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1-1-1992

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The authors thank the following for their cooperation in providing information for this case: Dow Corning Corporation, the Food and Drug Administration, McGhan Medical Corporation (INAMED), Mentor Corporation, Canon Communications Inc., CNN MoneyLine, Daniel Bolton, Esq., of Ropers & Majeski, and Tom Talcott of Talcott Development.

DOW CORNING AND THE SILICONE IMPLANT CONTROVERSY

Working Paper 92-0904\*

by

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## DOW CORNING AND THE SILICONE IMPLANT CONTROVERSY

*During 1991, the silicone breast implant issue created an unprecedented challenge for Dow Corning that will continue for some time. We are taking responsible action to resolve the situation in the best interests of the needs and concerns of women. I ask that you keep informed so that you can represent your company accurately to customers, suppliers and members of our communities. And I encourage you to keep the issue in perspective and not allow the extensive media coverage to distract you from the fulfillment of your jobs.*

*Lawrence Reed  
President & COO  
Dow Corning Corporation  
1991 Report for Employees*

*The silicone breast implant fiasco is a sad case of corporate indifference and regulatory mismanagement.*

*Representative Ted Weiss (D-N.Y.)  
House Subcommittee Chairman  
New York Times, 3/20/92*

On April 16, 1992, the US Food and Drug Administration (FDA) lifted its January 6 moratorium on silicone gel-filled breast implants, but limiting availability and use for only special conditions. Given its concern about implant safety, the FDA required all future recipients to enroll in clinical studies. In its May 27, 1992 *Update On Silicone Gel-Filled Breast Implants*, the FDA acknowledged that "there is public health need for the implants among patients who have lost a breast because of cancer or trauma, or who have a serious malformation of the breast requiring reconstruction. Thus any woman who needs the implant to reconstruct the breast will be permitted access to such studies. Implants for the purpose of augmentation (breast enlargement) will be available only to a very limited number of women who

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This case is intended as a basis for class discussion rather than to illustrate either effective or ineffective management. No judgment or conclusion is implied either for or against any individual, organization or institution. Every attempt has been made to report information accurately and all information sources are cited where appropriate.

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are enrolled in controlled clinical studies approved by FDA and designed to study specific safety questions relevant to the device."

### **THE IMPLANT MARKET AND INDUSTRY PRIOR TO APRIL 1992**

The breast implant market generated annual revenues of approximately \$500 million prior to the controversy. The FDA estimates that approximately 2 million women in the U.S. have received breast implants.<sup>1</sup> Since their introduction in 1964 by Dow Corning, silicone-filled breast implants gained popularity<sup>2</sup> and had slowly shifted from being predominantly reconstructive to being used for cosmetic augmentation purposes. The FDA estimated that 80% of the procedures were performed for cosmetic reasons and 20% for reconstructive purposes (for cancer patients who had undergone mastectomies). According to Business Week (6/10/91), breast implants formed the third most popular procedure in plastic surgery after nose reconstruction and liposuction. Between 100,000 and 150,000 implant procedures were performed each year until the FDA's moratorium in January 1992. According to the Los Angeles Times (1/7/92), surgeons' fees accounted for the bulk of the implant industry's \$500 million revenues in 1991. Sales of the devices totaled about \$50 million in 1991.

The industry consisted of the following firms prior to April 1992:

#### **Dow Corning Corporation**

Dow Corning Corporation was the world's first and largest silicone gel-filled breast implant manufacturer. It commanded approximately 35% of the market<sup>3</sup> until March 19, 1992 when the company withdrew from the market. Founded in 1943, Dow Corning is a 50/50 joint venture of Dow Chemical Company and Corning

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<sup>1</sup>Two estimates made by the FDA stated that some 1 million women have breast implants in place. All other references gave the 2 million women estimate.

<sup>2</sup>Between 1981 and 1988, the number of procedures done nationally grew 63% to 620,000. 20% of the operations performed annually in the U.S. were done in New York, second only to Los Angeles. (New York Business Journal, 1/13/92).

<sup>3</sup>The American Medical News states that Dow Corning had a 20% share of the breast implant market. Other references reflect the 35% market share. According to Canon Communications, Inc., publisher of the *Medical Device and Diagnostic Industry*, there is no official market share information. There is no dispute, however, of Dow Corning's market leader status.

Incorporated. Its principal business is to develop, manufacture and market silicones, related specialty chemicals, polycrystalline silicone, and specialty health care products. Operating worldwide, Dow Corning is a diversified, high technology firm with around 5,000 products, 40,000 customers, 8,000 employees, and 4,900 total active worldwide patents (1,300 U.S. active). In 1991, 8% of its sales revenue was spent on research and development. Three related companies are Hemlock Semiconductor Corp., which manufactures polycrystalline silicon, Dow Corning STI which makes silicone rubber, and Dow Corning Wright, a manufacturer of orthopaedic medical devices. Dow Corning Wright was the division responsible for silicone implants.

Company estimates suggest that there were approximately 750,000 Dow Corning implants worldwide by 1991. According to the company's *1991 Report for Employees*, despite an 8.1% increase in sales revenue in 1991 (\$1,845 million ending 12/91), net income (\$153 million) fell 10.6% from 1990. Dow Corning explained, "Profits were hurt by charges for anticipated venture losses, legal contract disputes, and breast implant matters. These charges reduced 1991 Profit After Tax by \$36 million."<sup>4</sup> Implant sales, however, generated less than 1% of Dow Corning's 1991 sales revenues.<sup>5</sup> See Exhibit 1 - Company Financial History.

