

THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS

I. Introduction

Under the Rules of the House of Representatives, Rule X, 2(b)(2), the Committee on Government Operations is authorized to "review and study, on a continuing basis, the operation of Government activities at all levels with a view to determining their economy and efficiency." The committee has assigned this responsibility, as it pertains to the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), to the Human Resources and Intergovernmental Relations Subcommittee.

Pursuant to its authority, the subcommittee conducted an investigation of the safety and effectiveness of silicone breast implants, the regulation of those devices by the FDA, and research support by the NIH.

On December 18, 1990, the subcommittee conducted a hearing on the FDA's regulation of silicone breast implants.¹ The hearing included testimony from the following FDA witnesses: Walter Gundaker, Acting Director, Center for Devices and Radiological Health; Mr. Robert Sheridan, Director, Office of Device Evaluation; and Dr. Joseph Arcarese, Director, Office of Training and Assistance. Other witnesses included Dr. Nir Kossovsky, assistant professor of pathology and laboratory medicine at the University of California at Los Angeles; Dr. Frank Vasey, professor of medicine at the University of South Florida; Dr. Pierre Blais former senior scientific advisor for the Department of National Health and Welfare of Canada; Dr. Norman Anderson, former Chair of the FDA panel that reviewed the breast implant issue in 1988-90; Mr. Thomas D. Talcott, an engineer specializing in silicone implants for 20 years at Dow Corning; and Mr. Robert Rylee, vice president of Dow Corning Wright. Implant patients Sybil Goldrich, cofounder of Command Trust Network; Rosemary Locke of My Image After Breast Cancer; and Janet Van Winkle, founder of the American Silicone Implant Survivors (AS IS), also testified. Officials of three other manufacturers, Mentor, McGhan, and Surgitek, declined the subcommittee's invitation to testify.

¹Hearing before a subcommittee of the Committee on Government Operation, House of Representatives, "Is the FDA Protecting Patients From the Dangers of Silicone Breast Implants?," December 18, 1990, hereafter referred to as Hearing.

II. Background

Approximately 1 million American women have had breast implants. At the time that the subcommittee held its hearing in December 1990, approximately 100,000 operations were performed each year, most of them for augmentation purposes, to enlarge healthy breasts. Approximately 20 percent were for reconstruction after breast cancer or to correct other deformities. No information is available on the number of surgeries that were replacements of previously implanted prostheses, making it impossible to determine the number of women who currently have breast implants made of silicone gel or saline. Although breast implants had been on the market since the 1960's most were sold between 1980-1990.²

In December 1990, there were many different types of silicone breast implants on the U.S. market, made by at least six manufacturers. The FDA had received more than 4,300 reports of serious injury or malfunction.³ This was assumed to represent a fraction of the problems associated with the implants, since research has indicated that only approximately 5 percent of adverse reactions are reported to the FDA.⁴

A. BREAST INJECTIONS, BREAST IMPLANTS, AND THE FDA

Since the turn of the century, substances have been injected into women's breasts to enlarge them.⁵ Silicone injections were first used among Japanese women in the late 1940's and Las Vegas showgirls in the 1950's.⁶ The silicone was modified by adding cottonseed oil or other types of oil, which was intended to cause scarring and thus prevent migration of the silicone to other parts of the body. According to Dr. Norman Anderson, associate professor of medicine and surgery at Johns Hopkins University School of Medicine, approximately 50,000 American women had their breasts injected with liquid silicone. There were serious medical problems, resulting from these injections, including deaths. In 1965, the FDA classified silicone injections as a drug under the FDA's jurisdiction, and began to regulate the device. Dow Corning Corporation applied for a Notice of Claimed Investigational Exemption for a New Drug (IND) for facial augmentation in 1965; breast augmentation was

²Documents with various estimates regarding the number of annual procedures are in subcommittee files.

³Adverse reaction reports are in subcommittee files.

⁴Rogers, A.S et al. (1988). Physician knowledge, attitudes, and behavior related to reporting adverse drug events, *Archives of Internal Medicine*, Vol. 148, pp. 1596-1600.

⁵A mixture of paraffin, petroleum jelly, and olive oil was used. See Bates, H.K.; Cunny, H.C.; & LaBorde, J.B. Developmental Toxicity Evaluation of Polymethylsiloxane Injection in the Sprague-Dawley Rat. Paper presented at the FDA conference on silicone devices, February 1991, p. 128 of conference proceedings; in subcommittee files.

⁶This brief description of the history of silicone injections is from Hearing, testimony of Dr. Norman Anderson, associate professor of medicine and surgery, Johns Hopkins University School of Medicine, pp. 30-31.

not permitted in the study because of the known medical risks.⁷ The FDA has never approved silicone injections for sale for human use.

Because of the recognized dangers of liquid silicone injections, silicone gel breast prostheses were made available in the early 1960's. It was believed that the replacement of liquid silicone with silicone gel in a silicone envelope would prevent the silicone from migrating to other parts of the body.⁸ These implants were first used prior to Federal regulations requiring proof of safety and efficacy for most medical devices.

The FDA's authority to regulate breast implants is based on the 1976 Medical Device Amendments (Public Law 94-295) to the Food, Drug, and Cosmetic Act (21 USC § 360 (c)).⁹ This law required FDA to issue regulations classifying all medical devices into one of three classes; only the highest risk devices (Class III) would require proof of safety and effectiveness. Prior to 1976, a small number of devices, including liquid injectable silicone, were regulated as drugs, but silicone implants were not.

With the passage of the 1976 law, regulatory responsibilities for medical devices were assigned to the FDA's Center for Devices and Radiological Health. Breast implants were "grandfathered" into the market, meaning that the manufacturers could continue to sell their products and were not required to prove to the FDA that the implants were safe and effective. Whereas silicone injections were immediately classified as a Class III medical device as a result of the 1976 law, thus requiring proof of safety and effectiveness, the FDA did not immediately classify breast implants. Manufacturers and plastic surgeons argued that the implants had been safely used for more than 10 years, and the FDA did not use its authority to require manufacturers to prove safety and effectiveness.

By the late 1970's, many scientists and physicians had expressed serious concerns about the safety of breast implants to the FDA. However, in 1978, an FDA advisory panel, which included several plastic surgeons, proposed classifying the implants as Class II, which would not have required proof of safety or efficacy.¹⁰ Despite that recommendation, in January 1982, the FDA published its proposed rule to classify silicone breast implants as Class III in the *Federal Register*.¹¹ The FDA advisory panel met again in January of 1983 and unanimously recommended that the FDA classify silicone gel breast implants as Class III devices.¹² Finally, the FDA classified silicone and saline breast implants as Class III devices in June 1988.¹³

As a Class III device, the FDA had the authority to require the manufacturers to submit premarket approval (PMA) applications for all breast implants, which would

⁷The IND is in subcommittee files.

⁸Hearing, testimony of Dr. Norman Anderson, p. 31.

⁹Johnson, Judith A. *Breast Implants: Safety and FDA Regulation*, CRS, September 9, 1992, p. 2.

¹⁰A brief history is published in the *Federal Register*, January 19, 1982, Vol. 47, No. 12, p. 2820; in subcommittee files.

¹¹*Ibid.*, pp. 2810-2853.

¹²A brief history is presented in the Proposed Rule in the *Federal Register*, Vol. 55, No. 96, May 17, 1990, p. 20,570.

¹³*Federal Register* announcement, June 24, 1988, Vol. 53, No. 122, pp. 23,856-23,877 is in subcommittee files.

demonstrate safety and effectiveness. In the United States, Dow Corning, Mentor Corporation, Bristol-Myers Squibb, and McGhan Medical Corporation shared 80 percent of the breast implant market, with several other manufacturers comprising the remainder. However, before PMA applications could be required, the FDA was required to publish a 515(b) regulation in the *Federal Register*, describing the known risks associated with the implants and the types of data needed to demonstrate that risks are outweighed by the benefits. The FDA could not require that manufacturers submit PMA applications until 30 months after the final classification regulation was issued. That 30-month period, intended to provide time for research and data analysis, ended in December 1990. If the final rule was not promulgated at least 90 days prior to that date, the PMA's could not be required until 90 days after promulgation of the final rule.

At the time of the subcommittee hearing in December 1990, the final rule requiring data on safety and effectiveness had not been promulgated; in fact, the FDA had not even written a draft of the final rule. When the FDA finally published the final rule on April 10, 1991, they were required to give manufacturers at least 90 days to respond with a PMA.

B. FDA CONCERNS: 1978-1990

RISKS OF SURGERY

It has been generally acknowledged that all surgery has some risks, and that breast implant surgery is no exception. The relatively rare but serious risks of surgery are from anesthesia and infection. A CDC study indicating that breast implants could cause infections was cited in the *Federal Register* proposed rule in 1982.¹⁴ Although most infections can be treated successfully, infections can cause serious problems and deformities.

There are other risks that are relatively unique to breast implants that have been known to the FDA for some time. For example, at a 1978 FDA Advisory Committee meeting on breast implants, researchers discussed evidence that silicone implants might leak even if they are intact.¹⁵ This was inconsistent with information provided to patients at that time, who were told that the silicone would only leak as the result of breakage caused by an accident or similar trauma.

In November 1988, the FDA's General and Plastic Surgery Devices Advisory Committee met to provide advice regarding the types of information and studies needed to determine safety and effectiveness.¹⁶

At that meeting, an FDA official, Dr. Nirmal Mishra, listed the following potential risks of silicone breast implants:

1. Capsular contracture (the contraction of fibrous tissue growth around the breast implant, which can cause painful hardening of the breast or distortion of the shape of

¹⁴*Federal Register* from January 19, 1982 is in subcommittee files.

¹⁵This is described in *Federal Register*, January 19, 1982, op. cit.

¹⁶Information regarding that meeting is from official transcript of the General and Plastic Surgery Devices Panel, November 22, 1988, or the minutes of the meeting; both are in subcommittee files.

- the breast).
2. Implant failure (breakage).
 3. Microleakage (“sweating” or “bleeding” of silicone outside the implant) and macroleakage caused by rupture of the implant outer shell.
 4. Migration of silicone to the lymphatic system, lungs, liver, spleen, and possibly other organs.
 5. Interference with the accuracy of mammogram (thus decreasing a woman’s chance of early detection of cancer).
 6. Calcification of the fibrous capsule.
 7. Immune disorders (including potentially fatal diseases such as lupus and scleroderma).
 8. Cancer.

CAPSULAR CONTRACTURE

The most common, widely acknowledged problem is “capsular contracture,” which has occurred in up to 75 percent of patients in published studies, averaging 40 percent.¹⁷ Capsular contracture occurs when the implant become surrounded by a protective layer of scar tissue (called a capsule) inside the body. The exact cause is not known; some researchers believe the capsule is a normal response to a foreign body, whereas others believe it results from bleeding, infection, or silicone leakage. Regardless of the cause, if the scar tissue shrinks around the implant, it will make the breast harder, possibly painful, and sometimes misshapened.

Contracture can occur weeks or years after implantation, but it usually occurs within a few months. Contracture can cause unnatural firmness or can cause the breast to be hard and very painful. Women with severe contracture describe their fear of being touched because of the embarrassment of having a breast that feels like a rock, or hugged because of concerns about hurting the other person.¹⁸ According to a review of medical research by FDA scientists, “Once contracture develops, the rate of recurrence is high. Afflicted women are often plagued by multiple, and frequently ineffective, secondary operative procedures.”¹⁹

Many surgeons prefer to treat contracture without surgery, using a technique called closed capsulotomy, where the surgeon squeezes the hardened breast by hand. This often successfully breaks the capsule, but the procedure may be painful; moreover, manufacturers warn that this procedure may cause the implant to rupture, thus risking problems due to silicone leakage and requiring replacement of the implant. The alternative, “open” capsulotomy, is a surgical procedure whereby the surgeon removes the tissue capsule or replaces the entire implant and capsule.

¹⁷Hearing, testimony of Dr. Nir Kossovsky, assistant professor of pathology and laboratory medicine, University of California at Los Angeles, p. 61. Articles published in medical journals indicate similar statistics; these are in subcommittee files.

¹⁸Jones, J. (March 2, 1992) Body of evidence. *People*, p. 59.

¹⁹Document send to FDA advisory committee members for November 22, 1988, meeting; in subcommittee files.

SILICONE LEAKAGE AND MIGRATION, AND AUTOIMMUNE DISEASE

According to a summary prepared by FDA scientists in 1988, leakage or migration of silicone within the body can cause breast deformities, ulceration, burning sensation and pain, enlarged lymph nodes, palpable masses, and respiratory distress.²⁰ In addition, the summary pointed out that the presence of silica in the envelope could cause silicosis and other serious problems.

During the 1980's, several medical journals published articles about serious connective tissue disorders among women with breast implants, including death or crippling from diseases such as scleroderma.²¹ These diseases were believed to represent immune reactions to implants, apparently because silicone or silica migrated from the implant to other parts of the body.²² Migration can occur when the implant ruptures, or when it "sweats" or "bleeds".

Because liquid silicone is known to cause serious problems, enlarging breasts with silicone injections has been illegal for many years in the United States. If breast implants are prone to rupture, then the possibility of leakage of implants is of obvious concern, given the well-known problems with injections. Although the silicone gel used in implants would be expected to migrate less than liquid silicone, researchers have found that the gel can break down into liquid form in the body, and the liquid silicone can then migrate.²³

Concerns about leakage resulted in the increased popularity of the "double lumen" implant, which has two "envelopes": the inner envelope contains silicone gel, similar to the standard implant; but saline solution fills out the area between the outer envelope and the inner envelope. However, scientists believe that this type of implant will also bleed silicone and silica into human tissue.²⁴

When a silicone implant ruptures, it needs to be replaced. Every time surgery is required, the risks of the surgery itself are repeated; in addition, there is a financial burden as well as aesthetic problems that can arise due to scar tissue. If implants need to be replaced every 5-15 years, this can be a major problem for younger women, many of whom are in their twenties or thirties when they first choose breast implants for augmentation.

INTERFERENCE WITH MAMMOGRAPHY

The difficulty of cancer screening for women with breast implants is well established, because both silicone and saline implants interfere with mammography. For example, an article published in a plastic surgery journal in July 1988 reported that 22-83

²⁰Ibid.

²¹See, for example, Spiera, H. (1988). Scleroderma after silicone augmentation mammoplasty. *Journal of the American Medical Association*, Vol. 260, pp. 236-238.

²²A summary of this literature was written by an FDA scientist, Hoan My Do Luu, and is in Hearing, pp. 116-121, and by Dr. Nirmal Mishra, Deputy Director of FDA's Division of Surgical and Rehabilitation Devices and is in Hearing, pp. 123-126.

²³Memo Record from Hoan My Do Luu, August 15, 1988, in Hearing, p. 141.

²⁴See, for example, in Hearing, testimony of Dr. Pierre Blais, independent consultant, Ottawa, Canada. p. 47; *Silicone Implants and Breast Cancer: Epidemiological Review of Human Data*, an FDA draft report, 1988, in subcommittee files.

percent of glandular tissue is obscured by breast implants.²⁵ Mammography problems caused by breast implants were discussed at the FDA advisory committee meeting in November 1988. If a patient's breasts are firm or hard due to contracture, it is difficult to compress the breast as required for a mammogram; if the mammography is performed, the implant could hide a tumor or make it more difficult to identify the early changes caused by carcinoma.²⁶ As a result of these problems, some women with implants avoid mammographies, which is also dangerous.

In addition to information about these health risks that was presented by an FDA scientist at the 1988 FDA advisory committee meeting, four women testified about their own implant experiences. Ms. Ellen Mohny described an acid-like burning sensation, constant infections, weakening of the limbs, and dizziness; she had needed to use a wheelchair or walker for 5 years as a result of pain in her hip. When the surgeons tried to remove the implants, no trace of one of the silicone envelopes could be found. Sybil Goldrich, a mastectomy patient, described her serious infections, hardening, migration of the implants, and pain, which resulted in five operations over a period of 10 months. As a result of her experiences, she became the cofounder of Command Trust Network, a support and information group for women with breast implants. The other two reconstruction patients, Rose Kushner and Rosemary Locke, described their positive experiences with breast implants, and urged they remain available.

