

The Safety of Silicone Breast Implants

Silicone breast implants have been sold in the United States since the early 1960's, although their long term safety in human beings was not studied until the 1990's. Because of the lack of medical scrutiny, it is not known how many women in the United States have silicone breast implants, although experts estimate one million. The major controversy that has emerged in recent years is whether silicone breast implants are safe, and whether they are responsible for the illnesses that have been reported by many of the more than 400,000 women who have filed law suits against the manufacturers. *This Briefing Paper focuses on the published epidemiological research on silicone breast implants, summarizing what is known and what is not known about the health risks.*

The use of silicone to increase breast size started shortly after the end of World War II, when liquid silicone was first injected directly into the breasts of Japanese prostitutes to make them more attractive to American G.I.'s (Anderson, 1990). In some cases, the silicone migrated to other parts of the body, such as the arms, lungs, and liver, causing horrible deformities or even death. Rather than stopping the procedures, however, efforts were made to improve the results by mixing the liquid silicone with additives such as oil, to produce scarring that would keep the silicone in place. Within a few years, similar procedures spread to Las Vegas, Hollywood, and elsewhere in the United States, where equally disastrous results for an estimated 50,000 women led to controversy about whether the problems were caused by the silicone or the additives.

Because of the continuing safety and aesthetic problems, in the early 1960's two plastic surgeons suggested to Dow Corning Corporation that they develop silicone breast implants, which were composed of a silicone elastomer envelope containing silicone gel (Braley, 1972). Saline implants, which consist of silicone envelopes filled with saline, were developed in 1968. Like the injections, these implants were produced and sold without having been tested on human beings to determine whether they were safe or effective.

In 1976, the Medical Device Amendments to the Food, Drug, and Cosmetic Act gave the Food and Drug Administration (FDA) the responsibility to regulate all

medical devices for the first time (see chronology in Table 1). Since breast implants had previously been sold in this country, they were "grandfathered in" and therefore allowed to stay on the market even though the manufacturers had not submitted proof of their safety and efficacy to the FDA (Kessler, Merkatz, & Schapiro, 1993). The FDA was responsible for eventually requiring that "grandfathered" medical devices be proven safe and effective, however, and FDA scientists considered implantable devices a high priority since their likelihood of harm seemed greater than for non-implanted devices such as surgical gloves, which the FDA also regulated.

By the 1980's, silicone breast implants had become a major segment of plastic surgery practices in the United States. Approximately 80 percent of the implants were used to increase the size of healthy breasts, while 20 percent were for reconstruction after mastectomy for cancer or other illnesses or trauma (Brown, Langone, & Brinton, 1998). In 1988, the FDA publicly announced that in 30 months, manufacturers would be required to submit research data proving that their silicone gel implants were safe and effective.

By 1990, approximately one million American women had breast implants, but there were still no published clinical trials, case/control studies, or epidemiological research studies indicating whether they were safe.¹ In December of 1990, a Congressional subcommittee responsible for monitoring the FDA, chaired by the late Rep. Ted Weiss (D-NY), held hearings