Dow Corning first entered the silicone-filled breast implant market in 1964 when the Cronin Implant was invented by Senior Surgeon Tom Cronin at Dow Corning. Market resistance to the thick gel and shell led to a modified design in 1969, which included a seamless envelope and softer silicone gel. However, according to

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<sup>4</sup>Dow Corning stopped producing silicone-gel filled breast implants and took a \$25 million charge against 4th quarter 1991 earnings, which included a \$10 million research fund announced on 3/19/92. (Wall Street Journal, 1/15/92).

<sup>5</sup>According to attorney Daniel Bolton, Dow Corning was responsible for the original national testing of silicone breast implants, a position which later subjected the company to being named as CO-defendants in lawsuits against other implant makers.

Tom Talcott, an employee at Dow Corning between 1952 to 1976<sup>6</sup>, the modified design had a higher failure rate than the earlier design.

Subsequent product redesign led to the SILASTIC MSI Brand Mammary Implant H.P. Gel Filled design. The SILASTIC MSI Mammary Implant H.P. is a silicone gel-filled breast implant made with a micro structure silicone envelope. The silicone envelope consists of medical grade high performance (H.P.) silicone elastomer with an integral surface micro structure and a fluorosilicone barrier layer laminated to the inner surface of the envelope. The company's product information stated that the fluorosilicone coating within the envelope provided an effective barrier to significantly reduce "gel bleed", the passage of small quantities of silicone through the elastomeric shell of the implant. (If the gel happened to become mixed with body fluids, it may lose viscosity, and hence possibly be more difficult to remove). The company maintained that the product was safe and that most women were, and would continue to be, happy with their implants (New York Times, 3/20/1992).

In its *1992-93 Profile*, the company detailed eight basic corporate values: Integrity, Employees, Customers, Quality, Technology, Environment, Safety, and Profit. See Exhibit 2 - **Dow Corning Corporate Values**. These values were also reflected throughout its *1991 Report for Employees*.

### **Other Implant Makers**

In addition to Dow Corning, there were several silicone breast implant makers in early 1992, including Surgitek, a subsidiary of Bristol-Myers Squibb, McGhan Medical Corp., a subsidiary of INAMED Corporation of Carpinteria, CA, Mentor Corporation of Santa Barbara, CA, and Bioplasty of Roseville, MN.

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<sup>6</sup>In fall 1974, Talcott was made a member of the task force for the biological testing of the second generation breast implants. Talcott contends that the silicone gel breast implant was too fluid, posing a potential danger to the patient and presented his recommendation to suspend the product to the group in 1975. Following unsuccessful pleas, Talcott resigned in protest in 2/76. Information provided by Talcott was a factor in the FDA's decision to impose the moratorium on 1/6/92.

**Bristol-Myers Squibb**

Headquartered in New York, NY, Bristol-Myers Squibb manufactures and distributes cardiovascular and other pharmaceutical products, medical devices such as orthopaedic implants and surgical instruments, non-prescription health products such as baby formula, toiletries, beauty aids and household products. Surgitek was the subsidiary responsible for the manufacturing of silicone gel implants. Preliminary data in a 1991 FDA study on polyurethane foam, a material used as a coating for certain kinds of silicone gel-filled breast implants, suggested that the foam might degrade into a substance called 2-toluene diamine (TDA), which has been shown to cause cancer in laboratory animals.

In April 1991, Surgitek voluntarily suspended shipment of its Meme and Replicon polyurethane foal-coated implants and requested doctors to delay implantation while the FDA evaluated laboratory and risk assessment data on a possible link between polyurethane foam and cancer. Surgitek set up a toll free number for inquiries by patients and physicians. In August 1991, with litigation pending against the company, Bristol-Myers Squibb officially withdrew from the implant market.

**McGhan (INAMED) Corporation**

McGhan Medical Corporation, a wholly-owned subsidiary of INAMED, is engaged in the development, manufacture and sales of a number of implantable products, including mammary prostheses, tissue expanders and facial implants for plastic and reconstructive surgery as well as custom prostheses for a variety of surgical applications and procedures. In its mammary prosthesis product line-up for 1991, McGhan produced different models, shapes and sizes of implants including but not limited to double-lumen, saline, and gel-filled mammary implants. The company's Biocell™ implant incorporates its own patented low-bleed technology along with its patented textured surface technology. Along with other subsidiaries of INAMED,

McGhan also manufactures saline-filled mammary prostheses. A news release (January 7, 1992) stated that the company's strategic plan for 1992 would "emphasize the marketing and sale of saline-filled implants to achieve a leading world-wide market share." Anticipating an increase in demand for saline implants (which remained unaffected by the FDA's moratorium), the company stepped up manufacturing levels and product inventories during the second half of 1991. The company has filed for FDA permission to continue implant operations.

McGhan reported a net loss of \$2.8 million or \$.35 per share on sales of \$42 million for the year ended December 31, 1991. The company attributed the loss to the write-off of approximately \$4.4 million of inventories and intangible assets related to the silicone gel-filled implants covered by the FDA regulation. The company has disclosed that several INAMED subsidiaries were defendants in 130 pending court actions for general and/or punitive damages. McGhan is self-insured, with no product liability coverage on the majority of its implant products.