CANCER

In March 1988, Dow Corning submitted pathology results of a 1985-87, 2-year rat study of two kinds of silicone gel implants.²⁷ Dow claimed in their report that the study showed that silicone gel did not cause cancer, because the only tumors were fibrosarcoma, which the company claimed were due to a "solid-state" carcinogenic effect that does not occur in humans. However, the FDA reviewer, Hoan My Do Luu, expressed concerns about the malignant tumors found in approximately one-fourth of the rats, which were "large and had extensive necrosis"; she stated that "more than half of these tumors are fatal".²⁸ Many of the tumors metastasized to distant organs, such as lungs, liver, kidneys, and skin. In addition, the gel was found to have "spread into surrounding tissue" and "migrated to distant sites such as [the] lymphatic region".²⁹

The FDA reviewer quoted scientists who reported that such tumors had been detected in humans. The reviewer concluded, "It would be irresponsible to disregard the possibility of malignant development of permanent implants in humans." The Acting Chief of FDA's Health Sciences Branch, Melvin Stratmeyer, reviewed the information provided by several different FDA divisions, and summarized that, "The conclusion of this report is that silicone can cause cancers in rats; there is no direct proof that silicone causes cancers in humans;

²⁵Hayes, H.; Vandergrift, M.S.; & Diner, W.C. (July 1988) Mammography and breast implants. *Plastic and Reconstructive Surgery*, pp. 1-6.

²⁶Johnson, Judith A., September 9, 1992, CRS Report, op. cit., p. 14.

²⁷Described in an FDA memorandum to the file from Hoan My Do Luu, August 15, 1988, in Hearing, p. 134.

²⁸Ibid., p. 134, 141.

²⁹Ibid., p. 135.

however, there is considerable reason to suspect that silicone can do so.”³⁰ The FDA also asked for advice from the National Center for Toxicological Research.³¹

Despite the concerns about this research expressed within FDA, at the public FDA advisory committee meeting in November 1988, FDA officials minimized their concerns about the cancer findings, and emphasized that the results were inconclusive. The official minutes of the meeting describes the presentation by the Director of the Office of Device Evaluation, Robert Sheridan, as concluding that “the types of tumors seen in the rats would be unlikely to occur in humans, and that, if a human cancer risk does exist, it would be small, therefore FDA does not believe that regulatory action is currently warranted.”³²

At the 1988 FDA advisory committee meeting, the director of Public Citizen’s Health Research Group, Dr. Sidney Wolfe, expressed concern about the cancer risks indicated by the Dow Corning rat study.³³ For more than 2 years after the advisory committee meeting, FDA and Dow Corning repeatedly fought efforts by the Health Research Group to have the study documents made public under the Freedom of Information Act.³⁴

Most of those who spoke in defense of silicone implants at the 1988 FDA advisory committee meeting claimed that the Dow Corning rat study did not provide evidence that implants would cause cancer in humans. In addition, Dow Corning and other implant supporters cited an epidemiological study conducted by Dr. Dennis Deapen and his colleagues, funded by three implant manufacturers. The study was of 3,000 women in California, which indicated no increased risk of breast cancer. However, an FDA review of the Deapen study that had been conducted during the summer of 1988 “found numerous sources of errors, biases, and methodological limitations” in the study.³⁵ Most notably, the FDA reviewers criticized the fact that the patients were studied for an average of 6.2 years, which is “probably too short to detect breast cancer ... considering that the latency period for foreign body carcinogenesis in humans appears to be in the range of 20-30 years.”³⁶ By 1989, the plastic surgeons had reported on the same data again, this time reporting “increased frequencies of lung and vulvar cancers” among breast implant patients.³⁷

POLYURETHANE, TDA, AND CANCER

By March 1990, an FDA pharmacologist had written an internal memorandum expressing concerns that there could be a cancer risk associated with silicone breast implants that were covered with polyurethane foam.³⁸ The foam is similar to that used for chair

³⁰Memorandum from Melvin E. Stratmeyer to the Director, Office of Science and Technology, Center for Devices and Radiological Health, FDA, August 9, 1988, in Hearing, p. 144.

³¹See memo in Hearing, pp. 130-133.

³²Minutes of the November 22, 1988, meeting, p. 2; in subcommittee file.

³³Transcript and minutes of meeting are in subcommittee files.

³⁴Court documents are in subcommittee files.

³⁵The August 1988 FDA internal report entitled “A Consideration of the Potential of Silicone to Cause Cancers in Humans” is published in Hearing, pp. 145-152.

³⁶Ibid., p. 146.

³⁷This paper was presented at the annual ASPRS meeting on May 10, 1989, and is available in subcommittee files.

³⁸Memorandum dated March 20, 1990, revised May 27, 1990, from Pharmacologist to Deputy Director of the Office of Device Evaluation, FDA, in Hearing, pp. 204-221.

cushions or filters for air conditioners. These implants were sold by Surgitek, a subsidiary of Bristol-Myers Squibb; the most popular model was called “the Mème”.³⁹

The March 1990 memorandum reviewed the previous evaluations of foam degradation from polyurethane covered implants. This included adverse reaction reports dating from 1984-1988 indicating that the foam came off the implant or broke down into fragments, or was “partially digested”. By 1986, there were two reports of foam from implants that “disappears”.

Based on 1989 and 1990 studies conducted for Surgitek on the breakdown of foam into 2,4 toluenediamine (TDA), a known animal carcinogen, the FDA pharmacologist estimated that the lifetime cancer risk would range from 6 in 1 million to 130-180 in 1 million.⁴⁰

On April 10, 1990, Dr. James Dillon, a research chemist from FDA’s Office of Science and Technology, wrote a memorandum to Hoan My Do Luu, the FDA pharmacologist, which stated, “Based on a review of inhouse documents, extramural research, case reports, and research proposals concerning the polyurethane foam used to manufacture the Natural Y Mammary Prosthesis, I conclude that this material presents an unreasonable risk when used as a degradable (intentional or otherwise) coating on the device.”⁴¹ Dr. Dillon supported Ms. Luu’s proposal to conduct a pharmacokinetics study to determine the levels of TDA resulting from breakdown of the foam in conditions similar to those found in the human body.

C. FDA DELAYS AND INACTION

The major delay in the regulation of breast implants occurred between the 1982 publication of the proposed rule classifying implants as Class III devices, and the publication of the final rule in June 1988. However, after the final rule was published, the 30-month wait for PMA’s could have ended in December 1990.

In late 1988, the Acting Director of FDA’s Office of Device Evaluation stated that FDA would move quickly to regulate breast implants, and would require PMA’s by the end of 1990. Instead, the proposed regulations were issued in-May 1990, the comment period ended in August 1990, and the final regulations were not published until April 1991.

D. IMPLANT PATIENTS AS GUINEA PIGS

There has been a considerable amount of research on breast implants, much of it published in plastic surgery medical journals. A subcommittee review of research published between 1970-1990 indicates a pattern of small studies, bias, and use of patients as guinea pigs in research.⁴²

³⁹Replicon and Optimam were other models sold by Surgitek. A previous model was called the “Natural Y”.

⁴⁰Memorandum dated March 20, 1990, op. cit., p. 213.

⁴¹Memorandum from James Dillon, Ph.D., to Hoan My Do Luu, April 10, 1990, in Hearing, pp. 222-238. The Natural Y model was replaced with the Mème.

⁴²This research was reviewed in a memorandum from Dr. Diana Zuckerman, subcommittee staff, to Chairman Ted Weiss, December 1991. The articles are in subcommittee files.

A good example has been the research regarding capsular contracture. A subcommittee review of 20 major articles dating from the early 1970's to the late 1980's indicated that many articles were written to describe efforts by plastic surgeons to reduce capsular contracture problems by using different implants or surgical techniques.⁴³ Every few years, there was a new discovery, usually accompanied by concerns expressed about the problems of doing things the "old way". For example, silicone implants with dacron patches were very popular in the early 1970's; then the researchers reported that the dacron disintegrated or caused severe contracture problems. Implants with dacron patches were therefore criticized in the journal articles, and implants that did not have dacron patches were praised as preferable. Similarly, one favored surgical technique was replaced by another technique. In article after article, the old model or old technique was associated with between 50-75 percent serious contracture problems, and the new model or new technique reduced that to approximately 30 percent serious contracture problems. However, every few years, each "new way" was discredited when the proportion of long-term problems for that model or technique increased. The short-term success of the new technique would therefore make the new way seem superior. Since many of the articles were written by surgeons about their patients, it is not surprising that virtually all articles heralded some major improvement discovered by the surgeon.

One of the "new" products that was promoted in journal articles was the polyurethane-covered silicone breast implant, which was designed to prevent capsular contracture. Early short-term studies indicated that patients had fewer contracture problems with these implants;⁴⁴ however, by 1990 Canadian scientists were reporting that when polyurethane broke down in the body, "it cannot be completely removed without disfiguring surgery".⁴⁵ In addition, as discussed earlier in this report, by 1990 there were reports of potential cancer risk caused by the polyurethane covering breaking down into TDA in the body.⁴⁶

In 1989, Dr. Richard Grossman, a plastic surgeon who had written an early text on how to perform breast augmentation surgery, notified FDA that for years "it has been the custom and practice" of manufacturers to modify the implants based on ideas of surgeons, and then provide these custom-made prototypes that would be tried out on patients to see how they worked.⁴⁷ Apparently, no animal studies were done first. He admitted having participated in such "studies" for four companies. In 1989, he wrote that this seemed unethical, and he told the FDA that he had stopped performing implant surgery because he believes the complication rate, which he estimated to be 20-25 percent in his practice, was unacceptably high.

⁴³Memorandum from Dr. Diana Zuckerman to Chairman Ted Weiss, op. cit.

⁴⁴See, for example, Hester, T.R.; Nahai, F.; Bostwick J.; & Cukic J. (1988). A 5-year experience with polyurethane-covered mammary prostheses for treatment of capsular contracture, primary augmentation mammoplasty, and breast reconstruction. *Clinics in Plastic Surgery*, pp. 569-585.

⁴⁵Hearing, testimony of Dr. Pierre Blais, private consultant, Ottawa, Canada, p. 47.

⁴⁶Hearing, testimony of Dr. Pierre Blais, pp. 40-56.

⁴⁷Letter in subcommittee files.

III. Findings and Conclusions

A. FDA IGNORED WARNINGS ABOUT THE NEED TO REGULATE BREAST IMPLANTS FOR MORE THAN 12 YEARS

Scientists started expressing strong concerns about the safety of silicone breast implants in the late 1970's, and their concerns were discussed at the 1978 FDA advisory committee meeting. By the early 1980's, most of the risks that eventually led to removal from the market were known or suspected, and included in the proposed rule in the *Federal Register*. However, FDA did virtually nothing between the time that the proposed rule was published in 1982 until it was finalized in 1988.

At the November 1988 FDA advisory committee meeting, the warnings of earlier years had become more urgent, and a lawyer, a former Dow engineer, and other experts testified that they had seen protected court documents indicating that manufacturers were hiding safety information from FDA and the public.⁴⁸ Several women described their own terrible experiences with implants. In addition to individuals who expressed concerns to the FDA, Public Citizen's Health Research Group and the National Women's Health Network both testified before the FDA. The Health Research Group focused on concerns about the rat study indicating potential cancer risks. The National Women's Health Network urged the FDA to ensure informed consent of patients and require an objective clinical trial in order to determine the long-term safety of breast implants.

The November 1988 FDA advisory panel on breast implants expressed considerable concern about their safety. The panel made four recommendations.⁴⁹

The first recommendation was to reconvene in 2 months to evaluate any new data and recommend need for future studies. This recommendation was followed; a meeting was held in January 1989.

The second recommendation was to establish a national registry of women who have implants. This was opposed within FDA as too expensive and unlikely to be useful, and as setting a precedent that might cause problems for the agency.⁵⁰ Moreover, the FDA was concerned about the viability of a registry because the American Society of Plastic and Reconstructive Surgeons did not support it. Despite the very strong arguments of the panel chair in support of the registry, the proposal was quietly abandoned by FDA.

⁴⁸Meeting transcript and minutes are in subcommittee files.

⁴⁹The summary of the minutes of the meeting and the transcript of the meeting are in subcommittee files. The committee's chairman, Dr. Norman Anderson, described the recommendations in his testimony before the subcommittee, in Hearing, pp. 35-39.

⁵⁰Memorandum from John Villforth, Director of the Center for Devices and Radiological Health, December 1, 1988, p. 2; in Hearing, p. 172.

The third recommendation was to develop a mandatory program to inform the public of potential risks of breast implants, possibly including informed consent prior to surgery. An internal FDA memo indicated that the general counsel would be approached regarding the mandatory information program.⁵¹ However, it was decided that the regulations required for a mandatory program would be so strongly opposed by the plastic surgeons and manufacturers, that it was more practical to develop a voluntary program instead.⁵² At the January 1989 panel meeting, the FDA announced plans to develop a brochure and videotapes to educate women about the risks of implants prior to surgery.⁵³

The brochures and videotape were to be distributed *voluntarily* in the offices of plastic surgeons. The educational materials were to be developed by consensus by a diverse group of 23 individuals representing consumer organizations, manufacturers, and health professionals; each representative was given the authority to veto any decision. The timetable was to hold the first meeting of the working group in March 1989, and have a final brochure by the fall of 1990. However, there was considerable disagreement about what warnings were appropriate in the brochure, and in 1990 the American Society of Plastic and Reconstructive Surgeons warned that they would veto the brochure unless the names of the consumer support groups were deleted from the resources section of the brochure.⁵⁴ The brochure had still not been approved when FDA decided to require manufacturers to include a package insert aimed at patients in September 1991. In July 1992, Joseph Arcarese, FDA's Director of the Office of Training and Assistance, who was in charge of this project, proposed that "instead of vainly trying to develop a final and complete set of breast implant brochures (formally printed and distributed, as we had once hoped), we focus our resources on the development and public distribution of periodic updates of the press releases, talk papers, and backgrounders for use by FDA staff and others to reach the public" as well as a "companion piece" that would "address such issues as having realistic expectations about breast implants and the options for placement of incisions and implants".⁵⁵ FDA is to make use of outside consultation for the companion piece but it "by no means will be a consensus process".

The fourth recommendation was that FDA should keep the public, physicians, industry, and the panel informed as new information was received. This was not rigorously followed. There were several FDA articles and press releases in 1988, but little else was distributed prior to the subcommittee hearing in December 1990.

Prior to the subcommittee's December 1990 hearing, FDA officials indicated no sense of urgency or concern about the need to regulate silicone breast implants. At that point, the FDA had already received 4,300 reports of serious injury or malfunction of breast

⁵¹Memorandum from John Villforth, December 1, 1988. op. cit.

⁵²Ibid.

⁵³Minutes of this meeting and related documents are in subcommittee files.

⁵⁴Hearing, testimony of Sybil Goldrich, co-founder, Command Trust Network. p. 25.

⁵⁵July 14, 1992, memorandum from Director, Office of Training and Assistance, to Director, Center for Devices and Radiological Health; in subcommittee files.

implants. After the public became informed about the symptoms associated with breast implants, the number of adverse reaction reports increased to 14,259 by June 1992.⁵⁶

B. SCIENTISTS HAVE BEEN CONCERNED ABOUT THE RISKS OF CONNECTIVE TISSUE/AUTOIMMUNE DISORDERS SINCE 1975

In February 1975, an internal Dow Corning document indicated concerns about inflammatory reactions to breast implants in Dow's animal studies.⁵⁷ The reaction, which could indicate an immune response, was noted at 7 days, 14 days, and still persisting at 21 days. The scientists hoped it was due to the insertion method, rather than the implant itself. Despite the concerns and uncertainty of the cause, Dow documents indicate that they were distributing breast implants to doctors for implantation that same month.⁵⁸

Other manufacturers had similar concerns. At Medical Engineering Corporation, a company that later sold its implant business to Surgitek, a 1977 interoffice memorandum sent to its president, Dave Sanders, reported on a meeting that was held to create a Breast Implant Manufacturers Association. The Medical Engineering Corporation representative reported that a plastic surgeon at the meeting stated that he believed that capsular contracture was "a result of an antibody reaction from an immunological response".⁵⁹ However, other memoranda from the same company indicate that proposed studies to evaluate this issue were never conducted.

