Approved: April 7, 1994
Date

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Chairperson Joann Flower at 1:30 p.m. on March 16, 1994 in Room 423-S of the Capitol.

All members were present except: Rep. Wells, excused

Committee staff present: Emalene Correll, Legislative Research Department
William Wolff, Legislative Research Department
Norman Furse, Revisor of Statutes
Sue Hill, Committee Secretary

Conferees appearing before the committee:
Senator Pat Ranson
Attorney General Robert Stephan
Lori Callahan, Kansas Medical Mutual Insurance Company/Kansas Medical Insurance Services Corporation
Sharron Watson, interested citizen
Carrie Shearburn, interested citizen
Linda Thompson, (written testimony only)
Senator Praeger
Terry Larson, Kansas Alliance for the Mentally Ill
Walter H. Crockett, AARP
Jerry Slaughter, Executive Director, Kansas Medical Society
Secretary Donna Whiteman, Department of SRS
Sharon Huffman, Kansas Commission on Disability Concerns
Gina McDonald, Executive Director, Kansas Association of Centers for Independent Living

Others attending: See attached list

Chair called the meeting to order drawing attention to Committee minutes of March 14th. If there are no corrections or suggestions by 5:00 p.m. tomorrow, (March 17), these minutes will be considered approved as presented.

Chair drew attention to **SB 683** and requested a staff briefing. Mr. Furse noted, on page 6, lines 34-36 is language newly amended in the Senate Committee to reflect what is not dissimilar from that found in the Healing Arts Act related to breast removal/breast surgery. Prior to surgery, the person licensed to practice medicine and surgery must inform the patient of the known risks associated with breast implantation as specified in the standardized summary supplied by the Board of Healing Arts. He detailed this standardized summary; the content of the summary; noted is not to be construed to authorize in any manner the right to recommend or restrict the patient's right to select the method of treatment. This summary is not to be construed as a recommendation of treatment. He explained.

HEARING BEGAN ON **SB 683.**

Senator Ranson offered a hand-out containing background information in regard to risks, and health hazards from breast implantation; staff reports prepared by the Human Resources Department, the FDA's regulation of silicone breast implants; diseases related to breast implants; a paper on silicone (MSI) Mammary Implant H.P. related news articles. (see (Attachment No. 1) She noted, perhaps the women who are present today to give testimony will not be helped, but hopefully other women can be helped in the future. She stated she had become involved with this issue during her door-to-door campaign calls in 1992. There was a constituent who educated her in regard to the problems implant patients face, some have become terribly ill, she learned of a support group. At this time Attorney General Stephan had become involved and offered help, i.e., a task force was established. Senator Ranson then introduced Attorney General Bob Stephan.

SB 683 continued.

Attorney General Robert Stephan offered a hand-out (Attachment No. 2). He stated a Task Force on Silicone Induced Disease, chaired by Dr. Carol W. Konek, had been established as a result of conversations with women in Wichita who were afflicted with Silicone Induced Disease. These women advised me they were unfamiliar with the political system and sought assistance in trying to find answers to problems they faced as a result of silicone breast implants. He expressed appreciation for the initiatives of Senator Ranson. There are more than 350 women in Kansas who suffer from diseases caused by silicone breast implants. There are also men in the state who have incurred the same diseases from silicone implants. Those persons who receive implants should be made aware of information available regarding advantages, disadvantages, and risks association with implementation. These common sense requests are contained in **SB 683.**

Lori Callahan, Kansas Medical Mutual Insurance Company, (KaMMCO) (Attachment No.3) offered neutral testimony on **SB 683**. She noted as a medical malpractice company, KaMMCO was concerned with language that changed common law rather than codifying it. The Senate Committee amendment addresses those concerns and we are confident the provisions will provide positive changes without oppressive results. She asked this Committee consider no further amendments.

Sharron Watson, the mother of Carrie Watson Shearburn, (who will also testify), offered hand-out (Attachment No. 4). She related the story of the decision on behalf of their daughter for breast implant surgery when Carrie was 16 years old. She detailed the trauma her daughter has experienced, listed the numerous diseases she has incurred as a result of the silicone implant, which she will battle for the rest of her life. Carrie's children are also at great risk of having auto-immune disease. There are millions of women who were not informed before they conceived and nursed their children. There are 60,000 little boys with testicular silicone implants whose parents were not informed of risks. There are 100,000 men with penile silicone implants who were not properly informed as to the material used. Informed consent would give all of us the right to decide our futures, would save perhaps thousands from being experimental guinea pigs like our daughter and her children. The 1988 F.D.A. Classified implants as a Class 3 medical device which means they are a high risk device and require proof of safety. She asked, shouldn't any implanted device require proof of safety if it were in your body? She stated, she could tell all that is in her heart and mind, it is too painful. The last two years she has met hundreds of women who desperately need medical attention and help. She urged support for **SB 683.**

