

that Mary Nell began what would become a lifetime commitment to volunteerism. Her unwavering support for fellow Americans is reflected in her activities that included volunteering her time at recruiting stations and at Cardinal Spellman's Foundling Home in New York.

At the end of World War II, she moved to New York City, where she defied the limits that hindered the progress of women in the workforce. By rising to positions of authority and respect in prominent companies such as American Cynamid and Alexander's Department Store, Mary Nell served as an inspiration to countless women who made the decision to pursue a professional career.

Upon her return to Missouri, Mary Nell continued her pursuit of knowledge and graduated from the University of Missouri-Columbia with a degree in Business Administration. Since that time, she has focused her efforts on a passion for music and joined the Women's Symphony League, Friends of Music of the University of Missouri, the University of Missouri's Arts & Sciences Alum Association Board and later served on the Missouri Symphony Society Board of Directors.

Mary Nell's time, energy and generous spirit have been invaluable to the Missouri Symphony Society as well as the Missouri Theatre. She has been critical in the creation of a thriving arts community in my hometown of Columbia. I am eternally grateful for her devotion to our community, and it is my pleasure to share Mary Nell Porter's accomplishment and valuable contributions with my colleagues.

THE UNITED STATES COMMISSION  
ON AN OPEN SOCIETY WITH SECURITY ACT

**HON. ELEANOR HOLMES NORTON**

OF THE DISTRICT OF COLUMBIA  
IN THE HOUSE OF REPRESENTATIVES  
*Wednesday, April 6, 2005*

Ms. NORTON. Mr. Speaker, today, I reintroduce the United States Commission on an Open Society and Security Act, expressing an idea I began working on when the first signs of the closing of parts of our open society appeared after the Oklahoma City bombing tragedy, well before 9/11. This bill has grown more urgent as increasing varieties of security throughout the country have proliferated without any thought about their effect on common freedoms and ordinary access. The bill I introduce today would begin a systematic investigation that takes full account of the importance of maintaining our democratic traditions while responding adequately to the real and substantial threats terrorism poses.

To be useful in accomplishing its difficult mission, the commission would be composed not only of military and security experts, but for the first time, they would be at the same table with experts from such fields as business, architecture, technology, law, city planning, art, engineering, philosophy, history, sociology, and psychology. To date, questions of security most often have been left almost exclusively to security and military experts. They are indispensable participants, but these experts cannot alone resolve all the new and unprecedented issues raised by terrorism in an open society. In order to strike the balance required by our democratic traditions, a cross

cutting group needs to be working together at the same table.

For years now before our eyes, parts of our open society have gradually been closed down because of terrorism and fear of terrorism—whether checkpoints at the Capital even when there are no alerts or applications of technology without regard to their effects on privacy. However, particularly following the unprecedented terrorist attack on our country, Americans have a right to expect additional and increased security adequate to protect citizens against this new frightening threat. People expect government to be committed and smart enough to undertake this awesome new responsibility without depriving them of their personal liberty. These years in our history will long be remembered by the rise of terrorism in the world and in this country. As a result, American society faces new and unprecedented challenges. We must provide ever-higher levels of security for our people and public spaces while maintaining a free and open democratic society. As yet, our country has no systematic process or strategy for meeting these challenges.

When we have been faced with unprecedented and perplexing issues in the past, we have had the good sense to investigate them deeply and to move to resolve them. Examples include the National Commission on Terrorist Attacks Upon the United States (also known as the 9/11 Commission), the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction (also known as the Silberman Robb Commission) and the Kerner Commission following riotous uprisings that swept American cities in the 1960's and 1970's.

The important difference in the Commission proposed by this bill is that it seeks to act before a crisis in basic freedoms gradually takes hold and becomes entrenched. Because global terrorism is likely to be long lasting, we can not afford to allow the proliferation of security that most often requires no advance civilian oversight or analysis of alternatives and repercussions on freedom and commerce.

