

DECISIONS IN THE DARK

The FDA, Breast Cancer Survivors, and Silicone Implants



National Research Center
for Women & Families

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—2006—

A Report by:

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INTRODUCTION

Decisions in the Dark: The FDA, Breast Cancer Survivors, and Silicone Implants

More than 200,000 U.S. women will be newly diagnosed with breast cancer this year, adding to the millions who were previously diagnosed.¹ Although three out of four of these women will be eligible for lumpectomies, statistics indicate that approximately half will undergo mastectomies instead.² Many of those women will choose some type of reconstructive surgery, often immediately after surgery.³

For thousands of women, that choice will involve silicone gel breast implants. Although not available to the general public, silicone gel breast implants are available for breast cancer survivors as “investigational devices” since 1992 under a Food and Drug Administration (FDA) compassionate need exemption.^a The exact number of women who have silicone breast implants as a result of that exemption is not publicly known, but implant makers have stated that more than 70,000 women have been implanted with silicone gel implants since 1992.⁴ Although the compassionate need exemption is often described as a clinical trial for breast cancer reconstruction patients, most of the women who received implants under the exemption never had breast cancer. Instead, according to information provided to the FDA, in most cases a physician arranged for silicone

implants when patients’ previous saline or silicone breast implants were unsatisfactory, or for “reconstruction” for women whose breasts were described as “deformed” because they sagged from aging or breastfeeding.

Although silicone gel breast implants are widely available to breast cancer patients in the United States, concern about the risks discourages many women who instead choose other alternatives such as saline breast implants or autologous tissue transfer, which involves rebuilding a breast using tissue and fat from the abdomen or back. Patients are especially concerned about the short-term and long-term risks of local complications in the breast area, such as infection, necrosis (death of skin or tissue), chronic pain, capsular contracture, implant breakage, and silicone leakage. Although the existence of these complications is well documented, plastic surgeons disagree on the percentage of women who are likely to experience one or more of these problems, or the extent to which these complications are harmful to a woman’s physical or mental health or quality of life. The most informative studies based on breast cancer patients have not been published, and the results are therefore not well known or understood. Even less is known about systemic health problems that have been reported by

^a Silicone gel implants will sometimes be referred to as silicone implants throughout this report.

scientists at the FDA, based on short-term industry data, or long-term complications or systemic health problems.

This year, more than 200,000 women will need to decide on treatment for their breast cancer. For many, the most wrenching decision is whether to have a lumpectomy (which removes just the cancer and a margin of healthy tissue around it) or mastectomy (which removes the entire breast). That decision will be influenced, for many women, by the availability of silicone breast implants, information about FDA approval status, and advice about implant safety. Unfortunately, their decisions are being made in the absence of adequate unbiased, accurate, and easy-to-understand information, particularly regarding the long-term safety of implants for breast cancer survivors. Information is even more limited for women of color, even though African American, Hispanic, and Asian American women comprise 23 percent of the adult female population and tens of thousands of these women are diagnosed with breast cancer every year.⁵ Despite growing awareness of racial disparities in reactions to medical products, breast cancer patients from those racial and ethnic groups have not been systemically studied to determine whether silicone breast implants are safe for them.

This report examines what is known and not known about safety in the short-term and long-term. The report summarizes

research findings analyzed by government scientists and information from peer-reviewed published articles; explains differences in research findings from various studies; delineates the important safety questions that have not yet been answered; and recommends solutions that will help ensure that breast cancer patients have the information they need to make the choices that are best for them.

BACKGROUND

Decisions in the Dark: The FDA, Breast Cancer Survivors, and Silicone Implants

Breast Implants and the FDA

When breast implants were first sold in the 1960s, manufacturers were not required to conduct safety studies. The safety of medical devices did not come under federal scrutiny until 1976, when a law was passed to ensure that all medical devices, including breast implants, were regulated by the FDA. Although any implant has the potential to cause health problems, breast implants were initially “grandfathered in,” which allowed them to continue to be sold without requiring any safety studies.

The FDA gave breast implant manufacturers until 1991 – 15 years – to conduct research and provide data to prove that their silicone gel breast implants were safe. However, when the studies were reviewed by FDA scientists, not a single company was able to demonstrate the safety and effectiveness of its products. Despite considerable pressure from the manufacturers and letters from numerous Members of Congress, the agency did not approve the implants for sale to the general public. However, the FDA agreed to a compassionate need exemption in 1992 that allowed the implants to remain available on a limited basis, intended primarily for women with breast cancer who wanted to undergo breast reconstruction or for women who already had implants they wanted to replace.⁶

When the compassionate need exemption was put in place in 1992, there were no empirical studies of the safety of silicone gel breast implants for mastectomy patients, and very few empirical studies of augmentation patients. During the subsequent years, dozens of studies were conducted on augmentation patients, most of which were funded by Dow Corning, the company that manufactures silicone and had settled a class action suit brought by women who experienced implant rupture, leakage, and health problems after getting breast implants.⁷ Those studies, which included more women with implants for a very short period of time than women with implants for at least 10 years, were frequently used as evidence of the safety of breast implants. Few of these studies focused on reconstruction patients.

“I was told by my doctors I needed mastectomies, radiation therapy, and breast implants. I trusted the doctors whom I felt had just saved my life.

I didn’t know that safety studies of breast cancer survivors with implants had never been done.”

— Anne Stansell, New Mexico

Since 2000, several well-designed studies conducted by scientists at the National Cancer Institute (NCI) examined the health

status of women with implants for at least 7 years, compared to other plastic surgery patients, and found the implanted women at increased risk of dying from brain cancer, lung disease, or suicide.⁸ FDA scientists have published several articles indicating a high rupture rate among women with silicone breast implants for at least 6 years, leakage outside the scar tissue surrounding the implant among 21% of women with implants for at least 6 years, and an increase in fibromyalgia and several other autoimmune diseases among women with leaking implants, compared to women whose implants are not leaking.^{9 10} Other government scientists have reported silicone migrating from the implant area to the lymph nodes and other parts of the body.¹¹ Unfortunately, none of these studies included any breast cancer reconstruction patients.

To date, the FDA has never approved any silicone gel breast implants for sale to the general public, consistently citing the lack of adequate clinical safety data. However, in 2005, the agency signaled its intention to possibly approve silicone implants made by two manufacturers, Mentor Corporation and Inamed Corporation, sending “approvable letters” to each company regarding its intention to approve their implants if certain conditions could be met. As of February 2006, those conditions had not yet been made public, and no announcement has been made regarding if, when, and under what circumstances

the current restrictions on silicone gel breast implants will be lifted.