As early as 1982, researchers at the University of Chicago Department of Surgery had written to Dow Corning to notify them that their work on implanted silicone indicated that the body's reaction to silicone created giant cells called macrophages that erode the silicone envelope and can migrate to the lymph nodes.⁶⁰ Dr. Robert Parsons, professor of surgery, expressed his belief that the body's immune reaction could be causing such problems as capsular contracture. The research was conducted by Dr. Parsons, Dr. John Heggens, and "a very talented junior medical student, Nir Kossovsky".⁶¹ Requests for funding from Dow Corning for further research to better understand this immune response were rejected by Dow Corning.⁶²

In early 1990, FDA scientists were describing their concerns about growing evidence that silicone could cause connective tissue disorders, also called autoimmune disorders, including potentially fatal diseases such as scleroderma.⁶³ Their concerns were based on a small but growing body of literature by pathologists and other nonsurgeons who were

⁵⁶December 14, 1992, Associated Press wire story; in subcommittee files. Adverse reaction reports are also in subcommittee files.

⁵⁷"21-Day Verbal Report" from Richard Kurger, February 26, 1975, publicly distributed by Dow Corning on February 10, 1992, and in subcommittee files.

⁵⁸Mammary Task Force Minutes, March 21, 1975, publicly distributed by Dow Corning on February 10, 1992, and in subcommittee files.

⁵⁹April 16, 1977, memorandum from Jerry Helmer to Dave Sanders; in subcommittee files.

⁶⁰Letter from Dr. Robert Parsons to Gene Jukubczak at Dow Corning, May 14, 1982, released publicly by Dow Corning on February 10, 1992, and in subcommittee files.

⁶¹Ibid.

⁶²Hearing, testimony of Dr. Nir Kossovsky, p. 92.

⁶³FDA memoranda from Hoan My Do Luu and Dr. Nirmal Mishra describing these concerns are in Hearing, pp. 116-121 and 123-126

evaluating the dangers of silicone implants. They described a report dating back to 1964, and several reports published between 1983-1988. By March 1990, there were 90 cases of connective tissue or autoimmune diseases linked to silicone in the published medical literature.⁶⁴

At the subcommittee hearing in December 1990, Dr. Nir Kossovsky, by that time an assistant professor of pathology and laboratory medicine at UCLA, testified about this review of research on humans, and animal research conducted by Dr. John Hegggers and himself. Dr. Kossovsky testified that silicone gel is not as “biocompatible” as many physicians thought.⁶⁵ He testified that a type of white blood cell called macrophages are formed in reaction to foreign bodies, such as a silicone implant, and will attempt to “eat” the silicone, thus causing inflammation. He also testified that there was very little funding available for research on silicone and other implant materials, and that such research was crucial to establish their safety.

Dr. Kossovsky testified that silicone bleeds from intact implants, and “can go anywhere in the body. There is no safe place, per se. Why one will respond with a systemic reaction and another will not is simply not known.”⁶⁶ He stated that more research is needed to understand the kinds of immune responses experienced by breast implant patients.

Dr. Frank Vasey, professor of medicine at the University of South Florida, testified about his research on 30 implant patients with major problems related to connective tissue disease or immune disorders, such as lupus, scleroderma, Sjogren’s syndrome, arthritis, and severe muscle pain. Surgeons had removed implants from 18 such patients; 3 months to 2 years later, all but two of the women had significantly improved.⁶⁷ In some cases, seriously ill patients improved dramatically or appeared to be cured. By March 1992, Dr. Vasey had presented data on 50 breast implant patients with rheumatic disease symptoms, such as chronic fatigue (84 percent), muscle pain (84 percent), joint pain (60 percent), and Raynaud’s syndrome (14 percent). The women had the implants for an average of 4.5 years before the onset of symptoms; this ranged between 0-13 years. Of the 32 who chose to have their implants removed, 26 (81 percent) had improved or had a complete resolution of all symptoms by the time the study was completed, an average of 19 months later.⁶⁸

In October 1992, Dr. William Shaw, a plastic surgeon at the University of California at Los Angeles, reported at the ASPRS annual meeting that breast implant patients with local and systemic medical problems improved after the implants were removed. Of 150 patients, 90 percent of local complaints, such as pain, were relieved, and 70 percent of systemic symptoms improved.⁶⁹

⁶⁴These are described in a memorandum from Hoan My Do Luu, March 29, 1990, in Hearing, pp. 116-121. Although some of the illnesses were called “human adjuvant disease” in the medical literature, that term was no longer considered accurate by the time of the subcommittee hearing.

⁶⁵Hearing, testimony of Dr. Nir Kossovsky, pp. 56-79.

⁶⁶*Ibid.*, p. 92.

⁶⁷Hearing, testimony of Dr. Frank Vasey, p. 80.

⁶⁸Presented at the annual Southwest regional meeting of the American College of Rheumatology, New Orleans, March, 1992.

⁶⁹Elias, M. (October 13, 1992). Benefits of implant removal, *USA Today*, p. 1D.

In August 1992, a study published in *The Lancet* reported that silicone shunts had been found to cause “severe, apparently immune-mediated reactions”.⁷⁰ The authors, who included Dr. John Hegggers from the University of Texas, concluded that, “These findings show that specific immune reactivity [to silicone] can develop in human beings.” The patients developed severe inflammatory reactions, despite the absence of infection. The reactions were found to be immunological using an enzyme-linked immunosorbent assay.

The research on breast implants has implications for much of surgery and plastic surgery, because silicone is widely used for a variety of prostheses. If all types of silicone implants are potentially dangerous, it would have implications for millions of patients; if only the gel-filled silicone implants are dangerous, it would have implications for the few other gel prostheses, such as testicular implants. Even the saline-filled breast implants are in silicone “envelopes”, so if those outer shells bleed silicone or silica, that could still cause problems.

C. PHYSICIANS, ENGINEERS, AND EMPLOYEES OF IMPLANT MANUFACTURERS HAVE BEEN CONCERNED ABOUT BREAKAGE AND LEAKAGE OF SILICONE GEL IMPLANTS SINCE THE 1970’S

In the 1970’s, several implant manufacturers changed their breast implants from a thick envelope and firm gel filling to a thinner envelope and more fluid gel, in order to make the implants seem more natural.⁷¹ Even before Dow Corning’s new implants were generally marketed, scientists and physicians were reporting problems to the company, and were expressing their concerns about the implants’ safety.

For example, in March 1975, the task force that Dow Corning had assigned to review the new breast implants received an internal memorandum that mentioned “the possible migration of gel noted in one of the monkey tests”.⁷²

In May 1975, Tom Talcott, a Dow Corning engineer who later testified before the subcommittee, wrote a memorandum to his colleagues regarding silicone bleeding from breast implants. He wrote, “We are hearing complaints from the field about the demonstration samples they are receiving. The general claim is that the units bleed profusely after they have been flexed vigorously. ... Please run appropriate testing when you receive these samples to determine if a bleed rate problem exists.”⁷³

By December 1975, Dr. Thomas Cronin, who designed the original silicone breast implants, wrote a letter to Art Rathjen, senior clinical research specialist at Dow Corning, describing a reconstruction patient who “produced 100 c.c. of straw-colored fluid daily for

⁷⁰Goldblum, R.M.; Pelley, R.P.; O’Donell, A.A.; Pyron, D.; & Hegggers, J.P. (1992) Antibodies to silicone elastomers and reactions to ventriculoperitoneal shunts, *The Lancet*, Vol. 340, pp. 510-513.

⁷¹Hearing, testimony of Thomas Talcott, former engineer for Dow Corning, pp. 82-83.

⁷²March 11, 1975, memorandum from W. Larson and T. Brodhagen to A. Rathjen (Mammary Task Force); this was made publicly available by Dow on February 10, 1992, and is in subcommittee files.

⁷³May 13, 1975, memorandum from Tom Talcott to Wil Larson, publicly released by Dow Corning on February 10, 1992, and in subcommittee files.

one month”.⁷⁴ After 1 month, the implant was removed, and he found “the implant ruptured and gel was free in the cavity”.

In June 1976, Art Rathjen expressed concerns about a report from Dr. Richard Phares, a plastic surgeon from St. Petersburg, Florida, regarding postsurgical rejections of breast implants that seemed to be caused by “greasy implants” that prevented healing.”⁷⁵ Rathjen wrote a memorandum to his colleagues which warned, “I have proposed again and again that we must begin an indepth study of our gel, envelope, and bleed phenomenon. Capsule contracture isn’t the only problem. Time is going to run out for us if we don’t get underway.”⁷⁶

In January 1977, a Dow Corning salesman from Chicago wrote to Dow Corning in Hemlock, Michigan, to express his concerns about ruptured implants.⁷⁷ He wrote that one of his customers, a Dr. Bader, was “threatening to switch” to a different brand “after having two consecutive ruptures” with the Dow implants.

In December 1977, an internal Dow memorandum described rupture problems of four doctors in Ohio and Michigan, ranging from 11 percent to 32 percent of their annual procedures.⁷⁸ The concerned salesman wrote, “I am sure that some of these were the fault of the doctor, but that alone could not account for such a high percentage of ruptures. These doctors have on the average ten years of experience in this procedure.” In March 1978, the same salesman wrote another internal Dow memorandum describing “an excessive number of ruptures in [the Detroit] area over the past six months”.⁷⁹ One doctor had reported four consecutive ruptures of the Dow implant to the salesman. The salesman wrote, “I find it difficult to comprehend that I am the only one experiencing a rupture problem of this proportion. All of the ... doctors have made the same comment: ‘Noticing a difference in our envelope’ ... my question is: ‘Are we making the envelope different, and is it weaker?’ ... I have lost more business recently due to ruptures than I lost last year due to competitors’ sales efforts.”

In September 1981, Dr. Charles Vinnik, a plastic surgeon in Las Vegas, wrote to Mr. Robert Rylee, the vice president of Dow Corning, about his concerns about “shell failure” of silicone gel implants, which resulted in “considerable silicone reaction to the extruded material” that was “as marked a reaction as we ever saw with the silicone injections”.⁸⁰ The medical report described an implant that was “totally disrupted with the implant shell

⁷⁴December 11, 1975, letter from Thomas Cronin, M.D. to Art Rathjen, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁷⁵May 4, 1976, report of telephone call from Dr. Richard Phares to Mr. Bicket, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁷⁶June 8, 1976, memorandum from A.H. Rathjen to A.E. Bey and C.W. Lenz, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁷⁷January 21, 1977, memorandum from Cran Caterer to John Woodward, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁷⁸December 15, 1977, memorandum from Frank Lewis to Milt Hinsch, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁷⁹March 2, 1978, memorandum from Frank Lewis to Milt Hinsch, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁸⁰September 23, 1981, letter from Dr. Charles Vinnik to Mr. Bob Rylee. This letter is included in the documents released by Dow Corning on February 10, 1992, and is in subcommittee files.

incorporated within the gel mass” and a “roughly 4x6 cm irregular nodular mass” which was “an obvious siliconoma”.⁸¹ In November of that year, Gene Jakubczak of Dow Corning described a telephone conversation with Dr. Vinnik during which Vinnik estimated a 5 percent failure rate with Dow silicone breast implants.⁸²

In February 1984, Eldon Frisch, a Dow Corning scientist, wrote a memorandum to his colleagues at Dow Corning about a visit with Dr. Vinnik. He expressed his concern that the breast exercise instructions that Dr. Vinnik and many other plastic surgeons were providing to patients, aimed at preventing capsular contracture, could be causing “progressive weakening and ultimately rupture”.⁸³ He also hypothesized that the exercises could cause the gel to break down, “making it less cohesive”. However, there is no evidence that this information was made available to plastic surgeons, and similar breast exercises were still recommended by most surgeons when the memorandum was made available by Dow Corning in February 1992.

By September 1985, Dr. Vinnik had written to Dow Corning that he had evidence that silicone gel in ruptured implants could become “terribly runny” due to “prolonged contact with tissue fluids and fat”.⁸⁴ In the same letter, Dr. Vinnik wrote “Inasmuch as this is not generally known by my colleagues, I feel that your company has both a moral and legal obligation to make this information available through your representatives and in your literature. I am loathe to publish my series of cases as I feel that it may open Pandora’s Box. I do feel, however, that rapid dissemination of this information is very necessary to protect your company and my colleagues.”

Similarly, in October 1985, Dr. David Mobley, a plastic surgeon from Jacksonville, Florida, wrote to the president of Dow Corning to inform him that he was “terminating our consignment agreement for mammary implants” because they had “recurring problems over the past two years with spontaneous unexplainable rupture”.⁸⁵

The leakage and rupture problems reported to Dow Corning were also apparent to other breast implant manufacturers. The president of Medical Engineering Corporation (MEC), a company whose breast implants were later manufactured by Surgitek, received a letter in September 1977 describing “siliconized” breast tissue; the “silicone was found in dense pockets that probably streamed out of the original site”.⁸⁶ That company’s Scientific Affairs Committee speculated that silicone oil bleeding through the silicone shell into body

⁸¹September 16, 1981, Operative Report of Charles Vinnek, M.D., among the Dow documents released on February 10, 1992, and in subcommittee files.

⁸²Memorandum from Gene Jakubczak to Sue Peters, November 16, 1991, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁸³February 29, 1984, memorandum from Eldon Frisch to Rich Dumas, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁸⁴Letter from Charles Vinnek to Mr. Bruce Reuter, Dow Corning Wright, September 11, 1985, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁸⁵October 15, 1985, letter from Dr. David Mobley to Dan Hayes, president, Dow Corning, made publicly available by Dow Corning on February 10, 1992, and in subcommittee files.

⁸⁶September 26, 1977, letter from Emilio Mora to Wilfred Lynch; Exhibit 2 in *Johnson vs. MEC*; in subcommittee files.

tissue could eventually cause FDA to remove silicone gel implants from the market.⁸⁷ By 1979, the president of MEC sent a memorandum to three colleagues that described the results of a dog study, which showed “low but definite concentrations of silicon in [selected] organs with the highest concentrations observed in kidney and liver tissue”.⁸⁸ One year later, a study that the company conducted to assess the effect of rough handling of gel implants determined that “Rough handling of any sort will affect the gel cohesion of our mammary implants. However, when left undisturbed for 15 or more days, the gel will return to acceptable limits.”⁸⁹ The employee recommended that the implants “should be processed with the minimum amount of handling” but did not speculate on the implications for women whose implanted prostheses would be constantly in contact with breast tissue.

Dr. Pierre Blais is a scientist who worked in the Canadian Department of National Health and Welfare for 13 years, investigating the safety of breast implants and other devices.⁹⁰ At the subcommittee hearing, Dr. Blais testified that the design of breast implants is “absurd” and

the constituent materials are ill-chosen. Physiologically, and in terms of engineering, they do not reflect the knowledge of our times. The testing that is done on them over the last three decades is trivial, if not totally irrelevant. Their performance is far below that of products used in other medical areas. ... Laboratory work on collected prostheses indicates a safe lifetime of less than 4 years for many types of prostheses. We are recovering [explanted] prostheses or fragments thereof where the shell and gel are chemically changed. Shells are weak like wet paper. You can tear them easily. Even if they are superficially intact at the moment of explantation, they cannot sustain capsulotomy, or any type of medical procedure to reduce contracture or to obtain biopsies. The device is finished. To top it off, we have found something else. The tissue around it ... forms an abrasive substance, a material like sandpaper which will ensure the demise of the prosthesis well within the 5-year limit.⁹¹

Dr. Blais conducted research on breast implants with several scientists at Laval University in Canada. Two months before Dr. Blais testified before the subcommittee, the president of Surgitek sent a memorandum describing plans to bring pressure on one of the scientists, Dr. Guidoin, by sending letters of complaint about Guidoin’s research to his supervisor at Laval University, his department head, and the president of Laval.⁹²

In 1991, Dr. Donna deCamara and her colleagues from the University of Illinois School of Medicine presented research data at the annual meeting of the American Society of Plastic and Reconstructive Surgeons (ASPRS), which indicated that silicone gel implants

⁸⁷ April 15, 1977, memorandum discussing research options; Exhibit 1 in *Johnson vs. MEC*; in subcommittee files.