Carrie Shearburn offered statistical data, (see Attachment No. 5). She stated in 1991 polyurethane implants were taken off the market and women were never informed that polyurethane products used for automobiles and carpet cleaners, were never really intended to be placed in a woman's body. She showed shocking/graphic photos of women's breasts, detailing the different medical problems caused by silicone contamination in the body. Plastic Surgeons tell women an implant will last a lifetime, when in reality they last 4-7 years. She drew attention to a data packet on a silicone safety report. This packet, is opened in the operating room seconds before the implantation. The patient has never had an opportunity to see the data. She detailed the report, i.e., mammography may be more difficult to perform, and will likely affect implants, may obscure any small malignant tumor; manufacturers say it is not possible to predict the life expectancy of a silicone breast implant; manufacturers say they cannot warrant the integrity of the implant if closed capsulotomy is performed. Implants may rupture under normal living experience, accidental trauma, vigorous exercise, athletic participation. However, surgeons tell women, as they told my parents, she said, that there was no way the implant could rupture except perhaps in an auto accident causing heavy chest trauma. She stated the data insert she detailed has been out for 10 years, however, no patient was ever allowed to read it before breast implant surgery. Had women been provided access to this packet of information, probably most would have made different choices. The Dow Company has had 30 years to prove safety. She stated, it is interesting that when Dow Corning was asked by the FDA to prove safety, they locked their doors to the breast implant factory. She also detailed diseases that affect children that have become at-risk because data now indicates there can be silicone gel settle in breast milk. She named many of the diseases caused in children from this problem. Her own three children are ill, she is ill, and she held up for view, a huge packet of hospital bracelets and medication bottles that she said, is her life. She asked for help for others and urged favorable consideration of **SB 683.**

Senator Ranson spoke again, noting this is a very serious problem that has been ignored for many many years. Still implants are being done for clinical reasons. We feel, if the facts were presented many of these patients would have made different decisions. Questions were asked, i.e., the waiting period between information distribution and surgery; is there a definition on "informed consent"; "informed consent" was detailed by staff; the Senate amendment was detailed. There was discussion regarding broader language, i.e., to cover all silicone implants. Senator Ranson said she wished this broader language had been amended in the Senate.

SB 683 continued:

Ms. Correll noted on page 4, line 33, (m), page 5, line 15, it is understood that **SB 683** would create a defense for the provider who had complied with the informed consent procedure, yet other procedures that are potentially harmful would not require this same extraordinary type of informed consent procedure, there would be then, no protection for the provider. Ms. Callahan answered questions in this regard, i.e.,(the requirements regarding the document regarding risks, treatment, hazards, etc.).

Ms. Correll stated there is currently a provision requiring that certain information be given to patients who are considering breast surgery. Line 33, page 4 extending through line 15 on page 5, notes there is no conclusive presumption that the provider has complied with all the informed consent requirements, simply because they have supplied the information, unlike what apparently would be created by **SB 683** in terms of the silicone implantation.

Mr. Larry Buening also answered questions.

Chairperson Flower stated it is apparent there are problems and concerns, and perhaps more of the questions could be answered when the bill is brought before the Committee for discussion.

Chair then CLOSED HEARINGS ON **SB 683.**

Chair requested a staff briefing on **SB 816.** Ms. Correll gave a comprehensive explanation of **SB 816**, and noted new law would be created relating the Joint Committee of the Legislature and Sub-Committees of that Committee and the functions thereof. She detailed, i.e.,the purpose of, duties of the Committee; noted in line 17, a Senate amendment changed "therefor" to "thereof". An Oversite Committee will be created, and she detailed the composition of that Committee. Language on page 2, line 5, is confusing and may need some clarification in regard to "committee shall take action only by majority vote of the entire committee, whether or not present and voting".

Recorded as (Attachment No. 6), is written testimony from a Ms. Linda Thomas.

