

**Testimony of
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Thank you, Chairman Pallone and members of the House Energy and Commerce Health Subcommittee, for the opportunity to testify at this hearing on breast cancer screening recommendations. As always, the National Breast Cancer Coalition commends your attention to our shared mission to eradicate breast cancer. We welcome the opportunity to explain our position on screening and to clear up some of the confusion over the new guidelines issued by the United States Preventive Services Task Force (Task Force).

I am Fran Visco, a 22-year breast cancer survivor, a wife and mother, lawyer, and President of the National Breast Cancer Coalition (NBCC). I was diagnosed at age 39 when my son David was 14 months old. As you may know, NBCC is made up of hundreds of organizations from across the country. Our Board of Directors consists of 25 of these organizations and represents the diversity that is breast cancer. These groups come together under our umbrella to focus on systems change in public policy, health care and research. NBCC's mission is to eradicate breast cancer. NBCC's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to implement new models of research; improve access to high quality health care and breast cancer clinical trials for all women; and expand the influence of breast cancer advocates wherever breast cancer decisions are made.

NBCC trains advocates to understand the process, concepts and language of scientific research and we analyze scientific information for our members and the public from the perspective of lay advocates. We have no agenda other than our mission to end breast cancer. We believe in evidence based approaches to health care as the key to quality care.

Before I speak to the Task Force recommendations, I want to focus on the goal that we all share, and that is to make certain that everyone has access to the quality health care they need. That goal is NBCC's number one priority because we know that we will not end breast cancer until we achieve it. There are many components to that goal. One is legislation reforming the system to guarantee coverage to everyone.

Another component is achieving quality in health care. What do we mean by quality care? While we can legislate some aspects of achieving quality, as the Institute of Medicine (IOM) pointed out in its report *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001), a key aspect of quality health care is evidence. Legislation can support the science of generating evidence, but the scientific process is what gives us the evidence. The IOM explained

that to achieve quality, the system must provide “services based on scientific knowledge to all who could benefit and refrain from providing services to those not likely to benefit (avoiding underuse and overuse respectively).” This applies to screening interventions as well as treatments.

We should look at the Task Force recommendations in the context of an analysis of quality, effective health care. What is the evidence of benefit? What is the evidence of harm? How do we balance the two and does this change along a continuum of age and known risk?

US Preventive Services Task Force Guidelines

The US Preventive Services Task Force (“Task Force”) released revised breast cancer screening guidelines on November 16, 2009. The Task Force recommends against routine mammography screening for women 40-49 years old. They instead encourage these women to make individual decisions regarding screening based on assessment of the risks and benefits. The Task Force recommends biennial screening for women 50-74 years old. The recommendations are based on a systematic review of randomized, controlled trials with 10 or more years of follow-up, and on six statistical models of screening outcomes.

The Task Force also recommends against teaching breast self exam based on the evidence, again, from large randomized, controlled clinical trials.

Reaction to the Task Force Recommendations

We want to note that the attacks against the makeup of the Task Force are misplaced. Screening is an issue of primary care; it is a health intervention for a healthy population. The experts in this area – those with the scientific training and the objectivity to do the necessary analyses – are primary care health professionals and methodologists such as epidemiologists and biostatisticians, not radiologists or medical oncologists.

The outrage that met the new recommendations was unsettling to us as individuals and organizations that are dedicated to ending breast cancer. The outrage seemed to be based on a misunderstanding of what the Task Force actually did and said. Could the Task Force have communicated the changes better? Without question. But that does not change the fact that they were the right experts, looking carefully at the evidence and objectively making recommendations.

Many in the public were shocked by these changes in breast cancer screening guidelines, but these guidelines and this controversy are not new. The new recommendations do not differ dramatically from the prior guidelines. Moreover, the American College of Physicians released similar guidelines a few years ago. A National Institutes of Health (NIH) consensus panel came to similar conclusions in 1997. In fact, historically, the scientific evidence has not supported the breast cancer screening methods that have been vigorously promoted in our country. Today, we have even more evidence and a greater understanding of breast cancer, but it appears that once again, emotion and conventional wisdom are taking precedent over science, evidence, and progress.