Table 1.
Chronology of Events Related to Breast Implants¹

1962:	The first silicone breast implants, made by Dow Corning, are implanted.		continue to be available while the manufacturers collected additional data.
1976:	The Medical Device Amendments to the Food, Drug, and Cosmetic Act gave the FDA the responsibility to regulate all medical devices, including breast implants, for the first time. An FDA expert panel recommended that breast implants be placed in class II, ² because their safety was considered well-established.	Dec. 1991:	A California jury awarded more than \$7 million to an implant patient, primarily for punitive damages. Within a few weeks, internal Dow Corning documents from the trial came to the attention of the FDA and the media.
Jan. 1982:	Because of reported problems, the FDA announced a proposal to place breast implants in class III, which would require studies of safety and effectiveness.	Jan. 1992:	The FDA called for a moratorium on the use of silicone gel implants until new safety information could be reviewed by the panel.
June 1988:	The FDA classified all breast implants into class III. After 30 months, the FDA could require that manufacturers provide data showing the safety and effectiveness of these devices.	Feb. 1992:	The FDA's expert panel met again to review new information on silicone gel implants, including case reports of autoimmune diseases and evidence that some early models leaked excessively.
Dec. 1990:	The U.S. House of Representatives Subcommittee on Human Resources and Intergovernmental Relations held a hearing criticizing the FDA for not requiring manufacturers to submit safety data.	Mar. 1992:	Dow Corning stopped selling all types of silicone implants.
1991:	The manufacturer of polyurethane-coated silicone breast implants removed them from the market; research indicated that the foam would degrade and release TDA, a known animal carcinogen. About 10 percent of women with breast implants had the polyurethane-coated type.	Apr. 1992:	The FDA announced that silicone gel implants could be sold only as part of controlled clinical studies for reconstruction after mastectomy, correction of congenital deformities, or replacement for ruptured silicone gel implants. The FDA approved Mentor Corporation's study in July.
Apr. 1991:	The FDA required manufacturers of silicone gel implants to submit data showing the safety and effectiveness of the implants by July 9, 1991.	Jan. 1993:	The U.S. House of Representatives Subcommittee on Human Resources and Intergovernmental Relations issued a report criticizing the FDA's poor monitoring of silicone breast implants. The FDA published a proposal in the Federal Register calling for safety and effectiveness data for saline breast implants.
Sept. 1991:	The FDA required manufacturers to disseminate information to patients on the risks associated with breast implants.	Mar. 1994:	Four breast implant manufacturers put together a global settlement proposal with a cap of \$4.25 billion over 30 years. This settlement collapsed when Dow Corning filed for bankruptcy protection in 1995.
Nov. 1991:	The FDA convened an expert panel to consider whether the data were sufficient to establish that silicone gel implants are safe and effective. Despite the lack of data, the panel advised the FDA that breast implants filled a public health need and should	Dec. 1994:	The FDA issued a Talk Paper describing the types of studies required to demonstrate the safety and effectiveness of saline breast implants. Pre-clinical data were submitted throughout 1995, and final clinical data are expected by early 1999.

¹ This chronology is based in part on the FDA's *Breast Implants* Information Update, July, 1997.

² The FDA has three regulatory categories for medical devices. Class I and class II are for devices whose safety and effectiveness are well-established. Class II devices require safeguards, such as performance standards or surveillance studies. Class III devices must be proven safe and effective before they can be sold.

aimed at encouraging the FDA to follow through on its 1988 announcement by requiring implant manufacturers to submit safety studies (Hearing of the Government Operations Subcommittee on Human Resources and Intergovernmental Relations, Dec. 18, 1990).² Dr. Diana Zuckerman of the Congressional committee staff reviewed copies of all the studies and other documents in the FDA's possession regarding the safety and efficacy of breast implants. In reading these boxes of documents, Congressional staff found that for many years, FDA scientists and advisors had expressed their concerns to FDA policy makers regarding the potential health risks of breast implants in internal memoranda (reproduced in Hearing, Dec. 18, 1990). The staff concluded that there was no evidence that independent, systematic research had been conducted on human beings to evaluate the long-term safety of the implants (Staff Report of the Committee on Government Operations, December 1992). Instead, most of the published reports were in plastic surgery or cosmetic surgery journals, where surgeons would describe the experiences of their patients, primarily in terms of cosmetic results. These case reports were not systematic studies and did not evaluate potentially serious short-term or long-term problems, such as silicone migration, implant rupture, infection, or systemic disease. There was also a survey distributed by plastic surgeons to their former patients, which indicated high customer satisfaction; although this was referred to as a study, it was a marketing survey rather than a scientific study, and could not provide accurate medical information.

In 1991, when the FDA finally reviewed the implant manufacturers' studies to determine the safety and efficacy of breast implants, it became clear that many of the studies of women with implants had just been started. After contentious FDA hearings and a great deal of public controversy, in 1992 the FDA removed silicone breast implants from the market because of the lack of safety data (Kessler, 1992). The greatest concern was the growing evidence that breast implants did not "last a lifetime" as had been claimed, and would eventually break, leaking silicone into the breast that could migrate to other parts of the body, including vital organs. There was also clear evidence that even implants that were intact could "bleed" liquid silicone into the breast area, and this silicone could also migrate. Several journal articles indicated that implant patients might be at risk for autoimmune disease or cancer as a result of this leaking silicone. In addition, breast cancer was

considered a potentially serious risk, because the implants interfered with mammography.