⁸⁸ July 17, 1979, memorandum from Wilfred Lynch to Dave Sanders (president of Medical Engineering Corporation), with copies to G. Carter (later president of Surgitek) and B. Stith; in subcommittee files.

⁸⁹ April 24, 1980, memorandum from D. Hannon to Dave Sanders and three other employees; in subcommittee files.

⁹⁰ Hearing, testimony of Dr. Pierre Blais, p. 40.

⁹¹ Hearing, testimony of Dr. Pierre Blais, p. 41.

⁹² September 5, 1990, memorandum; in subcommittee files.

were likely to break as they aged, regardless of whether a woman experienced trauma. In a study of 51 implants removed from 31 women, deCamara found that 27 (53 percent) were ruptured, an additional 7 (14 percent) were leaking, and 17 (33 percent) were intact.⁹³ The implants had been in place for 1-17 years but most were removed for reasons that were not related to symptoms or problems. Only one of the women had reported a trauma that could have harmed the implant. The investigators reported that the percentage of ruptured implants increased dramatically after 7 years, and virtually all the implants that were more than 10 years old were ruptured or leaking.

In April 1992, the Breast Implant Task Force of the U.S. Public Health Service held a meeting at NIH. Dr. Hollis Caffee of the ASPRS Educational Foundation was one of the speakers. He stated that implants made more than 10 years ago and removed now are almost always broken.⁹⁴

D. FDA IGNORED THEIR OWN SCIENTISTS' ADVICE TO REJECT MANUFACTURERS' PMA APPLICATIONS IN 1991

At the subcommittee hearing in December 1990, the FDA promised that the final rule regarding breast implant data would be published in 3 months. FDA published the final rule on April 10, 1991, and gave manufacturers 90 days to respond with a PMA. The due date was July 9, 1991. From that date of submission, FDA had 45 days to determine whether each manufacturer had provided sufficient evidence of safety and efficacy for FDA to conduct a thorough review. If FDA had determined the data were grossly insufficient, they could have refused to file the application and notified the manufacturer that their product could not be sold.

In August 1991, FDA announced that seven premarket approval applications (PMA's) submitted by Dow Corning, McGhan, Mentor, and Bioplasty (MISTI model) had been accepted for filing, which meant that a full review would be conducted by FDA, and an FDA advisory committee would meet to review the materials and make recommendations about whether the implants should be approved.⁹⁵ Three other applications were rejected and the manufacturers were notified that their products could no longer be sold.

The FDA then had until January 6, 1992, to accept or reject the seven remaining applications. However, FDA wrote to all four companies, notifying them that their applications were seriously flawed, and recommended that they amend their applications by providing additional information by January 6.⁹⁶ If the companies had done so, their applications would have been reviewed after the additional information was provided, but

⁹³deCamara, D.L.; Sheridan, J.M.; & Kammer, B.A. Rupture and aging of silicone breast implants. This paper is in subcommittee files and was reported in *USA Today*, September 1991.

⁹⁴Dr. Caffee also stated that he did not know if the very high rupture rate would be true for asymptomatic women, since most women whose implants are removed have had symptoms. See minutes of the April 13, 1992 meeting; in subcommittee files.

⁹⁵Several applications from these four companies, as well as applications from other companies, were rejected. These PMA's and the letters informing the companies that their applications would not be filed are in subcommittee files.

⁹⁶These letters are in subcommittee files.

they would have to remove their products from the market on January 6, 1992. until they were approved.

The FDA's decision to conduct a full review of the seven PMA's was contrary to the recommendations to reject those applications which were made by the FDA statisticians, biologists, and other scientific experts. The FDA scientists consistently criticized the PMA studies for their major methodological flaws, and concluded that the studies of women with implants that were submitted by the companies were inadequate to provide evidence of safety or efficacy. Although breast prostheses are intended for use over many years, FDA reviewers noted that there was almost no information about the experiences of women who had implants for more than a few months, even though 1 million American women had breast implants, many for more than 10 years. This is important because thousands of women with implants have reported that they were healthy for several months, but experienced unexpected health problems several years later, including lupus and other potentially fatal autoimmune diseases. FDA scientists were therefore concerned that the excellent short-term results reported by many patients were not necessarily indicative of long-term safety.

A summary of the FDA reviewers' criticisms of the seven PMA's follows.⁹⁷

DOW CORNING

The Dow Corning application contained the most information, and its critique was written by the leader of the FDA's Breast Prosthesis PMA Task Force. In an August 12 memo to the file, he stated that the Dow Corning clinical studies are "so weak that they cannot provide a reasonable assurance of the safety and effectiveness of these devices" because they provide "no assurance that the full range of complications are included, no dependable measure of the incidence of complications, no reliable measure of the revision rate, and no quantitative measure of patient benefit". In his detailed criticism, he specified that the physicians who conducted the research were instructed "to report only complications associated with the implant. As a result the only complications reported are those at the implant site. This prevents these investigations from detecting systemic adverse effects or complications resulting [from] implantation of the devices." He also stated this "causes an underestimate of both the types and incidence of complications". "Furthermore, each patient was examined only once after surgery and the number of patients examined at each time point is very small" making it difficult to determine the rate of complications at any point in time.

McGHAN

In the McGhan prospective clinical study, 10 percent of the 318 patients in their study were not evaluated at the time they were discharged after surgery, and 65 percent of the implants were not assessed at the second required visit (3-6 months). The statistician pointed out that this lack of followup makes it impossible to draw any conclusions about

⁹⁷These reviews are in subcommittee files.

long-term safety or effectiveness. In addition, only three reconstruction patients were in the study, making it impossible to draw any conclusions about their experiences. The statistician reported that the company's, "historical cohort study" suffered from "strong potential for bias" and was therefore of no use in providing support for safety or effectiveness. An FDA biologist pointed out that the company studied only two of the four implant models listed on the PMA. This obviously makes it impossible to determine safety or effectiveness for the two "multi-lumen" models that were not studied. In addition, only 39 reconstruction patients and 101 augmentation patients were studied, and many potential medical problems, such as breast disease or carcinoma, were not evaluated for all patients. A subcommittee review of that PMA indicates that two-thirds of the women included in that study had prostheses implanted in 1989 or 1990, and therefore could not be used to assess long-term risks.

BIOPLASTY

Similarly, a statistician reported that in the study of 860 patients with MISTI implants, only 6 percent of the patients were assessed at the 2-year followup. Even so, the company calculated their claims of safety and effectiveness as if they had followed large numbers of patients for 2 years.⁹⁸ There were only 21 reconstruction patients, which the company acknowledged was too few to draw any conclusions about. Most importantly, no questions were asked about patients' problems with autoimmune disease or cancer; the company stated that the physicians conducting the study refused to allow the company to contact the patients to ask those questions, "fearing that it may cause undue concern or violate patient confidentiality". The company blamed the media, saying it "created an environment in which gathering that information was, at best, difficult".

MENTOR

The FDA statistician that reviewed the Mentor applications criticized them for failing to include important information, such as when patients were assessed subsequent to surgery, or whether appropriate steps were taken to avoid bias in the study. A subcommittee-review of the application reveals that the 806 patients in one study were apparently evaluated on the basis of the medical records, which did not necessarily provide any long-term information. For a second study, 128 of those patients were interviewed on the telephone to evaluate their satisfaction with the implants. The 128 women comprised 27 percent of the patients who were selected for the interview; it was therefore impossible to draw any conclusions about patient satisfaction based on that sample. In a third study by Mentor, 273 augmentation patients were included in a retrospective study of complications, but the information available was for an unspecified time, and based on available medical records of the plastic surgeon. Since such records would not be expected to include information on

⁹⁸These patients include those with single-lumen or double-lumen implants.

autoimmune disease or cancer, this study was criticized as inadequate in the safety information it provided.

There are no written explanations of why the scientists' recommendations not to file the PMA's were overruled by FDA officials. In fact, there are no written justifications of any kind regarding why the seven PMA's were filed by FDA. This is unusual; within every agency of HHS there is usually a written justification for any decision of this importance. According to the FDA briefing provided to subcommittee staff, the main reasons for filing the PMA's were concern that a rejection would result in a lengthy appeals process, and hope that filing would result in the companies providing better safety information that could be made available to the public. However, the months between FDA's filing and the November 1991 meeting of the FDA advisory panel provided the manufacturers and plastic surgeons with the opportunity to lobby the FDA and Congress on behalf of their product.

E. PROFESSIONAL PRO-IMPLANT LOBBYISTS INCLUDED FORMER FDA OFFICIALS AND PROVIDED PATIENT LOBBYISTS WITH MISLEADING INFORMATION

The American Society of Plastic and Reconstructive Surgeons (ASPRS) charged an additional assessment of \$1,050 to each of its members to put together a major lobbying campaign, which began in early October 1991. They hired three lobbying firms. Lobbyists included Deborah Steelman, a former White House aide who at that time was still advising the President on health issues; Roger Stone, a long-time Republican campaign strategist with extensive White House ties; Charles Black, a former aide to President Bush who was soon to become a senior advisor to Bush's reelection campaign; Mark Heller, an attorney who had worked in FDA's Office of the General Counsel; Stuart Pape, a former FDA official who had coauthored articles with Dr. Kessler and was a personal friend; and Nancy Taylor, a consultant who had formerly worked with Kessler when they were aides to Senator Orrin Hatch.⁹⁹ Senator Hatch was considered responsible for supporting Kessler's appointment as Commissioner. Mark Heller had testified as an FDA official at the subcommittee's December 1990 breast implant hearing, and his wife is associated with the Komen Foundation, which supports research on breast cancer. The Komen Foundation testified on behalf of breast implants at the November 1991 FDA advisory panel meeting.

In early October 1991, ASPRS paid for almost 400 women to fly to Washington to lobby their Senators and Congressmen about the importance of breast implants to self-esteem.¹⁰⁰ Surgeons and their nurses and patients also wrote more than 20,000 letters to Congress and the FDA. According to the Federal Election Commission, the ASPRS PAC contributed \$62,450 to 61 Senators and Congressmen in 1991-92, including key members of Congress.¹⁰¹ According to ASPRS, their "PlastyPac" donations "will be used to express the

⁹⁹Drew, C. and Tackett, M. (December 8, 1992) Access equals clout: The blitzing of FDA, *Chicago Tribune*; in subcommittee files.

¹⁰⁰Ibid.

¹⁰¹FEC printout of PAC contributions; in subcommittee files.

Society's support and gratitude to legislators who help us communicate our message on breast implants and other issues to key publics and policy makers".¹⁰²

After the subcommittee hearing in December 1990, Chairman Weiss received many letters from implant patients with problems or from women who were grateful to Congress for exposing the potential risks. However, after the ASPRS lobbying was initiated, Representative Weiss received thousands of letters from women with implants, plastic surgeons, and their nurses. Some were form letters, and those that were personally written were very similar to the model letters that ASPRS provided to surgeons to provide to their patients. As a result of lobbying, more than 200 Congressmen and Senators wrote to the FDA Commissioner advising him to keep implants on the market.

Subcommittee staff analyzed whether the women writing to Chairman Weiss to defend implants were different from those who wrote to describe their problems. Not all the women gave much information about their implants, but those who did tended to have had implants for 3 years or less. Of the 700 randomly selected letters analyzed by the subcommittee, 60 percent had implants for 3 years or less, and 68 Percent for 4 years or less.¹⁰³ In contrast, the women with problems tended to have had implants for 5-10 years or even longer. This is consistent with experts' finding that most women with problems have implants that ruptured 7 years or more after their surgery.

The subcommittee also analyzed the content of the letters it received. All letters defending implants included information provided in the model letters sent by the ASPRS, some of which were based on information that was incorrect or misleading.

The ASPRS had claimed that breast implants were being regulated more stringently than other medical devices. This is inconsistent with the fact that the law requires that all devices be proven safe or effective before they can be sold. In the case of breast implants, the FDA had "grandfathered" the device after the 1976 Medical Devices law, had ignored more than 12 years of scientific advice that the implants could be dangerous, and had allowed them to be sold even before requiring data be submitted to prove their safety.

The ASPRS had claimed that anecdotes from a few "disgruntled patients" had caused a media hysteria and pressured Representative Weiss to "require new regulations" regarding breast implants. In fact, the congressional hearing had included testimony from scientific experts, and was also based on evidence that FDA's own scientists had been urging the agency to take implants off the market for years. This ASPRS argument also ignored the fact that 4,300 adverse reactions had been reported to FDA by late 1990, and that thousands of implant patients had joined support and information groups such as Command Trust Network. Moreover, Representative Weiss never recommended any new regulations regarding breast implants.

¹⁰²October 15, 1991, issue of *Breast Implant Bulletin*; in subcommittee files.

¹⁰³This analysis is in subcommittee files.

The ASPRS argued that women deserve “the right to choose” and that Congress and the FDA is taking that right away from women. However, the plastic surgeons, the consumer groups, and the FDA differ considerably about what is an informed choice. FDA policy required that research be conducted to determine long-term risks, such as cancer and connective tissue disorders, and that implants be removed from the market if manufacturers do not prove they are safe.

The ASPRS speculated that women would be afraid to go to doctors when they find a lump or unwilling to have surgery if silicone implants are not an option. This does not take into account the three other options for such women: (1) saline implants; (2) lumpectomy (removal of the tumor instead of removal of the breast); and (3) surgical procedures that entail moving body tissue from the abdomen or buttocks to reconstruct the breasts.

The ASPRS also quoted a survey they had conducted, which claimed that more than 90 percent of women with breast implants were very satisfied. However, less than half of the women who were sent questionnaires in that survey completed them. Scientists have criticized the survey as a marketing device, not a scientific study. Since there was no way to know if women who were unhappy with their implants had the opportunity to participate in the survey, FDA therefore ignored its findings. In fact, the PMA’s clearly indicated that there is no long-term safety data on breast implants.

The plastic surgeons argued that their personal experience proves that implants are safe. However, when women have problems with arthritis or other connective tissue disorders, they go to rheumatologists, not plastic surgeons. Until recently, few physicians knew that autoimmune disorders were even a possible risk of implants.

The ASPRS also argued that if breast implants are removed from the market, all other silicone implants should be removed. In fact, most implants are made of solid silicone; if there are problems, they can easily be surgically removed. Silicone gel implants are unique in that the gel can migrate to other organs, causing serious problems and sometimes making it impossible to remove completely.

Breast implant manufacturers also lobbied for their products. For example, Bristol-Myers Squibb interviewed several implant patients who they believed would be credible witnesses at an FDA committee meeting on polyurethane-covered implants in July 1991. The women wrote to FDA requesting permission to testify at the July 31 meeting, never mentioning in their letters that the company would reimburse their travel expenses.¹⁰⁴

When Dr. Kessler called for a moratorium on breast implants in January 1992, ASPRS lobbying efforts focused on his removal from the decision-making process, and the removal of several members of the FDA advisory panel. According to investigative reporters for the *Chicago Tribune*, lobbyists arranged for the president of ASPRS to call HHS Secretary Sullivan in January, and Charles Black, who was at that time an advisor to

¹⁰⁴Copies of correspondence and internal memoranda about these witnesses are in subcommittee files.

President Bush's reelection campaign, wrote a letter to Secretary Sullivan.¹⁰⁵ Lobbyists also arranged conversations with staff members of Vice President Quayle's Competitiveness Council, and with Sam Skinner, President Bush's Chief of Staff. These efforts met with limited success; Dr. Norman Anderson, former chair of the advisory committee, was stripped of his vote, but Dr. Kessler remained very involved in the process and decisionmaking.