HEARINGS BEGAN ON **SB 816.**

Senator Praeger ((Attachment No. 7) stated her reasons for supporting **SB 816,** i.e., Kansas insurance reform has expanded portability, guaranteed issue to members of group plans, eliminated the pre-existing condition exclusions, compressed rates for small employee groups. She has recommended legislation that will reduce the waiting period in the Kansas Uninsurable Health Plan from 1 year to 90 days. Cost containment is being studied, i.e., claims forms, a system for collecting/analyzing health data; working towards a managed care system for delivering services to the Medicaid population which can control costs and provide quality care. She detailed the responsibilities of the Oversite Committee. She noted the differences between this Oversite Committee and the 403 Commission, i.e., the Committee guiding health reform making recommendations for responses to federal reform mandates, would be legislatively-driven, and not driven by a new bureaucracy as was created by the 403 Commission. She answered questions, i.e., if the leadership of the legislature felt that public hearings needed to be held; she was sure that the option to take legislation directly to the houses for debate would not be followed, but that the hearings would be held; this legislation is not intended to by-pass public hearings; the Oversite Committee composition was discussed; this Committee was not intended to be partisan. She has no objection to minority representation.

Noted, it was stated that reports were given to the Joint Committee last Fall on the 403 Commission and the Harder plan, but no hearings were conducted. Actually the Harder plan was just a concept at that time and Dr. Harder spoke on that concept.

There was a question as to whether or not there was a fiscal note on **SB 816.** Staff noted the language that authorizes the expenditure for the staff director is subject to appropriations, meaning, if there are no funds appropriated, it is left up to the discretion of the Legislative Coordinating Council.

It was requested by a Committee member that some idea of what costs are involved be made available to Committee when they debate **SB 816.**

SB 816 continued:
Terry Larson, Kansas Alliance for the Mentally Ill, (KaAMI) (Attachment No.8), stated they wish to do nothing to impede **SB 816.** However, they do have an objection, i.e., it appears to represent another delaying tactic. The 403 Commission chaired by Dr. Roy was charged with developing a plan. Through numerous town meetings, many thousands of work by Commission members and staff, this was democracy at its best, i.e., going to communities, receiving input from citizens that represented a broad array of personal/public interests. Now these findings and recommendations have been placed on a back burner without a hearing. She stated, if nothing else will happen with respect to health care reform, then please support **SB 816.** She asked that the legislature begin to explore current discrimination in health insurance regarding mental illnesses. She stated support for the continuation of the mental health mandate in all health insurance for Kansans, but knows that mental illnesses does not belong under mental health, but should be included with other physical diseases.

Walter Crockett (AARP, (see (Attachment No. 9),stated, Kansas AARP met with leadership of the Kansas Commission on Health Care, with Secretary Harder before health care reform bills were introduced to determine if their proposals satisfied the AARP criteria for health care reform. He stated, they do not understand how the legislature could allow the Kansas Commission on Health Care to conduct meetings and hearings for 27 months, and then not even hold a public hearing on the bill it proposed. We urge this Committee to recommend that **HB 3075** at least receive a public hearing before this session ends. He noted the AARP uses the following criteria to evaluate proposals for health care reform, i.e., universal coverage of all Kansans; comprehensive benefits, including preventive care as well as assistance with long-term-care, and prescription drugs; cost containment; fair and affordable financing; and consumer involvement in governing the health care system. The present bill provides only some measure of consumer involvement. It is said that there is no interest in Kansas in health care reform. He disputed that fact, and explained. If **SB 816** is the best this legislature can produce, then they have no alternative but to support it.

Jerry Slaughter, (Attachment No. 10) stated, all across the country, it is very difficult to achieve successes on the health care reform issue. There is no consensus on what to do. Most people agree on the fundamental issues, i.e., universal coverage; insurability; simplicity of coverage; responsibility. But how do we get there, and how quickly, is difficult to predict. He stated the Kansas Medical Society supports whatever process is available. There has been a lot of fast-track, get ahead of the curve programs initiated, but he noted, there are states who have done that and are now backing off or at least are delaying implementation of key parts of their programs because it is difficult to do anything without the federal government; difficult to finance broad reform. This does not diminish the need for reform, but we should look at reality. If debate on this issue continues, the Kansas Medical Society hopes to be included in that debate. He feels it is appropriate that these key decisions be made by the Legislative body.

Commissioner Epps spoke in the absence of Secretary Whiteman. He stated support for **SB 816**, noted support also with the appointment of the Secretary of SRS to the Oversight Committee and the addition of consumers of health care to each Sub-committee. He noted one in every ten dollars appropriated by the Legislature goes to the SRS Medicaid program. He drew attention to ongoing concerns, i.e., the complexity of proposed federal legislation; the potential impact on the Medicaid program in Kansas. (See Attachment No. 11).