Although there were serious safety concerns, the lack of adequate studies meant that there was no clear research evidence regarding whether or not breast implants increase the risk of disease. In response to the request of some breast cancer advocacy groups that silicone gel implants fulfilled a "public health need" after a mastectomy, they remained available in what were described as very large clinical trials for women with mastectomies or to replace implants that were broken (Kessler, 1992). In these "clinical trials," the FDA instructed the manufacturer to restrict the use of silicone gel implants to patients for whom the physician determined that saline breast implants were not appropriate.³ FDA scientists believed that the saline implants were safer than the silicone gel implants, because although both types of implants were made with a silicone envelope, the saline and other chemicals inside the saline implants were believed to be safer than silicone gel.⁴ However, the saline implants had also been grandfathered onto the market and their manufacturers had not yet been required to provide evidence of safety to the FDA.

Research Findings

In the last few years, several articles have been published in well-respected medical journals, supporting some of the concerns expressed in 1992, and contradicting others. There is now clear evidence that many silicone gel breast implants rupture in the body, leaking silicone, sometimes without the woman's knowledge, and that this is much more likely among the thinner "second generation" silicone gel implants that were sold between 1973-87 (Peters, Smith, Fornasier et al., 1997). There has been no epidemiological evidence of increased risk of breast cancer in the published studies, although more research is needed to rule out a long-term risk of cancer (Brinton & Brown, 1997). The research also seems to indicate that several specific connective tissue diseases are not frequent problems among women with breast implants. However, there are conflicting results in published research, and many of the studies have been criticized for not evaluating enough women to draw conclusions about rare diseases and for not studying many of the symptoms and illnesses that women with implants have reported to their doctors. The most recent review of the autoimmune research, published in the *Journal of the American Medical Women's Association* in 1998 by scientists at the FDA and the National Cancer Institute,

concluded that “the samples were too small to rule out an increase” and the studies were not properly designed to evaluate an “atypical syndrome” that could be unique to silicone (Brown, Langone, & Brinton, 1998). The published studies with their findings and shortcomings are described in greater detail below.

Methodological Shortcomings of Existing Epidemiological Studies

In order to determine whether breast implants are safe, it is necessary to conduct systematic long-term studies that evaluate the association between breast implants and the illnesses and symptoms that women with breast implants report. Prospective studies, which evaluate patients during the years following their implantation, are expensive and take many years to complete, so most studies have instead looked back at the health problems of women who have had implants for periods of time ranging from a few months to a few years. This review by the Institute for Women’s Policy Research of the major published studies and of the reviews of those studies (e.g. Brown, Langone, & Brinton, 1998; Rawls, 1995; Silverman, Brown, Bright et al., 1996) indicates several basic methodological weaknesses:

1. *Virtually all of the studies focus on auto-immune diseases or cancer rather than the other health problems that the women are reporting, such as muscle pain and memory loss.*
2. *Most studies evaluate whether an individual has a well-established diagnosis for specified diseases, such as lupus and scleroderma, rather than evaluating the prevalence of symptoms that could be associated with a new or “atypical” syndrome.* There is scientific evidence that chemical exposures can cause “scleroderma-like” symptoms and other rheumatic diseases (Miller, in press; Zschunke, Ziegler, & Haustein, 1990).
3. *The studies do not provide long-term data,* despite an expected latency period for many diseases. Systemic illnesses may be more likely after implants are ruptured, which typically occurs 8-14 years after implantation (Robinson, Bradley & Wilson, 1995).
4. *The comparison samples in some studies are women who sought medical care, rather than healthy women.* Since most women who choose implants

for augmentation are young and healthy, implant patients should be compared to a “control group” of similarly young, healthy women.

