NBCC

NATIONAL BREAST CANCER COALITION

grassroots advocacy in action

TESTIMONY OF FRAN VISCO, J.D.
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BEFORE THE
U.S. SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS,
SUBCOMMITTEE ON PUBLIC HEALTH
AND THE

APPROPRIATIONS SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES AND EDUCATION

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Introduction

Thank you, Chairmen, members of the Senate Health, Education, Labor and Pensions Aging Subcommittee, and members of the Senate Appropriations Labor, Health and Human Services and Education Subcommittee, for your dedication and leadership in working with the National Breast Cancer Coalition (NBCC) in our fight to eradicate breast cancer.

I am Fran Visco, a breast cancer survivor, a wife and mother, a lawyer, and President of the National Breast Cancer Coalition.

The National Breast Cancer Coalition is a grassroots organization dedicated to ending breast cancer through the power of action and advocacy. The Coalition's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to design and 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 in all aspects of the breast cancer decision making process.

On behalf of NBCC, which is made up of more than 600 member organizations and 70,000 individual members, I would like to thank you for the opportunity to testify today on this critically important issue.

I believe it's very important to put the current debate about the effectiveness of screening mammography in the right context. What this debate is really about is saving women's lives, and improving the quality of their lives – not about attacking or defending mammography. For decades, mammography has been linked to preventing breast cancer

deaths. We used to think that the earlier we catch breast cancer, the easier it will be to treat. Yet, we are beginning to better understand the complexities of this disease. And we are realizing that the concept of early detection being the key to reducing mortality may not be the whole story. Some very small cancers can be very aggressive, regardless of when they are detected, and other big tumors caught later may never cause of death. We must consider screening mammography, not only in terms of how early and effectively it detects tumors, but also in terms of the impact early detection will have on a woman's treatment options in light of what we now know about this disease.

We also must be clear about the realities and limitations of the early detection tools that exist today. Currently, there is no truly early detection. Often, by the time a tumor is found, it has been in the breast for 6 to 10 years. The goal must be to detect the tumors at their earliest stage, or prevent them in the first place.

Mammography should be accepted for what it is: followed by treatment, it may extend the lives of some women who have breast cancer, but it does not prevent or cure breast cancer, and it has many limitations.

At best, this is simply not good enough. We need more reliable and less invasive tools developed to detect breast cancer. We need more targeted and more effective treatments for this disease and a better understanding of how one tumor differs from another. And, we need a clearer understanding of what causes this disease, and how to prevent it.

It is also important to keep in mind that this debate is not about diagnostic mammography (for women with symptoms of breast cancer), but about screening mammography (the healthy population of women). This issue must be considered in the context of the limited health care dollars available for breast cancer. What are the best use of resources to reduce mortality and improve quality of life for women?

The National Breast Cancer Coalition respects the difficult challenge in developing a public health message, which may differ from the personal decisions that individual women and their doctors will make. But, our goal today is to explain what we do and do not know about how to reduce breast cancer mortality. The truth is not always clear, but we believe that women deserve to be fully informed, and that they are capable of understanding the complexities around this disease.

Background

The National Breast Cancer Coalition believes that the debate over the effectiveness of mammography in reducing breast cancer mortality is vitally important. For too long, mammography has been inextricably and erroneously linked with "prevention" of breast cancer. Mammography screening of women age 40 and above has become the standard of care for women in the United States. It has become a multi-billion dollar business. Organizations exist solely to raise awareness about mammograms and breast self-examination. Legislation has proposed to teach high school students about breast self-examination. Campaigns directed to the public about the importance of screening are increasing in number. For much of the public, mammography is the most important, if not the only, issue in breast cancer.

Women are told that early detection saves lives. Yet, the evidence of mortality reduction from screening is conflicting and continues to be questioned by scientists, policy makers and some members of the public. Breast self examination has become part of the culture of breast cancer, even though there is no evidence whatsoever to support its efficacy.

The fact that breast cancer screening is now high on this nation's agenda must not color the analysis of the evidence. Recommendations on breast cancer screening must have as their goal saving women's lives, not preserving an infrastructure.

In my testimony today, I will make four major points.

First, I will explain NBCC's position on mammography screening.