Sharon Huffman Chairman on Disability Concerns, (Attachment No. 12) stated opposition to **SB 816**, noting it does not adequately address the issue of guaranteeing comprehensive health care reform for people with disabilities residing in Kansas. The Kansas Commission on Disability Concerns (KCDC) believes all people with disabilities are entitled to be equal citizens, equal partners in Kansas society. She stated, the health care needs of people with disabilities are not currently being met. She asked Committee to take a closer look at **SB 816,** to guarantee adequate representation from consumers with disabilities; to allow public hearings be held to provide consumers with disabilities to actively participate, to require the Oversite Committee to take the needs of people with disabilities into consideration when making recommendations. She stated, you will not find the word "disability" mentioned in **SB 816.** KCDC cannot support a proposal that does not guarantee involvement of persons with disabilities.

Gina McDonald, Kansas Association of Centers for Independent Living, (Attachment No. 13) spoke in opposition to **SB 816.** There is already a twelve member Joint Committee for the 90's that is politically balanced. The Committee proposed in **SB 816** would be Republican dominated. The 403 Commission has already accomplished many of the proposed activities of the new Committee. She detailed those activities. **SB 816** offers no concrete solutions to the health crisis in Kansas. We do not need another study to determine that we cannot afford health insurance, and when we can, it does not cover our pre-existing conditions. We need meaningful changes to the system today.

Chair thanked conferees for their cooperation, and their curtesy to others in the time taken for their testimony.

SB 816:

Numerous questions were asked of several conferees, i.e., Ms. Hoffman and Ms. McDonald, when asked, stated they do not feel they will be well represented because they do not know what kind of authority the SubCommittees of this Oversight Committee will have. The population of persons with disabilities have been on Advisory Committees until they are ready to turn blue, and have yet to see any kinds of changes made on their behalf. Too often Advisory Committees are token Committees. If these Subcommittees are not designed to accept input from the persons with disabilities then, No, they do not feel they have good representation. When asked, Ms. Larson said, if they had a preference on which Committee they felt would better serve this population, they would prefer the Joint Committee because it is already in place, and further if they had an opportunity to push one, it would be the Roy Commission. When asked if they think they will get fair consideration in a health care package that passes with Representatives working diligently in their communities representing all people, Ms. Huffman replied, if that were true, there would have been a hearing on Dr. Roy's 403 Commission bill.

It was noted, the Legislation had no idea what the 403 Commission proposal would cost. There was incredible opposition to it in Wichita at the hearings; there were those who thought Bill Roy was not accountable to the people who went to the meetings; people who felt he was serving his own agenda; during the hearings, there were still many unanswered questions, no idea of fiscal impact that came out of that Committee.

It was noted there is no expiration date for the 403 Commission.

Noted are questions asked by a Committee member.

Proposed language establishes a legislative body outside of the legislature. Why would we be interested in establishing a legislative body outside of the legislature? What health care "Reform" Committee will be establish next year ? Why are we continually looking at bills (often partisan) to "reinvent" committees and processes we already have?

At this point Chairperson Flower stated, she questioned that this would be a body outside of the legislature.

Further questions, i.e., it appears Commissioner Epps, Department of SRS has testified in favor of **SB 816.**, perhaps then, the Minority Leader inquired if the Department is pleased with the exclusion of the executive department of the government from any involvement with the health care reform, i.e., no governmental appointees, serving only in an advisory capacity). She asked why the Oversight Committee was preferred to the Joint Committee and if **SB 816** is preferred, then obviously the Department prefers the repeal of the Joint Committee. If this is the case, perhaps the Department may wish to submit a revision of the testimony for the Committee's consideration.

Mr. Slaughter stated, when asked, when the plan of the federal government is known, then we can move quickly, if preliminary ground work has been done at the state level, i.e., the work done by this body set out in **SB 816.** He stated further, the Kansas Medical Society is willing to work with any group, although, there are concerns, because they feel the decisions that will need to be made fundamentally are legislative decisions and should be made by the legislature. He explained.

Chair stated, at the time of 403 Commission was chaired by Dr. Bill Roy, the only legislator on that Commission was Senator Walker, and she doesn't recall hearing any protests regarding political imbalance with that Commission.

Meeting adjourned 3:08 p.m.
The next meeting is scheduled for March 17, 1994.