With only existing tools and thinking, we have been left to muddle through, using blunt 19th century approaches, such as crude blockades and other denials of access, or risking the right to privacy using applications of the latest technology with little attention to privacy. The threat of terrorism to our democratic society is too serious to be left to ad hoc problem-solving. Such approaches are often as inadequate as they are menacing.

We can do better, but only if we recognize and then come to grips with the complexities associated with maintaining a society of free and open access in a world characterized by unprecedented terrorism. The place to begin is with a high-level presidential commission of wise men and women expert in a broad spectrum of disciplines who can help chart the new course that will be required to protect both our people and our precious democratic institutions and traditions.

THE SAFETY OF SILICONE BREAST IMPLANTS

**HON. CHARLIE NORWOOD**

OF GEORGIA  
IN THE HOUSE OF REPRESENTATIVES  
*Wednesday, April 6, 2005*

Mr. NORWOOD. Mr. Speaker, in addition to my remarks today, I am also submitting a letter written by Dr. Scott Spear to the Senate Health Education Labor and Pensions Committee and the House Energy and Commerce Committee. In it, Dr. Spear, who is the President of the American Society of Plastic Surgeons, brings to light an important health issue that the Food and Drug Administration (FDA) is currently debating: the safety of silicone gel-filled breast implants. The FDA's General and Plastic Surgery Devices Panel has scheduled an upcoming hearing that will focus primarily on the safety of these products for the American consumer. The information that Dr. Spear shares in his letter is important for us to take note of as this panel continues its work to make an informed, science-based decision on the safety of these implants. In addition, I am submitting for the RECORD a pamphlet entitled *Safety of Silicone Breast Implants* that reviews the long term studies that have been performed on silicone gel-filled breast implants. Taken along with Dr. Spear's letter, this brochure makes a compelling argument that in determining the very real and unquestionably important issue of determining the safety of these implants, we must set preconceived notions aside, and ensure that science dictates our actions. I urge my colleagues to review these two documents and I encourage you to join me in supporting the unbiased and open-minded work of the FDA panel as it determines the safety of silicone gel-filled breast implants for American consumers.

MARCH 4, 2005.

*U.S. Senate Health, Education, Labor, and Pensions Committee, U.S. House Energy and Commerce Committee, (Members and Health Legislative Assistants).*

DEAR SENATORS: The Food and Drug Administration (FDA) is conducting an ongoing regulatory process regarding breast implants, which the American Society of Plastic Surgeons (ASPS) fully supports. As physicians and patient advocates, we support sound science and have confidence that the FDA will review valid scientific data and make its decisions based on the best interests of patients. Moreover, we believe a strong post-market surveillance process will serve the best interests of our patients.

As part of this process, the FDA's General and Plastic Surgery Devices Panel will be conducting hearings on April 11-13 regarding the pre-market approval (PMA) applications of two manufacturers' silicone gel-filled breast implants. The FDA appointed panel represents areas of expertise and judgment relevant to the product under review including academicians in specific fields, such as from radiology, oncology, biostatistics, ethics, plastic surgery, general surgery and other disciplines. Each panelist is rigorously screened and cleared by the FDA in advance of their participation. Historically, panelists have been permitted to engage in educational activities promoting patient care. These activities have not been deemed conflicts of interest. Anti-breast implant advocates continue to raise this issue to discredit qualified and reputable clinicians.

As a matter of background, the FDA's General and Plastic Surgery Devices Panel conducted a similar hearing in October 2003. The

hearings were conducted in a highly open and transparent process, with more than 20 hours of public testimony and signification deliberation. Ultimately, the 2003 Advisory Panel recommended approval of the device with a number of conditions. The conditions outlined by the panel include development of a model informed consent form, patient education, surgeon education, patient follow-up and exams, annual reports to FDA, implant retrieval testing, a breast implant registry, and recommendation for removal of ruptured implants. In January 2004, the FDA decided to postpone action pending submission of additional manufacturer data outlined in a revised draft guidance to be addressed at this subsequent panel hearing.

Given the level of interest in the FDA's review of silicone breast implants, it is important that Members of Congress are provided accurate and science-based information concerning these medical devices.