### **Mentor Corporation**

In operation since 1969, Mentor Corporation develops, manufactures and markets specialized medical products in the areas of plastic and reconstructive surgery, urology and ophthalmology. Plastic surgery products include surgically implantable prostheses for cosmetic and reconstructive surgery, principally breast implants and tissue expanders. Urologic products include disposable products for the management of certain urinary/gastrointestinal disorders. Ophthalmic products include surgical equipment, primarily coagulators used to control bleeding during ophthalmic or other microsurgery, and diagnostic equipment. Headquartered in Santa Barbara, CA, Mentor has manufacturing and research facilities in California, Massachusetts, Minnesota, Missouri and Texas. According to company records, Mentor's plastic surgery business accounts for about 30% of revenues. Mentor produces both silicone-gel implants and saline-filled implants used for breast augmentation and reconstruction in connection



with congenital deformity or following cancer surgery, or for other medical reasons. Mentor's *1992 Annual Report* states, "we purchased the silicone gel used in our implants from an outside supplier and believe that it is the responsibility of that supplier to defend it and indemnify us against claims of injurious effects on the body."<sup>7</sup> Mentor is filing for premarket approval and is resuming shipment of silicone gel implants in accordance with the FDA guidelines.

### **Bioplasty, Inc.**

Headquartered in Roseville, MN, Bioplasty manufactures and markets medical products. In an interview with the Minneapolis-St. Paul City Business Journal in January 1992, Bioplasty CEO Arthur Beisang said that the company awaited FDA approval to start selling its non-silicone implants. The company withdrew its MISTI GOLD implant PMA application in 1991 after the FDA said that the company did not have enough data to prove the product's safety. According to Beisang, Bioplasty's other implants are made of an inorganic polymer that, unlike silicone, is excreted by the body if the implant ruptures. Following the FDA's moratorium and its panel recommendation to restrict the use of silicone gel-filled implants in early 1992, Bioplasty withdrew from the market.

### **THE SILICONE IMPLANT CONTROVERSY**

In the 1980s, silicone implants came under scrutiny for possible implant rupture and migration of silicone into the recipient's body, allegedly resulting in mixed connective tissue disorders. However, there were apparently two sides to this issue, as detailed below:

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<sup>7</sup>The silicone gel used in Mentor's implants was supplied by Dow Corning.

### **Proponents for Implant Use**

Many groups supported the use of silicone implants, including implant recipients themselves, plastic surgeons and consumer advocacy groups. During the FDA hearings in late 1991, hundreds of women with breast implants testified before Congress about their emotional benefits. During a January 1992 news conference at which officials of the American Cancer Society's Texas Division reiterated their opposition to a ban on silicone implants, Silvia Mercado of Fort Worth, a cancer survivor, said, "It helped me put the episode of cancer behind me and helped me get on with my life." Mercado is a member of an organization called Women for Implants in Dallas. Similarly, Garry Brody, a member of the American Society of Plastic and Reconstructive Surgeons' Devices Reviewing Committee, stated in an interview with USA Today (January 21, 1992) that "problems surrounding silicone implants are rare and uncommon."

While silicone-lined saline-filled implants provide an alternative, they are not recommended in certain mastectomy cases and are more likely to puncture or shift, according to Dr. George Peters, President of the Texas Division of the American Cancer Society's Texas Chapter and a breast cancer surgeon at Baylor University Medical Center (Dallas Morning News, 1/92). Experts appear to agree that the consistency of the silicone gel most resembles that of the human tissue. It is also easy to work with as far as molding and forming, says Jerry Kuester, who researches medical device safety concerns for the Public Citizen Health Research Group (USA Today 1/ 21/92).

### **Opponents to the Implants**

Opponents of the silicone breast implant contend that Dow Corning and other implant makers withheld information regarding the silicone implants and failed to

inform the implant recipients of potential danger.<sup>8</sup> Among the critics is Tom Talcott, a former member of Dow Corning's product development task force from 1974 to 1976. Mr. Talcott has stated that his efforts to express concern over the silicone gel breast implant to members of the product and marketing team at Dow Corning were unsuccessful. According to information provided by Talcott, he contended that while Dow Corning's management agreed that the gel should not be placed directly in human breasts, they believed that it would be acceptable to store the fluid in a biological capsule or envelope. Talcott's belief has spurred him to lead a crusade in breast implant litigation over the past 10 years.