Because a health message has been given over and over again and has become rooted in the public consciousness does not make it correct. Indeed, too many times, policy, messaging and

beliefs have taken hold when there was in fact no real evidence behind them, and these actions resulted in harm to women. We are all familiar with the story of Autologous Bone Marrow Transplants (ABMT) in treating breast cancer. The community believed more chemotherapy would be better and that transplants worked in some cancers so why not breast cancer? While clinical trials were launched, too many women received the treatment outside of the trials, the trials did not accrue and it took many more years than it should have to get the real answer. Women died from the treatment itself. NBCC said from the beginning that we needed the trials to get the answers. When we finally had the evidence, it was clear that ABMT was not better than conventional chemotherapy. And yet laws were passed in various states mandating insurance coverage of this treatment, an example of misplaced advocacy when evidence did not exist.

We also know the story of hormone replacement therapy (HRT) becoming a widely used intervention for women based on the belief, without evidence, that it would help cardiac health among other benefits. Yet when the clinical trials were completed, we found out that HRT increased a women's risk of breast cancer and other harms. Many women took HRT when we had no evidence of its effectiveness and many women were harmed, which has now been recognized in the legal system.

NBCC has taken the position many times before and we do so again today, that we cannot afford to waste our limited resources on public and other health interventions that have not been shown effective. These resources would be better spent on identifying interventions that really do work, such as better ways to detect, treat, and prevent breast cancer.

NBCC Analysis

The NBCC hopes that the Task Force revised, evidence-based guidelines on breast cancer screening will help to put screening and its limitations into proper perspective. For over ten years, NBCC has expressed concern about public health screening messages that were not backed up by the evidence. Women have followed the lead of many in the health care arena over the years and have increasingly put their faith in faulty screening methods.

Progress has always required the ability to adjust, but because of how deeply these messages have been ingrained in the American public, changes are being met with resistance and a firestorm has erupted. These recommendations have challenged deeply held beliefs, the reasons some organizations exist, and not only significant financial interests of those who provide screening and follow-up services, but also of the significant number of companies that use the public health messages to market their products. Further adding to the backlash, these recommendations have also been seized on, and the facts manipulated by, those wishing to derail health care reform.

The result has been an incredible amount of misinformation presented to the public regarding breast cancer, screening, and these guidelines.

I would like to address several of the misconceptions.

First, let me say strongly and loudly, mammograms do NOT prevent breast cancer. I have read and heard a number of statements to that effect. Mammograms may find cancer that is already present but they do nothing to stop tumors from forming.

Next, to those that claim these changes represent an example of rationing of care, I would like to point out that the Task Force did not consider cost when developing their recommendations, and in fact increased recommended screening to include women up to 74 years old. The Task Force began its review of the evidence over two years ago. The Task Force recommendations became tied in with the health care reform debate because of legislative proposals to use their recommendations to decide which screening and preventive services should be covered free of charge, not in deciding what should be covered at all. It just makes good fiscal sense and good health sense to cover preventive services that have been proven effective. If we continue on a course of health care reform based on beliefs and politics, rather than science and evidence, we will continue to have one of the most expensive, but least effective health care systems in the world.

Some are concerned that screening guidelines that do not recommend mammography under 50 as a matter of routine will prevent underserved women from entering the medical system at all. We would counter that the solution is to enact universal access to medical care for all, not to depend on a faulty test that exposes women to radiation and the risks of false positives, in order to gain them medical care. Disadvantaged women deserve the same access to quality, evidence-based care as advantaged women. Disadvantaged women have the same rights as all women to learn the facts and understand the evidence behind medical procedures.

Others have expressed concern about those women who do have breast cancer in their 40s – how will it be detected under these new guidelines? The truth is, based on evidence from randomized clinical trials, the highest level of scientific evidence, mammography and breast self exams do not work in finding life-threatening cancers in this age group or in reducing mortality. The new recommendations give these women control over the decision of whether to undergo screening, after understanding harms and possible benefits.