5. *Even in the largest epidemiological studies, the sample sizes are not large enough to identify substantial increases in the rate of rare diseases.* Diseases such as scleroderma that are diagnosed in less than one in 10,000 women in the general population (Zschunke, Ziegler & Haustein, 1990) can only be meaningfully evaluated in large samples; it is therefore surprising that the studies that have been conducted included only a few hundred or, at most, a few thousand women with breast implants.
6. *Most of the studies used convenience samples, which collected information intended for a different purpose, or collected data on patients from a few medical practices.* The results are not necessarily generalizable to all women with implants, and the medical information is sometimes limited because the data that were collected did not necessarily include the most relevant information.

Two studies, conducted by researchers at the Mayo Clinic and Harvard, have been frequently cited by some manufacturers and physicians as “clear evidence” that silicone breast implants are safe. The authors of these studies are more cautious than the individuals who cite them, pointing out that the studies focused only on several well-defined diseases but not other diseases or symptoms, and that the study samples were too small to detect even a doubling of some rare diseases. These studies deserve careful scrutiny and several of their limitations are described below.

“Mayo Clinic” Study

The first published “Mayo Clinic” study compared patients in Olmstead County, Minnesota who had breast implants with patients without breast implants regarding the reporting of classic criteria of rheumatological diseases in their medical records (Gabriel, Fallon, Kurland et al., 1994). The study made good use of existing medical information, but it did not supplement medical records with questionnaire or interview data, and it focused on classic disease criteria, so the results do not include information about other symptoms or “atypical” diseases. In addition, the comparison sample consisted of patients receiving medical care in facilities in the county, whereas most breast implant patients are very

healthy women. The 749 implant patients in this sample are too few to provide reliable information about an increase in rare diseases, such as lupus and scleroderma; the authors estimated that they would need to study 62,000 women with implants for an average of 10 years to determine whether there was a doubling of the risks of rare diseases such as scleroderma, since their estimated incidence is usually estimated to be less than two per 100,000 women.

“Harvard” Nurses Study

The nurses study, conducted by researchers at Harvard University, was somewhat larger, including 1,183 nurses with breast implants, but only 876 were classified as having silicone gel implants (Sanchez-Guerrero et al., 1993). Like the Mayo Clinic study, this study evaluated connective tissue diseases using standardized criteria and did not study other types of illnesses, and the number of implant patients was too small to study very rare diseases such as scleroderma and lupus. Although this study also evaluated 41 “signs or symptoms” of connective tissue disease, these symptoms were not evaluated individually; instead, they were used to create ‘possible’ diagnoses of classic connective tissue diseases for women with several symptoms of those diseases.

The Harvard study was designed to minimize “reporting bias” of health problems by implant patients, by excluding any health problems diagnosed after May 1990, which was six months before the major media coverage of implant problems. The study was not designed to minimize some other kinds of bias; for example, the authors did not remove from the analysis the women who reported having received breast implants between 1952-1961, an obviously inaccurate response since breast implants had not yet been invented during that time. The inclusion of these misreported years increased the average years of implantation, which was reported to be 10 years. Moreover, implants sold prior to 1973 were made of a more rubbery silicone envelope and thicker gel and are less likely to break (Peters, Smith, Fornasier et al., 1997). Therefore, the experts who are most concerned about implants believe that these thicker implants are less likely to cause illness. If thicker implants are safer, including women with thicker implants in the same analysis with other implant patients decreases the likelihood of a significant association with health risks. The study also included women with implants for only one month; including women who have

had implants for such a short time again decreases the likelihood of finding an association with systemic health problems.

Other Studies Often Cited as Finding No Significant Risk

There are more than one dozen other published abstracts and studies that found no statistically significant health risks associated with breast implants. Each of these studies has several of the shortcomings numbered above. The authors have noted that their studies are inconclusive, usually because of the sample sizes and sometimes for other reasons, such as the small number of years after implantation. Several abstracts are based on unpublished studies with extremely small samples, so this review will focus on the most substantial, published studies, which also have clear limitations. For example, one study of autoimmune diseases included only 250 patients who had implants for an average of approximately 2.5 years (Shusterman, Kroll, Reece et al., 1993), and another study evaluated connective tissue diseases among 125 implant patients (Weisman, Vecchione, Albert et al., 1998). Even with their larger comparison samples, both of these studies include too few implant patients to provide meaningful information about these rare diseases. A recent Scottish study contacted all patients in South East Scotland who had silicone breast implants inserted between 1982-1990, but this resulted in an analysis of only 110 augmentation patients and 207 mastectomy patients (Park, Black, Sarhadi et al., 1998); these two groups were analyzed separately, although they were much too small to provide useful data when analyzed either separately or together.⁵