#### **DOW CORNING: LITIGATION AND RESPONSES**

Dow Corning's silicone gel-filled breast implants first came under legal scrutiny in 1984 when a San Francisco federal court jury concluded that the company had committed fraud in marketing its implant as safe. The jurors awarded Maria Stern of Nevada \$1.5 million in punitive damages. Dow Corning appealed and the case was settled for an undisclosed sum. (Business Week 6/10/91). Following the Stern case, Dow Corning changed its product literature to include a warning intended for surgeons to pass along to patients. A 1985 package insert mentions the possibility of immune system sensitivity and possible silicone migration following rupture. A 1987 company "position statement" discounted the immune-system problem, saying it was linked to silicone of lesser purity than was used in the company's implants. Shortly after, the company began a program to replace ruptured implants and those removed because patients complained of adverse reactions.<sup>9</sup>

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<sup>8</sup>The National Resources Defense Council and Consumers Union approached Dow Corning, Bioplasty, McGhan Medical and Mentor with the information that their top officials could be jailed if they do not comply with California's corporate criminal liability law and disclose all product hazards. (Wall Street Journal 1/17/92)

<sup>9</sup>In the *Supplemental Information to Most Frequent Questions* prepared by the Dow Corning Information Center, the company states, "The number of cases of connective tissue disease reported in women with silicone breast implants is small and likely within the number expected by chance alone... The first cases of possible connective tissue disease were published in Japan in 1964. Over the past 26 years, more than

In 1988, Mariann Hopkins sued Dow Corning with attorney Daniel Bolton who had represented other implant recipients. Hopkins refused several Dow Corning attempts to settle out of court, the last of which amounted to \$1.8 million. (Dallas Morning News, 2/92). The New York Times reported on December 17, 1991, the jury found Dow Corning guilty of fraud and malice in marketing the implants and awarded Hopkins \$7.3 million, the largest amount ever in an implant suit.<sup>10</sup> The lawsuit contended that the disease was caused by a leak of the gel. Hopkins received the silicone implants in 1976 following a double mastectomy. Hopkins was diagnosed with mixed connective tissue disease, an irreversible, autoimmune illness with symptoms similar to those of rheumatoid arthritis. In response to the verdict, Dow Corning published the following statement, "We are particularly disappointed because the jury still make this unjustified award to the plaintiff, despite the fact that two of her doctors - whom Dow Corning called as witnesses - said in court that the plaintiff's mixed connective tissue disease preceded her breast implant surgery." Dow Corning charged that symptoms of the plaintiff's mixed connective tissue disease were identified at least two years before she had the breast implants. According to Bolton, there are approximately 200 law suits pending against Dow Corning. Other implant makers are also being sued for damages. It has been reported that Dow Corning's breast implant legal liability could exceed \$1 billion.<sup>11</sup>

The company's overall position on the role of its implants can be summarized in the words of Mr. Robert Rylee, Chairman Healthcare Businesses, Dow Corning Wright, "It is not my role in life, nor our company's role, to tell her (potential implant

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100 cases have been published in the medical literature on women who have developed connective tissue disease. 1/3 of these women have silicone breast implant devices."

<sup>10</sup>The company is appealing the decision.

<sup>11</sup>The liability does not stop at Dow Corning. Dow Chemicals and Corning, the parent companies, have been sued by an investor, who accused the firms' joint venture of securities law violations and of allegedly not revealing possible problems concerning the firm's silicone gel breast implants. (Wall Street Journal, 1/20/92). CNN's MoneyLine 4/13/92 broadcast stated that potential law suits against all breast implant makers may potentially exceed \$1 - 2 billion.

recipient) that she cannot do that. I think it is important for the woman to have the right to make that choice, to make an intelligent, informed decision." (Wall Street Journal 1/14/92).

### **THE FDA'S ROLE - THE MEDICAL DEVICE AMENDMENTS OF 1976**

Silicone breast implants had been available in the US. for more than 30 years prior to the moratorium. The first implant was reported to be available on the market in 1962 when the FDA did not have jurisdiction over device regulation. On May 28, 1976, the Medical Device Amendments to the Food, Drug and Cosmetic Act of 1938 went into effect, empowering the FDA to regulate medical devices through the establishment of a premarket approval process similar to that for drugs. However, the FDA had neither the resources nor the inclination to launch countless new investigations.<sup>12</sup> Consequently, about 90% of the devices already on the market, including silicone breast implants, were "grandfathered" out of the approval process. (American Medical News 2/17/92). Under the Medical Device Amendments, devices are categorized into three classes:

**Class I devices:** Those devices for which "general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device" (e.g. adhesive bandages, toothbrushes, eyeglasses, and thermometers).

**Class II devices:** Those devices for which "a performance standard exists to provide reasonable assurance of safety and effectiveness" (e.g. cardiac monitors, anesthesia machines and defibrillators, and magnetic resonance imagers).

**Class III devices:** Those devices "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury" e.g. silicone-gel breast prostheses (implants), IUDs, endolymphatic shunts, and osseous implants. In 1986, approximately 140 devices, or 8% of the total, were in Class III.

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<sup>12</sup>According to the May 1986 issue of *FDA Consumer*, the number of premarket approval applications increased by about 56% from 1980 to 1985. With the rising workload and the greater complexity of devices, the amount of review time increased from an average of 230 days per application in 1980 to about 350 days in 1985. The Center for Devices and Radiological Health had streamlined the internal review procedures and issued guidelines for manufacturers.

Following these amendments, manufacturers of Class III devices were required to do one of two things: either submit evidence for reclassification as Class I or II device, or file a premarket approval (PMA) application, accompanied by scientific data sufficient to establish the product's safety and efficacy. In June 1988, the FDA classified the implants into Class III - which gave it the authority to ask for safety and effectiveness data after the prescribed waiting period of 30 months.