Meanwhile, more than a dozen public health organizations, researchers, physicians, and nonprofit organizations have petitioned the FDA to deny the companies’ current applications for FDA approval, stating that neither Inamed nor Mentor has yet met its “statutory burden of providing a reasonable assurance that its silicone implant products are safe.”¹² The original petition, and supplements that were filed several months later, raised specific concerns about the shortcomings in safety data for breast cancer reconstruction patients.

Institute of Medicine Report on Breast Implants

In 1999, the National Academy of Sciences’ Institute of Medicine (IOM) published a report entitled *Safety of Silicone Breast Implants*. The report is frequently quoted as evidence that breast implants are safe, but in fact, the report does not reach that conclusion. On the contrary, the report was the first to highlight the risks of local complications at a time when relatively few studies had examined the frequency of those problems. Although there were no long-term studies of complications among women with implants when the report was completed, the authors concluded that complications from breast implants “continue to accumulate” over the life of the product.¹³

The IOM report included only 17 studies of the potential impact of breast implants on connective tissue diseases, which were the primary health concern in the late 1990s. Almost all the 17 studies reviewed in the IOM report were funded by Dow Corning; none were funded by the federal government. Unfortunately, only seven of those studies included reconstruction patients, and all these samples were too small to adequately study relatively uncommon diseases such as scleroderma, which affects approximately one in 1,000 women and therefore requires a large sample to determine increased risk. All of the studies included a large percentage of women with implants for less than 5 years, which is too short a time to examine the risks of diseases such as lupus, which take several years to develop and diagnose.

“First, these complications occur frequently enough to be a cause for concern... Second, risks accumulate over the lifetime of the implant, but quantitative data on this point are lacking for modern implants and are deficient historically for a number of reasons... Among these are lack of data from representative samples of the population... Third, information concerning the nature and relatively high frequency of local complications and reoperations is an essential element of adequate informed consent.”

— *Institute of Medicine report Safety of Silicone Breast Implants, Page 5*

Racial Diversity in Breast Cancer Patients

Although the percentage of women of color diagnosed with breast cancer is somewhat lower than the percentage of white women, women with lower socio-economic status and those who lack adequate insurance, many of whom are women of color, are more likely to undergo mastectomies and less likely to undergo lumpectomies, compared to more affluent, insured women with the same diagnoses.^{14 15} Breast implants are therefore an option that many women of color consider when they are diagnosed with breast cancer. However, very few women of color have been studied to determine the impact of implants on their health.

None of the published studies, including those reviewed in the IOM report or published subsequently, have examined whether women of color react differently to breast implants than white women. In fact, many of the studies funded by Dow Corning were conducted in Denmark, Sweden, Finland, and other countries where virtually all the patients were white. The large studies that the FDA required implant makers to conduct as a condition of FDA approval were therefore the best opportunity for a diverse group of reconstruction patients. Unfortunately, these studies included very few women of color. For example, almost all of the 250 women in Inamed’s 2003 study of breast cancer patients with implants were white; the study included only six African

American women, five Asian American women, and 11 Hispanic women.¹⁶ Mentor's total sample of 251 breast cancer patients included only 20 who were not categorized as Caucasian, although some of them did not list their race and the company did not provide information about the number of African Americans, Asian Americans, or Hispanics.¹⁷ Neither Mentor nor Inamed specified how many women of color were included in their MRI rupture studies of breast cancer reconstruction patients.

"Our organization is dedicated to ensuring that African American breast cancer patients obtain the best possible medical treatment. It's not fair to these women that so few have been studied to make sure silicone breast implants are safe for them. That's why it is essential that implant studies include substantial numbers of women of color, analyzed separately to determine any differences in safety."

— *Bettye Green, RN, President of African American Women in Touch*

Racial diversity in studies of breast implants is very important because there are racial differences in scarring and in autoimmune disease, both of which are associated with implants. African Americans and Asian Americans are more likely to develop keloid scars, a type of excessive and unattractive scarring. Since capsular contracture is a painful and disfiguring condition caused by tight and

sometimes hardened scar tissue around the implant (under the skin), it is important to determine if there are racial differences in that complication of breast implants. And, of course, breast implants would be less attractive if they caused unsightly scarring of the skin in the breast area. In addition, African American women are more susceptible to autoimmune disease than white women. Since autoimmune diseases are the major controversy regarding silicone breast implants, it is essential to determine whether implants are linked to autoimmune symptoms or diseases among African American women, since there is some evidence that autoimmune symptoms increased for white women with Inamed or Mentor silicone gel breast implants.

Have Any Safety Questions Been Resolved?

There is a great deal of controversy about the safety of silicone gel breast implants, but there are several issues that have apparently been resolved. The first is the question of whether breast implants cause breast cancer. There are no studies that indicate that breast implants increase the risk of breast cancer, and several studies that indicate they do not increase the risk.¹⁸ Cancers usually develop 15-20 years after an exposure, so the most appropriate study design would include women with implants for at least 15 years. A study of recurrence among breast cancer reconstruction patients would also be useful. Although no

such studies have been conducted, the evidence thus far suggests that breast implants do not significantly increase the risk of breast cancer or the recurrence of breast cancer.

There is also general agreement that the complication rate for reconstruction patients is quite high. As will be described in greater detail later in this report, the only controversy about complications is regarding exactly how high the complication rates are, and how much they increase over time. Implant rupture and leakage are the greatest focus of concern for many women, and there is considerable controversy about how often they occur, and the potential health risks they pose.

The greatest controversy about silicone implants has been whether they cause systemic diseases, especially connective tissue or autoimmune diseases and symptoms. The studies that have been conducted do not indicate a significant increase in traditionally defined autoimmune diseases in the short-term. There is disagreement, however, about the potential for increases in symptoms in the short-term and symptoms as well as diseases in the long-term. This report will describe how most of the studies that attempt to address those questions have excluded breast cancer reconstruction patients.

FDA Reviews Silicone Breast Implants for Breast Cancer Patients: 2003-2006

Although there are now hundreds of published articles regarding the safety of silicone gel breast implants, few studies focus on reconstruction patients, and even fewer are prospective studies that examine the health of breast cancer reconstruction patients prior to getting implants and follow them for years to study how the implants affect them over time. Industry studies should be scrutinized carefully because of potential bias; nevertheless, recent studies conducted by implant makers as part of the FDA approval process have been among the best-designed studies of the safety of implants for reconstruction patients.