A Swedish study was based on a much larger sample, of more than 7,400 women with implants, averaging 8 years of follow-up information (Nyren, McLaughlin, Yin et al. 1998; Nyren, Yin, Josefsson et al., 1998). The results indicated no statistically significant increase in hospitalization due to neurological or connective tissue disease among implant patients; however, the authors acknowledge that even this sample size is too small to draw conclusions about any link between breast implants and the rare diseases that were studied. This study had similar limitations to other implant studies: only 56 percent of the implant patients had silicone gel implants, many of the patients had implants for a short period of time and implant patients were compared to breast reduction patients. However, this study has a more important flaw that limits the usefulness of the results: patients were considered ill only if their illness resulted

in hospitalization, which excludes many patients with these diseases.

Given the rarity of many of the diseases analyzed in these studies, focusing on women with connective tissue diseases rather than women with implants is a reasonable alternative strategy chosen by several researchers. However, because so few women have breast implants, these samples still need to exceed several thousand in order to have statistical power to determine whether the implants are associated with disease. They also need appropriate comparison samples of women in the general population with similar health habits and demographic backgrounds. Table 2 indicates the comparison samples and inadequate sample sizes of the studies that have been conducted. Two of these studies reported nonsignificant higher rates of illness among implant patients. A third study, which included rheumatological patients, as its comparison sample, found nonsignificantly lower prevalence of certain types of illness among implant patients, but neglected to mention that there were higher levels of many other types of rheumatological illnesses among implant patients. The samples were so small that none of the differences were statistically significant and therefore they could have occurred by chance.

Studies Finding Significant Health Problems Among Implant Patients

Two of the largest studies have found statistically significant health problems among breast implants patients. In a study of 10,800 American women with all types of breast implants, Hennekens, Lee, Cook et al.

(1996) found a statistically significant 24 percent increase in self-reported connective tissue diseases among implant patients compared to other women. These women were part of a much larger study of more than 426,000 women health professionals, who completed questionnaires between 1992-95. Although self-reported illnesses are considered less accurate than medical diagnoses, the fact that the women reporting them are health professionals increases the findings' credibility. The results suggest that breast implant research might be more likely to indicate health risks when the samples are larger and a wider range of connective tissue diseases are evaluated.

A study of 2,570 Danish women with breast implants also found a statistically significant association between breast implants and "muscular rheumatism, fibrositis, and myalgia" but not with rarer connective tissue diseases such as scleroderma or lupus (Friis, Mellekjær, McLaughlin et al., 1997). These symptoms were more than twice as likely among breast implant patients. Breast reduction patients and breast cancer patients without implants also had higher than expected reports of these symptoms, although the increase was not as dramatic as for implant patients. Like the previous studies, this study sample was too small to study rare diseases. There were other shortcomings: a very small minority had their implants for ten years or more, not all the implants were silicone gel, and illness was measured by hospitalization.

A new area of research is examining possible effects on the children of women with silicone breast implants (e.g. Levine & Ilowite, 1994). Given the lack of epidemiological studies, children's health will not be included in this review.

Table 2.
Nonsignificant Findings in Studies of Connective Tissue Patients

Hochberg et al., 1996	837 scleroderma patients compared to random control group matched for race, sex, and age group	7% more implant patients among scleroderma patients
Burns et al., 1996	274 scleroderma patients compared to random control group matched for race, sex, and age	30% more implant patients among scleroderma patients
Goldman et al., 1995	721 patients with Rheumatoid Arthritis or connective tissue disease compared to other rheumatology patients	55% fewer implant patients with these illnesses, but higher rates of implant patients among other rheumatology patients

What Kind of Research is Needed?