With the prioritizing of devices to receive PMA approval notification, breast implant manufacturers were not officially notified until May 17, 1990, when a notice appeared in the Federal Register proposing a regulation to require silicone breast implant manufacturers to file PMAs. On April 10, 1991, the FDA issued a final ruling requiring all manufacturers of silicone gel-filled mammary prostheses to file premarket approval applications for each specific mammary prosthesis they intend to market with the FDA within 90 days after the effective date of the regulation, or cease sale and/or distribution of their products. **See Exhibit 3 - Silicone Breast Implant Health Risks.** With this ruling, implant manufacturers had until July 9, 1991, to file premarket approval applications. By July 9, 1991, several implant makers, Dow Corning Wright, McGhan Medical Corporation, Mentor Corporation, Bioplasty, Inc., and Surgitek (Bristol-Myers Squibb) submitted their safety data to the FDA for review. On August 22, the FDA decided not to proceed with a full-scale review of the safety and effectiveness data submitted by three manufacturers of silicone gel-filled breast implants "because the submissions contain little or no information based on human studies." Affected were applications submitted by Joseph F. Cavon, MD, of Santa Ana, CA., Surgitek, and Bioplasty for its MISTI GOLD model. Applications by Dow Corning, McGhan, Mentor, and Bioplasty for its other models would undergo the full review process. According to Dow Corning's records, the company submitted 50,000 pages of information addressing 30 years of safety studies, manufacturing processes, product design and labeling on July 8, 1991.

On November 15, following testimony by FDA scientists and implant manufacturers, the FDA's General and Plastic Surgery Devices Panel advised the FDA that data submitted by the four manufacturers of silicone gel-filled breast implants did not provide reasonable assurance of the safety and effectiveness of these devices. However, the panel chairperson, Dr. Elizabeth Connell of Emory University School of Medicine, emphasized that the group did not find evidence that the implants were unsafe and that there was not enough information about the risks and benefits of their use. Despite the lack of data, the panel of outside experts voted unanimously to advise the agency that the implants serve a public health need and that they should continue to be available while the manufacturers collect additional data. Under the law, the agency had 180 days from the day of the committee's non-binding recommendations to decide whether to approve silicone gel-filled breast implants for continued marketing.

### **The Voluntary Moratorium**

A number of hearings were held during the months of November and December. On January 6, 1992, FDA Commissioner Dr. David Kessler called for a voluntary moratorium on the use of silicone gel-filled breast implants until "new information" on their safety could be thoroughly reviewed by an independent advisory panel and the agency could make a final decision in light of the panel's review. In addressing the press, Dr. David Kessler said, "Women considering breast implants deserve to know whether these products are safe enough for use. I'm calling for a delay in the use of these products until our advisory panel can meet to consider new information which was not available when it met in November." Part of the "new information" included some 90 Dow Corning documents comprising 10 scientific reports or studies and 80 memos and company documents. These documents were revealed during a product liability case against Dow Corning Wright.<sup>13</sup>

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<sup>13</sup>The Wall Street Journal (1/13/92) reported the following: "There is evidence that the firm (Dow Corning) rushed a silicone-gel implant to market in 1975 after a crash development program undertaken to insure that the product would be made available in time to be grandfathered out of device legislation."

The FDA's concerns about the implants were stated by Dr. Kessler as follows:

- We still do not know how often the implants leak, and when they do, we do not know exactly what materials get into the body.
- We still do not know how often the implants break, or how long they last.
- We still do not know how often women with the implants suffer adverse effects. For example, there are reports that painful hardening of the implant can occur in anywhere from 10% to 70% of patients.
- We still do not know to what extent the implants interfere with mammography examinations. This is especially important because the implants have been used in thousands of healthy women each year.
- We still do not know whether the implants can increase a woman's risk of developing cancer.
- And we still do not know enough about the relationship between these devices and autoimmune and connective tissue diseases.

Per the moratorium, manufacturers were requested to stop distributing the devices and plastic surgeons were requested to stop recommending them until the agency could review further data on the safety of silicone implants. Unless a woman is having problems with her implants, the FDA does not recommend that the implants be removed. However, if a woman is having symptoms suspected of being implant related, she should seek a doctor's advice.

#### **The Panel's Final Recommendations**

In its Advisory Panel Meeting on February 18 - 20, the panel recommended that FDA permit the use of the implants under clinical protocols that will allow access to all women requiring breast reconstruction. (*Medical Devices Bulletin 2/92*) However, the panel reached a consensus that there was insufficient data to show a cause and effect relationship between implants and certain immune-related or connective tissue disorders.

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Talcott's testimony and internal memos pointed to the hasty development program. According to company documents and as Talcott contends, Dow Corning had thought that silicone might spur some immune response. Although the implants were tested on animals, there is no evidence that the devices were tested in or under animal breast tissue (*New York Times*, 1/13/92).