#### PATIENT SAFETY

The ASPS believes that the FDA's scrutiny of this product is appropriate to ensure patient safety. We are not interested in supporting any device that is not proven safe. In 2000, the Institute of Medicine (IOM) issued an exhaustive report that reviewed and analyzed the scientific literature on silicone breast implants. The IOM concluded that there is no link between silicone breast implants and systemic disease. The primary safety issues for women who choose breast implants are local in nature and include the following complications: (1) Capsular contracture or tightening of natural scar tissue around the implant (contracture is unpredictable and, when severe, may require corrective surgery); (2) Implant rupture, which carries risk of additional surgery for replacement; and (3) Infections associated with breast implants, which are generally not common. The IOM report noted that while breast implants have improved over time, patient safety issues associated with local complications require additional research. The ASPS has supported and is supporting continued research in these and other areas.

Our clinical experience over 35 years with breast augmentation surgery shows an excellent track record and the demand for breast augmentation surgery has grown steadily with nearly 250,000 procedures performed in 2003. The ASPS believes that an important component of patient safety and satisfaction with breast augmentation depends on patients being fully informed about both the benefits and risks of the surgical procedure. Consequently, ASPS has developed a comprehensive document that covers all of the risks and potential complications in breast implant surgery for plastic surgeons to use when discussing the procedure with their patients.

#### CHOICE

Currently saline-filled breast implants, approved by the FDA in 2000, are the only implants available for general use in breast augmentation. Silicone gel-filled implants may only be used in clinical trials for reconstructive breast surgery and limited clinical trials for breast augmentation. The FDA's device approval process will determine whether requirements for safety and efficacy have been met and whether women should have additional choices regarding the type of implants they may select for breast surgery. The implant type that provides the best aesthetic outcome depends on a variety of individual patient factors. In all cases, patient safety and informed decision making should be primary considerations in selecting a particular type of implant.

Like other implantable medical devices, breast implants may not last a lifetime. Hundreds of thousands of women understand

this fact and still choose to undergo breast implant surgery. Current research shows that an overwhelming majority are happy with their decision.

#### HISTORY/SCIENCE

It is important to distinguish between anecdotal and scientific evidence with regard to breast implants. Anecdotal evidence and junk science do not provide valid contributions to the review and analysis of this device. Plastic surgeons actively support valid scientific research on the safety and efficacy of breast implants, as well as the psychological impact of breast augmentation. The following are select areas of scientific research that Congress should be aware of in relation to breast implants.

The National Academy of Sciences' Institute of Medicine report, issued in 2000, found no scientific evidence of an association between silicone breast implants and disease; the report represents a comprehensive and unbiased review of breast implant safety by top experts in a variety of medical fields. *Safety of Silicone Breast Implants*, Institute of Medicine, National Academy Press, 2000.

Recent studies about suicide among Scandinavian women who have breast implants warrant further investigation. Suicide is a very complicated problem with many contributing factors; biological, genetic, social and cultural. It is important to note that the recent studies do not show a "cause and effect" relationship between breast implants and suicide. Plastic surgeons and the medical community in the U.S. have studied breast implants, breast augmentation patients, and breast reconstruction patients for more than 30 years with no indication of a relationship between breast implant surgery and suicide. Further investigation of this issue is appropriate. Mortality among augmentation mammoplasty patients. *Epidemiology*. 2001; 12:321-326. Total and cause specific mortality among Swedish women with cosmetic breast implants: prospective study. *Brit Med j*. 326:527-528, 2003.

The National Institutes of Health (NIH) issued a report to Congress in May of 2003 on the status of its research on the long-term health effects of breast implants. The report stated that there was not sufficient evidence to support any relationship between breast implants and connective tissue disorders. The NIH report also cited a recent National Cancer Institute (NCI) finding that women with breast implants showed a slight decrease in the risk for breast cancer. *National Institutes of Health. Breast implants: status of research at the National Institutes of Health*, May 2003.

Since the Institute of Medicine report in 2000, numerous studies have been conducted which investigate the purported connection of breast implants to cancer. However, researchers have consistently found no persuasive evidence of causal association between breast implants and any type of cancer. *Breast Implants and Cancer: Causation, Delayed Detection and Survival*, May, 2001 *Plastic and Reconstructive Surgery*.