Overall, most of the published epidemiological studies found no statistically significant health problems among implant patients, but they usually did not include information about many of the symptoms that breast implant patients have reported to their physicians, and they had methodological shortcomings that minimized the likelihood of finding significant health risks. Well-designed epidemiological studies would be substantially different from most existing studies, and would include the following design and assessment strategies:

1. The first step would be to **analyze the effects of specific types of implants separately**, instead of combining them. For example, saline implants should be analyzed separately from silicone gel implants; if there are too few saline implant patients to analyze separately, they should be excluded from the analysis rather than be included with the silicone gel patients. This is important because many experts believe that saline implants are safer than silicone gel implants; by including saline implants in a study of silicone implants, the researchers have increased the likelihood of finding no health risks.

There are also **different types of silicone implants that should be analyzed separately**. In an ideal study, each brand of implant would be studied separately, but since many women do not know what kind of implant they have, and since some implants were not used by large numbers of women, this is not possible. Nevertheless, it is essential to analyze the polyurethane-covered implants separately, since it is known that the polyurethane sometimes disintegrates and can break down into TDA, a known animal carcinogen (Brinton & Brown, 1997). Separate analyses should also be conducted on double lumen breast implants, which consist of a silicone envelope that contains saline, antibiotics, and other substances surrounding an inner silicone envelope filled with silicone gel.

In addition, it is essential to **separately analyze different “generations” of silicone gel implants**, because the “second generation” implants sold between 1973-87 are thought to be the most likely to cause problems, and the newest implants are of great interest because they are still being sold today. The implants sold in the 1960’s are thought to be relatively safe because they have a thicker gel and thicker

envelope than those sold since then and are therefore unlikely to break and leak large amounts of silicone (Peters, Smith, Fornasier, et al., 1997). In contrast, the implants sold in the 1990’s are reportedly thinner than those from the 1960’s but possibly less likely to bleed silicone than those in the 1970’s and 1980’s; in addition, they have been implanted for fewer years so they probably are less likely to be associated with health problems at this point in time. Since virtually all the large studies have included implants from the 1960’s, 1970’s, 1980’s, and several have included implants from the 1990’s, one would expect that these studies would be less likely to find evidence of health risks than studies that focus on the thinner “second generation” implants.

2. Research should focus on **long-term implant use**. Most of the studies have included women who had implants for short periods of time, such as one month. Since experts believe that long-term implantation is more likely to cause problems, analyzing a group of women that includes women who had implants for less than one year, or even less than five years, probably decreases the likelihood of finding a statistically significant association with illness.
3. One cost-effective strategy would be to conduct research on women with **ruptured implants**, since experts believe that silicone gel or liquid that has escaped from the implant is more likely to cause problems than an intact implant. This is related to the first and second points noted above, since implants that have been in place longer are more likely to be ruptured than recently inserted implants, and second generation implants are probably more likely to rupture than those older or younger. There are many reports of implants that ruptured within the first five years of use, however, so the duration of the implant placement is not the only factor influencing likelihood of rupture. By focusing on the “worst case scenario” of women with ruptured implants, and comparing them to women with intact implants for similar periods of time and women of the same age and similar demographic traits but no implants, it would be possible to gather more meaningful information using smaller samples.
4. Another essential design issue is to **separately analyze breast cancer patients and augmentation patients**. They have been analyzed together in most studies. The “public health need” of breast cancer

patients is a major reason why silicone breast implants have remained on the market despite limited safety information, and yet very few breast cancer patients have been studied. There is some evidence that they have more implant problems than augmentation patients. Most breast cancer patients do not choose silicone gel breast implants, but it is essential that research be conducted on an appropriate number of the women who do.

5. In terms of outcomes, research is needed to evaluate **many measures of illness and health, not just auto-immune disease and cancer.** Implanted women report many symptoms, and some of these symptoms are not necessarily related to auto-immune disease or cancer. The selection of those diseases as a focus may have more to do with litigation than with current knowledge about implant problems. It would be appropriate to look at a wider range of illnesses and symptoms, and determine how women with implants differ from other women of similar age and health habits. After all, the important issue for women is whether implants increase their risk of serious illness, not limited to cancer and classically defined connective tissue diseases.

Of course, when rare diseases are being studied, the number of women with implants must be adequate to meaningfully evaluate an increased risk of that disease.