Second, I will respond to the recent studies about what more we now know regarding the effectiveness of mammography reducing mortality.

Third, I will discuss what these new data mean for women, and for the decisions they must make.

Finally, I will give NBCC's recommendations for where we need to go from here.

The National Breast Cancer Coalition's Position on Screening Mammography

The National Breast Cancer Coalition has long acknowledged the limitations of mammography screening. For years, NBCC has said that mammography is not the answer to the breast cancer epidemic. Although it may be difficult to accept, it is vital that women know the truth about breast cancer screening and the false sense of security it provides. As breast cancer activists, NBCC welcomes the long overdue criticism and discussion of the effectiveness of existing breast cancer screening methods.

We must accept that we do not know how to detect breast cancer truly early or how to prevent or cure this disease. Instead, we should focus our attention on getting those answers. NBCC believes the goal must be to focus research efforts on true prevention and on stopping breast cancer from occurring altogether. We must work together to find new, more accurate ways to detect and treat this disease.

The Coalition also believes that women who have access to mammography must have access to treatment. Screening alone does not reduce mortality. It is for that reason that NBCC was proud to be the originators, and lead advocates on working with Members

of Congress, many who sit on your Committees, to enact the Breast and Cervical Cancer Treatment Act in the 106th Congress. As you know, this law ensures that low-income women screened and diagnosed with breast cancer through federal programs can now have access to the treatment they need. NBCC had to fight four, very long, hard years to get women in this program treated as well as screened. There was a lot of opposition along the way, mainly because people were afraid that we were criticizing screening. This debate must not be about saving screening, but rather, about reducing breast cancer mortality. It is about women's lives.

NBCC also believes that mammography should be of the highest quality possible. The Coalition commends your Committees' leadership in enacting the Mammography Quality Standards Act (MQSA), which established minimum national quality standards for mammography facilities and personnel as well as a rigorous annual inspection program to ensure those standards are being met. We appreciated the opportunity to testify before Congress during reauthorization of this program in 1998, at which time we urged that the women be notified directly of the results of their mammogram, and that Congress continue to ensure the highest quality mammography by maintaining the rigorous inspection process initially contemplated.

NBCC supports reauthorization of this important program this year, and would be happy to provide the Committee with additional information or recommendations.

NBCC's Response to the Evidence

The National Breast Cancer Coalition's general position on mammography is that guidelines on mammography screening should only be issued if scientific studies prove that such programs save lives, and if the benefits outweigh the risks.

As your Committees know, there are seven published randomized trials of mammography screening. The oldest of these trials, the New York Trial, was conducted in the 1960's. Four of the trials were conducted in Sweden, one was conducted in Canada, one was conducted in the United Kingdom, and one was conducted in the United States. The seven trials are known as:

The New York trial or HIP trial- enrolled women 40-64

The Malmo trial- enrolled women 45-69

The Two-County trial- enrolled women over age 40

The Edinburgh trial- enrolled women ages 45-64

The Canadian trial (parts 1 and 2)- enrolled women ages 40-59

The Stockholm trial- enrolled women ages 40-64

The Goteborg trial- enrolled women ages 39-5

Two of these trials – the Malmo and Canadian trials – found that mammography did not benefit women. In these trials, the women who got mammography screening had the same breast cancer mortality as the women who did not. The other five trials

found that mammography did benefit women and reduce breast cancer mortality by about 30% on average. Although a majority (five of seven) of the trials found that mammography is beneficial, we cannot simply conclude that mammography saves lives.

First, the reliability and quality of each trial must be evaluated. Some trials may have been poorly carried out, and some trials may not be applicable to the general population of women. Also, it is important to note that a majority of trials does not necessarily represent a majority in the number of individuals who participated in the trials.

Many scientists have critiqued these trials, however, the most thorough peer reviewed evaluation to date was recently conducted by Drs. Gotzsche and Olsen, Danish scientists affiliated with the well-respected Cochrane Collaboration. These scientists set out to review and evaluate all seven of the mammography trials to determine the quality of each. The authors had no conflicts of interest and were unbiased at the start of the review. Their findings were published in a recent issue of The Lancet medical journal as a systematic review.