### **The FDA Decision**

The panel's recommendations were incorporated into the FDA's decision on April 16, 1992, when the FDA lifted the moratorium. Silicone-filled breast implants are now restricted to patients with breast cancer, traumatic injuries and serious congenital deformities, and women participating in clinical studies. The moratorium was lifted in three stages: Stage 1 began on April 20, 1992, for women whose breast reconstruction began before the moratorium with placement of a temporary tissue expander and who were awaiting a permanent implant and women whose implants have ruptured. Stage 2 would take several months to set up and will consist of clinical studies open to breast cancer patients and women with serious breast injuries and abnormality. Stage 3 includes intensive research studies and prospective clinical investigations open to limited number of women for reconstructive or cosmetic purposes. With the decision, the FDA is working with manufacturers to set up a centralized registry so that women with implants can be notified quickly of significant new findings about the devices. The FDA also requires further laboratory studies to look at the chemical composition and toxicity of the silicone material that "bleeds" out of the implant shell, the strength of the implant shell, its resistance to rupture, and the physical and chemical changes that the implants may undergo in the human body.<sup>14</sup>

### **DOW CORNING'S FINAL DECISION**

Dow Corning's response to the controversy took shape through several measures: In early 1991, the company set a \$250 million insurance fund to cover its potential implant liability. On July 24, 1991, it opened the Implant Information Center to provide facts about silicone breast implants to women through a toll free number. On January 29, 1992, the company retained a special counsel to conduct a complete

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<sup>14</sup>Further information may be obtained from the FDA by calling 1-800-532-4440 or 1-800-688-6167 for the hearing impaired.

investigation of its development, production, and marketing of silicone breast implants. The investigation will also examine the appropriateness and timeliness of management judgments and decisions over the development of the product. Dow Corning said that it has taken this action to provide an independent objective forum for a reasoned review by qualified experts regarding its conduct in the development and marketing of this device. At the conclusion of the investigation, a written report will be made available to the FDA and the general public.

To cooperate with the FDA, Dow Corning released 15 reports of scientific studies and 94 internal, non-scientific company documents on February 10, 1992, following allegations of withholding relevant data. At the same time, it appointed Keith R. McKennon, formerly Executive Vice President of The Dow Chemical Company, as Chairman of the Board and CEO of Dow Corning, replacing Lawrence Reed who will continue as President and COO. As CEO, McKennon would focus on the complex issues related to silicone breast implants, while Reed would direct Dow Corning's global operations, the company said.

Finally, on March 19, 1992, McKennon ended the company's 30-year trade in silicone gel implants worldwide and announced a \$10 million research fund to continue the study of silicone breast implant safety. "The single, most important objective of this research is to answer those remaining questions women may have about their implants," said McKennon. Dow Corning also reaffirmed its program to provide financial support for implant removals.<sup>15</sup> Dow Corning withdrew its Pre-market Approval Applications on April 14, 1992.

#### **THE INDUSTRY AFTER APRIL 1992**

By summer 1992, there are only two manufacturers still actively pursuing the implant market: McGhan Medical Corporation and Mentor Corporation, both of

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<sup>15</sup>This program provides up to \$1,200 of medical assistance per patient. The cost of implant removal is estimated from \$500 to \$5,000, depending on situation.

California. In a news release (May 18, 1992), McGhan Chairman of the Board Donald K. McGhan said, "Although the Company is still unable to manufacture or ship gel-filled implants, our customers are accepting the Company's saline-filled implants for most applications. The Company does expect to renew manufacturing and shipping of gel-filled implants as soon as the FDA allows." Meanwhile, Mentor, saw Dow Corning's and other manufacturers' withdrawal a welcomed opportunity. In its 1992 Annual Report (year ended 3/31/92), the company states, "We are looking forward to serve the needs of the market while working with the medical profession and the FDA to increase our knowledge and advance the technology of breast implants." Mentor reported record sales and earnings for the first quarter ended June 30, 1992. According to the company's news release dated 7/16/92, "Sales growth was led primarily by a resurgence in plastic surgery sales following the lifting of the FDA moratorium on breast implants, by strong international sales, and by a strong performance from urological surgical products."

*The recommendation reflected the panel's struggle to balance the obligation to ensure that devices are safe and effective with the effort to meet a compelling public health need.*

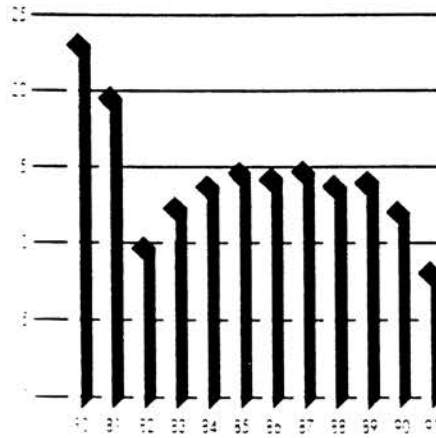
*American Medical News, March 9, 1992*

*Let me make very clear that Dow Corning remains satisfied that Dow Corning implants produced over the years have filled an important medical need for thousands of women, and did not and do not represent an unreasonable risk. Based on past experience, we believe that the vast majority of women who have our implants will remain satisfied with the device. Our reasons for not resuming production and sales, therefore, are not related to issues of science or safety but to the existing condition of the marketplace.*

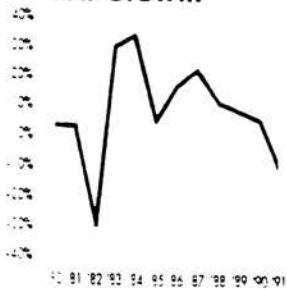
*Keith McKennon, Chairman of the Board & CEO  
Dow Corning Corporate News, March 19, 1992*