VISITOR REGISTER

HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE

DATE March 16, 1994

NAME	ORGANIZATION	ADDRESS
Sharon Hoffman	KCDC	Topeka
Pat Kenson	Senate	
Rozann Bozek	Wichita Survivors grp.	Hesston, KS.
Sharron Watson	~~El Dorado~~, " "	El Dorado Ks
Carrie Shearburn	" "	El Dorado, Ks
Linda Thomas	SJN	Lane KS
W. N. Crockett	AARP	Lawrence KS
Helby Smith	KPMA	Wichita
Anne Kimmel	AARP - AAUW	Topeka
George Gochel	AARP Health Care Reform	Topeka
Matt Jordan	Governor's office	
Judy Deeg	Sen. Burke	Topeka
Barb Sayre	Ks Com on Fwt H R	Topeka
Gerald Watson	Wichita Survivors Group	El Dorado Ks
Marty Kennedy	Div. of Budget	Topeka
Carolyn Strader	Wichita Survivor Grp	Topeka
Jean Ehrlich	KPCDD	Topeka
Lori Callahan	Kammco	Topeka
Chip Wheelen	KS Medical Soc	Topeka

Saline Implants Appear to Carry Hazards as Well

By Joan E. Rigdon
Staff Reporter of The Wall Street Journal

The Food and Drug Administration's partial ban on silicone-gel breast implants has sharply curtailed women's choices, but it hasn't cleared up questions about safety.

Only one company, Mentor Corp., still makes silicone-gel implants, and only women who qualify for limited FDA-approved clinical trials can get them.

That leaves women who want implants for cosmetic reasons with only one option: saline implants. But even those implants may not be safe. Researchers suspect that the hard silicone shells containing the saline can cause hardened breasts, immune disorders and other symptoms that have been associated with silicone gel.

Other dangers have been documented. In a paper published in 1983 in the Journal of Plastic and Reconstructive Surgery, researchers concluded that in rare cases, the saline can become contaminated and grow harmful bacteria. Last October, the Journal of the American Medical Association published a paper concluding that the presence of any implant, silicone or saline, impedes mammography. The devices reduce the area a doctor can see by 30% to 50%, according to the paper. The FDA will begin a review of saline implants later this year.

Most women aren't aware of the new concerns about saline implants, but they seem to be avoiding them anyway because of concerns about silicone-gel implants. In 1990, the last full year before the ban, 120,000 women received breast implants for cosmetic reasons. Since then, demand has "dropped precipitously," says Neal Handel, a plastic surgeon at the Breast Center, Van Nuys, Calif.

Dr. Handel estimates that his center, which specializes in breast cancer patients, will have fewer than 15 cosmetic patients this year, down from 80 last year. "Women have lost their appetite for this because of all the negative media public-

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Saline Breast Implants Now Appear to Carry Health Hazards Too

Continued From Page B1

ity" and concerns about safety, Dr. Handel says.

Price may be part of the issue. Only two companies make saline implants, Mentor and McGhan Medical Corp., a unit of Inamed Corp., and implant prices have more than doubled since October 1991 to $500 to $600 each. Mentor declined to comment, and Inamed declined to return repeated phone calls. But doctors say the companies will need the money to pay for research. "What do you expect? They're taking a tremendous risk by keeping their shops open," says G. Gregory Gallico III, an associate professor of surgery at Harvard University.

Conflicting information on what's safe has confused even the savviest consumers. Consider Karen Koskoff, a breast cancer patient and a member of the Breast Implant Litigation Committee of the American Trial Lawyers Association. After a double mastectomy three years ago, she got silicone implants because her doctor told her they were safe, she says.

When critics raised concerns about the devices, Ms. Koskoff did her own research and decided to switch to saline implants. Then, two months later, she found out that researchers have serious concerns about those implants, too.

She learned of the concerns at a trial lawyers association meeting she was moderating in January 1992. One speaker was warning the audience that if a client with saline implants complains of problems generally associated with silicone gel, "don't assume she's lying. Assume she's very ill," Ms. Koskoff recalls.

As the speaker listed potential safety problems with the implants, "I sat in front of the meeting with a large number of lawyers and tried not to cry," Ms. Koskoff says. "It was awful."

Even worse is the decision Ms. Koskoff faces now. She is determined to have her saline implants removed. But after a double mastectomy, getting implants and then replacing them, "I'm tired of getting cut up," she says. She will probably schedule surgery for later this year.

Some women are joining studies to get silicone-gel implants. The studies admit women who want to rebuild their breasts following surgery for breast cancer and women who want to replace implants that have broken or leaked inside their bodies.