The findings of the systematic review prompted an independent panel of experts (the PDQ screening and prevention editorial board) at the National Cancer Institute to conduct its own evaluation of the seven mammography trials. After its review, the panel concluded that there is insufficient evidence to show that mammography screening prevents breast cancer deaths in any age group of women. Moreover, it concurred with Drs. Goetze and Olsen that the Malmo and Canadian trials were the highest quality trials, and that they did not show that mammography reduces breast cancer mortality. Finally, the review found that mammography could also have negative effects – including more aggressive treatment and more unnecessary surgeries.

The authors of the systematic review do not state that there is proof that mammography is ineffective. Rather, the evidence is unclear.

Most recently, the United States Preventive Task Force (USPPSTF) recommended screening mammography, with or without clinical breast examination, every one to two years for women ages 40 and over. The Department of Health and Human Services (HHS), and the National Cancer Institute (NCI), have endorsed these recommendations.

NBCC believes that these recommendations were premature and that the Task Force should not have made recommendations until the individual data is released by the Swedish investigators and analyzed by an independent review.

It seems clear that in a situation like the present, where data exist that could answer the questions posed, those data should be released and analyzed before recommendations are made. In addition, the fact that data exist that could help answer the question of whether screening results in fewer breast cancer deaths, but more deaths from other types cancer or other causes, should have compelled the Task Force to demand the data before it made recommendations.

Moreover, the Task Force relied on evidence to recommend screening mammography for women age 40-49 that clearly does not rise to a level sufficient to support screening. In fact, only one trial was designed to answer the question of screening in women aged 40-49, and it found no benefit. In the remaining trials, women in that age group were a cohort of the larger population. In previous recommendations, the Task Force did not recommend screening women in this age group; since there is no new data to show a benefit for these women, it is unclear why the Task Force changed its recommendation.

What Does This Mean for Women Trying to Make Informed Healthcare Decisions?

The National Breast Cancer Coalition believes strongly that women deserve to know the truth. If the truth is that evidence is unclear, than they should know that. Progress in eradicating breast cancer means accepting uncertainty regarding best treatment and detection methods. Women and doctors have to understand, and live with this uncertainty, understand the risks, and make individual decisions.

This issue is not black and white. The public needs to accept uncertainty, and move toward educating themselves so they can make their own decisions on an individual basis. Women are capable of understanding that to date, no screening tool allows for truly early detection of breast cancer. Meaning, by the time a tumor is detected, it has been in the breast for 6-10 years. Women also need to understand that some cancers will never spread to other parts of the body, so detecting these cancers won't save lives – rather, treatment would be unnecessary, and possibly harmful. We just don't know.

Where do we go from here?

First, the National Breast Cancer Coalition believes that the most useful thing we can do now is make certain that there is an independent review of the data. NBCC would like to first better understand what the results of these trials mean. The Swedish researchers must allow all of the individual data to be released to an independent reviewer like Medico Legal Investigations, Ltd. in Knebworth, England. This may resolve many of the concerns and questions raised by Drs. Gotzsche and Olsen, and may provide better answers about the effectiveness of mammography.

Second, the cost of mammograms cannot be ignored. Remember, we are not talking here about women who have been diagnosed with a disease. We are talking about the screening of a healthy population of women. Mammography screening is a multi-billion dollar expenditure. We must ask ourselves whether this is the best expenditure of finite dollars? Especially in light of the fact that we know using these

resources to buy healthcare for underserved and uninsured women would unquestionably reduce mortality.

We must ask the critical questions: What is the best use of resources? What are the pros and cons? This is a debate that must happen. These are the issues that we must grapple with before we decide to just accept the status quo.

Finally, NBCC urges the public not to just sit and fret over the lack of clear consensus on mammography. Instead, we need to be advocating for more research and resources going towards true prevention and better methods of treatment and detection.

Precious time, resources and attention continue to be diverted away from promising research and funneled into an oversold panacea for breast cancer detection. The issue is about saving women's lives, not saving the institution of mammography. We must continue to look ahead of the curve to see what more can be done regarding prevention and detection. Only then will we be able to eradicate this disease.

I want to thank these Committees for the opportunity to testify today. I have enclosed NBCC's Question and Answer document on mammography, and ask that it be included in the record. I would be happy to answer any questions.