

# Silicone-Gel Breast Implants:

## Health and Regulatory Update 2000

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# Executive Summary



In January 1992 the Food and Drug Administration (FDA) implemented a voluntary but strongly-urged moratorium on the sale and use of silicone breast implants pending review of additional information.<sup>1</sup> By April 1992 the FDA had converted this moratorium to what was essentially a ban. The FDA did, however, allow continued use of the implants for women who had undergone mastectomies; it also allowed a small number of women who wanted implants for cosmetic purposes to enroll in long-term studies.

Since 1992 a large number of studies have appeared that exonerate the implants of the charges leveled against them. In 1993 the Council of Scientific Affairs of the American Medical Association (AMA) issued a report urging the AMA to “support the position that women have the right to choose silicone gel-filled or saline-filled breast implants for both augmentation and reconstruction after being fully informed about the risks and benefits.”<sup>2</sup> The American College of Rheumatology also issued a statement, that “there is no convincing evidence that these implants cause any generalized disease.”<sup>3</sup>

Most recently, on June 21, 1999, the Institute of Medicine of the National Academy of Sciences reported the conclusions of a 2-year investigation on the possible role of silicone gel implants in systemic diseases. This investigation discovered no association between silicone gel implants and cancer, immunologic disease, or other systemic diseases; moreover, they reported that implants pose no risk for breast-feeding or to unborn infants.<sup>4-6</sup> Nevertheless, the FDA’s ban remains in effect.

## Background: Silicone

**S**ilicon (no final “e”) is an element that appears throughout nature; it is, in fact, the basic ingredient of ordinary beach sand. *Silicone* is the generic name for a family of silicon-carbon-based polymers, or chains of molecules. If the molecules are linked together in relatively short chains, the silicone produced is a liquid. If the length or complexity of the molecule chain is increased, the silicone becomes increasingly more rigid; it becomes a gel, a foam, a hard resin or a rubbery material generally referred to as an elastomer.

One of the first uses of silicone in a medical implant came in the form of lifesaving tubes implanted into young children to funnel excess fluid from the brain into the chest cavity, where the fluid could be safely metabolized and excreted.<sup>7</sup> Since these “shunts” were first used, in the late 1950s, silicone in various forms has come to be an important part of many medical devices. It is used in tracheotomy tubes, in artificial lenses for the eye, in artificial heart valves, and in facial implants for birth defects or reconstructive surgery. It is also found in syringes and intravenous tubing. Today, over two million patients have implanted medical devices made partially or wholly of silicone.<sup>8</sup> Over time, silicone in medical devices has demonstrated a proven record of safety.

Many studies in the early medical literature concluded that silicone was safe for human use. By the time silicone breast implants began to be used in the early 1960s, a contemporary textbook for prosthetic surgeons had already identified silicone as an important implant material with diverse applications. In the 1960s, articles appeared noting the satisfactory response of animals to implanted silicone, including exposures in rats and dogs for up to three years.<sup>9-11</sup> A survey article on “Silicone Breast Implants and Rheumatic Disease” in the February 1994 issue of *Arthritis & Rheumatism* referenced seven additional animal studies published between 1965 and 1968 that found no evidence of significant adverse reactions to silicone.<sup>12</sup> Medical reports of silicone being used successfully to correct deformities had also been reported as early as 1950.<sup>13</sup>

Animal and clinical research on the safety and efficacy of silicone and implantable silicone devices continued throughout the 1960s, ’70s and ’80s, reaching its peak with a flood of epidemiological studies on human populations in the 1990s. In a 1991 application to the FDA seeking approval for the continued sale of its own brand of silicone-gel breast implant, one manufacturer submitted more than 230 studies attesting to the safety of the device. Altogether, more than 2,000 studies

on silicone and silicone implantable devices have been reported in the past half century.

## Background: Breast Implants

Approximately one million American women have received silicone breast implants for over three decades.<sup>14,15</sup> These implants may have been placed either for augmentation—to make a breast larger—or for reconstruction. The 1995 study conducted by McGhan Medical Corporation found that 95 percent of patients who underwent augmentation with saline implants were satisfied with their surgery three years postoperatively.<sup>16</sup> Thus, patients undergoing breast augmentation with saline implants are among the most satisfied and happy patients in the plastic surgeon’s practice.

Breast reconstruction is typically performed to replace a breast lost during mastectomy (the surgical procedure to remove a breast cancer) or to correct cosmetic defects secondary to less invasive surgery. However, breast reconstruction is also necessary to correct congenital breast deformities, which may range from complete absence of the breast to more subtle asymmetries of breast size and shape. For instance, in the congenital anomaly known as Poland’s syndrome, not only is the breast absent or extremely small, but the muscle which provides the normal shape to the upper chest (the pectoralis major muscle) is also absent. Surgical correction of this deformity is complex, and an essential component of the reconstructive process involves breast implants of various types.<sup>17,18</sup> Reconstructed breasts can appear quite similar to natural ones and can thus greatly reduce one of the most traumatic aspects of mastectomy or congenital breast deformity. Multiple psychological studies have concluded that breast reconstruction plays a critical role in restoring and improving quality of life for women with acquired or congenital breast deformities.<sup>19</sup> About 40 percent of implants are thought to be for reconstruction.<sup>20</sup>

The use of silicone-gel implants in breast surgery dates back to 1963, when two doctors wrapped a thin envelope of rubbery silicone elastomer around a soft but firm silicone-gel compound. A variety of improvements have been made in both the gel compound and the containing envelope over the years, but today’s basic implant design remains the same. Since the ban on implants containing silicone gel, implants with a silicone elastomer shell containing normal saline (“salt-water”) have been used as an alternative. However, saline breast

implants are generally thought not to have as natural a feel or appearance as do silicone gel breast implants. Since the ban on silicone gel implants, research has been conducted to find a suitable substitute; however, none of the potential substitutes, such as soy or peanut oil-filled prostheses, have progressed beyond the experimental stage in the United States.

## Silicone Leakage and Silicone Antibodies

There are two ways that silicone can be absorbed into the body from an implant. One is when microscopic droplets of silicone fluid “bleed” through the envelope of a gel-filled implant.<sup>21</sup> The amount of silicone fluid bled is normally about one to two grams.<sup>22</sup> “Low bleed” implants have been available since the early 1980s and have reduced the amount of silicone escaping from the implant.<sup>23</sup> In any event, because scar tissue quickly forms around the implant, the gel usually goes no further than one or two millimeters beyond the implant wall.<sup>24</sup> This contrasts starkly with the spreading inkblot of silicone that has been depicted in television graphics.

The other way is through rupture. According to the FDA, about four to six percent of silicone gel implants have ruptured.<sup>25</sup> Nevertheless, as in the case of the bleeding silicone droplets, the scar “capsule” would also tend to hold in any silicone released during a rupture. This explains why so many such ruptures, which are known as “silent ruptures,” are outwardly undetectable. The gel that has gone beyond the ruptured pouch still remains in place inside the “capsule.”<sup>26</sup>

Even when it is exposed to the body’s blood system, silicone does not migrate well, because it’s “hydrophobic”—it repels aqueous (water) liquids like blood and lymph. Nevertheless, silicone has occasionally been identified in lymph nodes after breast or orthopedic implantation.<sup>27</sup>

The detection of antibodies against silicone in women with implants has been regarded by some as an indicator that implant leakage is a cause of illness. An antibody is something the body creates in reaction to a foreign substance. Antibodies are part of the body’s defense against pathogens such as bacteria and viruses. But antibodies will develop in response to nonpathogenic foreign bodies as well.<sup>28</sup> Moreover, as the British Department of Health stated in its 1994 overview of the clinical studies of breast cancer health risks, “The fact that anti-silicone antibodies have been detected both in silicone implant recipients and, at a lower titre [level], in people who had not received

medical silicones, raises doubts about their significance.”<sup>29</sup>

The explanation for the presence of the antibodies may be that some forms of silicone are regularly ingested in foods, beverages and cosmetics. Silicone is found in items as diverse as puddings, cake mixes, antacids and lipsticks.<sup>30</sup> Furthermore, because silicone is used to coat the inside of hypodermic needles, diabetics are exposed to significant quantities of silicone through repeated injections.<sup>31</sup>