F. MANUFACTURERS HAVE NEVER PROVIDED PROOF OF SAFETY TO THE FDA

After completing their final review of the PMA's, FDA scientists concluded that the companies' studies were inadequate to provide evidence of safety or efficacy. Although breast prostheses are intended for use over many years, FDA reviewers noted that there was almost no information about the experiences of women who had implants for more than a few months, and almost no data at all on reconstruction patients.¹⁰⁶

When new drugs or devices are introduced onto the market, the number of patients evaluated is necessarily small. However, in the case of breast implants, there is a 30-year history involving approximately 1 million American women. Although the companies knew since at least 1982 that they would probably be required to provide safety data, and although they were warned in 1988 that data would be required in approximately 30 months, many of the studies were not started until 1990 or 1991. Whereas prospective studies that followed women for many years would have been considered ideal, a reasonable alternative would be to start a study in 1990 that asked patients from the 1970's or early 1980's about any medical problems they have had since their implant surgery. That kind of thorough retrospective study was not conducted by any of the manufacturers.

According to the reviews conduct by FDA scientists and statisticians, there are several major problems with most of the studies:¹⁰⁷

1. Most studied women for 2 years or less; this was not sufficient to evaluate the safety of a medical device that is meant to be permanent, especially when allegations have been made that they are likely to rupture after several years.
2. In many of the studies, the majority of women were lost to the study after a few months; it was therefore impossible to say whether an implant was safe since there was no information at all on most of the women who had the surgery.
3. In several studies, patients were not asked about any symptoms of connective tissue/autoimmune disorders, cancer, or other medical problems that have been associated with silicone breast implants. It is not sufficient to examine medical records kept by plastic surgeons, since women will only return to their plastic

¹⁰⁵Drew C. and Tackett, M. op. cit.

¹⁰⁶Reviewers comments and the complete PMA's are in subcommittee files.

¹⁰⁷This summary is based on reviews, previously described in detail in this report, and in subcommittee files.

surgeons for complications that they recognize to be associated with the surgery.

4. The number of reconstruction patients in most of the studies was so small that they could not provide persuasive evidence of safety. The Director of the Office of Device Evaluation, Robert Sheridan, informed subcommittee staff that for the purposes of filing the PMA, FDA assumed that the experiences of augmentation patients would be the same as those for reconstruction patients.¹⁰⁸ That assumption is impossible to defend, since there are no data to back it up.

5. Several manufacturers have no studies of women with certain models of implants that they sell, or they have studied fewer than 10 women with particular types of implants. Again, Robert Sheridan informed subcommittee staff that for the purposes of filing the PMA, the assumption was made that the safety of one model was the same as for other models. Again, that assumption is impossible to defend, since there are no data to back it up.

Several years are required to conduct a study of the long-term safety of breast implants and to determine how long they will remain intact inside the body. In some cases, well-designed studies were planned but had not been started at the time the PMA's were due.

In addition to the problems with the clinical trials, the animal studies also had major problems. For example, according to Dr. Norman Anderson, former chair of the FDA advisory panel that had reviewed the safety of breast implants, his review of all "10,000 pages" Dow submitted with its PMA indicated *that none of the animal studies evaluated silicone placed in or beneath the breast tissue.*¹⁰⁹ He pointed out that breast tissue is more sensitive than other kinds of tissue, so that it makes no sense to study the effect of implants elsewhere in the body; he compared it to studying an artificial hip for humans by implanting them in animal armpits.

In addition, there are apparently no studies of the "energy" required to rupture an implant, which was also supposed to be required for filing a PMA. This would be especially important, since the greatest concerns about the risks of silicone pertain to implants that have ruptured.

G. FDA OFFICIALS AND MANUFACTURERS PREVENTED THE 1991 FDA BREAST IMPLANT ADVISORY COMMITTEE FROM CONSIDERING CRUCIAL SAFETY INFORMATION

On November 13-14, 1991, an FDA scientific advisory panel determined that the four manufacturers of silicone gel breast implants did not provide sufficient evidence of safety or effectiveness. However, the panel also recommended that silicone breast implants remain on the market as a public health necessity, because of their known benefits (as described by satisfied patients), and because of lack of evidence of substantial risks.

¹⁰⁸Mr. Sheridan's comments at a briefing for subcommittee staff are summarized in subcommittee files.

¹⁰⁹Letter from Dr. Anderson to Dr. Kessler, January 9, 1992; in subcommittee files.

In order to conclude that silicone breast implants should be considered a public health necessity, the panel should have reviewed scientific data indicating whether the benefits of silicone breast implants were unique, compared to saline implants, lumpectomies, or other surgical alternatives. *The panel members were not provided with such information.* When Vivian Snyder, the consumer representative on the FDA advisory panel, asked about any such evidence, no objective data were provided in response. Instead, Rosemary Locke, a nonvoting panel member representing Y-Me, a pro-implant national breast cancer support group, responded that she believed that some breast cancer reconstruction patients would not have a satisfactory cosmetic result with saline implants.¹¹⁰ Research published in 1984 indicating that saline implants may be less likely to cause capsular contracture was not presented.¹¹¹

In addition, the Advisory Panel was not allowed to hear about research that had been presented by Dr. Donna deCamara 2 months earlier, indicating that implants were likely to break after 7 years. Her research had been presented at the annual meeting of the American Society of Plastic and Reconstructive Surgeons and had been reported in *USA Today* in September 1991, but was not made available to the panel members. When one panel member asked that the study be discussed, offering to give copies of the 3-page manuscript to panel members, he was informed by the Chair that he was not allowed to do so, because the document was not relevant to a specific PMA.¹¹²

Finally, the advisory panel was not provided with internal Dow Corning documents dating from 1960-1987, regarding the safety of breast implants. These documents had been under court seal, but their contents had been referred to at previous FDA meetings and the subcommittee hearing.

On February 10, 1992, under intense pressure following extensive media coverage of these memoranda, Dow Corning publicly released them for the first time.¹¹³ Many of the memoranda focused on implants that were developed in the 1970's, which were made with a thinner gel and a thinner outer "envelope". The implant was an attempt for a more natural feel, but caused problems because the implant felt greasy (apparently due to "bleed" of liquid silicone as the gel broke down).

The internal Dow documents indicated three major problems:

1. *Dow Corning scientists made repeated references to the lack of safety data, expressing concern that company spokesmen were misleading doctors when they said they had evidence that their product was safe. For example, Chuck Leach, a marketing executive, wrote in a 1977 memorandum that he had told plastic surgeons*

¹¹⁰Transcript of 1991 FDA advisory panel meeting, p. 254ff; in subcommittee files.

¹¹¹Asplund, O. (1984). Capsular contracture in silicone gel- and saline-filled breast implants after reconstruction. *Plastic and Reconstructive Surgery*, pp. 270-275.

¹¹²Transcript of the advisory committee meeting; in subcommittee files.

¹¹³The documents released by Dow Corning are in subcommittee files, and are available from Dow Corning.

“with fingers crossed” that studies of “contracture/gel migration” were underway.¹¹⁴ He also stated that Dow Corning “should not be comfortable with our current lack of focus and coordinated leadership” regarding research on the migration of silicone particles from breast implants and other silicone implants, and that decisions should be made about “what steps need to be taken to fill whatever gaps that may exist in our needed storeroom of knowledge. In my opinion, the black clouds are ominous and should be given more attention.”

2. *Dow Corning scientists were concerned that the 1970’s implants caused problems because they were made with thinner gel and thinner silicone envelopes.* There were repeated references to concerns about silicone rupture, silicone “bleeding” in women and even during sales displays, as well as migration to lymph nodes and other organs in animal studies, including studies of monkeys. The memoranda indicate concerns that this would harm sales, because surgeons would choose implants made by other companies, and little interest in its possible risks to patients. For example, several memoranda described the implants as “greasy”; one memorandum advised that the salesmen who show implants to doctors should wash the implants before showing them to potential customers.¹¹⁵ The latter memorandum said that washing was necessary because bleeding tended to occur the day after the implants were handled; the fact that this would mean the implant would bleed silicone inside the patient the day after surgery did not seem to be of concern.

3. *Scientific misconduct*, including Dow Corning’s failure to publish or disclose to FDA their own research results when they showed problems. For example, the company did not report that some of the animals they studied showed inflammation of the lymph nodes and other symptoms that could indicate immune disorders. Instead, Dow Corning published reports that indicated no problems, and in their submission to FDA, they excluded studies which showed problems. As a result, the FDA advisory panel and FDA staff could not judge the true risks of the implants.

In addition, the memoranda indicated that, despite problems with new models of implants in the 1970’s, Dow arranged to have them implanted in women patients *even before the animal studies were completed*. This is not consistent with ethical standards for research on humans.

Even after FDA demanded that Dow Corning provide the documents to them, the company refused to do so, instead sending documents to the company’s lawyers’ office in Washington, DC, in late December 1991. FDA was told they could go to the lawyers’ office

¹¹⁴The March 31, 1977 memorandum from C. Leach to B. Levier was released by Dow Corning on February 10, 1992, but had been quoted in articles in January 1992. In a January 8, 1992, letter to the editor of the *Midland Daily News*, Chuck Leach complained that his reference to crossed fingers had been misconstrued as a lie, when in fact cross fingers meant he was hopeful that it was true. Mr. Leach defended Dow Corning’s research program in his letter to the editor; however, in the original memorandum, he stated, “As best I can tell we have not taken significant action ... except for a ‘half-hearted’, low-priority program.”

¹¹⁵May 16, 1975, memorandum from Tom Salisbury to 45 Dow employees; this and the other memoranda about greasy implants were made publicly available by Dow on February 10, 1992, and are in subcommittee files.

to look at the documents, but the documents were not sent to FDA.¹¹⁶ Eventually, FDA staff went there, requested specific documents, and were given copies.

Most 1991 FDA advisory committee members were concerned about the lack of safety data, but determined it would be acceptable to keep breast implants on the market because of a lack of evidence that they were *unsafe*. Their votes presumably would have been influenced by the Dow Corning internal memoranda. FDA had not requested copies of these documents from the manufacturer, although FDA was aware of their existence. Moreover, the contents of the documents were being discussed in a California courtroom about the same time as the advisory panel deliberations.

The advisory panel recommended that the FDA permit continued sale of silicone breast implants under certain conditions: 1) If the FDA could ensure that potential patients receive accurate information about the known risks; 2) if a registry was developed to keep track of all women who have silicone breast implants; and 3) if the companies were required to submit safety data within the next 6 months, and long-term safety information within the next 2 years.

The FDA was required to make its decision about the approval and continued marketing of silicone gel breast implants on January 6, 1992. At that time, Dr. Kessler announced an indefinite moratorium on silicone breast implants. According to Dr. Kessler, he decided to request a moratorium because of the internal Dow documents that were made available to FDA in December, and because of information from rheumatologists who were concerned that many implant patients seemed to suffer from connective tissue diseases. Much of the information about connective tissue diseases and implants could have been available months earlier, but it was not made available to Dr. Kessler or the FDA advisory panel.

H. FDA CONCERNS ABOUT CANCER LED TO THE REMOVAL OF BREAST IMPLANTS COVERED WITH POLYURETHANE FROM THE MARKET IN 1991

Silicone breast implants covered with polyurethane foam had been manufactured by several different companies since 1971. They became popular in the late 1980's, when they were made by Cooper Surgical. In 1986 and 1988, FDA inspectors reported that the implants were made under nonsterile conditions; for example, company employees blew into the implants to test for inflation.¹¹⁷ In December 1988, Cooper Surgical sold the breast implant business to Surgitek, a subsidiary of Bristol-Myers Squibb.

By 1990, the Canadian Department of National Health was debating the cancer risks and other problems associated with silicone breast implants covered with polyurethane. At the subcommittee hearing in December 1990, an FDA scientist made the first public statement that FDA research indicated that the polyurethane that covers implants breaks down in the body to form a known animal carcinogen, TDA.¹¹⁸

¹¹⁶Correspondence describing this arrangement are in subcommittee files.

¹¹⁷Inspection reports and related documents are in subcommittee files.

¹¹⁸Hearing, testimony of Hoan My Do Luu, p. 159.

By March 1991, an FDA scientist warned the Director of the Division of Compliance that Surgitek had terminated a study that may have indicated a cancer risk from the polyurethane foam.¹¹⁹ In April 1991, FDA scientists were estimating the cancer risk as between .5 and 100 per million patients.¹²⁰ The 100 per million was based on total degradation of two breast implants; however, some plastic surgeons were recommending the use of two polyurethane implants stacked together on each breast. This would result in an estimate of 200 cancer patients per million.¹²¹

By May 1991, a scientist from Aegis Analytic Laboratory in Nashville contacted the FDA to inform them of a study of breast milk in an implant patient, which they had conducted at Surgitek's request.¹²² The scientist had informed the company that TDA had been found in the breast milk of a woman with polyurethane-covered implants, and he was concerned that the company was not making the information available to FDA or the public. Company officials argued that the laboratory finding was inaccurate, although the manufacturer had hired the lab to do the testing, and a third party retained by Surgitek had confirmed that the laboratory methods were appropriate and accurate.

A month earlier, on April 10, 1991, FDA had published its final rule regarding the July 9 deadline for submitting proof of safety and effectiveness. There was extensive media coverage of the potential risks of TDA from breakdown of the polyurethane foam, and FDA officials were repeatedly questioned about their cancer risk estimates.

As a result of these concerns, FDA informed Bristol-Myers Squibb that they would need additional data on the potential risks of TDA from the polyurethane, in addition to the safety data on silicone required by the other manufacturers. As a result, Surgitek temporarily withdrew its implants from the market, and later announced that it would shut down all manufacture of breast implants permanently. Approximately 200,000-400,000 American women are estimated to have had polyurethane-covered implants; most were implanted between 1985-1990.¹²³

FDA announced in April 1991 that they would require Bristol-Myers Squibb to conduct postmarket surveillance on the risks of their product, whether or not they intended to resume sales in the future. However, as of December 1992, more than 20 months later, the company had not provided any research data to FDA.

The company's apparent lack of research on the carcinogenic risks of their product is in sharp contrast to their interest in the psychological health of women with breast implants. In response to the 1990 public comment period for the proposed rule on breast implants, Bristol-Myers Squibb quoted research indicating that small-breasted women who did not want breast implants expressed attitudes that supports women's rights; the company

¹¹⁹Memorandum from Deputy Director, DSRD, to Director, Division of Compliance Operations, March 29, 1991; in Hearing, p. 407.

¹²⁰Note from Art Norris to Liz Jacobson, April 18, 1991; in Hearing, p. 395.

¹²¹Hester, T. R. and Cukic, J. (1991) Use of stacked polyurethane-covered mammary implants in aesthetic and reconstructive breast surgery. *Plastic and Reconstructive Surgery*, Vol. 88, No. 3, pp. 503-509.

¹²²These documents are in subcommittee files.

¹²³Kessler, G.; Cooper, J.D.; and Fee, W. (January 19, 1992) The implant business, *Newsday*; in subcommittee files.

interpreted this as indicating that they were more “deviant” than small-breasted women who wanted breast implants.¹²⁴

I. THE 1992 FDA ADVISORY PANEL LACKED CRUCIAL INFORMATION ABOUT INTERFERENCE WITH MAMMOGRAPHY AND OTHER PROBLEMS

The FDA advisory committee on breast implants was reconvened in 1992 to reconsider their recommendation on the basis of new information provided by the internal Dow documents and reports from rheumatologists. However, they still lacked crucial information about other risks, and about alternatives to silicone breast implants.

For example, information about potential problems with mammograms was based more on opinion than fact. In a study conducted between 1981 and 1985, Dr. Melvin Silverstein and his colleagues at the Breast Center, Van Nuys, California, had reported that silicone gel implants hinder the ability of mammography to visualize breast tissue.¹²⁵ A study of six patients published in 1988 reported that breast implants obscured 22-83 percent of the breast tissue, and concluded that 2-film mammography was not reliable for implant patients.¹²⁶ However, at the 1991 and 1992 FDA panel meetings, claims were made that a special mammography technique, called the Eklund method, was sufficiently accurate for implant patients. No information was provided to the panel about the proportion of radiology technicians trained in the method, and no before-and-after implant comparisons were provided.

