Testimony of Diana Zuckerman, Ph.D.
Submitted to
Senate Health, Education, Labor & Pensions Committee
Public Health Subcommittee

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My name is Dr. Diana Zuckerman and I am president of the National Center for Policy Research for Women & Families. Our organization is a nonprofit think tank dedicated to improving the lives of women and families by explaining and disseminating medical and scientific research information.

The Breast Implant Research and Information Act, S.961, calls for more research on breast implants, and I would like to tell you why this bill is so essential.

Breast implants have been sold in this country for almost 40 years, but we still know very little about their long-term health risks. In fact, almost a million women had breast implants before the first epidemiological study was published about health risks. Before then, there were just a few studies of rats and dogs, but no published studies of human beings.

In 1990, as a scientist working on what is now the House Committee on Government Reform, I started an investigation of the FDA's regulation of breast implants. We found that the FDA had ignored the concerns of its own scientists by allowing the sale of breast implants without requiring that the manufacturers prove that implants were safe. As a result of our hearing, the FDA finally required the manufacturers to submit studies of silicone gel implants. Unfortunately, those studies were so badly designed that they could not prove whether or not implants were safe.

In response to pressure on both sides, the FDA did something they almost never do – they refused to approve implants but allowed them to stay on the market as a "public health need." I think the last two months have shown us what a true public health need is – and breast augmentation does not qualify. But, at the time, there were fewer options for breast cancer patients than there are today, and the FDA was reluctant to make a different standard for augmentation patients – who comprise 80% of implant patients. Congress went along with the FDA decision, but required the NIH to conduct long-term research.

There were no studies of women with implants in 1990, but quite a few epidemiological studies have been conducted since then. I have carefully studied all of them. Despite what you may have heard in the media, the research and the report by the Institute of Medicine does not conclude that implants are safe – to the contrary, they show many serious problems related to implants, such as infections and the need for multiple surgeries.

Recently, three major new studies reported that women who have breast implants are at significant risk for several debilitating and fatal diseases.

One study, conducted by researchers at the National Cancer Institute (NCI) reported that women with implants were likely to die from brain cancer, lung cancer, other respiratory diseases, and suicide compared to other plastic surgery patients.

A second study, also by NCI, reported that women with breast implants are more likely to develop cancer compared to other women their age.

Both of these studies were of women who had either silicone or saline breast implants for at least 8 years. In contrast, the studies that have shown no increase in disease for women with implants included many women who had implants for very short periods of time – even as short as one month. Obviously, cancer and autoimmune diseases do not develop that quickly.

A third study, conducted by scientists at the FDA, found that women with leaking silicone gel breast implants are more likely to have several painful and potentially fatal autoimmune diseases. Implants were found to be increasingly likely to break as they got older, and most implants were broken by the time there were 10-15 years old. This study may provide an important clue: It is possible that illnesses reported by women with implants are a result of leaking implants – which would explain why most women do not have systemic health problems until after they have had implants for several years.

At the same time that these new studies were released, the plastic surgery organizations announced that almost 300,000 American women got breast implants last year, most of them for augmentation. Although they don't boast about it, these statistics also show that the number of teenage girls getting implants has more than doubled in the last 3 years.

These three new studies remind us that, although relatively few women become ill after having implants for a year or two, we need to be concerned about the long-term dangers. Women who are considering implants deserve to be accurately informed about the risks – what is known, and what is not known. And yet, hundreds of thousands of women are deciding to get implants because they mistakenly believe that implants are proven safe for long-term use.

The two studies conducted by NCI were mandated by Congress. They were designed to answer two essential questions:

1. do breast implants have health risks and
2. do women with implants die at a younger age than they otherwise would have?

These are still the essential questions and that is the purpose of S. 961. I am especially pleased that this legislation requires studies of women with implants after mastectomies. It is unfortunately true that not one single breast cancer patient was included in the studies that the federal government has conducted thus far. I want you to know that Congress requested that mastectomy patients be included in those studies, but the head of the NIH at the time, Dr. Bernadine Healy, refused. It's too late to fix those studies, but it is absolutely essential that studies of reconstruction patients be conducted as soon as possible. At this point, most of what we know is based on the manufacturers' own studies, which show that more than 70 percent of reconstruction patients have at least one serious complication within three years of getting saline implants, and one in four reconstruction patients need to have at least one additional surgery

within the first three years. We need to know what happens after three years, and we need to tell breast cancer patients about these complications so that they can make an informed decision about what would be best for them.

In addition to new studies, it would be very cost-effective for the NIH to continue to study the breast augmentation patients in the NCI and FDA studies that I described a few minutes ago. At the time the NCI studied the women's medical records, they had implants for at least 8 years. They have now had implants for at least 11 years, so it is important to study what has happened – whether the cancer rates, autoimmune diseases, and death rates of women with implants have increased or decreased in the last three years.

Although I am especially concerned about the lack of information about the long-term safety of reconstruction, I am also concerned about the thousands of teenage girls that are getting breast implants every year. We don't know what will happen to those girls, and unfortunately neither they nor their parents realize how little is known about long-term risks. It is time we answered that question. And S. 961 would help ensure that patients – and teenage patients' parents – know what the risks are before they decide whether or not to get implants.