In a two-phase study, Weinzweig et al. sought to determine if there is any correlation between tissue silicone levels and connective tissue disease in implanted women. These authors studied women with both silicone gel and saline implants and determined silicon levels in both the capsular tissue immediately surrounding the implants and the breast tissue itself. After extensive study, no statistically significant differences in tissue silicon levels could be found in relation to the presence or absence of autoimmune or connective-tissue diseases in the patients with silicone gel implants. These conclusions further strengthened the case against any association of silicone breast implants with autoimmune disease.<sup>32</sup>

Some of the attacks on silicone implants have also implicated saline implants in causing disease, even though such implants contain no silicone gel. The FDA had considered pulling saline-filled implants off the market as well, again not because of any evidence of harm caused by the implants, but for lack of enough evidence of their safety. Nevertheless, in late 1994 the FDA decided to allow saline implants to remain on the market.<sup>33</sup>

Silicone gel is generally preferred to saline for implants because gel gives the breast a more natural feel. Furthermore, a saline implant is less likely to produce a satisfactory aesthetic result when there is little existing breast tissue to cover it.<sup>34</sup> Wrinkles or ripples in the implant surface may be more easily visible through the skin, and the breast may not move or appear as natural as it should.

Experimentation is now under way with other filling substances such as soybean oil,<sup>35</sup> but these will require years of testing before they receive FDA approval. It is not clear that soybean oil would be free of adverse effects, even though it is a “natural” substance. In any event, whatever goes into the implant of the future, the silicone implants of today are in the bodies of a million or more women who need to know what risks, if any, these devices pose.

## Epidemiology

A great deal of epidemiologic data has been gathered regarding silicone breast implants. The possible risk of cancer from implanted silicone medical devices was for a long time the only serious risk considered by doctors and health regulators. There was a general concern that any type of implanted material, in any type of prosthesis, might be harmful in the long run. Early studies in patients with many types of medical implants made of silicone and other materials did not uncover a risk, however<sup>36–38</sup>; and the FDA concluded in 1988 that a long-term implantation study in rats, which produced some small, nonspreading tumors, was irrelevant to humans and did not merit concern. (Despite this conclusion, when the FDA study was leaked to Ralph Nader’s Health Research Group, they held a press conference calling for a ban on silicone implants because they could cause cancer in women.) More recently, larger epidemiological studies of women with breast implants have strengthened earlier conclusions that implants are not a cause of cancer.

On June 21, 1999, the Institute of Medicine (IOM) of the National Academy of Sciences released its final report after a 2-year investigation on the possible involvement of silicone gel implants in systemic or connective-tissue diseases including lupus, cancer, and scleroderma. This report was funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases and was created by a panel of 13 scientists under the auspices of the IOM, which is a private, nonprofit organization that provides governmental health policy advice. This report was in agreement with the findings of the National Science panel review released in 1998, which found no causal relationship between silicone implants and systemic diseases.

In the IOM report, it is clearly stated that there is no increase in recurrent breast cancer in women with breast implants; some of the studies reviewed by the IOM even suggested lower rates of breast cancer in implanted women.<sup>39,40</sup>

The possibility that silicone implants were linked to autoimmune disease—disease in which the body’s immune system essentially turns on itself—was first reported in Japanese medical literature in 1964; but since these were anecdotal reports of women who had received direct injections of liquid silicone (not gel) mixed with other oils or paraffin, the reports were considered irrelevant to American women.

It was not until 1988, when an article appeared in *The Journal of the American Medical Association (JAMA)*,<sup>41</sup> that the U.S. medical

community at large began considering the possibility that silicone exposure might cause disease in some patients. At the time there were only a dozen isolated case reports in the medical literature of illnesses in women with breast implants—a dozen among a pool of almost one million women who had received the implants. Because the diseases seen in these patients were expected to occur in some percentage of women anyway, and because the number of cases was so low, the association was generally thought to be coincidental, not causal. Nevertheless, the medical community saw the existence of these reports as a reason for further investigation.

The FDA, to which Congress in 1976 had given authority to regulate medical devices of all types, began to take notice. In 1988, after considerable public attention was given to the call for a ban by the Public Citizen Health Research Group, the agency decided to require further information on the safety and efficacy of silicone breast implants.<sup>42</sup> In 1989 the FDA issued a paper stating, “To sum it up, FDA does not believe that there is cause for alarm at present about the safety of silicone breast implants”<sup>43</sup>; but in 1990 the FDA outlined the data that manufacturers should submit on silicone-gel-filled breast implants. They were especially interested in information on certain diseases, including autoimmune disease and the effect implanted silicone might have on unborn children.<sup>44</sup> Thereafter, the FDA began setting deadlines for compliance with its requests.<sup>45</sup>

In one of the largest epidemiological studies examining the association between breast implants and connective-tissue disease, researchers from Harvard Medical School, Brigham and Women’s Hospital, and Harvard School of Public Health found a small but statistically significant relationship.<sup>46</sup> This was a cohort retrospective study which used data that was self-reported by female health professionals, but did not specify the type of breast implant. The authors of the study concluded that the data provided “reassuring evidence against a large hazard of breast implants on connective-tissue diseases.” These same authors, in a 1999 follow-up to the 1996 study, attempted to validate the self-reported diagnoses of connective tissue diseases by independent medical record review.<sup>47</sup> They found, however, confirmation rates of definite connective-tissue disease to be as low as 23 percent.

As more and more epidemiologic studies have been conducted, the scientific evidence demonstrating the safety of silicone breast implants has continued to mount. In March, 2000, Janowsky et al. published the results of their meta-analysis of the relation between silicone breast implants and the risk of connective tissue diseases in the *New England*

*Journal of Medicine (NEJM)*. These authors analyzed the results of 20 major studies on this subject. They found “no evidence of an association between breast implants in general, or silicone-gel-filled breast implants specifically, and any of the individual connective tissue diseases, all definite connective tissue diseases combined, or other autoimmune or rheumatic conditions.”<sup>48</sup>

Similarly, the IOM study released on June 21, 1999 found no evidence that silicone implants are responsible for any major diseases. Moreover, this study found no plausible evidence of a “novel autoimmune disease” because of silicone gel implants.<sup>49,50</sup>

## Alleged Health Problems with Silicone-Gel Breast Implants

A number of potential problems with implants have been highlighted during the ban on silicone gel breast implants. These include risks associated with gel bleed/rupture, possible delayed cancer detection in implanted women, possible increased cancer risk in implanted women, and possible autoimmune disease.

Silicone gel from implants is most commonly accused of causing autoimmune disease, also known as connective-tissue disease. Autoimmune disease can take many forms, including such diseases as rheumatoid arthritis, scleroderma, lupus, Sjogren’s Syndrome, fibromyalgia, and Raynaud’s Disease.

A large number of studies on both animals and humans have looked for a link between silicone exposure and connective-tissue or autoimmune disease. Indeed, when the British Department of Health undertook a review of the relevant literature, it found itself evaluating approximately 270 papers. In reviewing the animal studies, the British Department of Health concluded that the studies “provide no immunological reason for concern over the use of silicone gels in implants. Even under forcing conditions . . . responses to the silicones have been minimal and of questionable significance.”<sup>51</sup>

That there is a suspicion of an association between such illness and silicone implants is perhaps understandable. Such autoimmune diseases tend to occur in young, otherwise healthy women—the same group that is most likely to have had breast implants. Because of this, Dr. Richard Edelson, a scleroderma expert at the Yale University School of Medicine, says one would expect that some women with implants would also have scleroderma.<sup>52</sup> But Edelson could have said

the same about the other diseases as well. The question is this: Are women with silicone implants getting these diseases at levels higher than should be expected? The answer appears to be No.

