Testimony of the American College of Obstetricians and Gynecologists (ACOG)

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"Making Sense of the Mammography Controversy: What Women Need to Know"

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My name is Carolyn D. Runowicz, and I appreciate your invitation to testify today. I appear before you on behalf of the American College of Obstetricians and Gynecologists (ACOG), and as a practicing physician who is no stranger to dealing with concerned patients when scientific controversies raise questions about their health and safety. In this particular debate, I also wear a third hat: I am a 10-year breast cancer survivor.

The American College of Obstetricians and Gynecologists (ACOG) represents nearly 40,000 physicians dedicated to improving women's health care. Ninety-five percent of board-certified obstetricians and gynecologists in the United States are members of ACOG. Our members are seeing women on the front lines of the breast cancer struggle: we provide women with clinical breast exams, refer them most often for mammography, and often make the diagnosis. Some of us, like myself, are gynecologic oncologists and assist in treatment plans.

I am currently Vice Chair of the Department of Obstetrics and Gynecology at St. Luke's-Roosevelt Hospital in New York City. I also serve as Director of Gynecologic Oncology Research for the Women's Health Service Line of Continuum Health Partners, Inc. and I am Professor of Obstetrics, Gynecology and Women's Health at Albert Einstein College of Medicine (AECOM). Since 1994, I have chaired the gynecologic subcommittee of the Breast Cancer Prevention Trials that are part of the National Surgical Adjuvant Breast and Bowel Project.

ACOG agrees that an extensive and objective reassessment of all mammography data may be justified. In fact, ACOG continually updates its own clinical recommendations by periodically reviewing all data. Until further reanalysis of the data is conducted, ACOG continues to recommend mammography screening every one to two years for women in their forties and annual mammograms beginning at age 50.

We are here today because of publicity surrounding a study done by Danish researchers, members of the Cochrane Collaboration, recently published in *Lancet* (referred to here as the *Lancet* study). The *Lancet* study questions one of the most widely held beliefs in preventive medicine: that screening healthy people for cancer and detecting it early saves lives. It is important to note that this is not a new study, but a re-analysis of published data.

Scientific debate on critical issues like this one is common. ACOG supports periodic, evidence-based, peer-reviewed analysis of all available data on mammography—including a review of studies like the one in *Lancet.* We take its criticism of prior mammography research very seriously, and we want to make sure the *Lancet* study itself stands up to rigorous review.

In fact, the U.S. Preventive Services Task Force (USPSTF) announced last week a different conclusion than that of the *Lancet* study. The USPSTF review of the

data found that the pooled effect size of the combined trials was sizable and statistically significant. Breast cancer death among women randomized to screening in seven trials that included women older than 50 showed a 23% reduction in mortality.

In addition, an earlier independent analysis of individual-level data from the five Swedish trials cited in the *Lancet* study, conducted under the auspices of the Swedish board of health and published in 1993, showed a statistically significant 24% reduction in breast cancer mortality in the screened group.

With such conflicting data, where do we go from here?

Initially, I think all of us – members of Congress, doctors, patients, journalists, or researchers—need to understand the difference between the very rigorous standards that scientific evidence must meet to clearly prove the worth of a test, and the practicalities of what must be done in physicians' offices when conclusive scientific evidence (1) is not yet available, or (2) may never be available.

I make this second point because at this time and in the future there would be clear ethical and moral problems in performing the randomized, prospective clinical trials in breast cancer screening that medical scientists say are the highest quality of scientific proof. I ask you: how many women today would be willing to go without breast cancer screening in a clinical trial to prove or disprove a medical researcher's point? We may have to live with a certain amount of uncertainty, when it comes to the results of mammographic screening trials.

I also think we need to educate our patients about the facts behind the recent media hype on the usefulness of mammography. While the *Lancet* study has raised several important issues and I am very interested in the scientific debate, as a practicing physician I have to look at this through the eyes of individual patients.

It is important to explain to our patients that this debate has nothing to do with the effectiveness of breast cancer treatment. There is agreement that treatment saves lives. Instead, the debate is whether earlier treatment made possible by early detection of tumors is better than later treatment.

Then I explain why I believe that early treatment does make a difference. I am very careful to explain to women that early diagnosis combined with early treatment translates for many women into a better future. I believe that early detection in most cases helps us to prolong women's lives, even those destined to die from breast cancer. Early diagnosis can affect the quality of women's lives in positive ways.

I explain why I think the accumulation of research trial evidence over the years has strengthened the science behind breast cancer screening. There has been

an important decline in death rates from breast cancer, nearly 2% every year during the 1990s and nearly 4% since the mid-90s, which has been attributed to improvements in treatment and a trend towards earlier detection. In the 1980s, only 13% of U.S. women were getting mammograms and the average size of tumors was 3cm. By the late 1990s, 60% of women were having regular mammograms and the average size of tumors decreased to 2cm.

So, I note that although mammography is not a perfect screening tool, it is very effective. Mammography can have false-positive results, which may cause anxiety, biopsies, and cost – although these diminish from ages 40-70. However, the data in aggregate demonstrate improved health outcomes, with benefits outweighing the harmful effects.

I discuss the controversy and my own recommendations noting of course that the decision on whether to be screened is theirs. I explain that scientific debate on critical issues is common, but well-established guidelines should be followed unless there is compelling evidence to alter or abandon them.

The news stories have already had a large impact on patients. They are confused and express a loss of faith and confidence in mammography. Some misinterpret the media coverage and take away the message that mammography is “bad” and can even cause cancer!

Over the years, we have made significant strides in educating women about mammography by breaking down financial, physical, and psychological barriers to women seeking mammography screening. I fear that existing barriers and negative attitudes towards mammography might be reinforced by the negative attention and uncertainty generated by the media hype. It is too soon to know if women will turn away en masse from mammography and we will turn the clock back in the fight to treat breast cancer. I am also deeply concerned that the ongoing controversy about the value of screening mammography might discourage health insurance plans from covering this important screening tool.

As frustrating as this controversy may be to the women suffering from breast cancer, the silver lining is that it brings to light a goal I think we all share: the need to be even more vigilant in supporting research efforts to enhance not just early detection but also treatment, as well as prevention and finding a cure for breast cancer. Until then, mammography remains as one of a *number* of strategies that can help save or improve women’s lives.

Even if the screening tests we have now are not as good or as conclusive as we would like, they are the best we have at the moment. As a practicing physician, I would be derelict in my duties if I advised women to stop having mammograms.

On behalf of ACOG and my patients, I thank you for holding this hearing and for the opportunity to testify today. I am happy to answer any questions.