I hope the Committee will also undertake a careful review of the role of the FDA regarding the lack of long-term safety data on breast implants. Breast implants have been sold for almost 40 years, and yet the FDA has never required long-term safety data. They have not required that patients be informed of the risk of implants. Meanwhile, more than 127,000 adverse reactions have been reported regarding silicone gel implants and more than 65,000 for saline-filled implants – and yet the FDA has not even bothered to examine them. As this Committee considers legislation to reform the FDA in the coming year, I urge you to include a provision requiring long-term safety data for implanted medical devices that are already on the market. This is not like a new medical product: women who have had implants for many years are available to be studied, and the FDA should be mandated to do so.

I invite you and your staff to go to our website, www.center4policy.org, to read some of the medical and lay articles that we have written on the topic, and to link to FDA's consumer materials about breast implants.

Footnotes:

Brinton LA, Lubin JH, Burich MC, Colton T, Hoover RN. Mortality among augmentation mammoplasty patients. Epidemiology. 2001; 12:321-326.

Brinton LA, Lubin JH, Burich MC, Colton T, Hoover RN. Cancer risk at sites other than the breast following augmentation mammoplasty. Ann Epidemiol. 2001; 11:248-256.

Brown SL, Pennello G, Berg WA, Soo MS, Middleton MS. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. *J Rheumatol*. 2001; 28:996-1003.

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The Honorable Edward Kennedy
The Honorable Tom Harkin
U.S. Senate
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Dear Chairmen Kennedy and Harkin:

On behalf of the National Center for Policy Research for Women & Families, I would like to thank you for holding this important hearing, "Addressing Unmet Needs for Women's Health."

One of the greatest (but rarely discussed) obstacles facing women today is that the quality of health care is often dependent not just on their income and insurance, but on their age, race, what part of the country they live in, and the kind of medical facilities they use. Women rely on their doctors, and also sometimes on articles, advertisements, and on their friends and relatives to provide them with all the information they need to make a decision about their treatment options. That is why it is so important to make sure that information about the safest and most effective treatments is widely available to physicians and consumers.

That is why we enthusiastically support S. 946, the Women's Health Office Act of 2001. The Office on Women's Health of the U.S. Department of Health and Human Services and the offices within the HHS agencies have helped the federal government focus on health issues of great importance to women, and to make that information widely available. Providing greater resources and statutory authority to the Office of Women's Health at HHS, as well as its offices at the Centers for Disease Control, Agency for Healthcare Research and Quality, the Health Resources and Services Administration, and the Food and Drug Administration is of fundamental importance to women across the country. These agencies provide a valuable service in researching and promoting women's health, and they deserve the strongest possible support.

I'd like to share an example of why these offices are so essential.

Breast cancer screening and research are extremely important, but there is growing evidence that many breast cancer patients in the U.S. are not getting the medical care that they need. For example, experts agree that for most early-stage breast cancer, lumpectomy (which removes the cancer and surrounding tissue) is just as safe as mastectomy (which removes the entire breast), if the lumpectomy is followed by radiation treatment. However, one out of every two women who experts would consider eligible for lumpectomy will undergo mastectomy instead, in many cases because they are not fully informed of their options. Research indicates that women who live in many regions of the country, and those who are older, less educated, who have older doctors, and who use community hospitals are less likely to have lumpectomies than other women, even if they have the identical diagnosis. And a growing number of women who undergo lumpectomies are not getting the radiation treatment that would great reduce their risk of cancer recurrence.

Breast cancer is a devastating disease, and we believe women should make surgical choices based on whatever is best for them, regardless of where they live, where they receive care, their age and income, and other factors that have nothing to do with their diagnosis or preferences. Our Center brought this issue to the attention of the offices for women's health at HHS, and they have responded enthusiastically to our request to help strategize about how to minimize these treatment disparities. They also came together to support the first national conference on this issue, which we held at NIH in December, and a free booklet for breast cancer patients. This is just one example of how having offices for women's health helps bring together the knowledge and network of researchers and other experts to solve important health problems, and to make that information more widely available.

Unfortunately, the lack of research on breast reconstruction has made it impossible for breast cancer patients to be well informed about the risks and benefits. Many women who undergo mastectomies chose reconstruction with breast implants, never realizing that there is no research on the long-term risks of implants for breast cancer patients. A few months ago, I had the opportunity to testify before the Health Subcommittee of the House Committee on Energy and Commerce in support of HR 1961 and S. 961, the Breast Implant Research and Information Act. I strongly urge your support for this important bill, which calls for more long-term research on the safety of breast implants, as well as informed consent for women considering breast implants. A copy of my testimony is attached.

CPR for Women & Families is a nonpartisan, nonprofit organization that translates medical and scientific research information into information that can be used by policy makers, the media and the public. On behalf of all of us at CPR and the millions of women and families we represent, thank you for your commitment to improving women's health. We hope you will do everything possible to pass both of these bills.

Sincerely,

Diana Zuckerman, Ph.D.
President