In 2000, the Plastic Surgery Educational Foundation established the National Breast Implant Registry (NaBIR). It was founded to collect and analyze data regarding breast implant surgery to further understand the risks and benefits of this procedure. To date more than 21,000 women have registered with NaBIR and there are 316 surgical facilities entering data. We believe that NaBIR is quickly becoming a world standard for an electronic breast implant registry, as it is being considered in a number of European and Latin American countries. In December of 2002, the European Union mandated that participating countries implement breast implant registries by 2004; Denmark, Eng-

land, Finland, and Germany have already implemented programs. Australia and Brazil have also implemented registries.

The ASPS and its members support sound science and have been leaders in the research on the safety and efficacy of breast implant surgery. Our primary concern is the safety of our patients and we are strongly interested in the collection of accurate and reliable data pertaining to breast implants. We recently launched the medically-grounded online resource for women and other concerned parties, [www.reastimplantsafety.org](http://www.reastimplantsafety.org). We encourage you to visit the site for the latest information on breast implants and patient safety. We believe that the upcoming hearing of the FDA General and Plastic Surgery Devices panel will again be rigorous and the panel deliberations will be largely based on the findings of science, rather than emotion and anecdote.

The ASPS has offered to work with the FDA, public, and manufacturer in order to address many of the conditions attached to the panel's affirmative recommendation. Specifically, the panel recommended that the manufacturer work with professional organizations to create patient and surgeon education materials, a model informed consent form, and establish a breast implant registry and we are responding to that call. We hear stories every day of women whose lives have been dramatically improved with the use of this device. We are hopeful that the FDA's regulatory review process can continue moving toward a conclusion based on science.

Sincerely,

SCOTT L. SPEAR, MD,  
ASPS President.

#### SAFETY OF SILICONE BREAST IMPLANTS

##### BACKGROUND

In October, 2003, the General and Plastic Surgery Devices Panel convened by the Food and Drug Administration (FDA) concluded that there was a dearth of long-term safety data related to silicone breast implants. Contrary to this contention, there are in fact almost 100 published papers in the peer-reviewed biomedical literature assessing long-term effects of cosmetic breast implants, virtually all of which are reassuring in their lack of evidence for adverse effects.

Concerns about a link between silicone breast implants and various adverse health outcomes were initially raised in the 1980's and early 1990's by anecdotal case reports. However, as unanimously concluded by several independent expert review committees by the late 1990's,<sup>1-5</sup> these alleged health risks have not been supported by the numerous analytic epidemiologic studies of cosmetic breast implant recipients. Since publication of these independent reviews from various countries, including the United States, a large number of long-term cohort studies of connective tissue diseases, undefined connective tissue disease, cancer, neurologic disorders, mother-offspring effects and mortality have been published.<sup>6-38</sup>

##### CONNECTIVE TISSUE DISEASE

More than 20 case-control and cohort investigations have been conducted in in North America and Europe to evaluate the potential association between cosmetic silicone breast implants and the occurrence of CTDs. Initially, the primary concern was the occurrence of systemic sclerosis, although these epidemiologic studies have examined the occurrence of numerous other CTDs. The published case-control studies,<sup>39-49</sup> and cohort studies,<sup>6,18,35,37,50-59</sup> many of which have been large, long-term follow-up studies, have been remarkably consistent in finding no evidence

of an association between silicone breast implants and any individual CTD or all established CTDs combined. Moreover, meta-analyses, weight-of-the-evidence, and critical reviews have unanimously concluded that there is no evidence of an association between breast implants and any of the CTDs evaluated individually or combined.<sup>2-5,60-66</sup>

#### "ATYPICAL:" CONNECTIVE TISSUE DISEASE

An association has also been hypothesized between silicone breast implants and some new "atypical" disease, which does not fulfill established diagnostic criteria for any known CTD and may bear some resemblance to fibromyalgia.<sup>67</sup> Those studies which did include undefined CTD as an outcome, many of which have been large, long-term follow-up studies, have been strikingly consistent in finding no convincing evidence of an association between silicone breast implants and atypical connective tissue or rheumatic disease.<sup>2,5,6,8,14,18,24,46,68</sup>

