennially from age 50 years to age 69, 74, or 79 years are among the most efficient on the basis of the ratio of benefits to the number of screening examinations. If the goal of a screening program is to efficiently maximize the number of life-years gained, then the preferred strategy would be to screen biennially starting at age 40 years."

How might women be affected by the new recommendations against routine screening mammography for women in their 40s?

U.S. Census data demonstrate that there were 22,327,592 women aged 40-49 years in the United States as of July 1, 2008. Based on Surveillance Epidemiology and End Results Program (SEER) data, breast cancer deaths expected over 10 years were estimated at 204 deaths per 100,000 women aged 40-49 years (including both screen-detected and nonscreen-detected breast cancer). This 10-year death rate leads to an estimate of 45,492 deaths of U.S. women aged 40-49 years from breast cancer over 10 years. With a relative risk of 0.85 for breast cancer mortality for women in their 40s screened by mammography, an estimated 38,668 deaths would occur in a screened population over 10 years, approximately 6,800 fewer deaths than expected with the 10-year death rate. The fewer deaths expected with screening compared to the predicted deaths demonstrates the significant benefit of screening on mortality in this age group.

Why did the USPSTF recommend against teaching BSE?

The new USPSTF recommendations are based on a systematic evidence review by Heidi D. Nelson, MD, MPH, and colleagues published in the same issue of *Annals of Internal Medicine*. This systematic

evidence review identified two studies published since the 2002 recommendations. These studies found that teaching BSE did not reduce breast cancer mortality but resulted in additional imaging procedures and biopsies. Therefore, the USPSTF recommended against teaching BSE on the grounds that it has no benefit for women but places them at risk of harm.

Who uses the USPSTF recommendations?

The main audience for the USPSTF recommendations is the primary care clinician. The congressional mandate establishing the USPSTF charges it with reviewing "the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community."

However, although the USPSTF recognizes that its recommendations also have relevance for and are widely used by policymakers, managed care organizations, public and private payers, quality improvement organizations, research institutions, and patients, it also recognizes that its recommendations are only part of what needs to be considered in setting health care policy. The disclaimer that accompanies these new recommendations reads: "The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policymakers should understand the evidence but individualize decision making to the specific patient or situation."

How will the USPSTF recommendations be used in health care reform?

Health care reform legislation being considered in the House and Senate seeks to ensure coverage of preventive services as part of a basic benefits package in all health insurance plans, as well as patient cost-sharing protections for these services. In determining which services should be covered, the bills rely heavily on the USPSTF recommendations. At a minimum, covered preventive services would be those that receive an A or B grade from the USPSTF.

It is vital that covered preventive services not be limited solely to USPSTF grade A and B recommendations. The USPSTF has not issued recommendations for many vital preventive services in women's health care, such as preconception care, family planning counseling and services, and bundled services such as the annual well-woman examination. The USPSTF only makes and updates a handful of recommendations each year, far too few to address clinically appropriate preventive services that ought to be covered by any plan.

NEW YORK CITY HEALTH AND HOSPITALS CORPORATION

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NEW YORK CITY COUNCIL

COMMITTEE ON HEALTH AND

COMMITTEE ON WOMEN'S ISSUES

OVERSIGHT HEARING:

EVALUATING NEW RECOMMENDATIONS IN

BREAST CANCER SCREENING

ROSS WILSON, MD, FRACP, FJFICM

ACTING SENIOR VICE PRESIDENT

DEPUTY CHIEF MEDICAL OFFICER

NEW YORK CITY

HEALTH AND HOSPITALS CORPORATION

DECEMBER 10, 2009

Good afternoon Chairpersons Rivera and Mealy and members of the Committees on Health and Women's Issues, I am Dr. Ross Wilson, Acting Senior Vice President and Deputy Chief Medical Officer for the New York City Health and Hospitals Corporation (HHC). I am joined here this morning by Dr. Lynn Silver, the Assistant Commissioner for the Bureau of Chronic Disease Prevention and Control of the New York City Department of Health and Mental Hygiene. Thank you for the opportunity to discuss recent announcements that have been made regarding breast cancer screening.