This was not always the case. For example, the first breast implant reconstruction study conducted for the FDA by McGhan Medical (now part of Inamed), made public in 1991, included only 39 breast cancer patients. FDA demanded more of the implant makers after the companies failed to gain FDA approval in the early 1990s, and subsequent studies included 250 reconstruction patients for each implant manufacturer. In 2004, the FDA issued a Guidance Document for breast implant manufacturers, again clarifying the type of data implant makers needed to provide in order to meet the “reasonable assurance of safety” standard for their products.¹⁹ The FDA identified device ruptures and subsequent gel migration as “primary safety concerns” and therefore

recommended that manufacturers provide data regarding the rate of implant ruptures *over the lifetime* of the product (with clinical projections out to at least 10 years); describe the incidence of gel migration resulting from ruptures; and clearly describe the health consequences of ruptures and associated migration.

The FDA Guidance Document specified that manufacturers needed to include data from Magnetic Resonance Imaging (MRI) when reporting ruptures, because previous studies found that almost all implant ruptures were “silent” and were likely to only be detected with MRIs. According to Inamed’s own estimates, 86 percent of ruptures in their silicone breast implants are silent.²⁰

In 2004, in response to the FDA Guidance Document, Inamed applied for approval using prospective MRI data only for the first and third year for one-third of their Core Study sample, and Mentor applied for approval using MRI data for only the first and second year for their Core Study sample. These data were publicly examined at an FDA advisory panel meeting in April 2005.

Neither company specified how many women of color were included in their MRI reconstruction subsample. As noted previously, however, there were so few women of color in the total samples studied by both Mentor and Inamed, that it is very likely that there are fewer than eight

minority reconstruction patients who underwent MRIs to test for rupture in the Mentor sample, and even fewer in the Inamed sample. Rupture could potentially differ across racial groups if racial differences in scarring or other reactions to the implant create a hostile environment that weakens the implant shell. These samples are too small to determine if rupture rates do, in fact, differ for the different racial groups.

In January 2004, the FDA denied Inamed’s application to market silicone breast implants, stating that the company lacked adequate data regarding the rupture rate over the lifetime of the implants and the health consequences of implant ruptures.²¹ Inamed made several changes to their application and resubmitted it several months later. In 2005, when Inamed’s Core Study was publicly discussed at an FDA Advisory Panel meeting, it included MRI rupture data only for the first and third years that women had implants, not over the expected lifetime of 10 years. An FDA Advisory Panel member noted that it would be “impossible” to extrapolate 10-year rupture rates utilizing just two data points.²²

FINDINGS

Decisions in the Dark: The FDA, Breast Cancer Survivors, and Silicone Implants

1. Inamed's 2004-2005 application for FDA approval includes very little longitudinal data on breast cancer patients.

For its 2003-2005 applications for FDA approval, Inamed conducted two prospective studies that were designed to evaluate the health of implant patients over time. Inamed's larger study, called the Adjunct Study, included more than 17,000 reconstruction patients, many of them cancer patients, who had undergone reconstructive surgery up to 8 years earlier. These are the same women who are able to buy silicone gel breast implants in the United States under the compassionate need exemption described earlier in this report. Unfortunately, no MRI data were included in this study. The study is fatally flawed, moreover, because almost half the women left the study within 1 year, with three out of four leaving the study within 3 years. As a result of these and other shortcomings, the FDA concluded that Inamed's Adjunct Study was "of limited value to characterize the rupture rate, rupture rate over time, and the health consequences of rupture."²³

Inamed's Core Study of 1,000 women is smaller than the Adjunct Study, but superior because by 2004, the women in the study were evaluated for at least 3 years, and one-third underwent MRIs to check for rupture during the first and third

year after receiving implants. Since it was assumed that few breast implants would break within the first few years, it was surprising and disturbing when Inamed's Core Study revealed that 21 percent of reconstruction patients experienced ruptures within the first 3 years.²⁴ Prior studies indicate that the likelihood of ruptures increases over time, so such an elevated rate of ruptures in the first few years would bode poorly for the long-term safety of the product. Although it was not possible to predict the rate of rupture after 3 years, FDA scientists calculated how rupture was likely to continue over time, and concluded that the risk of rupture could potentially increase exponentially, with estimates of the cumulative 10-year rate ranging as high as 93 percent.²⁵

The FDA Advisory Panel recommended that the FDA not approve Inamed's application for approval, based in part on unanswered questions about long-term safety. Rather than improving and extending the Core Study, however, Inamed responded to the FDA's criticisms of its application by claiming that the rupture problems resulted from a single defective implant style (Style 153), which they subsequently removed from their application (and from their Core Study data analysis). Unfortunately, Style 153 was especially popular among breast cancer reconstruction patients, accounting for

almost two-thirds of the reconstruction sample.²⁶ When the company removed the women with Style 153 implants from their application and submitted its smaller data set in 2005, it had therefore removed almost two-thirds of the breast cancer patients. The original, well-designed study with a sample of 250 patients that the FDA had requested had shrunk to approximately 80. Since only one-third of the sample underwent MRIs, the MRI sample of reconstruction patients had dwindled to less than 30 women. Samples of less than 30 patients are generally considered too small for meaningful inferential statistics generalizing about issues, including safety, when responses to a medical product or other interventions are not the same for all people. Larger samples are more likely to accurately represent a population, which in this case is the population of reconstruction patients with Inamed silicone gel breast implants.

It is therefore premature to estimate the rupture or leakage rate for reconstruction patients with Inamed silicone gel breast implants based on a sample of less than 30 women.

“I agree with FDA scientists that implant studies that include large numbers of breast cancer survivors are essential to find out if silicone gel breast implants are safe for them.”

— Susan Wood, PhD, Former Director,
FDA’s Office of Women’s Health

The Inamed data are further compromised by excluding four of their eight implant styles from their Core Study. The company provided no information at all about rupture for those four implant styles. In addition, the company did not provide rupture data that was specific to any of its implant styles: all four implants that were studied were combined in the data analysis, rather than being analyzed separately. Since the company had determined that one of their implant styles had especially high rupture rates, and removed women with those implants from the sample, subsequent post hoc statistical analyses should have analyzed each style separately to determine if any of the other styles also were especially likely to break or leak. Those analyses were not conducted, so no information is available to reconstruction patients considering Inamed breast implants about which styles might last longest or cause the fewest problems.

As part of their original submission to the FDA, made public in April 2005, Inamed had not included any rupture or silicone leakage data for women with implants for 10 years. Inamed submitted a long-term study to the FDA several months later; although the study is not publicly available, it has been described as a study of women who had silicone implants for approximately 10 years. No information about the study results has ever been made public, so there is no information available to patients or their physicians about the long-term likelihood of rupture or

leakage among women with Inamed silicone gel breast implants, or the scientific validity or reliability of the study.