But the biggest consumers of silicone implants — women who want them for strictly cosmetic reasons — can't get them yet. Studies for that group, which will have limited enrollment, won't start accepting patients until the fall.

Even then it won't be easy to get in. Young women, once a target market for implant manufacturers, will probably be turned away because the studies require frequent diagnostic mammography, a procedure not recommended for women under age 35.

Moreover, being in a study is no picnic. Participants must fill out detailed questionnaires and agree to checkups and laboratory tests for several years following surgery. "This is not business as usual," says Carol Scheman, the FDA's deputy commissioner for external affairs.

Susan Leigh, a Tucson, Ariz., oncology nurse and breast cancer patient, says she agonized more over what kind of implants to get than she did over her mastectomies. It was "a tremendous conflict for me," she says. Last August, after several months of research and interviews with women with both types of implants, she asked her surgeon to insert saline implants.

But he balked, urging her to join a study to get silicone implants instead. "My plastic surgeon was actually antagonistic to me . . . because I even questioned the idea of silicone implants," Ms. Leigh says.

Unsure of what to do, she told the surgeon that she needed four more months to decide. Last month, she got another doctor to insert saline implants.

THE WALL STREET JOURNAL, THURSDAY, FEBRUARY 4, 1993

PH+W 3-16-94
Attm #1

The Breast Implant Controversy

■ **July 9, 1991** The Food and Drug Administration, acting in 1988, sets this deadline for manufacturers of silicone-gel breast implants to provide detailed safety data.

■ **Sept. 23, 1991** Bristol-Myers Squibb Co. says it will close its breast implant business because it can't meet the FDA deadline to prove safety.

■ **Dec. 13, 1991** A San Francisco federal court jury issues a $7.3 million verdict against Dow Corning Corp., concluding the company concealed evidence linking ruptures to immune disorders.

■ **Jan. 6, 1992** FDA Commissioner David Kessler, after reviewing company documents, announces a 45-day moratorium on the sale of silicone implants.

■ **Feb. 10, 1992** Dow Corning shakes up top management in the wake of an FDA inquiry into silicone implant safety.

■ **Feb. 18-20, 1992** An FDA panel hears testimony about the safety of silicone implants and decides to recommend limited sale of the devices.

■ **March 19, 1992** Dow Corning says it will stop making silicone implants.

■ **April 16, 1992** The FDA limits implants to clinical trials and to women needing reconstructive surgery because of effects of breast cancer, for example.

■ **Nov. 2, 1992** Dow Corning says its outside counsel, Griffin Bell, found evidence that company employees for several years faked records about the preparation of some silicone gel used in implants.

■ **Nov. 28, 1992** A Scripps Research Institute study, published in the Lancet, strengthens the link between silicone implants and autoimmune disorders. Women whose implants leaked experienced symptoms years sooner than women whose implants were intact.

■ **Dec. 23, 1992** A Houston woman wins a $25 million verdict against Bristol-Myers Squibb over silicone implants.

■ **Jan. 5, 1993** The FDA begins evaluating the safety of breast implants containing saline solution.

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attm #1-2
pg 2 of 3

Huge settlement near on silicone breast implants

Los Angeles Times/ Washington Post Service

Significant progress was made this weekend toward a record-setting $4.2 billion settlement to compensate thousands of women claiming injuries from silicone breast implants, according to attorneys for the women and three major corporations.

"It's a done deal," said a representative of one company, who spoke on condition of anonymity. Negotiators met over the weekend in Birmingham, Ala.

Another defense lawyer and attorneys for the women made similar comments, although they were not quite as definite.

"We made terrific progress with the Big 3 and some of the smaller defendants," said Stanley Chesley of Cincinnati, one of five plaintiffs' lawyers involved in the negotiations. The so-called Big 3 are Dow Corning Corp., Bristol-Myers Squibb Co. and Baxter Health Care Corp., the three chief distributors of the implants.

A $4.2 billion settlement would be twice as large as any settlement of a civil case in U.S. history, according to legal experts.

The money would provide funds to settle silicone-implant litigation worldwide over the next 30 years. For the plaintiffs, the settlement would compensate women for a wide range of medical problems, with the amount of compensation depending on the severity of injury. For the defendants, it would erect a partial ceiling on liability for companies participating in the deal.

Two major defendants, Minnesota Mining & Manufacturing Corp. and General Electric Co., have not joined the tentative settlement, Chesley said.