I would like to begin by saying that HHC continues to extensively promote the early detection and treatment of breast cancer as the primary tool for reducing the burden of disease. Our policy has not changed.

HHC's clinicians screen for breast cancer through providing clinical breast examinations and mammograms for women aged 40 years and older regardless of ability to pay. Last year, HHC's 16 hospitals and diagnostic and treatment centers provided more than 72,000 mammograms. HHC facilities use state-of-the-art digital mammography systems that produce digital breast images through computerization rather than traditional X-ray film, substantially increasing image resolution and reducing delays in generating results. I would like to thank members of the Council for providing funding for some of these digital mammography systems in prior City budgets.

The impact of breast cancer in New York City is significant. According to the Health Department, nearly, 5,000 women are diagnosed with breast cancer each year and more than 1,100 women died of breast cancer in 2007. Approximately three-quarters of new cases of breast cancer (2002-2006) and 86% of breast cancer deaths occur in women age 50 and older, but 18% of cases and 10% of deaths occurred in women ages 40-49. Mammography screening rates for breast cancer are high across the city at 78% in 2008. Rates of screening are similar or slightly higher in black and Latina women compared to white women, but lower in Asian women. In 2008, uninsured women were significantly less likely to be screened, 62%, in contrast to 80-82% for the insured. Screening rates are slightly lower in women age 40-49. While black women in New York are screened at the highest rate, they die more than any other group of women.

Breast cancer screening is effective at reducing mortality. But it is a less effective screening test than some other cancer screens. Even if all women over 40 are screened annually, mammography alone will prevent fewer than one-sixth to one-third of deaths, and so should not be our only strategy for reducing breast cancer deaths. Promoting mammography can and should remain a critical part of our efforts to reduce the burden of breast cancer on New York City women. Around the City, the main barriers to screening are lack of insurance and co-pays or deductibles – however, at HHC, we provide mammograms regardless of ability to pay. HHC and the City support key provisions of federal health care reform that would eliminate co-pays and deductibles for preventive care like breast cancer screening.

HHC closely monitors the availability of mammogram services and utilization of such services in women who are most at risk of breast cancer. We believe that we can only achieve optimum quality of care through rigorous self monitoring and by resolving issues that may impede the proper delivery of health care services to the population we serve. Of the 72,000 mammograms provided last year, many of these were for women who did not have health insurance or the ability to pay for such procedures. Any woman who does not have a primary care provider, or "medical home", can go to an HHC facility, register to become a patient and receive her annual mammography and any other services she needs.

HHC is committed to ensuring that a woman's lack of insurance coverage does not pose a barrier to accessing mammograms and needed care. HHC staff help patients obtain public health insurance for which they are eligible. We also offer services at little or no cost through the HHC Options fee-scale program.

The prevention of breast cancer continues to be challenging as the specific causes for breast cancer remain elusive. Furthermore, except for smoking, obesity, and lack of exercise, most of the risk factors associated with breast cancer cannot be easily controlled or prevented. The risk factors include:

- age (more common among women aged 50 and over);
- race (more common among Caucasian women, although mortality is higher among African-American women);

- family history of breast cancer (more common among those who have close blood relatives with breast cancer);
- early onset of menstruation (more common among women who had onset of menstruation at age 12);
- no children or late onset of pregnancy (more common among women who have no children or had first pregnancy over the age of 30); and
- did not breastfeed (women who breastfed for longer duration seems to have lesser risk for breast cancer).

In light of recent opinions and recommendations that have been published on the value of screening, it is critical to emphasize public education on the need to have a mammogram and importance of the doctor-patient relationship. HHC has traditionally conducted extensive public awareness and outreach efforts concerning the importance of cancer screenings throughout the year, but we specifically focus on breast cancer screenings in May when we sponsor our annual Mother's Day Mammogram Campaign.

The Mother's Day Mammogram Campaign is designed primarily to reach underserved women. The campaign stresses the importance of having a mammogram, an important and potentially life saving procedure. This multimedia effort has featured both radio and newspaper advertisements with wide circulations in minority and new immigrant communities. Materials are provided in multiple languages to community based organizations, many of whom serve non-English speaking communities. We also link them to a primary care provider if they need one.