2. Mentor’s application for FDA approval includes no long-term data on breast cancer patients and little short-term rupture data.

Mentor Corporation’s application to the FDA included more reconstruction patients, but studied them for a shorter period of time. The Mentor Core Study, the only Mentor study with MRI data on reconstruction patients, remarkably failed to include any data at all on four of the six product models for which the company sought approval.²⁷

Mentor provided MRI data for one-third of the 250 reconstruction patients in the sample: approximately 83 women. However, the MRIs were conducted in the first and second year that the women had breast implants, an even shorter period of time than the Inamed data. In their summary of the Inamed approval application, FDA scientists pointed out the lack of long-term data in the Core Study and concluded that Mentor’s Adjunct Study was “of no value in determining the rupture rate and the rate over the lifetime of the device.”²⁸

To supplement the short-term Core Study, Mentor provided a long-term MRI study, conducted by Drs. Sharpe and Collis, which included 100 patients from the

United Kingdom. The study had several substantial flaws, but for breast cancer patients it had one overwhelming shortcoming: no reconstruction patients were included. It therefore provided no useful information about the safety of Mentor silicone gel breast implants for reconstruction patients.

“It is a travesty that silicone breast implants have been used by breast cancer patients for 40 years but have not been tested on an adequate number to determine what the risks are. There is not a single study to determine the impact of an implant leaking silicone inside the body of a breast cancer patient. Is it ethical to make these products more available without requiring such research be done prior to FDA approval?”

— Art Caplan, PhD, Director of the Center for Bioethics at the University of Pennsylvania

According to the summary by FDA scientists, the data Mentor provided gave only a sketch, at best, of the long-term health impacts of its silicone gel breast implants, even for augmentation patients. The company is currently under investigation by the FDA’s Office of Criminal Investigations, examining allegations that it misrepresented rupture data.²⁹ Regardless of the outcome of the investigation, Mentor has not provided any useful information about rupture or silicone leakage for reconstruction patients who have had their implants for more than 2 years.

3. Cancer survivors with implants experience more complications and are more likely to need additional surgery to correct those problems, compared to augmentation patients.

The few studies that have included cancer patients show this group is at far greater risk for local complications, such as ruptures, hardening of the breasts, and additional surgeries, compared to women who receive implants for augmentation purposes only. Because of this, it is even more important to include breast cancer survivors in the research, as it is not possible to assume reconstruction patients will have the same outcomes as augmentation patients.

The most frequent complications resulting from breast implants for reconstructive surgery include:

- Capsular contracture (a hardening of scar tissue surrounding the implant, which causes the breast to feel hard and tender);
- Rupture of the implant, which can lead to gel migration;
- Wound complications (such as infections, bruising, and blood collection at the wound site or opening of the wound along incision lines); and
- Necrosis (death) of the skin or tissue.³⁰

In 1997, the *New England Journal of Medicine* published a study by Gabriel et al. which found that women who received

implants as part of reconstructive surgery experienced almost three times as many complications as women who received breast implants for augmentation.³¹

In 2003, FDA scientists analyzed data provided by Inamed, which reported many more complications among reconstruction patients with silicone gel implants compared to augmentation patients. For example, 46 percent of the reconstruction patients, compared to 19 percent of augmentation patients, required additional surgery to correct implant problems within 3 years.³² These surgeries are not the planned surgeries that result from the use of tissue expanders or the request for nipple reconstruction; they are unplanned surgeries that are needed to correct problems such as capsular contracture or implant rupture. The rupture rate after 3 years in reconstruction patients (6 percent) was also significantly higher than that of augmentation patients (1 percent). Capsular contracture was also twice as likely among reconstruction patients (16 percent) than it was in augmentation patients (8 percent). In addition, necrosis, which is a condition where breast tissue or skin dies around the implant, occurred in 6 percent of the reconstruction patients but was reported in less than 1 percent of augmentation patients.

Of the 250 breast cancer reconstruction patients enrolled in Inamed's Core Study of silicone gel breast implants, 221 continued

in the study. Many had not yet completed 3 years with their implants when the analyses were completed. The following table is a copy of FDA's slide #49 for their October 2003 presentation of Inamed data for reconstruction patients based on 3 years of follow-up.³³ Unfortunately, the FDA has not provided the public with similar data based on the entire reconstruction sample after 3 years in the study.

TABLE 1: COMPLICATIONS FOR INAMED RECONSTRUCTION PATIENTS

<i>Most Common Complications Within 3 Years</i>	
	<i>Rate</i>
RE-OPERATION	.46%
IMPLANT REMOVAL/REPLACEMENT	.25%
CAPSULAR CONTRACTURE (BAKER'S III/IV)*	.16%
IMPLANT RUPTURE	.6%
TISSUE/SKIN NECROSIS**	.6%
BREAST PAIN	.6%
SCARRING	.6%
INFECTION	.2%

* Baker III or IV capsular contracture is a painful condition where scar tissue around the implant tightens, thus causing the breast to become firm, hard, and distorted.

** Necrosis is a painful and disfiguring condition where the skin or tissue dies.

Mentor's Core Study of reconstruction patients also indicated high complication rates, although the rates for specific complications were not identical to Inamed. Like Inamed, Mentor found complication rates much higher for reconstruction patients than augmentation patients. For example, after just 2 years, 25 percent of

Mentor's reconstruction patients required a second surgery to fix an implant problem, compared to 12 percent of augmentation patients.

TABLE 2: COMPLICATIONS FOR MENTOR RECONSTRUCTION PATIENTS³⁴

<i>Most Common Complications Within 3 Years</i>	<i>Cumulative Risk Rates</i>
RE-OPERATION	.26%
IMPLANT REMOVAL WITH OR WITHOUT REPLACEMENT	.13%
CAPSULAR CONTRACTURE III/IV*	.9%
ASYMMETRY	.7%
PTOSIS (DROOPING)	.7%
HYPERTROPHIC SCARRING	.6%
INFECTION	.5%
SEROMA	.5%
BREAST MASS	.4%
WRINKLING	.3%
BREAST PAIN	.2%
HEMATOMA	.2%
IMPLANT MALPOSITION/ DISPLACEMENT	.2%

* Baker III or IV capsular contracture is a painful condition where scar tissue around the implant tightens, thus causing the breast to become firm, hard, and distorted.