#### FIBROMYALGIA

In 2001, Brown et al.<sup>35</sup> reported an excess of self-reported fibromyalgia among women who had ruptured implants with extracapsular silicone migration (extracapsular rupture) diagnosed by magnetic resonance imaging (MRI). However, this elevated risk ratio cannot be meaningfully interpreted, due to the inappropriate use of a combined group of women with intracapsular rupture and women with intact implants as the comparison group.<sup>68-70</sup> It is also noteworthy that the rates of fibromyalgia reported among women with intact implants or intracapsular ruptures in the study by Brown et al.<sup>36</sup> are remarkably high compared with the estimated prevalence rate of 3.4% for U.S. women<sup>71</sup> and with similar or lower prevalence rates reported in many other countries,<sup>6,55,72-76</sup> indicating a biased selection of women in that study.

Most recently, Holmich et al.<sup>18</sup> explicitly tested the hypothesis of an increased risk of fibromyalgia by rupture status among 238 unselected women with cosmetic silicone breast implants. There was no excess of undefined CTD or other chronic inflammatory condition, including fibromyalgia. None of the women with extracapsular rupture reported fibromyalgia. Thus, the finding by Brown et al.<sup>35</sup> of a greater than two-fold excess of self-reported fibromyalgia among women with extracapsular rupture was not confirmed in the study by Holmich et al.,<sup>18</sup> who concluded that implant rupture is not associated with fibromyalgia or other rheumatic conditions.

#### BREAST AND OTHER CANCERS

More than 10 epidemiologic studies, many of which have been large and able to assess long-term risks, have been conducted in Europe and North America to evaluate the potential association between cosmetic breast implants and the incidence of breast or other cancers, notably lung cancer, cancers of the cervix and vulva, leukemia, and multiple myeloma.<sup>17,23,24,32-34,77-83</sup> Although the primary concern has been breast cancer risk, epidemiologic studies have been remarkably consistent in finding no evidence of increased risk for breast or other cancers among women with breast implants; in fact; in most studies the risk of breast cancer was below expectation.<sup>1,2,84,85</sup> The rare reported excesses of lung and cervical cancer are likely due to confounding by lifestyle factors and/or reproductive characteristics. In fact only the cohort study by Brinton et al.,<sup>34</sup> which reported a significant excess of deaths from brain cancer, has reported an association with a cancer that is not a likely result of lifestyle factors such as smoking or other activities that are unrelated to implants. The extreme risk estimate for brain cancer

reported in this study, which suffers from several methodological shortcomings, is inconsistent with the overwhelming weight of the epidemiologic evidence and is biologically implausible.<sup>86</sup>

#### BREAST CANCER DETECTION

Concern has been raised that the ability to detect early breast cancer is limited in women with breast implants. The hypothesis that breast implants may interfere with physical breast examination or mammographic visualization of breast tumors, leading to delays in breast cancer diagnosis and worse prognosis among women receiving implants, is based on the findings of a few early clinical studies.<sup>87,88</sup> Many of them originating from the same clinic. However, the interpretation of these clinical case series is hampered by potential referral or ascertainment bias, small sample size and absence of a control group. The results of numerous analytic epidemiologic studies, which used control groups to provide comparison data, consistently show that women with breast implants do not in fact present with more advanced stages of breast cancer or experience shorter survival (the clinically relevant outcomes), thus indicating no delay in breast cancer detection following breast augmentation.<sup>19,32,71,89-97</sup>

In a recently published large-scale study,<sup>98</sup> women receiving silicone gel implants for breast reconstruction after breast cancer had significantly lower mortality rates than those women who did not receive breast implants after cancer surgery. Thus, there is no evidence that silicone gel implants adversely affect survival following breast cancer.