In addition to conducting public awareness campaigns, we recognize the importance of patient-provider relationship and encourage our providers to promote breast cancer screening to their patients. The provider's advice to the patient on the need for a mammogram is invaluable. We also recognize how important it is for our providers to keep up-to-date on evidence based practices so that they can provide the highest quality care and advice to their patients. We conduct periodic educational programs for our providers on breast cancer screening, and the effective management of breast cancer. The decision to undergo a mammogram is taken by a patient, in conjunction with their physician. Their physicians are familiar with the evolving scientific evidence and will make a recommendation for screening

which reflects that evidence and the individual patient's particular clinical situation.

In addition to mammography, there is also a need to focus efforts on reducing the numbers of New Yorkers at risk for breast cancer. An important part of the prevention equation is promoting changes to lifestyles that contribute to the breast cancer burden. Studies suggest that as many as 35% percent of breast cancer cases can be attributed to obesity, lack of physical activity, lack of breastfeeding, and alcohol consumption.

The Health Department promotes risk reductions through two major initiatives:

- A broad, multidimensional plan to prevent obesity by increasing access to healthy foods, decreasing consumption of unhealthy foods, and getting New Yorkers moving. As you know much of this work is being done in partnership with the City Council, and
- Targeted efforts for low-income, first-time mothers and their infants to encourage breastfeeding, through the Newborn Home Visiting Program, Nurse-Family Partnership, and other programs.

This concludes my written testimony. I now look forward to answering any questions you may have.

New York City Council

Committee on Health and Committee on Women's Issues

Hearing on Breast Cancer Guidelines

December 10, 2009

Good morning, distinguished members of both committees. I am Dr. Clare Bradley, Chief Medical Officer of the American Cancer Society's Eastern Division. On behalf of the 11 million cancer patients and survivors in America today, the Society thanks you for your leadership in the fight against cancer and your commitment to helping women gain access to life-saving early detection of breast cancer. I appreciate the opportunity to testify today about the important role mammograms play in combating breast cancer deaths.

As I am sure you all know, breast cancer is the leading cause of cancer among women in New York and the entire nation. In fact, as many New York women will be diagnosed this year with breast cancer as women and

men together are diagnosed with lung cancer—13,500. And yet, lung cancer will claim 3 and ½ times as many lives as will breast cancer. Why is this?

The primary answer to that question underlies the importance of your hearing today. Because screening and early detection, thanks to mammography, is a major reason the breast cancer death rates continue to decline in the United States. Not the only reason, but a major one.

The ACS in recent weeks has publicly disagreed with the recommendation of the United States Preventive Services Task Force with respect to mammography.

The scientific evidence supporting the value of mammography in effectively reducing deaths from breast cancer is strong. And in looking at that evidence, the Society, along with other medical groups, believes that screening mammography offers an identifiable and important survival benefit to women in the 40-49 age group.

More specifically, the Society believes that the reduction in mortality, and less invasive treatments associated with early detection of breast cancer using mammography, continues to justify a recommendation of annual screening in women beginning at age 40.

It is 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.

The data and literature examined by the U.S. Preventive Services Task Force in the lead-up to its November announcement on mammography is essentially the same data reviewed by an expert panel of breast cancer researchers and clinicians convened by the American Cancer Society in 2003.

However, in that earlier review, the Society's panel considered the additional findings of a population-based study of modern mammography which showed much stronger benefits from screening compared with the more limited data examined by the Task Force.

In addition, since that time, a number of advances are increasing the effectiveness of mammograms in the 40-49 population. For example;

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 indicates may be more effective in screening younger women and women with denser breasts;
- Introduction and use of new technology, including breast Magnetic Resonance Imaging (MRI), which has proven to be a particularly effective screening tool in high-risk women.

The American Cancer Society does not pretend that mammography screening is a *perfect* test. In fact, we are among the institutions funding research that is aimed at finding even better tools for detecting and treating breast cancer. And we need to identify which cancers are likely to grow and become lethal, and those that will not.

But the essential fact remains: mammogram screening saves lives, and we must refrain from doing things that undermine confidence in that. Rejecting a test because it is not perfect would be an incredible betrayal of the women in our society.