One of the largest studies of connective-tissue disease to date came from the Mayo Clinic in 1994. The study looked for evidence of 12 types of connective-tissue disease along with evidence of three other illnesses, including cancer other than breast cancer. The study concluded, “We found no association between breast implants and the connective-tissue diseases and other disorders that were studied.”<sup>53</sup>

Another large study was reported by researchers from the Universities of Maryland, Pittsburgh, and California and Johns Hopkins University. This study looked only at scleroderma, which is a rare disease. A total of 869 scleroderma patients from rheumatology clinics at three universities were compared with 2,061 women without the disease. Twelve patients (1.4 percent) had received breast implants prior to being diagnosed with scleroderma, as compared with 23 (1.1 percent) with breast implants among the control group. The differences between the groups were not significant. The authors of the study concluded, “These data extend previously published preliminary results and fail to demonstrate a significant causal association between augmentation mammoplasty and the development of systemic sclerosis (scleroderma).”<sup>54</sup>

Another large study of connective-tissue disease appeared in the *New England Journal of Medicine* in June 1995. It looked for evidence of 41 types of connective-tissue disease among 87,501 nurses, of whom 1,183 had implants. The study found no “association between silicone breast implants and connective-tissue diseases, defined according to a variety of standardized criteria.” Already anticipating the charge that they knew would be forthcoming from plaintiffs’ lawyers that silicone implants cause a special kind of autoimmune disease that doesn’t show up using standardized criteria, the authors added, “or signs or symptoms of these diseases.” Interestingly, the researchers found that women with silicone implants were *less* likely to report symptoms of these diseases or to complain of symptoms or signs of illness resembling connective-tissue disease.<sup>55</sup>

For many health professionals, the *NEJM* study, on top of the many others, was the final piece of proof needed. “I think we have enough data to end the moratorium,” Dr. George E. Erlich, a Philadelphia rheumatologist and head of the FDA arthritis advisory committee, told *The New York Times*. Erlich emphasized that he was speaking for himself and not for the FDA committee, but he added that

earlier that week the International League of the Associations of Rheumatology had agreed unanimously that there was no evidence linking implants to connective-tissue disease.<sup>56</sup> Yet the *NEJM* study was merely the largest of many such investigations. The British Department of Health 1995 overview declared, “None of these studies demonstrated that the coexistence of connective tissue disease with silicone gel breast implants is any more prevalent than would be expected by chance.”<sup>57</sup>

The British report went on to state: “It is unfortunate that this is not reflected in the public perception of these devices which, despite the scientific evidence, has been unduly influenced by media coverage of the FDA restrictions on the use of silicone-gel-filled breast implants and the outcome of legal actions.”<sup>58</sup>

The American Medical Association has gone so far as to urge that “physicians be informed of the current scientific data available in order to recognize and address the considerable public anxiety concerning the safety of breast implants, an anxiety not warranted based on current scientific evidence.”<sup>59</sup> In undoubtedly the strongest statement yet issued by a professional society on the implant issue, the American College of Rheumatology stated in October 1995 that recent epidemiological studies “provide compelling evidence that silicone implants expose patients to no demonstrable additional risk for connective tissue or rheumatic disease.” The college added in its statement that “Anecdotal evidence should no longer be used to support this relationship in the courts or by the FDA.”<sup>60</sup>

As noted above, the definitive study recently reported by the IOM has unequivocally dispelled any notion of an increased cancer risk or an increased incidence of any type of autoimmune or connective tissue disease in implanted women. Moreover, the report emphasizes that women are exposed to silicone constantly in their daily lives.

## Possible Complications Related to Breast Implants

The recently released IOM report determined that the major problems with breast implants are local, but not life-threatening, complications. These include implant removal, ruptures, deflations, capsular contracture, infection, bleeding/hematoma, and pain. Women with gel-filled implants and those undergoing reconstructive surgery seem to have a greater chance of complications than do women who have saline implants or implants for augmentation.<sup>61</sup>

Breast implants do not maintain lasting integrity forever, but there is no clearly defined rupture rate for them. Reported rupture rates for implants vary widely, from 0.3 to 77 percent.<sup>62,63</sup> Older implant models generally lasted for 10 to 15 years before rupturing; the life span of newer model implants has not yet been adequately determined. Published deflation rates for saline implants vary similarly. In one study, saline implant deflation rates in newer models are reported at 5–10 percent after 10 years,<sup>64</sup> while another cites a 33 percent rate.<sup>65</sup>

Capsular contracture is a buildup of scar tissue that may tighten around the implant. In some recipients this can become painful and can even change the shape of the breast. Implant removal may become necessary for any of these reasons. Reported rates of capsular contracture vary in the literature. In general, however, it is safe to say that capsular contracture occurs more often in reconstructive cases than in augmentation cases and also more often with silicone-gel-filled implants than with saline implants. Silicone gel implants have been reported to have capsular contracture rates ranging from 0 to 80 percent in various studies.<sup>66,67</sup> The Mentor Corporation has reported that 9 percent of augmentation patients (saline implants) and 30 percent of reconstruction patients develop capsular contracture at three years after surgery. Similarly, the McGhan Medical Corporation has reported contracture rates of 9 and 25 percent in augmentation and reconstruction patients, respectively, in patients with saline implants.<sup>68</sup>

Scar capsules form around all implanted devices, regardless of the material from which they are made, but the reason for severe capsular contracture in some breast-implant patients is not known. It could be due to an unseen infection or to differences in the techniques used by surgeons. Some researchers suggest that the smooth surface of the breast implant encourages this reaction.<sup>69</sup> The most recent medical literature reports that severe contracture of the scar capsule can occur in up to 20 percent of patients.<sup>70–73</sup> Contracture can be corrected, but surgery is sometimes necessary. In some cases the contracture may recur after the corrective surgery.<sup>74</sup>

The risk of infection in breast implants generally has been less than 5 percent in augmentation patients and less than 10 percent for reconstruction patients. The Mentor Corporation has reported a three-year infection risk of 2 percent in augmentation patients and less than 1 percent in reconstruction patients. Hematoma rates have been generally reported at 1–2 percent by Mentor Corporation and McGhan Medical Corporation.<sup>75</sup>

The IOM investigators determined that there is strong evidence

that placement of breast implants behind the chest muscles rather than in front of the muscles reduces the chance for local complications and reoperations.<sup>76,77</sup>

## Implant Related Issues: What Women Should Consider

### *Mammography*

It has also been alleged that if implants don't actually cause cancer, they can delay diagnoses by blocking X rays during mammography. While some studies suggest this may be true, the American College of Radiology has issued a statement that adequate examination is possible with commonly available techniques.<sup>78</sup> Some authorities believe the risk of missing a breast tumor is even less in women with implants because they are more compliant about testing for breast cancer.<sup>79</sup> The expert radiologist evaluating this issue for the FDA (at two advisory panels) concluded that with specialized techniques "the effectiveness of mammography to screen women with breast implants for cancer is generally similar to that of women without implants."<sup>80,81</sup>

Nevertheless, implants do complicate mammography in that the implant is radio-opaque to film-screening techniques. Additionally, some patients will develop thin layers of calcium in the scar tissue surrounding the implant. This usually happens 10 or more years following implantation. Despite this, these calcifications do not pose any problem to radiologists in terms either of obscuring small lesions or of mimicking true cancers. That is, the calcifications do not contribute to either false negative or false positive readings. The calcium deposits may affect the ability of mammography to detect lesions close to the capsule, however.

In order to minimize such potential problems, women with implants would be well advised to consult with a mammographer experienced with implants. Four X rays of the augmented breast will be needed, instead of the usual two, and the mammographer should employ the Eklund technique, in which breast tissue is pulled forward as the implant is pushed back, thus maximizing visualization of the breast tissue.<sup>82</sup> There is strong evidence that placement of implants behind the chest muscles enhances visualization of breast tissue, thus improving mammography.<sup>83</sup>

All women in the age and risk groups for which mammograms are

recommended should continue to have them, as recommended by the IOM's recent report. Regular breast self-exams as well as regular examination by a physician remain essential for women with breast implants, as they are for women without them.

### *Nursing/Breast-feeding*

In one highly publicized report in *The Journal of the American Medical Association*, researchers suggested that women with silicone-gel implants who breast-feed may pass autoimmune problems to their children. The report looked at 11 women with silicone implants, of whom eight breastfed. Of the breastfed children, six developed a rare disorder in the lower esophagus that often arises from scleroderma.<sup>84</sup> The implication was that these children were now suffering an early stage of the disease from exposure to the silicone in their mother's breast milk. One particularly alarming article relying on this study appeared in the July 1995 issue of *Redbook* under the title "Do Breast Implants Harm Babies?"<sup>85</sup> The article implied that the answer is probably yes. Unfortunately, the article completely ignored the flurry of letters to *JAMA* that the original study prompted.