6. **More research is needed on “local” problems, such as pain, hardening, and rupture.** Previous studies have focused on systemic illnesses, but local complications can seriously threaten a woman’s quality of life, and women need that information before they make a decision about whether to get implants or whether to remove them. Although there is general agreement that rupture and breast hardening are problems, there is considerable debate about the frequency and severity of these problems and whether they can evolve into diffuse soft tissue pain syndromes.
7. In all studies, every effort should be made to **statistically control for any differences between implant patients and other women that could influence health**, such as age, weight, diet, and health-related behaviors such as smoking. This is essential to any

epidemiological study, but only the most basic factors, such as age and race, were taken into account in most of the published studies.

In summary, much remains unknown about the risks of silicone breast implants. Studies that are not well-designed cannot provide conclusive information, whether there are two studies, 20 studies, or 200 studies. Therefore, breast implants cannot be considered safe based on the available research to date, and well-designed studies are essential in order to inform women about the safety of the implants that are currently in their bodies, as well as the newest implants that are still being chosen by thousands of women every year. Thus far, the burden of proof of safety has fallen primarily on manufacturers of breast implants under the regulatory oversight of the FDA. Unfortunately, this strategy failed for more than three decades, resulting in no epidemiological studies until law suits created a strong financial incentive to conduct research that would prove that implants are safe. In recent years, the major studies have primarily been funded by those with a financial interest in the outcome, such as the manufacturers or the American Society of Plastic and Reconstructive Surgeons, and the studies have tended to address the questions raised by litigation. Because the financial stakes are so high, it is especially difficult to trust the objectivity of manufacturer-sponsored studies, even when conducted by well-respected researchers.

Meanwhile, the FDA has allowed silicone gel implants to stay on the market in poorly implemented “clinical trials,” and still has not required a single study of saline breast implants to be submitted for review. The hope that new research will provide the answers must be tempered by the knowledge that there are strongly vested interests on both sides, because hundreds of thousands of women have silicone gel implants in their bodies and the number of women receiving saline breast implants is now more than 120,000 each year, an increase of more than 1,000 percent since 1990.

Among the many unanswered questions, one will determine whether the others are answered: will the scientific community, with the support of the U.S. Department of Health and Human Services and private foundations, have the will and the funding needed to conduct the well-designed, independent research necessary to determine the long-term and short-term safety of both silicone gel and saline breast implants?