At a court hearing in Birmingham on Friday, U.S. District Judge Sam Pointer, who is presiding over the thousands of breast-implant lawsuits represented in this negotiation, expressed concern that a tentative settlement first disclosed in September had not come to fruition, and that a March 8 deadline that he had set for a final version of an accord had come and gone.

On Friday afternoon, Pointer directed representatives of the companies and the plaintiffs to stay in Birmingham until they had drafted a deal. Lawyers worked late into the night Friday and Saturday, concluding their sessions at 2 a.m. Sunday, according to sources on both sides.

They gave the judge a copy of their draft agreement Sunday morning and are to meet with him again Wednesday. Any deal would have to be approved by Pointer.

One major point that has been resolved, according to lawyers on both sides, is how Dow Corning's share of the settlement — more than $2 billion — would be guaranteed.

Dow Corning was the world's largest maker of silicone breast implants until it stopped manufacturing them in 1992. The Midland, Mich., company also supplied silicone gel to many other implant-makers for decades. The company said in January that it had been named as a defendant in more than 6,800 lawsuits relating to silicone breast implants.

Use of the implants was restricted by the Food and Drug Administration in 1992, after mounting complaints by women and new information raising questions about implant safety was revealed in civil lawsuits. It is estimated that about 1 million women worldwide have breast implants. Lawyers on both sides have no clear idea how many women would file claims if the settlement is approved. About 12,000 lawsuits have already been filed.

Any settlement would have to be cleared by a plaintiffs' steering committee of 17 attorneys, as well as by the boards of the three companies. The companies also have to notify their insurance carriers, which would have to foot a hefty portion of the bill.

PH+W 3-16-94 Attn #13 pg 3 of 3

STATE OF KANSAS

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TESTIMONY BEFORE HOUSE PUBLIC HEALTH & WELFARE
Senate Bill 683
By Attorney General Robert T. Stephan
March 16, 1994

Chairperson Flower and Members of the Committee:

On August 13, 1993, I formed a Task Force on Silicone Induced Disease which is chaired by Dr. Carol W. Konek who is an Associate Professor at the Center for Women's Studies at Wichita State University. The task force came about as the result of a number of conversations with women in Wichita who were afflicted with Silicone Induced Disease and who advised me that they were unfamiliar with the political system and were seeking assistance in trying to find answers to the problems they faced as a result of silicone breast implants. It appeared to me that there was a need for appropriate legislation to address some of the concerns of those involved and I am appreciative of the initiatives of Senator Pat Ranson.

I know there are those who do not take this health issue seriously and that is unfortunate since it is estimated that more than 350 women in Kansas suffer from diseases caused by silicone breast implants. Silicone Induced Disease also occurs among the male population in our state.

Those who receive silicone implants should be made aware of all information in regard to the advantages, disadvantages and risks associated with implantation. Such information should be set out in writing and given to the patient involved. These are common sense requests and are contained in Senate Bill 683. At the most, this bill codifies existing case law and will assist in the fight to alleviate suffering resulting from a large health problem that exists in this state.

Many women are being misinformed about the dangers of silicone implants, not only to themselves, but to their children, and we need to make sure that these women and others who are considering implants receive the necessary assistance and information.

PHWW
3-16-94
Attm #2

KaMMCO

KANSAS MEDICAL MUTUAL INSURANCE COMPANY
AND
KANSAS MEDICAL INSURANCE SERVICES CORPORATION

TO: House Public Health and Welfare

FROM: Lori Callahan, General Counsel

RE: S.B. 683

DATE: March 16, 1994

The Kansas Medical Mutual Insurance Company (KaMMCO), is a Kansas domestic physician-owned, professional liability insurance company formed by the Kansas Medical Society. KaMMCO currently insures over 1,000 Kansas physicians.

KaMMCO appreciates the opportunity to testify as a neutral party on S.B. 683. As a medical malpractice company, KaMMCO was initially concerned with language in the bill that changed common law rather than codifying it. The bill was amended, however, by the Senate Public Health and Welfare Committee to address our concerns. As a result of these amendments, we now feel confident the provisions will provide positive changes without oppressive results. We would urge this committee to therefore consider no further amendments if it votes this bill favorable for passage.

We appreciate the opportunity to testify.