These letters noted that one of the two authors of the study, Dr. Jeremiah J. Levine, serves on the board of an anti-implant organization called Children Afflicted by Toxic Substances (CATS). CATS in turn has worked with an attorney who represents women who sue over implants. Dr. Levine helped prepare a questionnaire that this lawyer used to solicit children clients for a class action suit against implant manufacturers. In a disclaimer of sorts attached to the set of letters, the editors of *JAMA* let it be known that they had no idea that Levine was affiliated with CATS.<sup>86</sup>

Further, while Levine and his coauthor claimed that the children in their group were randomly selected, the original group of breast-feeding children whose mothers had silicone implants was winnowed down from 67 children to 11. A study from which more than 80 percent of the subjects drop out or are dropped, for whatever reason, is generally considered worthless. In this case one must consider the possibility that the 56 excluded children were kept out because they didn't have the symptoms the doctors were looking for.<sup>87</sup> One letter to *JAMA* also pointed out that the very act of anesthetizing the children may have been enough to cause the muscle problem that the study's authors claimed they found in the children of mothers with silicone implants.<sup>88</sup>

One of the more glaring problems with the original study was that it simply presumed that mothers with silicone implants had silicone in

their milk. The doctors never actually tested for silicone in the milk. But the author of a critical letter published in *JAMA* did test for silicone in the milk of two mothers with implants and could detect none.<sup>89</sup>

A Dow Corning study did find silicone in breast milk. However, the study found essentially the same amount of silicone in breast milk regardless of whether the mother had implants or not, which testifies to the ubiquity of silicone in our everyday environment.<sup>90</sup> In addition, the mother of two of the six children in the Levine study (a woman who is also a cofounder of CATS and a litigant against implant manufacturers both on her own behalf and on behalf of her children) has admitted on a variety of occasions that she suffers from the same esophageal abnormality as her children.<sup>91,92</sup> This suggestion of a genetic basis for the abnormality was not revealed in the Levine study.

The British Department of Health, in its 1994 overview of the clinical studies of breast health risks, stated that in view of “significant deficiencies in the study . . . it is of no value in assessing the health effects of silicones.” The overview added, “There is no evidence whatsoever to support the view that breast-feeding should be avoided by women with breast implants, and mothers should be given every reassurance that the advantages of breast-feeding strongly outweigh any improbable and unquantifiable risk attributed to silicone gel breast implants.”<sup>93</sup>

Most recently, the IOM study has clearly demonstrated that there is no danger in breast-feeding. The IOM recommends that mothers with breast implants for augmentation should try to breast-feed their babies.<sup>94</sup>

### *Other Issues*

Women should be aware that breast implants placed for either augmentation or reconstruction may be associated with alterations in nipple sensitivity. This may depend on the particular surgical technique used in each case. Overall, the 3-year risk of loss of nipple sensation has been reported to be 8-10 percent for augmentation cases and up to 35 percent for reconstruction cases.<sup>95</sup>

It must be remembered that breast implants do not last forever. Patients must always be counseled that there exists a very real possibility that they may have to have a second operation at some point in the future to replace their implants. In the experience of one of the authors of this report (RJR), implants need to be replaced every 15 years on average.<sup>96</sup>

Currently, women desiring primary breast augmentation are limit-

ed to saline implants only. Reconstructive patients may receive silicone gel-filled implants as part of one of a number of scientific study protocols only. A number of experimental implant fillers have been formulated; however, none is currently available in the United States. It is noteworthy that soy-filled implants have recently been taken off the market in Europe because of reports of leakage of the filler and some infections. So far, an adequate replacement for the silicone-gel-filled implant is not available in the United States.

### *The Special Case of Polyurethane*

Polyurethane implants, a gel-filled implant with a layer of polyurethane foam coating the silicone envelope, were voluntarily removed from the market by their manufacturer in 1991, after questions were raised about a possible cancer risk from chemical breakdown of the polyurethane foam. The purpose of the foam was to reduce the chance of capsular contraction. One of the breakdown products, 2-toluene diamine (TDA), is considered a probable animal carcinogen and a possible human one. An estimated 10 percent of implants currently in place are of this type.<sup>97</sup>

It turns out that like all the other serious charges against breast implants, this too, has proved to be unfounded. The difference is that in this case the FDA has admitted it. In June 1995 the FDA requested that Bristol-Myers Squibb conduct a study to determine how much TDA really ended up in the systems of women with polyurethane implants. The amount, if any, was concluded to be so small that even assuming that TDA is a definite human carcinogen, the risk of cancer was one in a million using the FDA's own rating system. Since only about 110,000 women have had such implants, the FDA stated in a position paper, "FDA estimates it is unlikely that exposure to TDA will cause cancer in even one of the women with these implants." It added, "The health risk connected with surgical removal of the implants is far greater than the risk of developing cancer."<sup>98</sup>

Patients with these implants should be made aware of this information and reassured regarding their implants. Unfortunately, these implants, which were judged by many plastic surgeons to provide excellent aesthetic results and texture, are now unavailable to patients.

## Forces Driving the Implant Controversy: The Media, Class Action Plaintiffs' Attorneys, and Activist Groups

Thus far, we have attempted to clarify the scientific issues surrounding the breast implant controversy. There appears to be little, if any, scientific basis for the ban on silicone breast implants. Below is a discussion of some of the social and medicolegal forces that have driven this controversy despite the weight of scientific evidence.

A 1990 episode of CBS's *Face-to-Face with Connie Chung* popularized concerns over the link between implants and disease. The program's host referred to leaking silicone as "an ooze of slimy gelatin that could be poisoning" women with implants.<sup>99</sup> Alarm over the program caused some women to have their implants removed and prompted lawsuits against implant makers. As Chung herself later put it, the show "unleashed a torrent of protests and investigations around the country."<sup>100</sup>

Soon, magazines were running articles with titles like "Toxic Breasts,"<sup>101</sup> "The Hazards of Silicone,"<sup>102</sup> and "Time Bombs in the Breasts."<sup>103</sup> An artist announced his intent to string brassieres across the Grand Canyon to dramatize "the puritanical obsession with the breast" as well as "breast implants and victimizing the health of women."<sup>104</sup> The height of hysteria may have been reached when, after the implementation of the FDA moratorium, one woman removed her own implants with razor blades after saying she had had no success in getting doctors to remove them, while another slashed one of hers open to force a doctor to remove her implants.<sup>105,106</sup>

In the meantime, a California jury in 1991 had awarded a woman named Mariann Hopkins \$7.3 million in a suit against an implant manufacturer.<sup>107</sup> Hopkins alleged that she suffered from joint pain, fatigue and other symptoms. She claimed that these symptoms were indications of an autoimmune disorder known as mixed connective tissue disease, which she maintained was caused by her ruptured silicone implants.<sup>108</sup>

This court decision—coupled with the FDA moratorium that shortly followed—unleashed a flood of litigation against implant manufacturers. Curiously, the FDA continues to recognize the safety of silicone for implants, as evidenced by the continued availability and FDA approval of silicone for implants in the testicles and penis, for the silicone-containing Norplant contraceptive device and for the silicone oil used in reattaching the retina in some cases of eye surgery. The FDA

also continues to allow silicone to be used in food, cosmetics and drugs.

Implants, both ruptured and intact, have been charged with causing a tremendous array of diseases. These include: memory loss, difficulty swallowing, joint pain, decreased sex drive, “skin tightening,” autoimmune diseases and even cancer. Some have referred to this broad constellation of symptoms as “silicone gel syndrome.”<sup>109</sup>

University of South Florida’s Dr. Frank Vasey, whose practice consists largely of treating women he has diagnosed as suffering from a variety of implant-related illnesses, and who often serves as an expert witness for plaintiffs’ lawyers, wrote *The Silicone Breast Implant Controversy*. In his book, Vasey lists no fewer than 19 symptoms or sets of symptoms that he says might be related to silicone released from implants, including memory loss, dry mouth, bladder problems, and sinus irritation.<sup>110</sup> One law firm’s ad soliciting clients listed 18 different categories of symptoms, many of which sublisted several other symptoms.<sup>111</sup> In short, there seems to be little agreement among those who provide diagnoses of “silicone disease” as to what exactly the symptoms are.

