Testimony of Pamela Noonan-Saraceni
Patient Representative Regarding Breast Implants
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Mr. Chairman, my name is Pam Noonan-Saraceni. As a breast cancer survivor who continues to endure the painful physical side-effects of silicone breast implants, I am pleased to have the opportunity to take part in this hearing.

Many believe the scientific and safety debate on breast implants is over and are wondering why breast implants are part of today's hearing. You believe this issue has reached its saturation point. But, breast implants remain a classic example of "what we don't know can hurt us."

Consider the number of women who have breast implants. The Institute of Medicine estimates that by 1997, 1.5 to 1.8 million American women had breast implants with nearly one third of these women being breast cancer survivors. In 1999 alone, nearly 83,000 women received implants following a mastectomy. In 2000, over 200,000 women received breast implants for cosmetic reasons.

Yet, in 1999, the Institute of Medicine concluded:

- First, reoperations and local complications are frequent enough to be a cause for concern and to justify the conclusion that they are the primary safety issue with silicone breast implants;
- Second, risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and deficient historically;
- Third, information concerning the nature and relatively high frequency of local complications and reoperations is an essential element of adequate informed consent for women undergoing breast implantation.

And in 1997, the Mayo Clinic found that one in four women required additional surgeries within five years of implantation because of problems related to the implants. The rate was higher for mastectomy patients: one in three women.

Despite over thirty years of use, the Food and Drug Administration has never approved silicone implants and just recently approved saline implants for the first time. Little is known about the long term effects of silicone and even less is known about saline. Yet their popularity is growing with a new generation of young women who, in spite of the past controversy, are being led to believe that improvements have been made to these implants, and therefore, they are now safe.

I believe breast implants should be an option for women. But, a safe option. Therefore, the role of the government cannot be overlooked. There are a number measures that the federal

government could implement to better protect women and preserve their health and their quality of life. These measures are encompassed in the legislation introduced by Representatives Roy Blunt and Gene Green. H.R. 1961, "The Breast Implant Research and Information Act," calls upon the FDA to strengthen informed consent documents given to patients in clinical trials for breast implants; directs the National Institute of Health to conduct independent research desperately needed on breast implant recipients; and ensures better FDA oversight of device manufacturers.

In order to better understand the need for this legislation, I would like to tell you a little bit about my personal experience. I was diagnosed with breast cancer and had a radical mastectomy in 1978. I was just 25 years old at the time. I waited 5 years before I decided to have reconstructive surgery. I was an active person. I played tennis, taught aerobics, and jogged. I had grown tired of the inconvenience of the prosthesis shifting and falling out when I perspired. I thought I had done my homework on breast implants prior to choosing the plastic surgeon to do my reconstruction. However, I was never advised of any of the health risks associated with the implants. In fact I was told repeatedly that they would "last a lifetime" and that "complications" were rare. Within 3 months of the initial reconstruction, I was back in the operating room. My body had formed a capsule around the implant and the implant had shifted up toward the collarbone. My symptoms of physical illness began slowly. In the summer of 1990 I began to experience joint pain and chronic fatigue. This was six years after my being implanted. I have been to various doctors and specialists and have a list of various diagnoses. Before I had the implant removed in June of 1994 (10 years after the initial reconstruction), I had to wear a partial prosthesis over the implant. Capsular contracture had again become a problem and I was misshapen and lopsided. The explantation was the 5th surgery at my breast site.

To date, my out of pocket medical expenses total almost $35,000. My husband and I are self-insured. The insurance policy that we took out in 1991 had an exclusion. I was not covered for any illness or disabilities related to the reconstructive surgery. Apparently, the insurance companies understood the health risks breast implants pose for women and were not willing to bear the financial costs.

I believe there are several areas that need improvement in order to protect women considering breast implants. The Breast Implant Research and Information Act, introduced by Senator Boxer and Congressmen Gene Green and Roy Blunt, is a tremendous step forward to safeguarding American women.

First: Informed Consent Must Be Strengthened

Insufficient and inaccurate information has posed many problems for women in breast implant trials. Even the Institute of Medicine recognized that women are not being adequately warned of rupture, painful local complications and multiple surgeries.