More recently, a study by Henriksen, Fryzek, Holmich et al., published in the December 2005 medical journal *Archives of Surgery*, reported high complication rates for silicone gel breast implants used for reconstruction after breast cancer.³⁵ The study, funded by Dow Corning, included Danish women who had breast

implants for periods ranging from 2 months to 4 years, and averaging 23 months. The authors reported that 21 percent of the women needed additional surgery – a rate four times higher than rates reported for augmentation patients. As is the case for the Mentor and Inamed studies, these surgeries are to correct implant problems, not the scheduled surgeries required at different stages of reconstruction. The study also found 31 percent of reconstruction patients developed at least one serious complication, and 16 percent developed at least two serious complications.

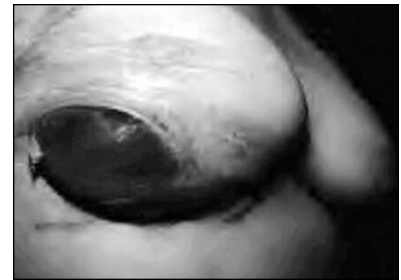
“When I was 22 years old I had a bilateral mastectomy, and I got silicone gel breast implants. My breasts started to get hard from capsular contracture after just 6 months. The implants were replaced, and those also hardened and were removed a few years later. This continued for years.

I had a total of 13 implants. One of the implants came through the skin and popped out on its own. After having a hole in my chest for years that would not heal, I had to have a tram flap.

Talk is cheap. It’s easy to call an implant ‘new and improved’ but you won’t know if it really is better until it has been inside a woman’s body for 5 or 10 or 15 years.”

— Kathy Nye, Pennsylvania

Although the authors described the complication rates as surprisingly high, they are less than half the rates reported by the FDA for the Inamed data.



Necrosis caused the implant to burst through Kathy Nye’s breast.

Unlike the Inamed study, the Dow Corning study did not include MRIs, and therefore did not include “silent” implant ruptures and the additional surgeries that would have increased if ruptures had been diagnosed with the MRIs. In addition, the Inamed study included women who had implants for 2-3 years and the Dow Corning study included women who had implants for an average of less than 2 years. The shorter follow-up time for women with implants may explain why the Dow Corning study has similar findings to the Mentor study, which is also based on many women with implants for only 2 years, and did not conduct MRIs during the third year. In contrast, more of the women in the Inamed study had implants for 3 years and had MRIs conducted during the third year.

4. Risks increase over time.

The FDA requested 10-year projections in breast implant safety data for good reason. Research shows that the longer a person lives with breast implants, the more likely she is to suffer some type of complication or rupture. All implants eventually break,

according to the FDA, the implant manufacturers, and the two plastic surgery medical societies. Although a recent study of augmentation patients funded by Dow Corning emphasized that most implants will last 10 years, even that study found that nearly all the implants broke in the subsequent 10 years of the device's life.³⁶ As shown earlier in this report, studies by

implant makers show a pattern of higher rupture rates for reconstruction patients.

The 1999 Institute of Medicine report described the increase in complications as implants age. Although the report was limited by the relatively few studies of implant

complications that were available at that time, the report concluded that complications from breast implants "continue to accumulate" over the life of the product.³⁷

In 2000, FDA researchers released a study of women with silicone gel implants for 6 to 28 years, with an average of 17 years. None of the women in the study were aware of problems with their implants. The FDA researchers found that 69 percent of the women experienced ruptures in one or more breasts, with 21 percent of those

women experiencing gel migration to other parts of the body.³⁸ Unfortunately, reconstruction patients were excluded from the sample.

In addition to silicone gel breast implants, breast cancer patients have the choice of saline breast implants or, in many cases, autologous tissue transfer surgery. Clearly, women considering breast implants to replace a breast lost to breast cancer need to be fully informed of the long-term consequences of this choice before they make it.

"I had reconstruction with the newest, best silicone implants that I was told were safe and would last my lifetime. At first all was well. But by the seventh year, burning, blister-like growths started on my neck. By year 16, I ended up in the ICU because of severe, burning chest pains. By the 25th year, though a non-smoker, I was coughing up hard, greasy, gold-colored plugs. MRI showed both implants extensively ruptured."

— Carolyn Wolf, Virginia

5. Implant makers report increased autoimmune symptoms among breast cancer reconstruction patients within 2 years.

In addition to local complications, the reconstruction patients in the Inamed Core Study were asked about numerous health symptoms both before they were implanted, and after 2 years with silicone



Photo by Anne Stansell

Silicone gel from these ruptured implants was very sticky and difficult to remove from the woman's body.

gel breast implants. These are considered to be potential symptoms of a systemic reaction or disease, rather than local complications. Overall, there were substantial increases in the number of reconstruction patients reporting joint pain, neurological symptoms, hair loss, rashes, and morning stiffness. Table 3 is copied from FDA's slide #55 presented at the October 2003 FDA advisory panel meeting.³⁹

TABLE 3: SIGNS AND SYMPTOMS AMONG INAMED RECONSTRUCTION PATIENTS

<i>Symptom</i>	<i>Pre-Implant</i>	<i>2 Year Follow-Up</i>
SKIN SYMPTOMS INCLUDING RASHES AND HAIR LOSS	.20 (12%)	.35 (22%)
MUSCLE SYMPTOMS	.56 (35%)	.65 (40%)
JOINT SYMPTOMS	.69 (43%)	.94 (60%)
NEUROLOGICAL SYMPTOMS	.78 (48%)	.97 (60%)
JOINT PAIN	.17 (11%)	.31 (19%)
MORNING STIFFNESS	.39 (10%)	.70 (18%)

TABLE 4: SIGNS AND SYMPTOMS AMONG MENTOR RECONSTRUCTION PATIENTS⁴⁰

<i>Reconstruction</i>	<i>Number with sign/symptom reported</i>	<i>Cumulative Incidence</i>
ANY SIGN/SYMPTOM	.44	.22%
JOINT PAIN	.17	.8%
JOINT SWELLING	.10	.5%

An important question is whether these changes from before implants to 2 years later could have been related to becoming 2 years older. According to the analyses presented by panel member and statistician Brent Blumenstein at the April 2005 meeting, it appears likely that the increase in symptoms was significant even when increases in age were statistically controlled. However, more analyses are needed to draw conclusions based on these data.

"I received my implants following a double mastectomy. During my first year, I experienced chest pain and headaches. By the eleventh year, a sonogram verified a silent rupture and my implants were removed. I was fortunate to see a doctor who had studied implanted women for over 20 years. I was diagnosed with several diseases, including rheumatoid arthritis and fibromyalgia."