While such a wide array of symptoms is alarming to some individuals, it’s important to note how completely unrelated many of the symptoms are. A good number of the symptoms listed by Vasey—such as fatigue, headaches and difficulty swallowing—can be brought on by suggestion: People who hear that implants may cause certain symptoms will often then develop them. We know that simply telling people that something should or could be making them sick can make them feel as if they *are* sick. This is why clinical trials in which one group of people receives a placebo—a non-drug—researchers often report that those people suffered an array of side effects.

Much of the evidence against implants is anecdotal: Some women who are sick and have implants might claim the two conditions are related. The media love anecdotes; but anecdotes, while high in entertainment value, are low in information value. Most anecdotes simply illustrate the logical fallacy known as *post hoc, ergo propter hoc* (after this, therefore because of it). People have a natural tendency to assume that because one thing happens after another, the first event must be responsible for the second. Thus, a woman gets implants one year, and some years later she develops symptoms that doctors can’t explain. Therefore (she reasons), the implants caused the symptoms. Vasey based his book on little more than anecdotes and case histories that were apparently gathered from women who had been sent to him by their attorneys.

Sometimes this fallacious line of reasoning is expressed in the very titles of implant-scare articles, as in the San Francisco *Examiner's* article about Mariann Hopkins, "After Breast Implant, Horror Began."<sup>112</sup> Nobody doubts that some of Hopkins's symptoms began after she received her implants; the question, however, is whether the first occurrence had any relation to the second. This is the same fallacy that had our forebears blaming black cats that crossed their paths for their own unexplained ills. Yet, in some cases the symptoms may not even have come after the implants. Indeed, in the Hopkins case itself one of her treating physicians testified that although her diagnosis of mixed connective tissue disease did not come until after her implants were put in, as early as two years before the implantation she already displayed symptoms of connective-tissue disease. Indeed, this physician said, another doctor was so concerned about Hopkins's symptoms that he subjected her to a battery of tests for one type of connective-tissue illness called systemic rheumatic disease. Those tests came back negative, but they were not tests specifically for mixed connective-tissue disease. Had they been, and had they come back positive, Hopkins would have proved \$7.3 million poorer for it.

It also bears noting that none of Hopkins's treating physicians testified at the trial that they believed her illness to be related to the implants. Instead, the jury was allowed to make its finding on the basis of outside testimony that implants could cause such disease—testimony from professional anti-implant witnesses like Dr. Vasey.

Some researchers claim that the presence of anti-silicone antibodies in women with breast implants supports a cause and effect relationship between the implants and autoimmune diseases. They assert that anti-silicone antibodies are not present in women who don't have such diseases. Claims, even if true, would not be conclusive proof that the implants caused the disease. At any rate, the claims are controversial. Consider the case of Dr. Nir Kossovsky of the University of California, Los Angeles.

Dr. Kossovsky, one of the best-known critics of silicone implants, was a witness at the FDA hearings that resulted in the moratorium. He is also a regular expert witness for plaintiffs in implant-related trials, including the landmark Hopkins trial. Kossovsky developed what he called Detecsil<sup>®</sup>, short for "detect silicone." "The Detecsil test confirms whether or not an individual has developed an immune response to silicone-associated proteins," declared an advertisement in the personal injury publication *Trial*.<sup>113</sup> The Detecsil tests sold for \$350.

In legal depositions supporting his expert witness testimony,

Kossovsky cited tests from the famed Scripps Clinic and Research Foundation in La Jolla, California, as corroborating his own tests.<sup>114,115</sup> He had indeed sent material to Scripps, but researchers there found no difference in the antibody titre of women with implants who had autoimmune disease and the antibodies of women with autoimmune disease but no implants. All the test found was a higher level of antibodies in anyone with autoimmune disease—exactly what one would expect.

Said Scripps in a letter: “Detecsil assay data from patients at Scripps Clinic does not support any association with silicone implants. This assay simply detects autoimmunity (in the presence or absence of silicone) in a manner inferior to existing assays.”<sup>116</sup> Scripps has disavowed Kossovsky’s statements, and in February 1994 wrote a letter of disavowal directly to him.<sup>117</sup> Two months earlier, in an article concerning (in part) Dr. Kossovsky, *The New York Times* had quoted Scripps immunologist Robert Ochs as saying: “Several companies claim to have antibody tests that detect silicone [in blood]. But to my knowledge, there is no test that can predict or indicate any specific immune response to silicone,” which is what the test must do to prove adverse health effects.<sup>118</sup> Despite this, in April 1994, Structured Biologicals announced it was marketing Detecsil,<sup>119</sup> and in May 1994 yet another Kossovsky deposition appeared invoking Scripps’s name and reputation.<sup>120</sup>

Ultimately the FDA stepped in, informing Structured Biologicals of what it already knew: that you cannot market a new medical product without FDA approval. It ordered that Detecsil not be distributed.<sup>121</sup>

Another company making claims for a test said to be able to detect silicone antibodies in women with autoimmune disease was Emerald Biomedical Services of Woodlands, Texas. Dr. Noel Rose of Johns Hopkins University in Baltimore, one of the most prominent researchers in the field, worked with Emerald to see if he could confirm their findings. Originally he did, but he later realized that he was finding the same positive reactions in women without silicone implants.<sup>122</sup>

In mid-October 1994, after Rose’s testing repeatedly failed to show that Emerald’s test was effective, Emerald broke off the relationship.<sup>123</sup> Yet, in a November 1994 letter to a Texas law firm that does implant litigation, Edward G. Ezrailson of Emerald stated that Rose “[had] independently validated” Emerald’s test.<sup>124</sup> General counsel at Johns Hopkins was compelled to ask Emerald to stop sending out information packets that falsely invoked Rose’s support.

In that same letter to the law firm, Ezrailson offered his services as an expert plaintiffs’ witness and bragged about the large settlements his

test and testimony had helped win:

Confirming an immune response to silicone gel, utilizing the [Emerald test] is an important component in establishing causation. . . . Since the [Emerald test] has been repeatedly validated through extensive blind and independent testing, several major law firms have requested that I, on behalf of Emerald, act as an expert consultant for their breast implant litigation clients. . . . We want to take this opportunity to offer our services in such a consulting capacity. As you will note from my enclosed résumé, I have served as expert in a variety of matters over the past seven years. During this time my testimony at deposition and trial has led, in part, to several excellent settlements or verdicts.<sup>125</sup>

Ezrailson has since ceased to claim that his test was validated by Johns Hopkins, but he continues to serve as an expert witness for plaintiffs and to cite Emerald test results in implant litigation. In its investigation, the IOM has found absolutely no correlation between autoimmune diseases and breast implants, firmly corroborating the findings of multiple prior epidemiologic studies.