However, a study published in the *Journal of the American Medical Association* in October 1992 indicated that women with little or no capsular contracture showed a 30 percent decline in the breast tissue that could be visualized with mammography; women with more severe contracture had a 50 percent reduction in the postsurgical mammogram.¹²⁷ The study included 68 women (126 breasts), who were given mammograms before and after implants. After implants, both compression and displacement types of mammograms were performed. Four patients (6 breasts) were unable to have postimplant displacement mammograms because of contracture.

J. IN 1992, DOW CORNING DISCLOSED THAT THE COMPANY SOLD IMPLANTS TO DOCTORS BEFORE THEY WERE SWORN TO BE SAFE IN ANIMALS, FAILED TO DISCLOSE PROBLEMS WITH THE IMPLANTS, AND SUBMITTED FABRICATED INFORMATION ABOUT QUALITY CONTROL

In February 1992, Dow Corning released internal documents indicating that breast prostheses were implanted in women before lifetime tests were conducted in animals. Moreover, preliminary animal studies had suggested that the silicone could migrate or cause

¹²⁴Comments submitted on behalf of Medical Engineering Corporation (Surgitek) to FDA, September 14, 1990, p. 7; in subcommittee files.

¹²⁵Silverstein, M.J. et al (1988). Breast cancer in women after augmentation mammoplasty, *Archives of Surgery*, pp. 681-685.

¹²⁶Hayes, H.; Vandergrift, M.S.; and Diner, W.C. (July 1988), op. cit.

¹²⁷Handel, N. et al. (October 14, 1992). Factors affecting mammographic visualization of the breast after augmentation mammoplasty. *Journal of the American Medical Association*, pp. 1913-1917. Little or no contracture was defined as a score 1 or 2 on the Baker scale.

other problems. These memoranda are quoted earlier in this report.

The company also released internal documents indicating that plastic surgeons were very concerned about silicone bleeding and implant rupture. These documents are also discussed previously in this report. In addition, in August 1992, FDA officials wrote to Dow Corning to reiterate concern about Dow Corning's failure to report capsular contracture, gel bleed, and other problems that were required under Medical Device Reporting (MDR) guidelines.¹²⁸ Dow Corning had complained that FDA's recent document entitled "MDR Reporting Guidance for Breast Implants" "establishes a completely new standard for reporting complaints from non-health-care professionals". FDA responded that this statement, as well as Dow's "interpretation of the definition of serious injury", which was used as the basis of reporting decisions, were "in error". This correspondence indicates a systemic problem in MDR standards at Dow Corning that would be expected to result in the company's significant underreporting of adverse reactions and other problems to FDA. According to Dow Corning, it also indicates that FDA investigators raised no objections to the company's underreporting when they reviewed company records in 1988 and 1990.¹²⁹

In January 1992, prior to the company's release of those documents, newspapers and network news programs were quoting internal Dow Corning memoranda extensively. Dow Corning hired former Attorney General Griffin B. Bell to conduct an internal investigation. The resulting report, completed in November 1992, indicated that in addition to the problems cited in the previously released memoranda, there were *manufacturing problems that had been covered up by fabricating test results*.

Keith McKennon, chairman and CEO of Dow Corning, announced in November 1992 that a quality control problem occurred during the manufacturing stage when the silicone bag filled with liquid silicone was cured, in order to turn the liquid into a gel. When problems occurred with the oven, due to a power failure or another reason, technicians replaced the records to make it appear that there was no problem.¹³⁰

McKennon explained that the company discovered the problem in 1987, and halted the practice. However, he stated that, "Dow Corning could not determine which lot histories contain replacement charts". He claimed that patients would not have been harmed because each implant was examined by a technician to ensure it was of the correct consistency.

Despite these disclaimers, there is no way to determine whether the subjective judgment of the technicians who felt each implant's consistency was accurate enough to ensure the safety of the product. Moreover, problems in curing could cause the gel to break down later, even if the consistency appeared appropriate at the time the implant was

¹²⁸August 7, 1992, letter from Leighton Hansel, Director of FDA's Division of Product Surveillance, Center for Device and Radiological Health, to Harvey Steinberg, Food and Drug Counsel, Dow Corning; in subcommittee files.

¹²⁹Letter from Harvey Steinberg, Food and Drug Counsel, Dow Corning, to Leighton Hansel, Director of FDA's Division of Product Surveillance, CDRH, September 17, 1992; in subcommittee files.
¹³⁰Press release from Dow Corning in subcommittee files.

manufactured. Most important, the fact that technicians fabricated test records on one of the most important tests of the implants calls into question the integrity of the entire quality control process for breast implants at the company.

K. PATIENTS HAVE BEEN MISLED ABOUT THE SAFETY OF BREAST IMPLANTS FOR AT LEAST THE LAST 15 YEARS

By the 1980's, breast implants had become one of the most common procedures in plastic surgery, and few doctors or patients expressed any concern that the implants were not proven safe or effective by the FDA. In fact, it is likely that most patients were not told that breast implants were not approved by FDA.¹³¹

In the 1970's, Dow Corning informed plastic surgeons that they had done all the testing necessary to conclude that breast implants were safe. However, in 1985, an internal Dow Corning memorandum from Jim Cooper warned his colleagues that the FDA was planning to require lifetime animal safety studies, a situation he described as "ominous".¹³² Cooper concluded that, "If lifetime carcinogenic testing is required", the silicone shell had been tested adequately but the silicone gel had not been. He wrote: "Most of our claims to date have been based on a two-year dog study (five materials). However, a dog study must continue for 7 years to qualify as lifetime testing. The materials used in the two-year dog test would not be approved under the lifetime test criteria."

Internal documents described previously in this report indicate that Medical Engineering Corporation, the breast implant company that was later sold to Bristol-Myers Squibb, did not always disclose the results of research that was potentially detrimental. In addition to those memoranda previously described, a 1978 document describing beagle studies indicated such adverse reactions as hemorrhage, possible pneumonia of the lung, and hyperplasia of lymphoid tissue in the large intestines.¹³³ The president's response was "sacrifice dogs ASAP" and "no organs of dogs in freezer". One year later, the president responded to a letter regarding animal maintenance cost with the note, "I thought we wiped out all dogs and had parts send to W.L. [a company vice president]. My rec[ommendation] - kill dogs; forget organs; just dispose of them."

The plastic surgeons apparently believed the safety claims of the manufacturers, without asking for proof. ASPRS distributed an information brochure about silicone breast implants that included information that was clearly inconsistent with FDA concerns and scientific data.¹³⁴ For example, the brochure claimed that capsular contracture affects "one out of ten women", whereas the research literature reported 30-40 percent contracture rates. The brochure also stated that "loose silicone does not appear to be a health risk", and compares the longevity of breast implants to "the kidney, heart, eyes, or any other body part". These statements ignored the research evidence regarding the dangers of migrating

¹³¹Hearing, testimony of Sybil Goldrich, pp. 3-10, 26.

¹³²January 8, 1985, memorandum from J. Cooper to C. Lentz, R. Rylee, H. Steinberg, and K. Yerrick, distributed publicly by Dow Corning on February 10, 1992, and in subcommittee files.

¹³³March 28, 1978, memorandum from W. Stith to Jerry Helmer; Exhibit 2 in *Johnson vs. MEC*; in subcommittee files.

¹³⁴The ASPRS brochure entitled "Straight Talk About Breast Implants", is in Hearing, pp. 179-185.

silicone, and the evidence that many women have their implants replaced ever 5-15 years.¹³⁵

As breast implants became more popular and widely advertised in the 1980's, FDA did little to remind manufacturers of the agency's regulatory restrictions. For example, a relatively new type of breast implant, called the MISTI GOLD, was advertised in the New York Times in 1991 as "FDA-approved".¹³⁶ It was not approved, but had been cleared for marketing by FDA. The outer shell was made of silicone, but the inside gel was made of polyvinyl pyrrolidone; long-term safety data in humans are not available. Despite the different type of gel used, the FDA allowed the MISTI GOLD implant to be sold because the agency agreed with the manufacturers claim that it was "substantially equivalent" to silicone get breast implants.¹³⁷

In 1988, the FDA advisory panel recommended that all potential patients *must* receive safety information prior to surgery, because of concerns that patients were not being adequately warned about the risks. Instead, the FDA decided to convene a group of representatives from the manufacturers, surgeons, and consumer groups, to develop a voluntary brochure. The brochure had not yet been approved when the implants were removed from the market in January 1992, because of veto threats by the ASPRS.

Meanwhile, in 1987, the State of Maryland enacted a law *requiring* that an education booklet be provided to potential patients prior to surgery. According to Maryland State Delegate Joan Pitkin, plastic surgeons tried in vain to have the law withdrawn or weakened; moreover, some plastic surgeons refused to distribute the booklets.¹³⁸

By late 1991, the public was becoming increasingly aware of the potential dangers of silicone breast implants because of media coverage of the congressional hearings, the FDA advisory committee meeting, and other activities. Dow Corning had initiated an 800 telephone hotline to answer the thousands of calls from concerned patients and women considering implants. The hotline was advertised in major newspapers with the claim "IF YOU WANT ACCURATE INFORMATION ABOUT BREAST IMPLANTS ... instead of innuendo and half truths ... call the Dow Corning Implant Information Center, where the information is based on 30 years of valid scientific research".¹³⁹

FDA staff called the number on various occasions, and reported the conversations in FDA memoranda. The Special Assistant to the Commissioner on Women's Health called on December 24, 1991, pretending to be a college student, and was told that "scientific data and

¹³⁵For example, an FDA analysis of adverse reactions, dated December 1, 1988, indicated a median implant duration of 7 years for ruptured implants. This memorandum was written by Brian Kunst, and is in subcommittee files.

¹³⁶The ad published in the *Good Health Magazine* of the *New York Times* is in subcommittee files.

¹³⁷In July 1991, 500 MISTI GOLD implants were seized by FDA, because they were a model that had not been grandfathered. FDA later refused to file the PMA for MISTI GOLD due to lack of safety data.

¹³⁸Hearing, testimony of Maryland State Delegate Joan Pitkin, pp. 243-244.

¹³⁹This is the exact wording of an ad from the *Baltimore Sun*, November 19, 1991; in subcommittee files.

research show that they are 100 percent safe. ... We [Dow Corning] have done lengthy studies as have thousands of plastic surgeons to show they are safe.”¹⁴⁰ Two FDA callers reported being told on December 30, 1991, that, “There has been significant testing on arthritis, scleroderma, lupus, and other problems with the immune system. There is no link between this or cancer or silicone problems.” One of the FDA callers was also told, “There is no detrimental effect to having silicone in the body.”

After FDA sent Dow Corning a warning letter about misinformation on their hotline on December 30, 1991, Dow representatives answering the hotline became much more cautious about what they said.¹⁴¹ For example, when an FDA employee called on February 5, 1992, pretending to be a mother concerned about her 20-year-old daughter’s plans to have implants, she was told that hotline counselors would not answer the question, “Are breast implants safe?”. However, the company sent an article from the Mayo Clinic, which claimed, “Breast implants are safe. ... Lupus and rheumatoid arthritis are no more common in women with implants than in the general population. ... Even if the implant breaks, the silicone that leaks has not been proven to be dangerous.”¹⁴²

L. PATIENTS CONTINUE TO BE MISLED BY THE FDA-APPROVED INFORMED CONSENT FORM

Despite the concerns about the dangers of silicone that were exposed by the internal Dow Corning memoranda in February 1992 and increasing evidence of the risks of silicone implants in studies conducted by plastic surgeons and scientists in recent years, medical associations have continued to pressure the FDA to minimize dangers to potential patients in their informed consent forms.

Informed consent has been a major issue for critics of FDA’s regulation of breast implants. Patients have reported that they were not told about the risks of breast implants prior to surgery, other than a brief mention of the risks of infection and anesthesia.¹⁴³ FDA’s regulation of devices requires that manufacturers list the risks of the device in a package insert for physicians; however, prior to September 1991, there were no similar warnings for patients.

Since 1988, FDA advisory committees reviewing breast implants have been vehement about the need for patients to receive adequate information about the risks and benefits prior to surgery. Since FDA’s 2-year attempt to produce a brochure by a committee of consumers, health professionals, and industry representatives failed, in 1992 FDA needed to develop an informed consent form to be used for the open availability protocol for reconstruction patients.

PLASTIC SURGEON’S ATTEMPTS TO CHANGE INFORMED CONSENT FORMS

On June 5, 1992, the executive director of the American Society of Plastic and Reconstructive Surgeons wrote to Dr. Alan Anderson, the acting Director of FDA’s Office

¹⁴⁰ All conversations quoted are from FDA memoranda in subcommittee files.

¹⁴¹ The warning letter is in subcommittee files.

¹⁴² Mayo Clinic Health Letter, March 1991, p.7; in subcommittee files.

¹⁴³ Letters from patients are in subcommittee files.

of Device Evaluation, to express the society's "dissatisfaction" with the FDA's draft informed consent form.¹⁴⁴ The society requested numerous revisions aimed at minimizing the risks of breast implants.

For example, ASPRS requested that FDA delete the statement that, "Manufacturers have not provided to FDA adequate scientific evidence" of their safety and effectiveness and also the statement that, "The number of women who now, or in the past, have had silicone gel-filled breast implants is not known. ... It is also not known how many of those women have had problems."

The society also requested that the statement that closed capsulotomy "must NOT be performed" be replaced with statements that, "While FDA and manufacturers recommend against closed capsulotomy ... some physicians, based on clinical experience, feel that closed capsulotomy is an appropriate treatment in some patients. However, patients must understand that closed capsulotomy could cause an implant to break and that would require surgery to replace the implant."

Despite recent evidence of the problems in detecting breast tumors, the society requested that warnings about formations of calcium deposits that could make it more difficult to detect "cancer on mammograms" delete the reference to cancer and replace it with "lesions". The society also requested that a statement be added that, "Special methods of mammographic examination minimize the amount of breast tissue that is 'hidden' by the implant." This statement would have been inconsistent with research showing that breast implants interfere with mammograms.

Regarding the dangers of cancer, the society suggested that a statement, "Although there is no evidence that silicone used in breast implants causes cancer in humans, the possibility has not been ruled out", to be changed to, "There is no evidence that silicone used in breast implants causes cancer in humans". No mention is made of the cancer caused by silicone in laboratory animals, either in the FDA version of the informed consent or the ASPRS version. However, the ASPRS refers to the findings of the Deapen study as evidence that implants do not cause cancer, even though scientist have criticized that study as inadequate. Moreover, the ASPRS neglected to mention that in 1991, Deapen and Brody reported that there were increased frequencies of lung cancer and vulvar cancer among the breast implant patients in their study.¹⁴⁵

The society also requested revisions that would minimize the risk of implant rupture, for example, adding, "On rare occasion, an injury can tear the scar envelope, and the gel can be driven into the subcutaneous planes" *before* the statement, "Silicone gel may migrate to the surrounding breast tissue and other parts of the body". The society also requested the addition of several caveats, including, "The free gel will usually be contained within the scar tissue capsule surrounding the implant," and, "Silicone is generally considered one of the

¹⁴⁴Letter and accompanying document from Dave Fellers, executive director, ASPRS, to Dr. Alan Anderson, Acting Director, FDA's Office of Device Evaluation, June 5, 1992.

¹⁴⁵A copy of the Deapen and Brody report, presented at the FDA's Conference on Silicone in Medical Devices on February 1, 1991, and at the annual meeting of ASPRS on May 10, 1989, is in subcommittee files.

least reactive materials used in medical devices”.

The ASPRS also requested that FDA delete the warnings that, “The surgical implantation of the device may interfere with a woman’s ability to nurse her baby. ... Although this is a known risk, the extent of the risk is unknown.” They suggested that FDA replace those warnings with: “There is no evidence that breast implants interfere with lactation and many women with implants have successfully nursed.”

The ASPRS also suggested additions that would have minimized the risk of connective tissue/autoimmune disorders, and replaced the phrase “connective tissue disorders” with “rheumatic disorders”.