— Sherry Henderson, Louisiana

6. Reconstruction patients are not happier than mastectomy patients without reconstruction.

Many people assume that women are willing to assume the risks associated with breast implants because the benefits of reconstructive surgery are so emotionally powerful. However, recent studies by NCI researchers and others suggest that the emotional and mental health benefits of reconstruction have been exaggerated and

that there are few if any measurable emotional benefits for most women. According to research conducted by scientists at the NCI, women who undergo reconstruction report the same quality of life as women who choose not to have reconstruction following mastectomy.⁴¹ In fact, counter-intuitively, implant patients were somewhat *more* likely to report that cancer harmed their sex life than women who underwent mastectomy without reconstruction. The researchers concluded that “Beyond the first year after diagnosis, a woman’s quality of life is more likely influenced by her age or exposure to adjuvant therapy than by her breast surgery.”

To more closely examine the claims of mental health and quality of life benefits of implants, the FDA required Mentor and Inamed to provide scientific evidence by comparing patients’ responses on various tests before implants and 2 years later. As presented by FDA scientists at the April 2005 Advisory Panel meeting, almost all Mentor and Inamed patients say they are satisfied with their implants after 2 years. However, their answers to several scientifically developed scales and questionnaires show that overall, their self-esteem and quality of life did not improve but rather remained the same 2 years after receiving implants. In contrast, augmentation patients generally showed a *decrease* in how good they felt about themselves and their quality of life after implants. Mentor reconstruction

patients showed no improvement or significant changes in self-esteem on the Rosenberg Self-Esteem Scale, in self-concept on the Tennessee Self-Concept Scale, or on physical or mental self-concept scales. This is very surprising considering that prior to getting implants, these women had either been recently diagnosed with breast cancer or had already recovered from mastectomies. FDA reviewers concluded that, for reconstruction patients, Mentor’s data did not indicate improved self-esteem, self-image, or quality of life, and research literature “that adequately evaluates the short-term or long-term psychological or psychosocial benefits of breast implants... was not provided by Mentor.”⁴²

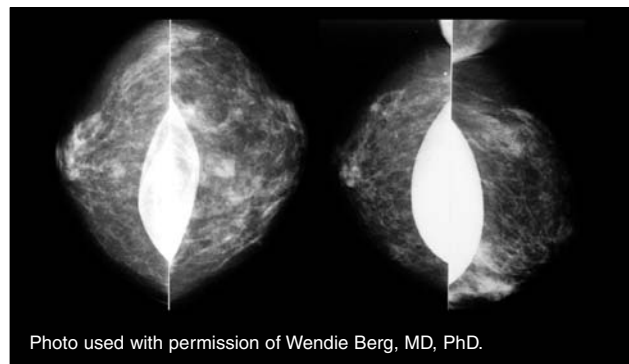
Similarly, the self-esteem, self-concept, and quality of life that Inamed measured with 18 different scales generally did not improve for reconstruction patients after receiving implants. In addition to showing no improvements in the same scales that Mentor used that were listed above, patients also showed no improvement on five important health concepts, including social functioning, mental health, and current health perceptions, and no improvements in body esteem or sexual attractiveness. The only improvements were in physical functioning, and those changes could have been related to recovery from cancer, or could have occurred by chance given the large number of statistical comparisons.⁴³

The surprising evidence that implants may not improve self-esteem or the quality of life for implant patients is further supported by five studies indicating an increase in suicides among women with implants. Four of the studies included augmentation only,^{9 44 45 46} but the one study of breast cancer patients found that women who undergo breast reconstruction after mastectomy have a statistically significant increased rate of suicide compared with mastectomy patients who do not undergo reconstruction. The number of suicides in the breast cancer patient study was small, and more research is needed before conclusions can be drawn.⁴⁷

7. Implants interfere with mammograms.

In addition to complications or health risks associated with using breast implants for reconstruction, implants can interfere with a diagnosis of breast cancer. Mammograms are the standard for early screening for breast cancer in healthy women and for women who have previously been treated for breast cancer. Unfortunately, breast implants appear as solid white ovals on mammograms, hiding tumors in breast tissue that is above or below the implant. This is not a problem for a woman with a breast implant that reconstructs a breast lost to mastectomy; although breast cancer can recur in any remaining breast tissue or in the skin, the detection of cancers in those areas do not require a mammogram.⁴⁸ However, it is not

uncommon for mastectomy patients who lost one breast to cancer to have two implants: one to replace the lost breast, and the other to make the remaining breast more similar to the reconstructed breast. Breasts that are reconstructed with implants tend to be higher and more youthful in appearance than is typical among women with breast cancer, most of whom are over 50 years of age. Breast cancer survivors are at increased risk of breast cancer in their remaining healthy breast, and an implant in that breast can obscure tumors that subsequently develop, making them less likely to be detected. And, of course, breast implants can also obscure cancerous tumors for healthy women choosing implants for augmentation.



Implants are seen as white shapes on mammograms. The implants hide breast tumors and for this woman, a tumor in the posterior portion of her breast is not visible.

Mammography technicians are specially trained to take extra views for women with breast implants (called Eklund views), in an effort to displace the implants and see more breast tissue. However, researchers

agree that breast implants significantly reduce the ability of radiologists to accurately examine breast tissue in mammography, even with the use of those implant displacement procedures.

“We know that breast cancer patients want to make informed decisions, but that just isn’t possible when the necessary long-term research hasn’t been done.”

— *Judy Norsigian, Executive Director,
Our Bodies Ourselves*

A booklet written by the FDA for women considering implants warns that they “should be aware that breast implants may interfere with the detection of cancer and that breast compression (hard pressure) during mammography may cause implant rupture/deflation.”⁴⁹

The FDA booklet’s warning about interference with detection is based on research indicating that implants obscure breast tissue, so that tumors will not be detected if they are in those areas. A study conducted by Diana Miglioretti and her colleagues, published in the January 2004 *Journal of the American Medical Association*, found a significant reduction in the ability to detect tumors in women with breast implants for augmentation, even with the displacement views. The screening mammograms missed 55% of the cancers in asymptomatic women with breast implants, compared with 33% in women of the same age who did not have

implants. The relatively large percentage of tumors that were not detected by mammography in this study was probably due to the relatively young age of the sample (40-60 years); mammograms are more accurate for women who are post-menopausal, and many of the women in this study were pre-menopausal. Despite the lower number of tumors detected among women with implants, those that were detected were similar in size to those in the women without implants.⁵⁰ More research is needed to determine if women with implants who subsequently develop breast cancer are diagnosed at a later stage because of problems with mammograms.

The reduced accuracy of mammograms is of concern to all women, but it is of particular concern for breast cancer survivors who have already undergone mastectomy in one breast and have implants in both breasts to achieve symmetry.

