

"MAMMOGRAPHY SCREENING FOR WOMEN AGES 40-49"

Statement of

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on Screening Mammography**

Before the

**Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Senator Arlen Specter, Chairman
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Good morning, Senator. I am Richard Klausner, Director of the National Cancer Institute. I am here to talk about mammography screening for women ages 40-49.

I want to thank you for your interest in this important issue. Two weeks ago, a conference was held at the NIH that brought together experts in all aspects of mammography and an independent consensus panel to address the often confusing and sometimes contentious debate that surrounds the question of the age at which a woman should begin regular mammography. On behalf of the NCI, I had asked for the conference in response to reports of new data, primarily from Sweden, that addresses the great gap in our knowledge concerning the potential benefit of population screening of women age 40-49 and, as hoped, the conference successfully stimulated the presentation and discussion of new and updated data.

From a scientific point of view, the value of any screening test used in a healthy population depends on the incidence of the disease, the mortality associated with that incidence as well as on the performance characteristics, shortcomings, and risks of the screening procedure. A woman's risk of breast cancer does not suddenly change at a particular age but gradually and steadily rises. It is not surprising therefore that the value of widespread screening follows a similar pattern. There is general agreement that the population of women between the ages of 50-69 benefits from regular mammography. While breast cancer does occur in very young women, there is general agreement that, because of its low incidence in this population, screening for all women in their 20's or 30's is not warranted. So we are left with the issue of women age 40 to 49. As a woman enters her forties, she is beginning to move from a time when regular population screening is not warranted to one where it is proven to be beneficial. The question is where that line is crossed. Is it age 40? Age 42? Age 46? Or Age 50?

Rather than concluding that there is only one right answer to the question, the Panel concluded that each woman should make an informed decision in the transition decade of her forties that is the right answer for her. Despite some press accounts, I stated at the end of the conference that I agreed with this conclusion of the Panel. My concern was with

the balance and tone of the discussion in the Panel's draft report. It is my opinion that the draft report of the Panel overly minimizes the benefits and overly emphasizes the risks for this population. A balanced statement of the pros and cons of screening is essential for a woman to make an informed decision whether to initiate regular mammography in her forties.

Do we now have evidence that would support a woman's decision if she decides to begin screening mammography in her forties? The best data we have is from 8 randomized clinical trials involving about 180,000 women, including the 5 Swedish studies. Few trials have enough instances of death from breast cancer to achieve statistical significance, but analyzed all together, by a procedure called meta-analysis, there is about a 15 percent reduction in mortality. The meta-analysis included eight randomized clinical trials that were conducted over the past 30 years from the United States, Sweden, Canada and Great Britain. I would be happy to discuss the interpretation of these studies in the question period. What does this mean to an individual woman? In general, a woman in her forties has a 1 in 66 chance of being diagnosed with breast cancer and about 1 chance in 190 of dying of breast cancer that develops in that decade. A 15 percent reduction would lower these odds of dying to about 1 in 220.

What does this mean? This year, over 30,000 women in their forties will be diagnosed with breast cancer and a 15 percent reduction in mortality would mean over 1600 lives saved. This year, about 27,000 women in their fifties will be diagnosed with breast cancer and over 3300 lives would be predicted to be saved via mammographic screening in that age group.

Why would a woman choose not to have a mammogram? What are the limitations and downsides of mammography? The first relates to false positives and the medical procedures involved in follow-up of the false positives. If women were to receive yearly mammograms for 10 years, it is estimated that as many as 30 percent of all women will have an apparent abnormality detected. An estimated one-fourth of these will result in biopsies and, for women in their 40's, only about one-fourth of these biopsies will prove to be cancer. In other words, most abnormal mammo-grams do not signify cancer. Beyond false positives, mammography may miss up to 25 percent of breast cancer in young women, a percentage that falls to 10-15 percent in older women (i.e., women over age 50).

What about the risks of radiation? This is a theoretical concern, but it is based largely on exposure to very high doses of radiation and in much younger women. While the risks of radiation should not be completely dismissed, there is no direct evidence that exposure of women in their 40's to the levels of radiation used in mammography causes breast cancer or poses any other health risk.

Where then do we go from here?

The National Cancer Advisory Board will discuss the issue of screening mammography of women in their forties in order to provide guidance to the NCI concerning how we

move forward with information, education and research. We must provide information to every woman and her physician or caregiver and to ensure that such information is accurate, current and user-friendly.

The NCI has long funded vigorous programs in digital mammography, in image analysis, and in non-ionizing approaches to cancer imaging such as ultrasound, MRI, optic scanning, microwaves, and other technologies. Dr. Blumenthal will describe some of these efforts in her opening statement.

The NCI will continue its long-standing commitment to support research in new modalities of imaging and molecular detection, and we must strive to enhance the value and reduce the limitations and problems of current mammography. The NCI, CDC and DoD are supporting the Breast Cancer Surveillance Consortium, a national mammographic screening and outcome database which, by the year 2000, will include over 1.8 million screened women and provide valuable data to improve the practice, interpretation, delivery and follow-up of mammography in this country.

Mammography is not a cure for breast cancer. Better screening methods will not ever replace the need to find real preventions and curative therapies. Mammography has an important place in our current approach to breast cancer, but we tend to overestimate its benefits. We must remember that 70 percent of breast cancer deaths in women over 50 will still occur even with regular mammography. We must be relentless in our search for a cure.

Women deserve to be active and educated participants in their own health care decisions, and we cannot produce certainty where it doesn't yet exist. Physicians and scientists must be active partners with consumers to use both the best evidence and the best judgment to help each woman reach a decision that is right for her. Based on current evidence, we must inform women about the pros and cons for initiating screening in their forties. We must be wholeheartedly committed to helping each woman weigh these pros and cons as a critical part of her health care.

Thank you. I would be pleased to answer any questions.