#### NEUROLOGIC DISEASE

With respect to other outcomes, during the past six years, three large, population-based cohort studies have been conducted to evaluate risk for neurologic disease among women with cosmetic breast implants,<sup>9,28,99</sup> and no association has been found.

#### OFFSPRING EFFECTS AND BREASTFEEDING

Similarly, three epidemiologic investigations,<sup>10,15,100</sup> all population-based retrospective cohort studies, have examined health outcomes among children born to mothers with silicone breast implants, and none has found evidence of adverse health outcomes among the children. Concerns about possible contamination of breast milk with silicone compounds and of potential adverse health effects to infants who are breastfed by mothers with silicone breast implants are not supported by the scientific literature. In fact, the American Academy of Pediatrics<sup>101</sup> policy statement on the transfer of drugs and other chemicals into human milk concluded that "The Committee on Drugs does not feel that the evidence currently justifies classifying silicone implants as a contraindication to breastfeeding." Similarly, the Institute of Medicine of the National Academy of Sciences<sup>2</sup> concluded that "convincing evidence is available that silicon concentrations in breast milk are the same in mothers with and without breast implants, and thus there are no data to support transmission of silicone to infants in breast milk of mothers with implants."

#### RUPTURE INCIDENCE

There has been only one published study to date that directly examined the true incidence rate of breast implant rupture by repeated MRI.<sup>21</sup> In a follow-up to their rupture prevalence study,<sup>12</sup> in which 271 women study had a baseline MRI in 1999, a repeat MRI was performed two years later and a rupture incidence analysis was performed based on 317 implants (in 186 women). The authors found an overall rupture incidence rate for definite ruptures of 5.3% per year. The rupture rate increased significantly with

implant age. For "third generation" implants (barrier-coated, low bleed implants available since 1988), the percentage of implants that remained intact was estimated as 98% at 5 years and 83%-85% at 10 years.<sup>21</sup> Only one prospective study to date has been conducted to address the possible health implications of ruptured, in situ silicone breast implants.

In this unique study, Holmich et al.,<sup>25</sup> examined the possible health implications, including changes over time in MRI findings, serological markers, or self-reported breast symptoms, of untreated silicone breast implant ruptures. Sixty-four women with implant rupture diagnosed by MRI were followed for two years, and a second MRI was performed. A control group of women with no evidence of rupture on either MRI was used for comparison. The majority of women had no visible MRI changes of their ruptured implants. There was no increase in autoantibody levels, and no increase in reported breast hardness. Women did report a significant increase in non-specific breast changes compared with women in the control group. The authors concluded that, for most women, rupture is a harmless condition which does not appear to progress or to produce significant clinical symptoms.

#### LONG-TERM FOLLOW-UP

Over the past six years, the majority of the epidemiologic cohort studies were performed in Scandinavia, where unique nationwide databases and data-linking possibilities exist. Table 1 presents the average years of follow-up and the maximum years of follow-up for these cohort studies, by country:

TABLE 1

| Country                             | Ave. yrs. of follow-up | Max. yrs. of follow-up |
|-------------------------------------|------------------------|------------------------|
| Denmark .....                       | 9                      | 23                     |
| Breiting et al. <sup>24</sup> ..... | 19                     | 35                     |
| Finland .....                       | 10                     | 30                     |
| Sweden .....                        | 11                     | 29                     |

These studies had, on average, a decade of follow-up and almost three decades of follow-up for the longest term implant recipients. In the recent Danish study by Breiting et al.,<sup>24</sup> the average years of follow-up was 19, with a maximum of 35 years. Thus, the large body of nationwide investigations originating in these populations belies the assertion that there is a dearth of data on long-term effects of silicone breast implants.

#### SUICIDE

Four mortality studies have reported elevated risks of suicide among women with cosmetic breast implants compared with the general population.<sup>20,29,30,34</sup> Recently, however, the suicide excess has been shown to be related to pre-implant psychiatric disorders.<sup>30</sup>

#### SUMMARY

In summary, after almost a decade of extensive epidemiologic research, the weight of the epidemiologic evidence is overwhelmingly reassuring that there are no long-term adverse effects associated with silicone breast implants.

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