What is perhaps the most serious charge against silicone implants is also the weakest—the charge that the implants may cause breast cancer. Although consumer advocacy groups such as Sidney Wolfe’s Public Citizen have made this claim,<sup>126</sup> repeated studies have shown no such link. Even Frank Vasey appears to downplay the risk.<sup>127</sup> The only cancers ever plausibly attributed to silicone were connective-tissue sarcomas that appeared in strains of rodents especially susceptible to cancer in a study released over four decades ago.<sup>128</sup>

Epidemiological studies have never found higher-than-normal rates of breast cancer in women with silicone implants. In 1995, a large study looked at a group of almost 11,000 women from the Alberta, Canada, area and compared the women who had implants with those without implants. The study concluded, “the incidence of breast cancer among the women who had breast augmentation could not be said to be either significantly higher or lower than that among the general population . . . .”<sup>129</sup>

Another breast cancer study began in 1986 and was updated in the April 1995 issue of the *Journal of Clinical Epidemiology*. In this study, the breast cancer incidence in 3,112 women in Los Angeles County who received silicone breast implants for cosmetic purposes between

1959 and 1981 was compared with overall county breast cancer rates. Twenty-one breast cancers were found in the implant group compared to an expected incidence of 31.7. The authors of the study concluded that there is no increase in breast cancer following augmentation mammoplasty.<sup>130</sup> Again, the IOM's landmark study released June 21, 1999, found no increased cancer risk in women with silicone gel breast implants.<sup>131</sup>

Finally, in one of the largest studies on the long-term health effects of silicone breast implants, researchers from the National Cancer Institute found no association between breast implants and the subsequent risk of breast cancer. The participants in this study included 13,500 women who had implant surgery for cosmetic reasons in both breasts sometime between 1962 and 1989. Women were followed for more than 10 years, and when they were compared to either the general population or women with other types of plastic surgery, there was no evidence of a change in breast cancer risk in the implant group. Indeed, the researchers found there was no altered breast cancer risk associated with any of the types of implants.<sup>132</sup>

## The Multi-Billion-Dollar Settlement: Proof of Guilt?

In April 1994, seven silicone breast-implant manufacturers agreed to a class action settlement, establishing a \$4.2 billion fund to compensate women with implants who later acquired one or more of eight specified disorders.<sup>133</sup> After it became clear that even this massive amount was not nearly enough to satisfy all the implant recipients who decided they wanted a piece of the settlement (plaintiffs' attorneys were saying that a total of \$24 billion might be needed to satisfy just the first set of claims against the companies), the largest contributor, Dow Corning, which was also facing some 20,000 lawsuits outside of the settlement, filed for Chapter 11 bankruptcy protection in May 1995. To many, the settlement itself, plus the huge amount of money involved, seems to be proof that the implant manufacturers knew their product to be harmful. "A woman would have to be a fool to get silicone breast implants knowing that the manufacturers have agreed to put together this pot of money to pay sick women," says Marie Walsh of the Breast Implant Information Foundation in Laguna Hills, California.<sup>134</sup> Her group disseminates information telling women that implants are harmful. But the manufacturers insist that the settlement merely reflects the fact that a number of

women will continue to win court cases and huge awards regardless of medical evidence,<sup>135</sup> and the record so far clearly supports that position. In a single case involving three women complaining of implant-related illness, a jury in 1994 awarded \$33.5 million. The judgment was later reversed by an appeals court and then settled.<sup>136</sup>

Defendants don't necessarily settle cases because they know they are in the wrong. Rather, they settle because of uncertainty regarding the outcome of a trial even though the scientific evidence backing them up is strong. They also settle because of the sheer expense of defending against thousands of lawsuits, even if they are without merit. A settlement allows a company to know exactly what its losses will be, rather than relying on the temperament of judges and juries. The problem with jurors is that while they generally mean well, they are almost never scientists or doctors. Yet, in cases such as those involving silicone implants, jurors are forced to behave as though they were trained experts. With a plaintiff's expert witnesses contradicting those of an implant-manufacturer defendant, all too many jurors will simply assess how sick they believe the woman to be and award her money on that basis.

## Why Has Science Been Ignored?

**I**f the evidence that silicone implants cause harm is so weak, why have these devices caused such commotion and such fear?

We have in recent decades moved from an age in which modern technology was revered to one in which it is widely feared.<sup>137</sup> Although life expectancy continues to rise steadily, many Americans fear that life is becoming ever more dangerous. It is unfortunately all too common to see various groups and individuals latch onto a view of specific products or processes as dangerous as part of a belief that technology in general is harmful. Such has been the case with environmental chemicals and genetically modified food. This also has been the case with silicone implants. To persons with such beliefs, worries over silicone implants become more a political issue than a health issue. To others it becomes a feminist issue. To still others, it becomes a financial opportunity. All of these views need to be considered to find out what went wrong with America's understanding of the implant issue.

## The FDA

When FDA Commissioner Kessler banned silicone implants, the impact went far beyond the moratorium. An editorial in the *New England Journal of Medicine* stated: “The widespread fear—and the multi-million-dollar lawsuits—have dated largely from the FDA’s removal of breast implants from the market.”<sup>138</sup> One study comparing the attitudes of women with implants before and after the FDA moratorium found that the level of satisfaction dropped markedly, from 98 percent satisfied before the moratorium to between 71 and 79 percent satisfied after. These findings were described as being similar to those found by the American Society for Plastic and Reconstructive Surgery in another poll.<sup>139</sup>

For evidence that the FDA spurred “multi-million-dollar lawsuits,” one need look no further than many of the attorneys’ advertisements soliciting silicone implant recipients. “THE FDA WARNS THAT SILICONE GEL-FILLED BREAST IMPLANTS PRESENT HEALTH RISKS”<sup>140</sup> blared one, in huge letters. “The Food and Drug Administration has called for a moratorium on silicone breast implants . . . ,”<sup>141</sup> began another. “In January of this year the Food and Drug Administration placed a moratorium on the further sale and insertion of artificial breast implants,”<sup>142</sup> began a third, incorrectly stating that all implants, not just the silicone ones, were affected.

Ultimately, why did the FDA declare a moratorium on silicone-gel implants despite a lack of evidence that they are harmful? It’s not enough to say that there was also a lack of evidence that they were not harmful. There was more evidence of nonharm by the time of Kessler’s ban than there had been in the previous years when the implants were allowed. James McGill Buchanan, the 1986 Nobel Prize winner for economics, has stated that bureaucracies, like individuals, act out of self-interest. Bureaucracies react to both public and political pressure, and in the matter of silicone-gel implants both public and political pressure came down on the FDA in the same direction. The public pressure came from repeated anecdotal reports in both the print and broadcast media. The moratorium, which became (in effect) a ban, occurred after more than a year of intense media pressure that included Connie Chung’s notorious show—a show that was rebroadcast a year later.

Congressional pressure was put on the FDA by the late Representative Ted Weiss (D-NY). He accused implant maker Dow Corning of possible misconduct in its effort to document the safety of silicone implants and called for both the Justice Department and the

FDA to investigate the company<sup>143</sup> (in May of 1995 the Justice Department dropped the investigation for lack of evidence).<sup>144</sup> Weiss was chairman of the committee that has jurisdiction over the FDA.

Pressure on the FDA came from the other side as well. It came from the AMA, from implant makers, from plastic surgeons and from breast cancer support groups. But this was not the sort of public pressure that can embarrass an agency, and the concerns of the breast cancer support community were dealt with by allowing silicone implants to continue to be used for breast reconstruction following mastectomy.

Ultimately, though, the most important issue may have been the nature of the regulated product, not its safety or efficacy. Former *New England Journal of Medicine* editor Marcia Angell has said that the FDA probably acted the way it did because implants are cosmetic. Nobody questions allowing the use of automobiles, even though they kill over 40,000 Americans a year, because we all have a common understanding of the worth of cars. “In the case of breast implants, the benefit has to do with the personal judgments about the quality of life, which are subjective and unique to each woman,” said Angell. But given “the difficulty of assessing the benefits, the FDA has acted as though there were none—at least when implants are used for augmentation . . . . The result is that [FDA Commissioner Kessler] may be holding breast implants to an impossibly high standard: Since there are no benefits, there should be no risks.”<sup>145</sup>

Yet there is much scientific evidence regarding the considerable psychological benefits of receiving breast implants, whether the implants are for augmentation or for reconstruction. One 1993 study of 83 women who received breast implants following cancer surgery reported an increased sense of well-being and of “both observed and stated satisfaction with levels of psychosocial and sexual function.”<sup>146</sup>

Another 1993 study found that “women who choose augmentation are not searching to achieve some ‘ideal’ beauty or exaggerated breast size. Instead, they are motivated to decrease their self-consciousness by attaining the breast size they perceive as adequate.” The same study reported that external factors, such as how other people might perceive them afterwards, were seldom an important factor in women’s decisions to undergo augmentation. This study goes a long way toward dispelling the common myth that women seeking augmentation are trying to live up to some sexist, male view of the perfect woman.<sup>147</sup>

In 1994 testimony before the FDA advisory panel on saline breast implants, Dr. Rebecca Anderson, a professor of surgery and a licensed psychologist at the Medical College of Wisconsin, summarized the

results of research she had conducted involving women who had received implants both for augmentation and for reconstruction:

The benefits of reconstructive surgery for the breast cancer patient from a psychological perspective are quite profound. These women experience a new sense of physical integrity or wholeness. They regain a sense of femininity and they report a reduction in disparity between their ideal and actual body image. . . . Women seek breast augmentation as a means of feeling more confident, more feminine, less shy and more attractive. They also hope to enhance their sense of self-esteem and to give themselves more options in clothing. [Another study] reported significant improvement in the way patients related to their body image and also a decrease in depression, improvement in their sexuality, better social relationships and improved self-esteem following augmentation.<sup>148</sup>

## The Media

Sometimes the media report the news. Sometimes they make it. In the matter of silicone implants, it has been a mix of both. Clearly, the media have had an impact on public perceptions, perceptions that in turn have both fueled litigation and contributed to the FDA moratorium. The moratorium in its turn fueled more litigation.