Unfortunately, the confusion being created by these new recommendations leads many women to wonder whether they should get an annual check-up, adding to the many other factors that discourage screening.

It is simply unacceptable that today, nearly 40 of American women aged 40 and up do not get regular mammograms. The most recent (2008) data for New York State indicate that 64% of all women over 40 got a regular mammogram – every two years. For many of the women who don't, it is often a matter of not having access to these tests, which is a major failure

of our health care system. As a result, too many women are at risk of being diagnosed at later stages of the disease after the cancer has spread. That leads to more invasive and arduous treatments, poorer prognoses and patient outcomes.

We know we can do better, and we greatly appreciate the efforts that you have made, to identify barriers and help overcome them.

. We are facing a turbulent time in health care.

--Here in New York, the state budget deficit is forcing significant cutbacks in cancer screening for the uninsured. We expect that fewer than one-half of the 24-thousand women over 40 who were screened in the Metropolitan area last year will be served this year.

--Congress is wrestling with major changes, and we at the ACS are pushing hard for universal access to quality coverage that includes cancer screenings, with no co-pays to stand in the way. Recent votes are encouraging.

--A number of private insurance plans already rule out a co-payment for mammography, and we are working here in New York City and State to make that practice uniform, if the federal government does not do so.

Americans need access to consistent and understandable health information that allows them to make meaningful decisions with their doctors about preventive services.

New York and 48 other states currently have laws requiring insurance companies to cover mammography for women beginning at age 40. Public officials from U.S. HHS Secretary Kathleen Sebelius to Gov. Paterson have reaffirmed the importance of this coverage.

We have made a great deal of progress in cancer prevention, detection, treatment and care over the last few decades. Let us work together to continue this progress.

I welcome any questions you may have.

Testimony
Dara P. Richardson-Heron, M.D.
Chief Executive Officer, Greater NYC Affiliate of Susan G. Komen for the Cure
December 10, 2009
3 pages

Much has been said and written about the report from the United States Preventive Services Task Force (USPSTF), which were released in early November 2009.

I would first like to state very clearly that 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.

Furthermore we continue to recommend self-breast awareness and physician examination. Many breast cancers are diagnosed and treated in a timely fashion because women feel lumps or find other abnormalities on self-examination, which lead them to seek medical attention and evaluation. In our large nation of diverse cultures, ethnicities and levels of education, it is very important that we continue to inform women about and help to demystify issues around breast health.

It is also very important to emphasize that the new guidelines are not intended for women who have already been diagnosed with breast cancer. Women with a family history of breast cancer or other significant risk factors should continue to have regular screening. This was not highlighted enough in any of the media reports on the USPSTF recommendations.

The messaging and release of the USPSTF information to the public could have and certainly should have been handled quite differently to ensure that the correct message was relayed. The report presents a statistical analysis which does not take into account clinical realities. Saving 1 life in ~1900 is significant, particularly if that life is your own life, your mother's life or the life of another family member, colleague or friend.

Despite what was contained in the report and relayed by the media, many individuals interpreted the information to mean "they don't need a mammogram until age 50". I am a physician, a breast cancer survivor of 12 years and CEO of the Greater NYC Affiliate of Susan G. Komen for the cure the world's largest source of nonprofit funds dedicated to curing breast cancer and the news was even confusing to me! I am most concerned that this confusion may erode decades of forward progress for women's health.

While there is 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 over 50.

75-90% of women have no risk factors or family history of breast cancer. The goal of routine screening is to identify breast cancer when it is in an early stage and much more responsive to treatment.

We must not lose sight of the critically important fact that fully one-third of the women (~23million women), who qualify for screening under today's guidelines are not being screened due to lack of access, education or awareness. That issue needs continued focus and attention: if we can make progress with screening in vulnerable populations, we could make more progress in the fight against breast cancer. This is issue that our organization has focused on for many years.