**Exhibit 1**  
**Company Financial History**  
 Source: Dow Corning Corporation 1991 Reports for Employees

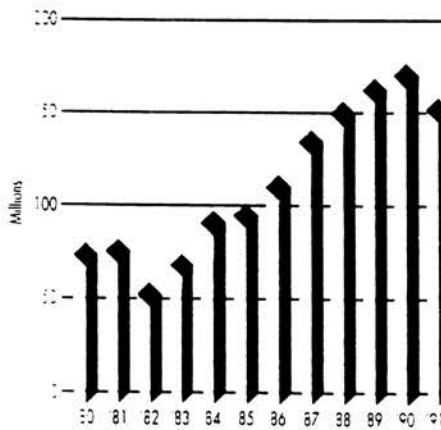
**Return On Assets**



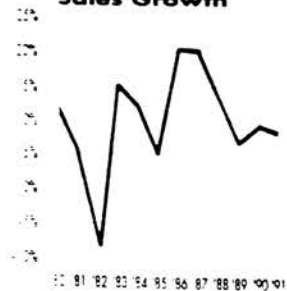
**PAT Growth**



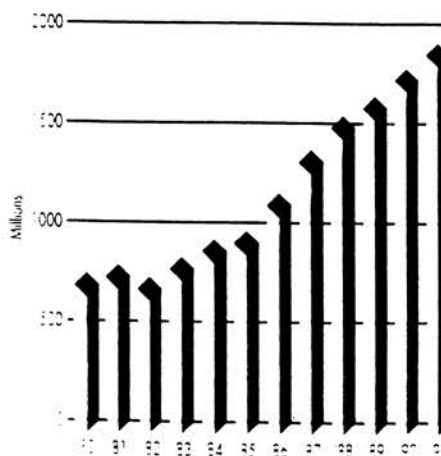
**Profit After Tax**



**Sales Growth**



**Sales**



**Exhibit 2**  
**Dow Corning Corporate Values**  
**Source: Dow Corning Corporation 1992-1993 Profile**

**Integrity:**

Our integrity is demonstrated in our ethical conduct and in our respect for the values cherished by the society of which we are a part.

**Employees**

Our employees are the source from which our ideas, actions and performance flow. The full potential of our people is best realized in an environment that breeds fairness, self-fulfillment, teamwork and dedication to excellence.

**Customers**

Our relationship with each customer is entered in the spirit of a long-term partnership and is predicated on making the customer's interests our interests.

**Quality**

Our never-ending quest for quality performance is based on our understanding our customers' needs for our willingness and capacity to fulfill those needs.

**Technology**

Our advancement of chemistry and related sciences in our chosen fields is the Value that more differentiates Dow Corning.

**Environment**

Our commitment to the safekeeping of the physical environment is founded on our appreciation of it as the basis for the existence of life.

**Safety**

Our attention to safety is based on our full-time commitment to injury-free work, individual self-worth and a consideration for the well-being of others.

**Profit**

Our long-term profit growth is essential to our long-term existence. How our profits are derived, and the purposes for which they are used, are influenced by our Values and our shareholders.

**Exhibit 3**

**Silicone Gel-Filled Implants Health Risks**

**Source: FDA Federal Register, September 26, 1991**

# ***FDA Recommended Patient Risk Information\****

## **SILICONE GEL-FILLED BREAST IMPLANTS**

The Food and Drug Administration believes that a patient considering silicone gel-filled breast implants should receive the following information about the possible risks involved. The patient should receive the information before surgery is scheduled, so that she has time to review the material and discuss it with her doctor. Each woman, with her doctor's help, must decide whether she is willing to accept the risks in order to achieve the expected benefits, which may vary, depending on the condition for which the implant is used.

In addition to posing the general risks associated with any surgical procedure (infection, delayed wound healing, etc.), silicone gel-filled breast implants have certain specific risks, including:

- Capsular contracture. The scar tissue that normally forms around the implant can tighten and squeeze the implant. This can cause unnatural firmness, pain and, in severe cases, a misshapen appearance.
- Calcium deposits in the tissue around the implant. This too can cause hardening and pain.
- Rupture of the implant. The implant can break due to injury or normal wear over time, releasing the silicone gel filling.
- Changes in nipple and breast sensation. There can be increased or decreased sensation, which can be temporary or permanent.

- Interference with mammography. The implant can interfere with the detection of early breast cancer through mammography because it can "hide" suspicious lesions in the breast. This makes it difficult to perform mammography and to interpret the results.

Although they may occur in only a small percentage of patients, some of these adverse effects, such as capsular contracture, calcium deposits and rupture, can require removing the implants.

In addition to these known risks, there are unanswered questions about silicone gel-filled breast implants. For example, even if the implant does not rupture, tiny amounts of the gel filling can gradually escape from the implant and may migrate to other parts of the body. It is unknown whether this is harmful to health in the long run. Questions have been raised about whether the escaped gel might cause autoimmune diseases such as lupus, scleroderma and rheumatoid arthritis in some women, or whether it might increase the risk of cancer. There is no scientific evidence at present that women with breast implants have an increased risk of these diseases, but the possibility cannot be ruled out. FDA has required the manufacturers of silicone gel-filled breast implants to submit data to answer these questions. (In contrast to the silicone gel-filled breast implants, saline-filled implants contain only salt water, so any risk that might be related to the gel would not occur with these products. But since both types of implants have a silicone rubber envelope, an increased risk of autoimmune diseases or cancer is possible even for the saline-filled implants.)