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References

- Anderson, N. Testimony before the Subcommittee on Human Resources and Intergovernmental Relations of the Committee on Government Operations, U.S. House of Representatives, December 18, 1990.
- Braley, S.A. The use of silicones in plastic surgery. *Plastic and Reconstructive Surgery* 1973; 51: 280-88.
- Brinton, L.A., and Brown, S.L. Breast implants and cancer. *Journal of the National Cancer Institute* 1997; 89: 1341-49.
- Brown, S. L., Langone, J.J., and Brinton, L.A. Silicone breast implants. *Journal of the American Medical Women's Association* 1998; 53: 21-24.
- Burns, C.J., Laing, T.J., Gillespie, B.W. et al. The epidemiology of scleroderma among women: Assessment of risk from exposures to silicone and silica. *Journal of Rheumatology* 1996; 23: 1904-11.
- Friis, S., Møllemejkjaer, L., McLaughlin, J.K. et al. Connective tissue disease and other rheumatic conditions following breast implants in Denmark. *Annals of Plastic Surgery* 1997; 39: 1-8.
- Gabriel, S.E., O'Fallon, W.M., Kurland, L.T. et al. Risk of connective-tissue diseases and other disorders after breast implantation. *New England Journal of Medicine* 1994; 330:1697-702.
- Goldman, J.A., Greenblatt, J., Joines, R. et al. Breast implants, rheumatoid arthritis, and connective tissue diseases in clinical practice. *Journal of Clinical Epidemiology* 1995; 48: 571-82.
- Hearing on protecting patients from dangers of silicone breast implants. Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations, U.S. House of Representatives, December 18, 1990.
- Hennekens, C.H., Lee, I.M., Cook, N.R. et al. Self-reported breast implants and connective-tissue diseases in female health professionals: A retrospective cohort study. *Journal of the American Medical Association* 1996; 275: 616-625.
- Hochberg, M. C., Perlmuter, D.L., Medsger, Jr., T.A. et al. Lack of association between augmentation mammoplasty and systemic sclerosis (Scleroderma). *Arthritis and Rheumatism* 1996; 39: 1125-1131.
- Kessler, D.A., Merkat, R.B. and Schapiro, R. A call for higher standards for breast implants. *Journal of the American Medical Association* 1993; 270: 2607-8.
- Kessler, D.A. The basis of the FDA's decision on breast implants. *New England Journal of Medicine* 1992; 326: 1713-15.
- Levine, J.J. and Ilowite, N.T. Scleroderma-like esophageal disease in children breast-fed by mothers with silicone breast implants. *JAMA* 1994; 271: 213-16.
- Miller, F.W. Genetics of environmentally associated rheumatic disease. In *Rheumatic Diseases and the Environment*, New York: Thompson Science, in press. J. Varga (Ed.)
- Nyren, O., McLaughlin, J.K., Yin, L. et al. Breast implants and risk of neurologic disease: A population-based cohort study in Sweden. *Neurology* 50 1998; 956-961.
- Nyren, O., Yin, L., Josefsson, S. et al. Risk of connective tissue disease and related disorders among women with breast implants: a nation-wide retrospective cohort study in Sweden. *British Medical Journal* 1998; 316: 417-422.
- Park, A. J., Black, R.J., Sarhadi, N.S. et al. Silicone gel-filled breast implants and connective tissue diseases. *Plastic and Reconstructive Surgery* 1998; 101: 261-268.
- Peters, W., Smith, D., Fornasier, V. et al. An outcome analysis of 100 women after explanation of silicone gel breast implants. *Annals of Plastic Surgery* 1997; 39: 9-19.
- Rawls, R.L. Epidemiological work clashes with case studies suggesting implant risk. *Chemical and Engineering News*, December 11, 1995; 15-17.
- Robinson, Jr., O. G., Bradley, E. L., and Wilson, D.S. Analysis of explanted silicone implants: A report of 300 patients. *Annals of Plastic Surgery* 1995; 34: 1-7.
- Sanchez-Guerrero, J., Colditz, G.A., Karlson, E.W. et al. Silicone breast implants and the risk of connective-tissue diseases and symptoms. *New England Journal of Medicine* 1995; 332: 1666-70.
- Shusterman, M.A., Kroll, S.S., Reece, G.P. et al. Incidence of autoimmune disease in patients after breast reconstruction with silicone gel implants versus autogenous tissue: A preliminary report. *Annals of Plastic Surgery* 1993; 31: 1-6.
- Silverman, B.G., Brown, S.L., Bright, R.A. Reported complications of silicone gel breast implants: An epidemiologic review. *Annals of Internal Medicine* 1996; 124: 744-56.
- Staff Report, The FDA's Regulation of Silicone Breast Implants, Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations, U.S. House of Representatives, December 1992.
- Weisman, M.H., Vecchione, T.R., Albert, D. et al. Connective-tissue disease following breast augmentation: A preliminary test of the human adjuvant disease hypothesis. *Plastic and Reconstructive Surgery* 1988; 82: 626-30.
- Zschunke, E., Ziegler, V., and Haustein, U. Occupationally induced connective tissue disorders. Pgs 172-82 in *Occupational Skin Disease*, R.A. Adams (Ed.); Philadelphia: W.B. Saunders, 1990, 172-82.

Notes:

- ¹ In 1990, there were published estimates of 2 million implanted women, which were later determined to be approximately double the accurate number based on the approximately 2 million breast implants that had been sold. Since many implants have been replaced at least once, and many women have had their implants removed, the estimated number of implant patients has been one million since the early 1990's.
 - ² Hereinafter referred to as Hearing, Dec. 18, 1990.
 - ³ These "clinical trials" do not have control groups or comparison samples, and patients have complained to the FDA that their efforts to report health problems have not been included in these "studies."
 - ⁴ Plastic surgeons frequently mix antibiotics and other chemicals with the saline that they put in the implants.
 - ⁵ The comparison samples in all these studies are larger, but the implant sample sizes remain a serious shortcoming.
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