AMA’S ATTEMPTS TO CHANGE INFORMED CONSENT FORMS

On June 18, 1992, 2 weeks after the ASPRS sent their letter to FDA, Dr. James Todd, the president of the American Medical Association, wrote a letter to the FDA Commissioner, Dr. Kessler, supporting several of ASPRS’ complaints about the informed consent document. Dr. Todd complained that the informed consent form “may raise unnecessary concerns to a woman whose decision has already been made in all probability because it goes beyond the known risks and refers to studies that are to be conducted”.¹⁴⁶ For example, he objected to the statement, “Because there is not enough research to show whether silicone gel filled breast implants cause birth defects, the FDA has required manufacturers to conduct studies on this issue and submit them for FDA review.”

Dr. Todd also objected to the FDA’s informed consent form’s prohibition on the performance of closed capsulotomy as an intrusion on “the treatment alliance established between practitioner and patient”.¹⁴⁷ Dr. Todd suggested that the statement instead explain that, “Closed capsulotomy could cause an implant to rupture”, but not make any statement about whether such procedures should be performed.

Finally, Dr. Todd objected to the statement that breast implants may interfere with a woman’s ability to nurse her baby, claiming that there is no evidence that this is the case.

FDA’S CAPITULATION TO CRITICISM OF INFORMED CONSENT FORMS

The FDA deleted many of the statements in the informed consent form that the ASPRS objected to in their letter. For example, the statement that, “The number of women who now, or in the past, have had silicone gel filled breast implants is not known”, was replaced with the statement, “Breast implants have been used in nearly two million women for nearly 30 years”, and the statement, “It is not known how many of those women have had problems”, was deleted.

The change in the number of implant patients is important, because it has implications for the apparent safety of the products. In 1992, FDA halved their earlier

¹⁴⁶Letter from James Todd, president, AMA, to Dr. David Kessler, Commissioner, FDA, June 18, 1992; in subcommittee files.

¹⁴⁷Ibid., p. 2.

estimate of 2 million to 1 million, because of evidence that the original estimate was in error.

According to a February 5, 1992, FDA memorandum, the 2 million estimate was based in part on the number of implants sold, not the number of patients. As a result, women with two implants were counted twice, and the approximately 20 percent of procedures that were replacement surgeries were also counted.¹⁴⁸ The original estimate also failed to take into account the fact that a proportion of breast implant cancer patients died.¹⁴⁹ By using the larger estimate favored by the plastic surgeons, the proportion of women with implant problems is instantly cut in half. Moreover, the statement that implants have been used by “nearly two million women for nearly 30 years” implies that any risks would be obvious by now; in fact, since most implant surgeries were done in the 1980’s, and since the earlier implants were sturdier and less likely to break, it may be that long-term risks have not yet come to doctors’ attention.¹⁵⁰

In response to the complaints of the ASPRS and AMA, the FDA informed consent form *deleted* the statement that closed capsulotomy “must NOT be performed”. It was replaced by much more ambivalent statements: “This technique is not recommended by the manufacturer, because it could result in several complications, such as breakage of the implant. However, your surgeon may feel this is the best method for correcting the firmness because, if it works, it is quick, simple, and avoids surgery, although it may be briefly painful.”¹⁵¹

The FDA weakened the warnings about gel migration in response to ASPRS concerns. The informed consent form now reads: “The gel released as a result of rupture may be contained within the capsule surrounding the implant. If the scar envelope also tears, the gel can travel (migrate) and be squeezed into the breast tissue or into the muscle or fatty tissue next to the breast, abdominal wall, or arm. Fortunately, this is uncommon. The risks from this escaped gel are unknown.” This *revised* statement in the informed consent form suggesting that rupture and migration are uncommon is inconsistent with the rupture rates ranging from 0-32 percent that were reported in the *FDA Consumer* magazine in June 1992. It is also inconsistent with the April 13, 1992, statement of Dr. Hollis Caffee of the ASPRS Educational Foundation at the Public Health Service Breast Implant Task Force Meeting, when he stated that implants made more than 10 years ago that are removed now are almost always broken.¹⁵² Moreover, the statement that gel migration through a torn capsule is “uncommon” is not based on data, since no studies have been conducted.

The FDA also diluted their warnings about breast feeding as requested by the ASPRS and AMA. The informed consent form now states: “Many women with breast implants have

¹⁴⁸February 5, 1992, memorandum from Dr. R. Bright to the record; in subcommittee files.

¹⁴⁹The 1 million number was used in Segal, M. (June 1992). Silicone breast implants; Available under tight controls, *FDA Consumer*; in subcommittee files.

¹⁵⁰According to ASPRS, the number of plastic surgery procedures they performed increased 69 percent from 1981 to 1990. See Mitka, M., *American Medical News*, September 23/30, 1991; in subcommittee files.

¹⁵¹The informed consent document is in subcommittee files.

¹⁵²Minutes of this meeting are in subcommittee files.

nursed their babies successfully. ... Any breast surgery, including breast implant surgery, could theoretically interfere with your ability to nurse your baby.” The term “theoretically” is misleading, since it is known that capsular contracture, pain, and other problems resulting from implants could make nursing impossible.

The FDA changed their warnings about birth defects, as requested by the ASPRS and AMA, to minimize patients’ concerns. The informed consent form now states: “Preliminary animal studies show no evidence that birth defects are caused by breast implants.” FDA did not mention that a support group called Children Affected by Toxic Substances (CATS) has been formed by breast implant patients whose children have health problems they believe are related to silicone exposure from the implants. In June 1992, an FDA official speculated that “while CATS is not yet a large nationally known organization, there are signs it soon could be”.¹⁵³

Despite the suggestions of the ASPRS, the informed consent form still includes warnings about the possible association between breast implants and connective tissue disorders similar to those in the earlier FDA draft.

M. FDA’S PUBLIC STATEMENT ABOUT BREAST IMPLANTS MINIMIZED THE RISKS

FDA’s decision to compromise the warnings in its informed consent form in response to the “dissatisfaction” of the ASPRS and AMA is the most recent example of the agency’s pattern of minimizing the risks of breast implants in their public statements.

During the period of increased media attention following the subcommittee hearing, FDA officials continued to make public statements that were far more optimistic about the safety of breast implants than their own scientists reported. In addition, internal documents of FDA officials indicated that they believed there was insufficient evidence of safety to keep any of the silicone implants on the market. But instead of staying neutral on the topic, FDA officials made statements that were used to support the undocumented safety claims of manufacturers and plastic surgeons.¹⁵⁴

In April 1991, the FDA distributed a Talk Paper to explain that polyurethane-covered implants would no longer be available.¹⁵⁵ The Talk Paper stated that polyurethane implants were voluntarily removed from the market, which ignored the fact that the FDA pressured Bristol-Meyers Squibb to “voluntarily” remove them due to concern about cancer risks. The FDA did not mention that the polyurethane had been found to be Scott Industrial Foam, a product made for automobile air filters and carpet-cleaning equipment and never intended to be implanted in the human body.¹⁵⁶

The April 1991 Talk Paper also said that the polyurethane from the implants breaks down to TDA, which “has been linked to cancer in laboratory animals”. That sounds less

¹⁵³ June 2, 1992, memorandum from Margaret T. Tolbert to Joseph Arcarese; in subcommittee files.

¹⁵⁴ Documents in subcommittee files.

¹⁵⁵ April 17, 1991, Talk Paper; in subcommittee files.

¹⁵⁶ Burton, T.M. (March 25, 1992). How industrial foam came to be employed in breast implants, *Wall Street Journal*, p. 1.

ominous than the more accurate explanation, which is that FDA has categorized TDA as an animal carcinogen and potential human carcinogen, as have the National Toxicology Program and the International Agency for Research on Cancer.

After the FDA advisory committee met in November 1991, the advisory committee chair made public statements that were not entirely consistent with the recommendations of committee members. Similarly, the FDA issued a Talk Paper that emphasized the committee's recommendation to allow continued marketing of silicone implants, rather than the restrictions they had imposed if continued sales were to be permitted. Several panel members wrote to the FDA Commissioner and each other to complain that these public statements did not convey their serious concerns about silicone implants as "potential health hazards".¹⁵⁷

**N. FDA INSPECTIONS IN 1992 INDICATED THAT MCGHAN HAD VIOLATED
GOOD MANUFACTURING PRACTICES, BUT FDA ALLOWED
MCGHAN SALES TO RESUME BEFORE PROBLEMS WERE CORRECTED**

By early 1992, only two manufacturers were still eligible to sell silicone breast implants in the United States, Mentor and McGhan. FDA conducted inspections of McGhan, and reported to the company president in early March that, "The firm has failed to adequately validate its PMA products and their manufacturing processes", and, "The Quality Assurance program, which is intended to assure and verify confidence in the quality of the process used to manufacture silicone gel breast implants, is inadequate".¹⁵⁸

For example, FDA inspectors warned that, "Quality Assurance did not recognize nor investigate the cluster of five complaints reporting sterility and/or irritation problems with the product". The inspectors also complained that a study of women with implants began 1 month *before* receiving approval for the study by an Institutional Review Board. Such approval is required by law to be received prior to starting the study.

On March 31, 1992, FDA wrote to the chief executive officer of McGhan, Donald McGhan, to notify him that, "There were serious failures on the part of your firm with respect to the way product complaints were received, evaluated, and investigated".¹⁵⁹ These included: "Failure to review and evaluate physician-submitted complaints", including "complaints involving injury or any hazard to patient safety", as well as failure to report complaints of "capsular contracture, leaks, tears, ruptures, deflations, [and] medical complications" to FDA's Medical Device Reporting system, as required by law. In the same letter, FDA also notified Mr. McGhan about deficiencies in the quality assurance program and manufacturing controls.

¹⁵⁷ Letters from Rita Freedman, Kathleen Anneken, Vivian Snyder, and Rosemary Locke are in subcommittee files.

¹⁵⁸ Document, dated March 5, 1992, is in subcommittee files.

¹⁵⁹ Letter from George Gerstenberg, District Director, Los Angeles District Office of FDA, to Mr. Donald K. McGhan, CEO and Chairman of the Board, March 31, 1992; in subcommittee files.

In June 1992, FDA completed its review of McGhan's response to FDA's warning letter, and concluded that, "Conditions exist whereby there is a reasonable probability that unsafe or ineffective devices will be produced and distributed".¹⁶⁰ On July 15, FDA's Associate Commissioner for Legislative Affairs wrote to Representative Marilyn Lloyd that, "FDA medical professionals have spoken with a number of plastic surgeons who contacted us about their patients needing McGhan implants. However, none of the plastic surgeons was able to justify medically the need for the McGhan over a Mentor implant. The reason for choosing one brand over another seemed, from these discussions, to be one of personal preference. Other plastic surgeons with whom our professionals spoke expressed the view that the brands are interchangeable."¹⁶¹

However, by July 29, 1992, Joseph Arcarese, FDA's Director of the Office of Training and Assistance, wrote a memorandum regarding the decision to form a group to develop a "compassionate need exemption policy" to allow McGhan implants to be sold.¹⁶² According to FDA memoranda, these efforts were primarily inspired by a letter from the husband of one of the patients waiting for McGhan implants.¹⁶³ The patient had testified at a Congressional hearing describing her anger at having to wait for a McGhan implant.¹⁶⁴

The compassionate need exemption policy was approved by FDA on October 23, 1992, and is currently in place.¹⁶⁵ FDA has permitted 1,500 McGhan silicone breast implants to be sold. Like other exceptions that FDA has made regarding breast implants, FDA's decision was not based on objective information; FDA has apparently neither requested nor received any scientific evidence that the McGhan silicone gel implant is superior to the Mentor silicone gel implant or to saline implants.

**O. FROM APRIL 1992 TO THE PRESENT, FDA HAS FAILED TO MONITOR
THE USE OF SILICONE BREAST IMPLANTS, DESPITE THE PROMISES OF
THE FDA COMMISSIONER**

Dr. Kessler announced in April 1992 that the moratorium on silicone breast implants would be lifted for patients who urgently needed the implants. Those categorized as "urgent need" included women who needed their silicone implants replaced because of rupture or contracture, mastectomy patients who were in the midst of their reconstruction process, and women who needed immediate reconstruction after mastectomy and were not suitable for saline implants.

¹⁶⁰Letter from George Gerstenberg District Director, Los Angeles District FDA Office to Mr. T. Jan Varner, president, McGhan Medical Corporation, June 19, 1992; in subcommittee files.

¹⁶¹July 15, 1992, letter in subcommittee files.

¹⁶²Memorandum from Joseph Arcarese to Carole Sierka, July 29, 1992; in subcommittee files.

¹⁶³Letter from Judd Funk to Ruth Merkatz, Special Assistant to the Commissioner for Women's Health Issues, July 17, 1992; in subcommittee files.

¹⁶⁴"Breast Implants: Ramifications of the FDA Ruling on Consumers", hearing before a subcommittee of the Select Committee on Aging, April 30, 1992.

¹⁶⁵Letter from Ronald M. Johnson, Director, Office of Compliance and Surveillance, Center for Devices and Radiological Health, to Mr. Jim McGhan, president, McGhan Medical Corporation, October 23, 1992; in subcommittee files.

The urgent need exceptions were permitted starting in late April 1992, as a temporary measure until the open availability research protocol for mastectomy patients and women

with severe deformities was approved. Because of delays in approving the open availability protocol, the urgent need surgeries were permitted until December 1, 1992.

In their announcement of the urgent need exceptions, the FDA stated, “The manufacturer must maintain records of the number of devices used under the urgent need provision (both those shipped for this use or already purchased), and the names and addresses of the physicians who implanted the devices under this provision. These records will be made available to the FDA upon request.”¹⁶⁶ Surgeons were told to provide information to Mentor, the manufacturer; however, during the 6 months that “urgent need” surgery was performed, the FDA gathered no information about the number of patients that received implants, nor the reasons given for their “urgent need”. The FDA therefore completely failed in their promise to “carefully monitor” the use of implants, to ensure that the restrictions required by FDA were followed; in fact, they did not monitor it at all.

It was not until after the subcommittee requested this information from FDA in December 1992 that FDA inspected Mentor to retrieve such information. They then learned that at least 3,581 women received silicone breast implants under the “urgent need” category.¹⁶⁷ FDA also learned that an examination of 37 closed patient files revealed that 12 (32 percent) did not have informed consent forms and 5 (14 Percent) had incomplete urgent need certifications. An examination of 32 working patient files revealed 26 (81 percent) urgent need certifications were missing and 2 (6 percent) were incomplete, and 7 (22 percent) consent forms were missing. This information was compiled by the FDA *after* the urgent need category was no longer in place.

When Dr. Kessler announced that the “open protocol” would permit silicone breast implants only for women with mastectomies or serious deformities caused by accident or disease, consumer groups expressed concern that these restrictions be carefully monitored.¹⁶⁸ They expressed concern that ASPRS had previously referred to small breasts as a “disease” that should be treated. However, Commissioner Kessler stated that FDA would carefully monitor the situation and would ensure that deformities would be defined narrowly, such as Poland syndrome.¹⁶⁹

Despite these assurances, FDA has had virtually no role in monitoring the open protocol since it began enrolling patients in September 1992. Physicians must sign a form stating that silicone breast implants are necessary because saline implants are unsuitable; however, those forms are sent to the manufacturer, not to the FDA. The FDA does not even have a list of physicians and the number of patients each has treated; such information would be a first step in assuring that doctors were not implanting silicone gel prostheses in most of their patients. Moreover, the FDA has not required any information about the proportion of patients for whom each doctor is using silicone or saline implants; this would provide valuable information needed to determine whether physicians are using silicone gel implants as a last resort when saline implants are not suitable.

¹⁶⁶“Use of Silicone Gel-filled Breast Implants Under Urgent Need Exemption”, revised July 17, 1992; in subcommittee files.

¹⁶⁷Summary of findings dated December 15, 1992 is in subcommittee files.

¹⁶⁸Newspaper interviews are in subcommittee files.