Additionally, I would like to point out additional and extremely important considerations that appear not to have been taken into account when the original USPSTF guideline analysis was done and the resulting recommendations were made including the following:

- It appears that no practicing clinicians were involved in the development of the recommendations;

- Breast cancer advocates were not involved in process;

- The USPSTF force acknowledges that with their recommendations, 20% of cancers that would have been found with our heretofore standard guidelines would be missed;

- Women who are not screened for early detection will present with more locally advanced or even metastatic disease;

- The cost of treating more advanced cancer is dramatically higher than the cost of curing a very early screening detected cancer – IN EVERY MEASURABLE WAY;

- Living with cancer is not better than NOT having cancer. It is costly in dollars and cents, medications, physician and ancillary costs, diagnostic tests (scans, x-rays, blood work), not to mention the cost to the quality of lives for the women and their families – days missed from work, need for additional help at home, expenses getting to and from clinic, out-of pocket cost for co-pays etc....;

- The endpoint used in the USPSTF analysis was "lives saved" or "mortality" which is the wrong endpoint for breast cancer. Thanks to research and improvements in treatments, we know that many women may live long and productive lives with locally advanced or metastatic disease - due to both the slow growing biology of some types of breast cancer and also better therapies;

- Recommending against self-examination sends wrong message. While technically correct that a rigorous clinical trial comparing monthly exam to not monthly exam in a subset of women (all of whom were well-educated about breast cancer) did not change mortality between the 2 groups – this is not a good reason to send a message to women NOT to practice breast self awareness so that they can notify a health care provider right away if they notice any abnormalities;

- For many women, particularly those who have no other entry point into the medical system, the annual mammogram is the only time they come to medical attention. This provides an opportunity for more than just an x-ray it may result in identification of other problems that may otherwise go unnoticed. If we remove this access we are doing a major disservice to women;

- The recommendation that each woman should have a "conversation" with her doctor is completely detached from the reality that millions of women have no regular physician!;

- A careful analysis of risk was not done. There are different levels of risk for different populations and we know that these different populations may need different screening. Some may even require earlier screening. However, in any case, reverting to NO screening in the absence of a better tool is clearly not the answer; and

- The recommendations ignore the unique, disproportionate and detrimental impact that breast cancer and the recommendations may have on women who are already underserved, uninsured, and have less access to preventive screening – this is especially true for women of color, women from restrictive cultural backgrounds, non-English speaking etc.

At Susan G. Komen for the Cure, we certainly understand that mammograms are not perfect but they are currently our best tool for early detection and risk assessment. We agree and fully support more research to identify screening tools that will be more effective, sensitive and specific than mammography. We also understand that it is possible that one day, hopefully in the very near future, guidelines for screening will be tailored to the individual.

However, until a better screening methodology is developed and proven to have safe and beneficial results, we must rely on our best screening tool which has been proven to save lives: mammography. Komen strongly urges women to continue breast self awareness, regular physician examination, and screening mammography. We also strongly support City, State and Federal funding and political advocacy for additional research and development of a better tool for early detection and hopefully a cure for breast cancer, the most common cancer among women in the United States, other than skin cancer and the second leading cause of cancer death in women, after lung cancer.

Self-help for Women with Breast or Ovarian Cancer

TESTIMONY
December 10, 2009

My name is Gail Garfield Schwartz and I am Advocacy Manager at SHARE: Self-Help for Women with Breast or Ovarian Cancer and a breast cancer survivor. SHARE appreciates the opportunity to testify today before the City Council's Committees on Health and Women's Issues.

SHARE is a 33 year old not for profit organization that provides peer support, information and resources to women and men affected by breast or ovarian cancer. Our goal is to empower those affected to make informed decisions about diagnostic procedures, treatment and post-treatment issues.

We speak with women on our hotlines and in our support groups who were diagnosed through a screening mammogram and others who felt a lump in their breast but had no sign of anything when they had a mammogram. We have known for a long time that while mammography is the best technology we currently have for screening, it is not without risks. These risks need to be measured against benefits to the individual undergoing the mammogram. The costs also have to be weighed against the benefits, a point I shall discuss further below.

The first point I want to make is that although each of us has a story to tell, quality health care and evidence-based medicine cannot be based on our personal stories. They must be based on the emerging and changing science that comes from good research.

With that in mind, I want to present for consideration by the City Council's Committees on Health and Women's Issues some issues concerning screening mammography and the new guidelines that have been developed by the US Preventive Task Force.