The American Medical Association's Council on Scientific Affairs, in its December 1994 position paper on silicone implants, stated, "Unfortunately, a number of journalists and media organizations have not presented a balanced and informed view on the safety of silicone implants during the past year. This type of press has created an undue amount of unnecessary anxiety in many women, which in turn has provoked litigious behavior and inappropriate demands for explant [removal of implant] surgery."<sup>149</sup>

The media have repeatedly claimed to have found the proverbial "smoking gun" showing evil intent on the part of implant manufacturers. Such was the case with an April 1994 front-page article in *The New York Times*. The article suggested that there was evidence that implant manufacturer Dow Corning knew back in 1975 that silicone was harmful to women. In fact, the 1975 study, conducted by Dow Corning itself, merely showed stimulation of the immune system in mice given large doses of a component of silicone.<sup>150</sup> This does not mean that silicone

causes illness, much less that Dow should have known that it would. The Dow Corning study was conducted to see if the component might make an effective immune-system stimulator for use in vaccines. Dow rejected it.<sup>151</sup> Often, media reports on the silicone implant story merely left the public in total confusion.

During a single three-day period in 1993, a well-read woman might have seen the following newspaper headlines: “Cancer Study Clears Implants” (*Chicago Sun-Times*),<sup>152</sup> “Studies Confirm Potential Cancer Risk from Coated Breast Implants” (*The New York Times*),<sup>153</sup> “Breast Implants’ Link to Cancer Confirmed” (*Houston Chronicle*)<sup>154</sup> and “Studies Confirm Silicone Implants’ Risk” (*Chicago Tribune*).<sup>155</sup> What was that woman reader to think? Were implants “cleared”? Was there a “potential” risk? Or was the risk “confirmed”? It would have helped to know that the headlines discussed two different studies. The *Sun-Times* article was about one study; the other three articles were about another, separate study. Further, it turns out that the *Houston Chronicle* story was merely a reprint of the *New York Times* story. The different headlines simply reflect how two different editors interpreted the same article.

There is more at work here than just the battle of the headlines, however. While only the *Sun-Times* discussed the negative study, that study actually looked at cancer rates among women with implants over a period of two decades. The other study focused on the polyurethane implants that had been pulled from the market by their manufacturer two years earlier. Far from “confirming” any cancer link, that study was merely a test to see if women with implants had detectable levels in their urine of TDA, the breakdown product from polyurethane that has caused cancer in some rodent studies. The three newspapers that played up the urine study ignored the long-term study that looked at a direct connection between cancer and implants and found none.

Whatever role sheer confusion on the part of the media played, the fact remains that opportunities to present the other side were often ignored. Such was the case in 1991, when CBS yanked, at the last minute, a Dow Corning rebuttal to the rebroadcast of the Connie Chung show that did so much to kick off the implant scare. CBS didn’t explain its decision<sup>156</sup>; apparently it felt its viewers would not benefit from an airing of both sides of the issue.

Although much media coverage of implants continues to be irresponsible, emphasizing or perhaps even exclusively discussing only anecdotal evidence, a number of newspapers have decided to emphasize scientific data and to present such anecdotal stories with skepticism.

One example was a 1994 *Los Angeles Times* article that stated, “While lawyers were busy over the past year hammering out a billion-dollar legal settlement for women with health problems possibly due to silicone-gel breast implants, doctors were gathering evidence indicating the implants may be safe for most women.” It then added, “In the past year, more than a dozen studies have appeared, seeming to absolve the implants of the most serious charge: silicone leaching from the implant can migrate throughout a woman’s body and cause a wide range of autoimmune disorders, such as lupus, scleroderma or rheumatoid arthritis.”<sup>157</sup>

Similarly, in 1995 *The New York Times* ran a number of investigative articles on the implant issue under such headlines as “Legal System and Science Come to Differing Conclusions on Silicone”<sup>158</sup> and “A Case of Justice or a Total Travesty?: How the Battle Over Breast Implants Took Dow Corning to Chapter 11.”<sup>159</sup> *The Wall Street Journal* weighed in with its own lengthy editorial in its May 19, 1995 edition. Entitled “The Breast Implant Tragedy,” the editorial likened the implant issue to a Greek tragedy, in which “the furies have driven the breast-implant players forward, oblivious to rational argument, dooming companies, consigning breast-cancer patients to personal tragedy, turning once esteemed courtrooms into a rabble of foolishness and avarice.”<sup>160</sup>

Unfortunately, by the time articles such as these began appearing, it was too late. The damage had been done.

## The Class Action Plaintiffs’ Attorneys

Critics often cite money as the only concern of the implant manufacturers. Few notice that the manufacturers’ greatest critics, the trial lawyers, have exactly that same motivation. One third of a \$33 million award can be a powerful incentive for a law firm. Not surprisingly, the Association of Trial Lawyers of America has conducted a large number of seminars for plaintiffs’ attorneys, assisted by selected data provided by Sidney Wolfe of Public Citizen.<sup>161</sup> The suing of implant manufacturers became a boom industry in the United States, with some lawyers out to convince women that even though they may feel just fine, they are really sick and must be properly compensated.

With so much money to spread around, it wasn’t difficult for lawyers to get doctors to find patients. This isn’t to say that all doctors who refer implant recipients to lawyers are dishonest. But as one physician put it, “One of the reasons the whole situation is abnormal is

because the attorneys were the people who first found the documents that convinced the doctors who do this work that there's something real happening and therefore encourage us to do more than just tell the patient they're depressed or anxious or something or they're aging."<sup>162</sup>

Some lawyers have located breast-implant clients by running ads with headlines such as "\$100,000.00 OR MORE MAY BE OWED TO YOU!"<sup>163</sup> "I get calls from women who say, 'Where do I pick up the money? I have implants,'" says Sandy Finestone of the Women's Implant Information Network in Irvine, California. "You dangle four billion dollars in front of them and it certainly gets their attention," she adds.<sup>164</sup> Finestone has two polyurethane implants that she makes clear will not be the subject of litigation.

For some at the FDA who were instrumental in the implant moratorium, the litigation explosion, involving advertisements mentioning a ban, proved a bitter lesson in the law of unintended consequences. One such person was Dr. Elizabeth Connell of Emory University, who headed the FDA panel recommending the moratorium. "A number of plaintiffs' attorneys saw this as an opportunity and seized it," she said later. "The intense litigation has nothing to do with medical science or truth."<sup>165</sup> Or as one rheumatologist put it after the June 1994 *NEJM* study finding no link between connective-tissue disease and silicone breast implants, "I think that if there had not been the endless litigation that it is unlikely that anyone would choose to study this issue further."<sup>166</sup>

But attorneys have not only ignored scientists; they've attacked them. After Dr. Sherine E. Gabriel published a study in the *NEJM* in June 1994, a lawyer claiming to represent two to three thousand implant recipients began filing legal demands against her. "The magnitude of the demands is staggering; the burden is staggering," she told *The New York Times*. "They want over 800 manuscripts from researchers that were here, they want hundreds of data bases, dozens of file cabinets and the entire medical records of all Olmsted County [Minnesota] women, whether or not they were in the study." As one might guess, Dr. Gabriel has said the demands have "severely compromised" her ability to do research and have made colleagues of hers back off from doing their own implant research for fear their findings would also infuriate plaintiffs' lawyers. "Some," she says, "determined that the price in terms of their own research careers is too high to pay."<sup>167</sup> In an October 1995 statement deploring this state of affairs, the American College of Rheumatology said that "Clinicians, scientists, academicians, and editors who have been harassed by plaintiffs' attorneys for their involvement in scientific research efforts related to sili-

cone implants deserve the continued support of their institutions and professional societies.”<sup>168</sup>