*\*Federal Register, September 26, 1991, pages 49098-49099*



BACKGROUND INFORMATION ON  
THE POSSIBLE HEALTH RISKS OF SILICONE BREAST IMPLANTS

(PREPARED DECEMBER 18, 1990)

(REVISED FEBRUARY 8, 1991)

Silicone gel-filled breast implants have been used for approximately 20 years, and at present about 2 million women in the U.S. have them. When the medical device law--the statute that gives the Food and Drug Administration (FDA) the authority to regulate products such as implants--was passed in 1976, it "grandfathered" devices that were already on the market, including breast implants. This means that the manufacturers of those products were not required to provide FDA with scientific evidence of safety and effectiveness, as they are with brand-new types of devices. That stipulation in the law is based on the premise that, generally speaking, more is known about the safety of a device that has been in use for some time than about one that is newly developed. But if questions arise over time that cast any doubt about a "grandfathered" device's safety, the law also gives FDA the authority to go back and require that its manufacturer provide us with evidence to demonstrate that it is safe and effective.

That is what FDA has chosen to do with silicone breast implants. Although it appears that most women with these implants do not suffer serious adverse effects, there are enough unanswered questions about possible risks that FDA has decided to require manufacturers to provide scientific data demonstrating their safety.

The possible risks of silicone breast implants fall into two basic categories: those related directly to the breast, and those that may involve distant parts of the body. One breast-related risk is that the implant may make it more difficult to see abnormalities in the breast when mammographic x-ray examinations are done, even if special views are made as part of the x-ray procedure. Another is the hardening, discomfort and pain that occurs in some patients, resulting from fibrous tissue growing around the implant. Still another is occasional breakage of the implant's outer envelope, causing the gel filling to be released.



Most of these breast-related effects are relatively easy to observe, and they are not unexpected. All implanted devices, from artificial hip joints to heart valves, will fail to work or will have adverse effects in a small proportion of patients--no type of device placed in the body for a long period of time can be considered perfect, and no surgical procedure is without risk. With breast implants, FDA needs more information on what percentage of patients experience these breast-related effects and how severe they are.

The possible effects of silicone breast implants on other parts of the body are far more uncertain and difficult to measure. For example, it is known that even in the absence of obvious leaks, minute quantities of the gel filling can migrate out of an intact breast implant over a long period of time and can travel throughout the body. It is not known whether this can be harmful over the long run or not. It has been suggested that these tiny amounts of silicone in the body could lead some people to develop auto-immune diseases in later years, and some scientists have raised the question of whether the silicone could have an effect on a developing fetus. But at this point there is no convincing evidence that these effects actually occur.

The long-term effect of greatest concern to most people is the possibility of cancer. That concern was aroused several years ago by a study of laboratory rats conducted by the Dow Corning Corporation, a leading manufacturer of silicone breast implants. The study showed an excess of a particular type of cancer called sarcoma in rats who had been implanted with silicone gel. FDA, too, was concerned about these results, and presented them to cancer experts within FDA and also at the National Institutes of Health.

The experts noted two reassuring facts about the study. First, sarcomas (the type of cancer produced in the rats) occur very rarely in humans; the vast majority of human breast cancers are of a distinctly different type, called carcinomas. Secondly, laboratory rats are extraordinarily susceptible to sarcomas caused by implanting foreign objects in their bodies; the experts pointed out that these animals develop sarcomas after the implantation of a wide variety of materials, most of them innocuous in humans. The experts concluded (a) that the results of the rat study are unlikely to apply to humans; (b) that although a risk from silicone breast implants cannot be completely ruled out, there are at present no convincing animal or human studies that point to such a risk; and (c) that if a cancer risk did exist from silicone breast implants, it would be very small.

To sum it up, FDA does not believe that there is cause for alarm at present about the safety of silicone breast implants. But answers are needed to the questions outlined above in order to establish once and for all just what the risks are. That is why FDA is going to require the manufacturers of the implants to supply scientific evidence of their safety. Manufacturers will have until the summer of 1991 to submit the data.

Silicone breast implants coated with polyurethane foam may pose certain additional hazards. FDA is particularly concerned that the polyurethane may break down in the body, and is conducting laboratory research to find out whether this is the case. Based on the results of this research, FDA will re-evaluate the risks and benefits associated with polyurethane-coated breast implants.

What should a woman who is contemplating a silicone breast implant do? For now, the best course of action is to discuss the situation frankly with her physician. (It is perfectly reasonable to ask the physician to see the informational material that comes with the implant, which describes possible adverse effects.) She needs to talk over the known, breast-related risks as well as the less well-understood, non-breast related risks described above, and to weigh these risks against the benefits of the procedure. That way she can make an informed decision about whether to proceed with the implant surgery.

If a woman who already has a silicone breast implant is concerned about the possible risks, she too should ask her physician's advice. Most of the readily-observed, breast-related adverse effects discussed above are well known to physicians, as are the ways to treat them. As to the possibility of effects on other parts of the body (related to the fetus, for example, or to autoimmune disease, or cancer), at this point these are only hypothetical questions. In weighing the possible long-term risks of silicone breast implants, it is important to bear in mind--and this applies to any number of substances we encounter in everyday life--that not being able to completely rule out a risk does not necessarily mean there is one.

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