First it is important to understand that screening mammography is different from diagnostic mammography. In the latter, a mammogram is taken when a woman (or a man) presents with symptoms, such as a lump in the breast. In the former, a mammography is taken to detect breast cancer before symptoms appear.

It is also important to bear in mind in speaking of screening tests that some people may be at high risk for breast cancer owing to known genetics or family history. Such cases do not fall into the basket we are calling "general screening."

The goal of all screening tests including general screening mammography is to decrease mortality. There would be no reason to screen unless it was believed that screening detects a cancer earlier than not screening, and also that this early detection allows earlier treatment and that earlier treatment will allow the screened individuals to live longer than they would live if their cancers were discovered later in their lives. Furthermore, there should be evidence that screening itself does not entail health risks.

What we currently know from published research cited by the US Preventive Services Task Force, is that there is no compelling evidence that this is the case for general screening mammograms for women under fifty years of age. Research to this effect has been accumulating for many years and has already been presented at many conferences on breast cancer. The research shows that to prevent one breast cancer death among women under 50, 1,904 screening mammographies must be performed every year over the course of 10 years. But to prevent one death from breast cancer among women 60 or older, only 377 screening mammographies need be performed every year over the course of 10 years.

Based on this research, the US Preventive Services Task Force, a reputable and well-respected government-appointed panel of experts that systematically reviews evidence and develops recommendations for clinical preventive services, has just released a new set of guidelines for breast cancer screening, including screening with mammography. The new guidelines support mammography screening for women over the age of 50 since the benefits outweigh the risks.

They do not support such screening for women under 50 unless the woman and her health care provider have reason to believe she is at high risk for breast cancer. For younger women, the risks seem to outweigh benefits.

The guidelines also support scheduling screening mammograms every two years since, based on the research, the benefits for yearly screening are no better than for screening every two years. That is to say, annual screenings do not reduce mortality from breast cancer any more than biennial screenings do.

So how do we sort this through, especially since we have been told over and over again that we must get screened with mammography at 40

and every year after that for the rest of our lives; that screening with mammography *will* save our lives? How do we give credibility to the research results that support the need to review and modify clinical practice guidelines so our practitioners use evidence based medicine in their practices?

Our understanding of the biology of breast cancer and the process of breast cancer has changed dramatically since the original screening guidelines were developed. How then do we help to translate this to the women and to their providers?

One of the ways to do this is to encourage women and their health providers (to the extent these women have health providers) to engage in a conversation about whether screening mammography is right for them: whether the benefits (reduced chance of dying from breast cancer) outweigh the harms of false positives, unnecessary biopsies and excessive radiation, as well as the limitations that may exist for women their age. Dense breasts, for example, mostly found in younger women, could interfere with a diagnosis through mammography. Many cancers may be detected and perforce treated, even though they might never develop into dangerous malignancies.

There are important challenges to government and to the non-profit community in making these facts understood by the public. In the comments to a SHARE blog on this subject, many women voiced strong opposition to the guidelines, which may very well be the result of years of an entrenched public awareness campaign around screening. One thread of opposition stems from the suspicion that the Task Force and its guidelines were solely motivated by the desire to reduce health care costs. "Like hell will I follow these guidelines" was a common attitude.

One can now easily envision a scenario in which health care providers follow the new guidelines and patients are outraged and frightened. We in government and in the not for profit sector have a responsibility to provide a forum for the exchange of information and the articulation of concerns from the public as well as from health care providers.

To be sure, doing this is more labor intensive than simply mouthing the simple but inaccurate message that "mammography saves lives," but it is far more valuable. It is a "teach them to fish" approach, rather than "give them a fish" approach. True public awareness about screening mammography must be based on a complete understanding of the evidence.

One final point is that, notwithstanding popular sentiment, cost savings in health care are important, and value-added health care expenditures are essential. The costs of health care are pooled in our society. Almost every

process offered any individual is paid for, in part, by the community, either through insurance premiums or through taxes. Thus a $300 screening mammogram that does an individual no good, multiplied by tens of thousands of individuals, is a highly questionable use of resources.

An article in the New England Journal of Medicine (November 25, 2009) reports: "A recent cost–benefit analysis showed that adherence to the current guidelines from the American Cancer Society costs more than $680,000 per quality-adjusted life-year (QALY) gained."