What about finding the cancers with breast self exam? Large well designed clinical trials have shown us that regimented, monthly exams do not lead to detection of more or earlier cancers and in fact cause harm by leading to twice as many women having unnecessary biopsies and additional imaging.

Does this mean women should not “know” their bodies? Of course not. The majority of women DO find their breast cancers because they feel them, while going about their lives, in the shower, getting dressed, during lovemaking. This is different from the regimented breast self examination that is the subject of the Task Force recommendations. Being familiar with your breasts, and reporting any changes or concerns to your doctor, is different from a monthly self examination done with a certain technique in order to search for cancer.

The harms from screening are not to be taken lightly. Harms include over diagnosis and false positives. According to research cited by the Task Force, false positives are 60% more likely when mammography is started at 40, rather than 50. False positives lead to increased imaging and radiation exposure, and increased biopsies and scarring which can interfere with future mammography. Over diagnosis would include treatment of cancers that would never have been life threatening, and treatment of cancers that may have regressed, or gone away on their own. The treatments for breast cancer are toxic and can be life threatening. The scenario of over diagnosis should not be dismissed as unimportant.

Is any of this good enough as our only method for detecting breast cancer in women of any age? No, it is not. We can do better and we must. But by refusing to look at the evidence and continuing to put faith in faulty methods, despite the evidence of their limitations and the harm they cause, society has become complacent. The urgency to develop new methods that will save women's lives has been lost.

Moving Forward

NBCC has always pushed for research to find better methods for detecting breast cancer and for ways to distinguish between lethal and non-threatening cancers. We have made progress in our knowledge of breast cancer over the past few decades and the screening tools we have at present do not take into account the differences we now see in the biology of breast cancer. We know that all breast cancers are not the same. Some breast cancers are slow-growing and have a good prognosis, whenever they are found, whether small or large. Some may be more threatening, but respond to treatment at whatever stage they are found. Other breast cancers are aggressive and fast growing, and we do not have the tools to find them early enough. We desperately need better methods for detecting these cancers, and better treatments once we find them.

The Task Force did not condemn breast cancer screening. It carefully looked at the updated evidence, at the long term evidence of benefit and harms and recommended that for women between the ages of 40 and 50, the decision to have a screening mammography be made on an individual basis, after an analysis of the benefits and harms. The recommendations give women control over their health care decisions. From its prior recommendation of screening every one to two years for women over 50, the Task Force recognized that the updated evidence and the various scientific modeling analyses performed, support screening every two years.

What do we tell women? Some argue that public health messages need to be simple and that changing the guidelines will only confuse women. We would argue that while public health messages may need to be simple, they also need to be truthful. We believe women deserve to know the facts. Women are capable of understanding the complexities of breast cancer and screening and have the right to make informed decisions regarding their health care.

The Task Force recommendations and the attention surrounding them also present an excellent opportunity to educate the public about the importance of science and evidence and to help them understand that as we learn more about health issues, recommendations will change to reflect that knowledge. And the public needs to know, not just possible benefits of medicine, but also the risks often associated with it. The public is ready to learn. Recently, NBCC received the results of its commissioned annual survey of Breast Cancer Awareness and Knowledge (Penn, Schoen and Berland, October 2009). Women across all age groups named comparative effectiveness research as the most beneficial tool in achieving quality in health care. Electronic medical records came in second. Clearly the public is becoming more sophisticated about these issues and the present discussion can help move us closer to public acceptance of a system based on quality care.

NBCC is committed to seeking what is best for women and their health. We will continue to push for universal access to quality health care for all, a thorough look at the evidence, and for public health officials to base guidelines and recommendations on that evidence. We must

address the facts about breast cancer and not rely on what we wish were true. We firmly believe that this is the only way we will make progress in eradicating this disease.

Mr. Chairman, I thank you so very much for this opportunity to testify before this Committee and for the Committee's commitment to our mission.