One study of reconstruction patients seemed to provide reassurance that implants are not increasing their risks of dying from breast cancer. Le, O’Malley, Glaser, et al., reported that women receiving implants after mastectomy were less likely to die from breast cancer than mastectomy patients who did not receive implants.⁴⁷ However, a critique by an NCI epidemiologist points out that there were several possible explanations for the lower death rate, such as differences in health

prior to making the decision to get implants.⁵¹

8. Mammograms can harm implants and implants can result in additional problems.

Although implant manufacturers and plastic surgeons encourage women with implants to undergo mammograms and claim that mammography is safe for them, recent FDA research shows that mammograms can cause implants to break and leak.

FDA scientists reviewed adverse events reported by women with breast implants, and found that two-thirds of the problems reported regarding mammograms pertained to ruptures suspected of occurring during the exams.⁵² If a woman has a saline breast implant that immediately deflates after a mammogram, the cause is obvious. However, for silicone breast implants it is more difficult to determine if these reports are accurate. Based on the FDA study, it is certainly likely that the symptoms that the women reported are related to mammograms either causing a rupture or causing silicone to leak out of a previously ruptured implant that had not yet been leaking. Since reconstructed breasts do not require mammograms, this is a problem for breast cancer survivors only if they have an implant in the contralateral (healthy) breast.

Mammograms are also a risk for women with implants for augmentation. As increasing numbers of women undergo breast augmentation after the age of 40, and as increasing numbers who underwent augmentation at a young age enter their 40's, more women than ever before will be undergoing mammograms with implants that are at least 10 years old. The compression inherent in the mammography process may cause ruptures and leakage.

The study by FDA scientists also found that women who had breast implants experienced several other difficulties during mammography.⁵² These problems included excessive pain and soreness and an inability to perform the test because of capsular contracture (hardening of the breast). The FDA scientists' analysis also included women's reports that the implants caused a delay in diagnosis of breast cancer.

In addition to the previously described problems, implants can result in more expensive screening methods and more likelihood of test results that look abnormal and are therefore followed by additional, otherwise unnecessary and possibly harmful or traumatic procedures. Calcification around the implant is one example. Calcifications that develop around silicone implants appear as white dots on mammograms and can be mistaken for signs of cancer. According to several well-respected physicians from

Johns Hopkins, Washington University, and elsewhere, these calcifications “confound mammographic breast cancer surveillance already made difficult by the obscuring effects of silicone breast implants.”⁵³ Although the studies are small and data are inconclusive, many experts believe that this may lead to unnecessary biopsies, surgical removal of the implant, and increased anxiety for the patient. In addition, the additional mammography views required for women with implants make the exam longer and more expensive, and expose the women to approximately twice as much radiation. Radiation exposure during mammography is generally safe, but doubling the exposure for many years could in and of itself increase the risk of subsequent cancer. And, if hardness and pain caused by capsular contraction make it impossible to even administer a mammogram on a woman with an implant,⁵⁴ it will be necessary to use other, more expensive tests to detect breast cancer, such as an MRI or ultrasound. Those more expensive tests may not be covered by insurance.

9. Most silicone gel implant ruptures are not detected without MRIs, but most breast cancer patients are not told to undergo regular breast MRIs.

Based on their own research, and their analysis of industry data from Inamed and Mentor, the FDA has concluded that most breast implant ruptures will not be detected unless MRIs are used. Almost all

ruptures are “silent;” the size and shape of the breast do not change noticeably at first, and there may be no obvious pain or other symptoms. The patient will not be able to detect most ruptures with a breast self-exam, and even an experienced physician will not be able to detect most ruptures with a clinical exam.

“Fifteen years ago I received a silicone breast implant during reconstructive surgery. Until recently, I was a satisfied customer. I had no problems, other than the breast getting somewhat hard. But then, it started to shrink.

There may be hundreds of thousands of women throughout the nation who have had implants who do not know they need periodic MRIs to determine if they are ruptured, how to find a facility that has the equipment to perform such MRIs, and what to do if the MRI reveals their implant has ruptured.”

— *Sonia Pressman Fuentes, Florida*

Unfortunately, breast coil MRIs are very expensive, and must be read by a radiologist who is experienced in detecting implant rupture and leakage. Even with the best MRIs and most experienced doctors, not all ruptures or leaks will be detected.¹⁰ Currently, the Web sites of the plastic surgery medical societies do not recommend regular MRIs to check for rupture, and anecdotal reports indicate that physicians rarely recommend MRIs even when symptoms suggest an implant might

be leaking. Many patients report finding it difficult to persuade their doctors to prescribe MRIs, or to find facilities with the breast coil MRIs needed to detect implant rupture. Instead, many physicians recommend mammograms to check for implant rupture, which are not only inaccurate but can also cause an old implant to break. A woman who fears that her old implant is broken can cause more harm than good by undergoing a mammogram that squeezes silicone out of the torn implant into her body during breast compression.

10. Breast implants can limit treatment options for later breast cancer.

Unfortunately, breast implants often limit a woman's options for less radical breast cancer treatments should a tumor subsequently be detected. According to a study of all breast cancer patients with a history of previous augmentation that were treated at the UCLA Breast Center between 1991 and 2001, lumpectomy surgery to conserve the breast by removing just the cancer rather than the entire breast is often not possible, making mastectomy a "more suitable choice for these patients."⁵⁵ The authors reported that the implants tend to cause "thinning of the overlying breast tissue with time," making the tumor-free margins needed for lumpectomy "difficult to obtain." If it is not possible to obtain clear margins during a lumpectomy, the surgeon is likely to recommend mastectomy as the next step. Additionally,

the radiation treatment that is an important adjuvant to lumpectomy "adversely affects breast implants," increasing the incidence of capsular contracture, infections, extrusion, and poor cosmetic results." Similar problems have been reported in other medical journal articles as well.⁵⁶ Other physicians have reported poor cosmetic outcomes in a third or more of patients when using lumpectomy and radiation with previously augmented patients.^{57 58}

Lumpectomy followed by radiation is a very safe and effective alternative to mastectomy, so the loss of that option for previously augmented patients is a serious shortcoming that women should be made aware of, whether they are considering implants for augmentation or are choosing an implant in their healthy breast after a mastectomy. Therefore, if a breast cancer survivor who chose a breast implant in her healthy breast to maintain symmetry with her reconstructed breast is later diagnosed with breast cancer in that previously healthy breast, she may not be able to choose lumpectomy (which removes only the cancer) rather than mastectomy (which removes the entire breast). Silicone implants also have the potential to interfere with sentinel node biopsy, which is a less physically damaging way to determine if breast cancer has spread to the woman's lymph nodes than traditional lymph node removal. For example, studies are needed to determine the accuracy of sentinel node biopsy in women whose implants have leaked silicone into their lymph nodes.