¹⁶⁹Transcript of Dr. Kessler’s April 16, 1992 press conference; in subcommittee files.

Moreover, the study protocol requires that doctors use silicone implants only for reconstruction or to correct deformities. However, the FDA has not required that doctors provide any information to FDA to document whether doctors are abiding by that agreement. Again, a first step would be to require a list of doctors and the number of patients treated for deformities and reconstruction. Since breast deformities are rare, any doctor with more than one “deformity” patient should be audited. However, since FDA did not require such a list from the surgeons, there is no basis on which to audit any medical records.

Therefore, under the current system, any doctor who believes that silicone implants are better than saline implants would be able to continue to use silicone implants, and any doctor who believes small breasts are a deformity could continue to perform augmentation surgery with silicone gel implants. Moreover, the preliminary analysis of the urgent need program indicates that many patients may not have signed informed consent forms, calling into question the informed consent process.

Even with limited information, the FDA should be able to determine whether the urgent need and open availability protocols are being abused. For example, 175,000 women every year are diagnosed with breast cancer. If 75 percent have mastectomies, that would be 131,000. Only 10 percent of mastectomy patients chose breast implants prior to the adverse publicity; that would equal 13,100. In the current climate, at most 25-50 percent would be expected to prefer silicone implants; this would equal 3,275-6,500 per year. Since FDA restrictions now require that silicone be used *only* when saline implants are not appropriate, that should be a small proportion of these patients.¹⁷⁰ Therefore, the fact that more than 3,500 women received silicone breast implants in 7 months under the urgent need exemption policy suggests that either there is “business as usual” in breast reconstruction, or a very large number of women found ruptures that necessitated their old implants being replaced.

FDA has approved 3,000 physicians to participate in the open protocol for breast reconstruction, which began December 1. Therefore, if more than 3,000 patients each year are receiving silicone gel implants in the current FDA study, or if any physician is performing a disproportionate share of that total, FDA would have reason to carefully investigate the implementation of the research protocol.

P. FDA HAS FAILED TO EVALUATE AVAILABLE SAFETY INFORMATION THAT LAWYERS HAVE OBTAINED FROM MANUFACTURERS

In recent years, several lawsuits have resulted in multimillion dollar punitive fines against breast implant manufacturers, based on the jury’s belief that safety information was withheld from patients. For example, the Dow Corning memoranda that were released in

¹⁷⁰ According to some experts, choice of silicone is usually a personal preference on the part of the surgeon rather than a choice made specifically for the needs of the patient. For example, see testimony of Betty Rollins at the FDA advisory committee meeting in February 1992.

February 1992 were primarily from a California case involving Mariann Hopkins, who was awarded \$7.3 million in December 1991, including \$6.5 million in punitive damages against the company.¹⁷¹ In December 1992, Pamela Jean Johnson, an implant patient from Texas, was awarded \$25 million from Bristol-Myers Squibb.¹⁷² Twenty million dollars were for punitive damages, based in part on internal documents from that company. Those documents are not under protective order.

In June 1992, Judge Sam Pointer of Alabama was appointed to oversee pretrial work of the multidistrict breast implant liability litigation involving 78 lawsuits.¹⁷³ The number of lawsuits since then has increased to more than 1,000. Judge Pointer refused to grant a blanket protective order to company documents, as had frequently been done in the past, and instead ruled that all previously entered protective orders in pending breast implant cases were “vacated and voided effective November 15, 1992”.¹⁷⁴ The manufacturers’ rights to seal documents will be determined on a case-by-case basis.

Thousands of pages of documents have already become available as a result of Judge Pointer’s ruling, and from the Johnson case; however, FDA has apparently not yet obtained those documents to determine if they contain new safety information. A preliminary review of several of these documents by subcommittee staff indicate that they contain information that could be helpful to patients, and could have implications for the availability of breast implants under the public health exemption FDA used to justify making silicone breast implants widely available to reconstruction patients.

Q. NIH HAS FAILED TO SUPPORT RESEARCH ON THE SAFETY OF BREAST IMPLANTS FOR CANCER PATIENTS

Prior to the subcommittee hearing in December 1990, the NIH had supported only one study of breast implants, a poorly designed study of cancer risk that was also supported by three breast implant manufacturers. According to FDA reviewers, the results of the study were not meaningful because the statistical analysis was inappropriate, and the women were not followed for a sufficiently long period of time.¹⁷⁵

After the controversies about the safety of breast implants became public in late 1990, NCI agreed to support a large study of women with silicone breast implants. However, the request for proposals specified that the study would be limited to augmentation patients and would exclude cancer patients who had implants for reconstruction.

In April 1992, Chairman Weiss joined with several members of the Congressional Caucus on Women’s Issues and Representative Henry Waxman, Chairman of the

¹⁷¹The award was upheld by a Federal judge in April; see Record damages upheld in breast implant rupture, *Baltimore Sun*, April 28, 1992; in subcommittee files.

¹⁷²Record \$25 million awarded in silicone-gel implants case, *New York Times*, December 24, 1992, p. A13; in subcommittee files.

¹⁷³Medical Devices, Diagnostics, and Instrumentation Report, July 6, 1992, p. 10; in subcommittee files.

¹⁷⁴Revised Case Management Order, September 15, 1992; in subcommittee files.

¹⁷⁵The FDA review is in Hearing, pp. 145-152.

Subcommittee on Health and the Environment, in a letter urging Dr. Bernadine Healy, the Director of NIH, to include breast cancer reconstruction patients in the NIH study. The members pointed out that fewer than 100 cancer patients had been studied by breast implant manufacturers. In a letter dated May 5, 1992, Dr. Healy informed the members that the NIH “care deeply about this population of women” but they would be excluded from the study.¹⁷⁶

The subcommittee received dozens of letters from implant patients who have been seriously ill for years, frequently with immune disorders, and their doctors never suggested that their illness might be related to their implants. In some cases, they have experienced a total recovery when the implants were removed. In other cases, silicone had been leaking for years, and not all of it could be removed.

Although the medical improvement of women whose implants have been removed is clear evidence that implants may cause these diseases, well-designed studies of thousands of women, followed for many years, would be more conclusive. These studies should include reconstruction patients as well as augmentation patients. Similarly, the “studies” conducted by plastic surgeons indicating that most of their patients are satisfied with their implants is not evidence that the implants are safe for most reconstruction or augmentation patients or for long-term use. Thus far, the studies conducted by plastic surgeons have relied on medical records that do not include all medical problems.

R. MEDICARE AND MEDICAID AND THE DEPARTMENT OF DEFENSE ARE REQUIRED TO PAY FOR REMOVAL OF BREAST IMPLANTS FOR MEDICAL REASONS

Breast implant surgery usually costs between \$3,000-7,000; however, the removal of a broken implant can be much more expensive. Women with implants who have connective tissue disease or other illnesses may lose their jobs and therefore their health insurance. Desperate women have removed their own implants because of their inability to afford explantation surgery.¹⁷⁷ Numerous women have contacted the subcommittee seeking information about possible sources of financial assistance for implant removal.

The subcommittee requested that the General Accounting Office (GAO) examine the extent to which Medicare, Medicaid, the Department of Defense, and CHAMPUS will pay for the removal of breast implants for medical reasons. According to GAO, “Most government and private insurers will pay for the removal of silicone breast implants. All insurers require that the patient’s physician determine that the procedure is medically necessary. Generally, this means that the patient is suffering health problems due to the breast implants or that the implants have ruptured or leaked.”¹⁷⁸

¹⁷⁶May 5, 1992, letter from Dr. Bernadine Healy; in subcommittee files.

¹⁷⁷Stanley, D. (May 15, 1992). Woman cuts self to force removal of breast implant, *Baltimore Sun*; in subcommittee files.

¹⁷⁸Letter report from Janet Shikles, GAO, to the Hon. Donald Payne, December 7, 1992, GAO/HRD-93-5R; in subcommittee files.

According to the GAO: “Medicare, Medicaid, DOD [Department of Defense], and most private insurers will pay for the removal of breast implants even when the original implant is done for cosmetic purposes. However, CHAMPUS will not pay for any complications that result from breast implants done for cosmetic purposes, including the removal of ruptured or leaking breast implants.”

The GAO was requested to examine Medicaid programs in eight States, several of which have many implant patients. The number of removals paid for by Medicaid has been small, however. In fiscal year 1992, the California Medicaid program paid for 12 claims for removal of implants or implant material; the program reimbursed only one quarter the cost of the procedure. In Florida, the number of claims increased from 1 in fiscal year 1991, to 18 (including capsule removal) in fiscal year 1992, and nine in the first 3 months of fiscal year 1993. In New York, Medicaid paid for 16 claims in fiscal year 1991 for the removal of breast implants or implant material (and 4 involving breast capsules).

In contrast, Texas Medicaid paid only three claims in fiscal year 1992 for removal of implants or implant material, and three claims for breast capsules. Moreover, GAO reported that Louisiana’s Medicaid program has not had any requests for the removal of implants in recent years. Because of this inactivity, such claims would be automatically denied, and the doctor or patient would then have to request that Medicaid reconsider. However, the Medicaid program claims that they would pay for explantation if a physician determined the procedure is medically necessary.

Whereas the Department of Defense will pay for the removal of a breast implant when medically necessary, CHAMPUS, which is provided to military dependents and retirees, will not pay for explantation. According to the GAO, CHAMPUS officials say that they have had only one inquiry about their reimbursement policies for explantation. They are developing a policy which would deny reimbursement, except possibly in cases of systemic infection.

From 1989 to 1991, the number of breast implant removal claims paid by Medicare increased by 91 percent, from 270 to 517. In addition, claims involving the removal of breast implant *material* increased by 63 percent, from 180 to 293. The average Medicare reimbursement was \$309 and \$326, respectively; this represented almost half of the amounts billed. However, Medicare also paid for 1,270 breast capsule procedures in 1991, an increase of 135 percent compared to 1989.

The discrepancy between the GAO findings and the reports of women unable to afford explantation may in part be caused by the low reimbursement rates paid by Medicare and Medicaid. It may be that women have difficulty finding physicians who will accept Medicare and Medicaid payments for explantation. Similarly, Dow Corning and Bristol-Myers Squibb will reimburse explantation under certain conditions, but generally offer less than the usual cost of explantation.

IV. Recommendations

1. THE COMMITTEE SHOULD URGE FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH TO IMPROVE THEIR REGULATION OF MEDICAL DEVICES

The subcommittee's investigation reveals that a great many scientists and other staff at FDA's Center for Devices and Radiological Health (CDRH) showed inspiring dedication and perseverance in their efforts to determine the safety and efficacy of breast implants since the late 1970's. Unfortunately, as the subcommittee staff has seen in many other investigations involving the FDA, the best efforts of those dedicated public servants were repeatedly undermined over a period of at least 15 years by decisionmakers within the agency, who ignored and overruled the warnings and suggestions of the individuals most knowledgeable about the product. Despite unprecedented media attention since the subcommittee hearing 2 years ago, and the leadership shown by the current FDA Commissioner, that pattern continues to the present day.

After a 6-year delay in classifying silicone breast implants as Class III devices, from 1982-88, the Center moved slowly forward in requiring data proving safety and efficacy as part of the PMA process. Similarly, the Center has not yet required PMA's from the manufacturers of saline breast implants, despite FDA officials' repeated promises to publish a proposed rule regarding those PMA's since 1988.

Moreover, the Office of Device Evaluation (ODE) failed to work with device manufacturers to clarify research needs in the years following the proposed rule in 1982. Although the manufacturers should have been aware of the scientific standards required of safety data, the agency could have done more to convey the urgency and seriousness of FDA's research requirements. As a result, the manufacturers had virtually no meaningful clinical data when they submitted their PMA's in July 1991.

By deciding to file the PMA's submitted by most of the manufacturers, over the objections and the recommendations of FDA scientists, CDRH wasted FDA's limited resources in a time-consuming approval process. This was unnecessary since the evidence was overwhelming that the manufacturers had not provided sufficient safety information to justify FDA approval.

Most notable, the system failed when FDA officials did not ensure that FDA advisory committee members had access to all public information about the potential risks of breast implants at their meetings in 1991 and 1992. There is no justification for the lack of comparative information regarding alternatives to silicone gel implants, most notably saline breast implants. Even more questionable were the decisions to block relevant information by

panel members when such studies were mentioned by consultants or panel members.

The FDA's Office of Compliance should now be urged to monitor the "open protocols" that were intended to restrict the use of silicone gel breast implants. A thorough review of the use of the urgent need exemptions should also be conducted, although it is too late to prevent apparent abuses in that program.

2. THE COMMITTEE SHOULD CONSIDER LEGISLATION TO CLOSE THE REVOLVING DOOR BETWEEN FDA AND INDUSTRY

The hiring of Mark Heller, who testified on behalf of FDA's Office of General Counsel at the subcommittee's December 1990 breast implant hearing, as a lobbyist for the ASPRS less than 1 year later, is just one example of how the revolving door between FDA and industry creates conflicts of interest.

Similarly, the hiring of James Benson, the Director of FDA's Center for Devices and Radiological Health, by the Health Industry Manufacturers Association calls into question FDA's ability to provide unbiased judgments based on scientific evidence.

There is no way to know when discussions about job offers begin with an FDA employee, and such discussions clearly create a conflict of interest for the FDA employee.

3. THE COMMITTEE SHOULD ASSURE THAT FDA REQUEST AND EXAMINE ALL RELEVANT DOCUMENTS THAT ARE NOT UNDER COURT PROTECTIVE ORDERS

Memoranda from the various manufacturers contain information regarding the safety of their implants, which in some cases have convinced juries that the implants were known to be unsafe. FDA scientists would not necessarily agree with those jury decisions, but the documents themselves are obviously crucial to FDA's appropriate regulation of these medical devices. FDA should therefore immediately request documents that are not protected under court seal, and examine them for relevance to their regulation of breast implants. When appropriate, the information contained in those documents should be reviewed by the FDA advisory committee or made publicly available.

4. THE COMMITTEE SHOULD RECOMMEND THAT THE PRESIDENT, BY EXECUTIVE ORDER, CLARIFY FDA'S AUTHORITY TO REVIEW PROTECTED COURT DOCUMENTS RELATED TO PRODUCTS THAT IT REGULATES

Information about problems with silicone breast implants was available to Dow Corning for more than 15 years before that information was provided to FDA or the public.

As stated in the subcommittee's report on the off-label use of drugs and devices (House Report 102-1064), which was released in November 1992, "FDA needs the authority to review all documents related to the safety and effectiveness of products it regulates, even when those documents have been protected by court orders." In that report, written before the 1992 election, the committee recommended that Congress clarify FDA's authority, since

there has been controversy about it. However, it would be equally appropriate, and much faster, for the President to sign an Executive Order clarifying the intent of current law.

5. FDA ADVISORY COMMITTEES SHOULD REVIEW ALL RELEVANT SAFETY AND EFFICACY INFORMATION

Under the current process, FDA advisory committees primarily review information provided by the manufacturer. The manufacturer is responsible for ensuring that information is complete and unbiased. However, the breast implant advisory committee meetings have made it clear that relevant information is not always included in those proceedings, thus biasing the outcome of the advisory committee meeting.

FDA should therefore revise their process to ensure that all relevant safety and efficacy information can be made available to advisory committee members, preferably before the meetings, and discussed publicly at the meetings. Relevant information should be included in presentations by FDA staff, consultants, or the researchers themselves.

6. THE COMMITTEE SHOULD ENSURE THAT FDA REQUIRE IMPLANT MANUFACTURERS TO PROVIDE INFORMATION ABOUT SAFETY AND EFFECTIVENESS TO PATIENTS AS WELL AS PHYSICIANS

Under current law, device manufacturers are required to provide “package inserts” to the physicians, who are the “users” of the product. Patients are categorized as the “wearers” of the product, and the manufacturer is not required to provide information intended for them.

In September 1991, the Commissioner of FDA made an exception for breast implants, requiring that manufacturers provide an information brochure for patients which included long-term as well as short-term risks. This is an appropriate requirement for *all* implants, since problems can occur long after the physician is involved in the patient’s medical care.

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