## The Activist Groups

Added to the many powerful forces opposing science on silicone implants was that of feminism. To many of the most vocal and influential feminists, a preference for big breasts represents female oppression. Susan K. Brownmiller, in her landmark 1984 book *Femininity*, opined: “Enlarging one’s breasts to suit male fantasies,” represents the exploitation of women. “Big breasts are one of many factors that have slowed women down in the competitive race of life,” she said. “Symbolically, in the conservative Fifties, when American women were encouraged to stay at home, the heavily inflated bosom was celebrated and fetishized as the feminine ideal. In decades of spirited feminist activity such as the Twenties and the present when women advance into untraditional jobs, small, streamlined breasts are glorified in fashion.”<sup>169</sup>

If preferring large breasts is oppression, say these feminists, then the implants used to enlarge one’s breasts are tools of oppression. Another feminist author, Rita Freedman, writing in *Beauty Bound*, claimed, “Having been taught that feminine beauty means having full, softly rounded breasts, women judge themselves against this standard. Missing the mark, they put on padded bras or suffer silicone implants.”<sup>170</sup> Naomi Wolf wrote in her 1991 bestseller *The Beauty Myth*, “Breast surgery, in its mangling of erotic feeling, is a form of sexual mutilation.”<sup>171</sup>

Having gone this far with imagery, it was just one more step to start actually blaming implants for physical ills. After anecdotes began to appear linking implants to disease, this became all the easier. Thus, Susan Faludi, in her best-selling book *Backlash: The War Against Women*, wrote matter-of-factly that, “ruptured, the leaking could cause toxicity, lupus, rheumatoid arthritis, and autoimmune diseases such as scleroderma.”<sup>172</sup> She provided no evidence of this, as indeed she could not; but it apparently seemed quite fitting to her—as well as to other feminists—that something that, in their minds, was so harmful to women as a class should also be harmful to them as individuals.

Unfortunately, two persons that Commissioner Kessler placed on the FDA implant review board were clearly prejudiced against implants for just these reasons. Not only didn’t they believe breast implants pro-

vided any benefits to women, but they found them morally repugnant as well. One had written in a letter to Kessler in 1991 that “the Federal government now has the power to deliver a profoundly important message to the American public involving basic values, concepts of beauty and health,” and went on to say that “it would be really wonderful if the FDA could address such attitude-impacting mental health issues as what is really healthy and normal and maybe even beautiful—healthy breasts of any size and shape.”

One of the panel members stated in a letter to Kessler that implants “perpetuate the myth of Barbie Doll’s Body” and wondered whether breast augmentation will become “like rhinoplasty, a rite of passage for affluent teens.”<sup>173</sup> This second member was none other than *Beauty Bound* author Rita Freedman.

Faludi’s book contained a general condemnation of what she considers society’s, men’s, and plastic surgeons’ efforts to encourage women to have plastic surgery. Some of it is both pointed and fair. Yet the participation of the feminists in the anti-implant crusade is ironic, since the virtual ban on silicone implants has resulted in the curtailment of what feminists have always proclaimed as their goal—a woman’s right to choose for herself. Faludi acknowledges that at one time one feminist journal, *Ms. Magazine*, “deemed plastic surgery a way of ‘reinventing’ yourself—a strategy for women who ‘dare to take control of their lives.’”<sup>174</sup> And it bears noting here that men, too, have flocked to the plastic surgeon’s operating table.

According to Dr. Marcia Angell, “It is possible to deplore the pressures that women feel to conform to a stereotyped standard of beauty, while at the same time defending their right to make their own decisions.” Indeed, Angell has said, the act of withdrawing implants could be viewed as sexist because “people are regularly permitted to take risks that are probably much greater than the likely risk from breast implants.” She cites as examples the risks associated with cigarette smoking and excess alcohol consumption.<sup>175</sup>

## Fomented Fear

Whatever damage implants might have caused may pale before the psychological and even physical damage done to those women who have been told they are virtually ticking time bombs. In her forward to Vasey’s book, implant recipient and talk show host Jenny Jones writes: “Not a day goes by that I don’t wonder how my exposure to sili-

cone is affecting my health. With every ache, every pain, the question arises: Is it the silicone?" She adds, "I don't ever expect to lose that fear."<sup>176</sup> It's unfortunate that she has spread that fear further by giving her support to such a book.

Says the Women's Implant Information Network's Finestone, "Women are going through unnecessary surgeries because of this." Of those who have undergone surgery, she says, "Some have had their emotional well-being and self-esteem hurt because of the change in their bodies."<sup>177</sup> After all, these women went through the discomfort and expense of having implants because they really wanted them; and almost all, according to the polls, were pleased with the effect. Now, as the title of one news story put it, "Women Cope with Agony of Having Silicone Breast Implants Removed."<sup>178</sup> Now they were being told they had to give it all up and that it might be too late to prevent the harm.

Unfortunately, the anti-silicone-implant crusade has given women something very tangible to fear. Because of the negative publicity, as early as 1991 insurance companies were starting to deny or restrict medical coverage to women with implants. Now, because some doctors and lawyers have tied various illnesses to implants, women with implants who do eventually get any of those illnesses may find themselves without medical coverage. The founder of the Washington, DC, chapter of the breast cancer support organization Y-ME told a congressional panel, "In some instances, it is easier for a cancer patient to obtain insurance than one who has implants."<sup>179</sup>

Like many health scares, the one over silicone implantation has been ignored in most of the world outside of the United States. Only a few other countries forbid the implant procedure within their borders. Most notable are Australia and Canada (this even though the Canadian Independent Advisory Committee review showed no causal link between silicone breast implants and serious illness).<sup>180</sup> While most countries haven't even considered removing silicone-gel implants from use, some, such as the United Kingdom, have reviewed the evidence and stated affirmatively that implants should remain available.<sup>181</sup> In June 1994 the 20-member European Committee on Quality Assurance and Medical Devices in Plastic Surgery issued a statement that it "does not support any restriction on the use of silicone-gel filled implants."<sup>182</sup>

American women have gone to other countries—including the United Kingdom,<sup>183</sup> France, Germany, Mexico, and countries in the Caribbean—to get implants.<sup>184</sup> The problem with this is not only that it makes it unaffordable for some women to get implants, but also that if something goes wrong after the surgery, the doctor may be thousands of

miles away. Malpractice suits are difficult to pursue in much of the world and virtually impossible in South and Central America.<sup>185</sup>

## Conclusion

Some 7.5 million medical devices are implanted in Americans each year, including 1.5 million patients who receive silicone eye lenses and 670,000 who get artificial silicone joints. Many of these devices are lifesaving, such as pacemakers, heart valves and shunts that draw fluid off the brain. Manufacturers have had to find new sources not only of silicone, but also of other important implant-device materials such as polyethylene, Teflon and polyacetal.<sup>186</sup> But the problems with the crusade against silicone implants don't end there. In a sense, the anti-silicone implant crusade is a microcosm for so much that is wrong with how scientific data and principles are distorted and ignored when there is greater gain to be had by doing so. The resoundingly antiscientific—and, until recently, successful—crusade against silicone implants portends problems for many other products that may be destroyed by analogous waves of hysteria.

Even though it has taken more than 8 years for scientific validation and vindication in the struggle to evaluate the status and safety of silicone-gel breast implants, certainly the scientific validation that has finally come has been worthwhile and serves as a lesson and model for future implant technology. Nothing manmade that is implanted in the human body lasts forever. All types of implants have a characteristic cycle of aging and eventually break down and rupture. Inherent in the process of implant aging is a range of complications that must be clearly delineated to patients in a manner based soundly on scientific evidence.

For further information about silicone breast implants to assist women in making informed decisions based on facts, not fears, visit the FDA's website at <<http://www.fda.gov/cdrh/breastimplants/>> and the Institute of Medicine's website at <<http://www.iom.edu/>>.

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