The informed consent agreement drawn up by the breast implant manufacturers is the only required information women receive about the implants and the study prior to surgery. This document contains inaccurate data on rupture and contracture rates, the efficacy of the implants, the risks and complications, and the need for future reoperations. It understates the FDA's concern about the safety of silicone breast implants, which first led to the 1992 moratorium, and makes many misleading statements about the rate of complications following implantation.

Furthermore, the informed consent agreement does not mention the effects of breast implants on future mammography. This is probably not a concern most cosmetic patients even consider. Yet, over 30% of the breast tissue can be obscured by the implant, which can delay the detection of cancer.

Until independent research is able to answer the long-term safety questions surrounding breast implants, women, at the very least, need to be informed about what we DO know:

- chronic pain, breast hardening, infections and breast deformity;
- the high rate of reoperations;
- the high rate of ruptures;
- problems associated with insurance coverage;
- the fact that implants do not last a lifetime and will have to be replaced every 8-10 years;
- inaccurate mammography.

Second: The Need for Long-Term Studies

The Breast Implant Research and Information Act directs the National Institutes of Health to conduct the independent research that is so desperately needed in this area. The lack of convincing data submitted by the manufacturers or the plastic surgeons on the incidence of device failure, implant rupture or gel bleed was of concern to the FDA in the early 1980s so much of a concern that an FDA panel headed by Dr. Norm Anderson recommended that silicone breast implants remain a Class III device, meaning their safety and efficacy was not proven.

Once product liability cases involving silicone breast implants became more and more common, the manufacturers began to pour money into new scientific research on breast implant safety. Dr. Anderson implored the manufacturers to put their money into an independent fund so that impartial scientists could decide which issues should be examined. His wish was not granted, and the ensuing research in large part ignored long term outcomes, incidence of device failure, the consequences of implant rupture, and the causes for tissue pain.

The latency period for breast implant complications and ruptures has been widely recognized in scientific circles. I had my implants for six years before my symptoms began to appear. But, the FDA only required manufacturers to follow women in saline implant trials for three years, and the agency recently announced that manufacturers of silicone breast implants will only be required to follow patients for 2 years in order to glean data for market approval. These studies will not provide meaningful data on the long-term safety and efficacy of the implant, and will do little to protect American women in the long run.

In its review of breast implant studies, the Institute of Medicine also concluded, "risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and are deficient historically."

In May of 1999, University of Florida researchers published their analysis of more than 35 studies, which examined more than 8,000 implants. According to this analysis, silicone breast implant rupture rates were found to be 30% at 5 years, 50% at 10 years and 70% at 17 years. According to the researchers, past studies that have been cited in support of silicone breast implant safety have "paid almost no attention to the health consequences of local complications

of pain, capsular contracture, disfigurement, chronic inflammation, rupture, silicone migration, and frequent surgical revisions." They conclude that the longer women have these devices in their bodies, the greater the risk of failure and numerous complications.

This study and the IOM review reinforce the need to study women for a long period to accurately assess the health effects of breast implants.

Furthermore, almost no research has been done to track mastectomy patients who suffer from local complications at a higher rate than other breast implant recipients.

I hope one day there is a cure for breast cancer. But until that day, the National Institutes of Health should be obligated to conduct the independent research so badly needed on breast implants. No woman should be put in a position of surviving breast cancer only to experience chronic pain, infections, or deformities from breast implants.

Conclusion

When I opted for reconstructive surgery using breast implants, I thought I had made an informed decision. I asked questions of my doctors; I read as much information as was available in 1983. I thought I was making a safe choice for myself. Almost immediately, I was back in the operating room. It took six years before I began to experience unusual and chronic pain in my joints. A series of doctors diagnosed me with several different illnesses, and I underwent two additional surgeries. Finally, ten years after my initial implantation, I had the implants removed and my symptoms began to improve.

Despite the breast implant manufacturers advertisements, breast reconstruction is *not* an essential part of the recovery process; being cancer free and feeling physically well enough to return to a normal life *is*. Had I known the additional physical, emotional and financial hurdles I would have to overcome due to breast implants, I would have made a different decision. I would have never chosen implants.

My personal story and what I've learned from the experiences of women like me across the country and around the world is my only breast implant expertise. I feel a tremendous responsibility to increase awareness about the unanswered safety questions that still surround breast implants. My hope is that other women, when faced with the same choices, can make their decisions based upon better informed consent and independent research. Please support the passage of S.1961, the Breast Implant Research and Information Act.

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