CONCLUSIONS AND RECOMMENDATIONS

Decisions in the Dark: The FDA, Breast Cancer Survivors, and Silicone Implants

This report summarizes research studies of silicone implants that are of particular interest to breast cancer patients and public health advocates, including studies conducted by implant manufacturers, the major silicone manufacturer, government scientists, and academic scientists. Although the focus and conclusions of the studies vary widely, there is surprising consistency in the data. There is clear evidence that implants have considerable short-term risks, as measured by local complications and the need for additional surgery. There is limited evidence of short-term risks of increased autoimmune symptoms; more research is needed and it is unfortunate that the FDA did not require more follow-up when initial results suggested significant increases in joint pain, fatigue, and other symptoms after only 2 years with breast implants.

The growing literature on implant problems related to mammography is also worrisome, even though there is no clear evidence that implants have a statistically significant impact on delaying the detection of breast cancer. The fact that many tumors are not detected because of implants indicates that individual women can certainly be harmed by mammograms that were inaccurate because of their implants. In addition, the fact that mammograms can cause implants to break and leak is certain to be a deterrent

to women who should have annual mammograms but might avoid doing so because they can't afford the \$5,000-10,000 it would cost to remove leaking silicone implants.

Unfortunately, our scrutiny of existing research indicates very few studies of the long-term risks of breast implants for reconstruction patients, if one defines long-term as 5-10 years. Although there is clear evidence that most implants break after approximately 10 years, some plastic surgeons and implant makers claim that the implants being sold today will last longer and are less likely to break or leak. Although most of the implants sold today are virtually identical to the implants sold 15 years ago, there are no published studies focused on breast cancer patients who had reconstruction with breast implants 10-15 years ago. As a result, little information is available about the long-term risks of rupture, other complications, or systemic health problems. We lack the long-term clinical data required by the FDA's own standards to ensure the short- or long-term safety of gel-filled silicone breast implants.

Ironically, when silicone breast implants were restricted because of safety concerns, they remained available to the one group that faces the highest risk of complications and adverse effects from implants: women

who have undergone breast reconstruction after mastectomy. Yet, when manufacturers submit data to the FDA in support of their marketing applications, it is this group that is least represented in the research.

This report focuses on research, but in the absence of long-term clinical trials or solid epidemiological studies, the voices of implant patients can illuminate the unanswered questions raised by the research findings. In testimony before the FDA, and in letters to our research center, reconstruction patients have shared medical records, letters from physicians, and personal stories of devastating experiences with breast implants. Many of these stories started with women who were happy with their implants for the first 3, 4, or even 10 years – the length of time of most of the women in the implant studies. It is often only after 10 years or more that leaking silicone apparently begins to affect women’s health, either with pain, granulomas (lumps) or other problems in the breast area, or joint pain, hair loss, and other systemic symptoms. These experiences, often supported by medical records and physician reports, can not tell us how often these types of serious problems occur. However, they should not be ignored and the patterns of these reports should be an essential part of epidemiological research.

Our recommendations include policies and procedures that can improve the information available and better ensure the safety of breast cancer patients considering reconstruction.

- 1.** The FDA should enforce its own guidelines requiring manufacturers to include meaningful long-term data regarding the safety and effectiveness of silicone breast implants for reconstruction patients, before approving any such devices for market. Decisions should be made on the basis of scientific criteria, including proof of long-term safety.
- 2.** The FDA should enforce its own guidelines requiring that marketing applications include sufficient MRI data to project long-term rupture rates for implants.
- 3.** The plastic and cosmetic surgery medical associations should provide more explicit guidelines for reconstruction patients on their Web sites, including instructions about the need for periodic MRIs to detect silent rupture, and guidelines about how to obtain prescriptions for MRIs and ensure that they are accurately interpreted.
- 4.** Physicians should provide their patients with explicit warnings about the risk of rupture of silicone gel implants that are more than 7-10 years old, especially during

mammography procedures. Physicians from a wide range of disciplines should be knowledgeable about the importance of removing or replacing old implants that may be ruptured to avoid or minimize silicone leakage.

5. The offices of women's health throughout the U.S. Department of Health and Human Services, including the FDA, have been instrumental in supporting implant research and providing useful information to patients and consumers. These offices should renew their efforts, focusing on research on implant safety for reconstruction patients and developing a shorter, plain language version of the current FDA Breast Implant Consumer Handbook. The booklet should be suitable for an 8th grade reading level, and should focus on the most important information for consumers. The current FDA Breast Implant Consumer Handbook includes a great deal of useful information, but the handbook is too long and complicated for most consumers, especially those under stress from a diagnosis of breast cancer.

6. The National Cancer Institute or the Agency for Healthcare Research and Quality should conduct prospective and retrospective research on the local complications and health risks of silicone breast implants for reconstruction patients. The studies should include medical examinations rather than medical records or self-reports, to ensure accuracy of the data. The research results should be made

widely available to patients in the form of consumer materials that are useful to help patients make treatment decisions.

7. The FDA should require that the patient booklets published by implant makers are suitable for an 8th grade reading level and focused on providing the most important risk information. The currently available booklets contain important information, but the booklets are too long, contain information that is not essential, and risk information is presented in a format that is difficult to understand and unlikely to be read by most consumers. The booklets are also not as available as they should be; even online versions are difficult to find. Content of the revised booklets should be reviewed and approved by the FDA. Separate booklets should be developed for reconstruction and augmentation patients. The FDA should also require, as a condition of any use of silicone implants for research or sale, that the booklets be available in the waiting rooms of plastic surgeons and on their Web sites and part of the informed consent process, with assurance that they are read and understood prior to scheduling surgery.

8. Breast cancer support and information groups should help ensure that breast cancer patients considering mastectomy have research-based, easy-to-understand information about what is known and not known about implant risks, including NCI's booklet on Surgery Choices for Women with Early-Stage Breast Cancer, the FDA's

Breast Implant Consumer Handbook, and shorter, easier to use materials when they become available, such as those described in #5 and #7 above.

The goals of these recommendations are to improve the implant safety research conducted on reconstruction patients, and to ensure that the thousands of women who consider silicone breast implants every year have explicit, easy-to-understand information about the known risks as well as the unanswered questions about long-term safety. Without better research, informed consent is not possible. However, the best research will not help patients make informed decisions unless the information is incorporated into easy-to-understand patient materials.

Without improved research, more appropriate patient materials, and the other recommended changes, women will continue to make uninformed choices that can lead to serious negative consequences for their health and well-being. Women who have already fought and survived breast cancer deserve to know how their choices will affect their future long-term health.

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