Statistician Donald Berry, MD, quoted in the same article, has calculated that for a woman in her 40s, a decade's worth of mammograms would increase her lifespan by an average of 5 days.

Clearly, there are more worthy expenditures. One more worthy expenditure would be to find better tools than the current ones... tools that will tell us not only that a malignancy is present, but also, how lethal it is. We need to encourage scientists to develop an understanding of exactly which types of cancers, whenever they are detected, are killers and which are not. New screening tools based on biology could be a far more valuable expenditure of scarce health care resources than doing screening mammograms on tens of thousands of young women unnecessarily.

Before I close, I would like to briefly address the issue raised by these new guidelines on breast self examination and dispel a misunderstanding. As I understand it, the Guidelines recommended not doing the highly formalized once a month at the same time each month and in the same way breast self examination since this procedure did not have an impact on mortality from the disease. That does not mean that women should not know their breasts...what they look like, how they feel, whether something looks or feels different and should be dealt with. That is how many women find their breast cancers...not through the rituals we were made to believe save our lives but during times when we shower, dress, lie in bed, make love.

Thank you again for the opportunity to present a SHARE breast cancer advocate's perspectives on this issue.

SCREENING MAMMOGRAPHY

Loretta Lawrence, MD, FACR
President, New York State Radiological Society
Director, Breast Imaging, North Shore-LIJ Health System

I am strongly opposed to the breast cancer screening recommendations released by the United States Preventative Services Task Force on November 16, 2009. I am a radiologist who has specialized in breast imaging for the past 22 years. The USPSTF is comprised of government appointed "health experts" that review published research and make recommendation regarding preventative health care. The panel of 16 "experts" responsible for the recent recommendations did not include a single expert in the breast cancer field. None were from breast imaging, radiation oncology, medical oncology or breast surgery.

The American College of Radiology response regarding benefits vs. concerns of annual screening mammography starting at age 40 included the following:

It is well known that mammography has reduced the breast cancer death rate in the U.S. by 30% since 1990 -- hardly a small benefit.

Based on the performance of screening mammography as it is currently practiced in the U.S.:

-one invasive cancer is found for every 556 mammograms performed in women in their 40's

-mammography only every other year in women 50-74 would miss 19-33% of cancers that could be detected by annual screening

-starting at age 50 would sacrifice 33 years of life for every 1000 women screened that could have been saved if screening started at age 40

-85% of all abnormal mammograms require only additional images to clarify whether cancer may be present (or not); only 2% of women who receive screening mammograms eventually require biopsy; USPSTF data showed that the rate of biopsy is actually lower among younger women

The USPSTF agrees that screening mammography decreases mortality from breast cancer in women in their 40's by 15%. However, the task force relied on studies with methodology flaws that underestimated the benefits of mammography. 20% of women whose deaths are from breast cancer are in the 40-49 age group. Many individual trials show the benefit of screening with the following % breast cancer mortality reduction in women aged 40-49 including: HIP 25%, Gothenberg 44%, Malmo 36%, Sweden 48%, British Columbia 39% .

The USPSTF recommends screening based on risk in the 40-49 age group. Only 10-25% of breast cancers occur in high risk women in that age group. Not screening the others would miss 75-90% of breast cancers in that group.

A review of all breast core biopsies in the LIJ database from 10/1/08-10/31/09 revealed that a total of 2040 core needle biopsies were performed in which 657 cancers were found (PPV=24%). In the group between 40-50 alone 642 biopsies were performed and

138 cancers were found (PPV=20%). 93 of these cancers were invasive. It is unconscionable to ignore these patients.

Regarding the question of how often women should be screened, even the USPSTF agrees that with increased screening, decreased mortality is achieved. Breast cancers grow at variable rates and in order to catch early and fast growing cancers, we must screen every year. This is especially true in the 40-49 age group who have denser breasts and their tumors are known to grow faster.

I strongly support the American Cancer Society (ACS) guidelines, which continue to recommend annual routine mammography screening for all healthy women age 40 and older. A major concern is that the USPSTF recommendations will be used by the possible health plans being considered in Congress which could lead insurance companies to stop covering annual breast cancer screenings beginning at age 40.

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