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Endorsed by the Kansas Medical Society

623 W. TENTH ST.-STE. 200 • TOPEKA, KANSAS 66612
913-232-2224 / 800-232-2259 / 913-232-4704 (FAX)

MY NAME IS SHARRON WATSON. I AM A WIFE, MOTHER AND GRANDMOTHER. I HAVE BEEN EMPLOYED BY KANSAS ALUMINUM INC., MANUFACTURERS OF KANAL WINDOWS AND DOOR PRODUCTS AS PLANT MANAGER FOR 20 YEARS. I MAKE JUDGEMENT CALLS AND DECISIONS EVERY DAY.

MOST IMPORTANT, I AM CARRIE WATSON SHEARBURN'S MOTHER.

WHEN CARRIE WAS 16, MY HUSBAND AND I MADE AN UN-INFORMED DECISION IN HER BEHALF. ON THE ADVICE OF TWO SPECIALISTS WE ALLOWED OUR BEAUTIFUL 16 YEAR OLD DAUGHTER TO RECEIVE TWO SILICONE BREAST IMPLANTS TO CORRECT A PHYSICAL DEFORMITY.

THIS IS THE RESULT OF THAT DECISION.

I'M HOLDING CARRIE'S MEDICAL HISTORY---95% OF IT TESTED AND WRITTEN IN **THE LAST TWO YEARS.**

THIS IS A LIST OF THE DISEASES CARRIE LIVES WITH BECAUSE OF SILICONE BREAST IMPLANTS.

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SHE HAS A-TYPICAL **MYASTHENIA GRAVIS,** A DEGENERATIVE MUSCLE-NERVE DISEASE THAT SHE WILL LIVE WITH THE REST OF HER LIFE. SHE HAS **SILICONE HUMAN ADJUVANT BREAST DISEASE, TOXIC CHEMICAL POISONING, LUNG DISEASE, ALTZHELMER LIKE DISEASE** FROM BRAIN DAMAGE. A-TYPICAL SIMPLY MEANS THAT IN HER LIFE TIME SHE SHOULD NEVER HAVE HAD ANY OF THESE DISEASES.

FOR YEARS WE WATCHED CARRIE'S HEALTH DETERIORATE WITH NO CLUE TO WHAT WAS TURNING A YOUNG WOMAN INTO A CRIPPLE.

THERE ARE ONE MILLION WOMEN WHO WERE NOT INFORMED BEFORE THEY CONCEIVED AND NURSED THEIR CHILDREN. THERE ARE 60,000 LITTLE BOYS WITH TESTICULAR SILICONE IMPLANTS WHOSE PARENTS WERE NOT INFORMED. THERE ARE 100,000 MEN WITH PENIAL SILICONE IMPLANTS WHO WERE NOT INFORMED AS TO THE MATERIAL USED.

WE HAVE 5 GRAND-CHILDREN AND 3 OF THOSE CHILDREN ARE CARRIE'S. ALL 3 ARE **"AT GREAT RISK"** OF HAVING AUTO-IMMUNE DISEASE AND RESEARCH BECOMES MORE FRIGHTENING EVERY DAY.

OUR DAUGHTER COULD BE YOUR DAUGHTER, OR YOUR DAUGHTER IN-LAW, AND OUR GRAND-CHILDREN COULD BE YOUR GRAND-CHILDREN.

INFORMED CONSENT WOULD GIVE ALL OF US THE RIGHT TO DECIDE OUR FUTURES. INFORMED CONSENT WILL SAVE THOUSANDS FROM BEING EXPERIMENTAL GUINEA PIGS LIKE OUR DAUGHTER AND HER CHILDREN.

IF INFORMED CONSENT BECOMES A LAW, IT MEANS WE ALL HAVE THE RIGHT TO KNOW THE PRO'S & CON'S OF SILICONE IMPLANTS. FOR YOUR INFORMATION--IN 1988 THE F.D.A. CLASSIFIED IMPLANTS AS A

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CLASS 3 MEDICAL DEVICE WHICH MEANS THEY ARE A HIGH RISK DEVICE AND REQUIRE PROOF OF SAFETY.

SHOULDN'T ANY IMPLANTED DEVICE REQUIRE PROOF OF SAFETY....IF IT WERE IN YOUR BODY.

I CANNOT TELL YOU ALL THAT IS IN MY HEART OR ON MY MIND. ITS MUCH TO PAINFUL. WHAT I CAN SAY IS IN THE LAST TWO YEARS I HAVE MET HUNDREDS OF WOMEN WHO DESPERATELY NEED MEDICAL ATTENTION AND HELP. WHAT YOU DO HERE IN TOPEKA WITH THE INFORMED CONCENT BILL WILL STOP THAT NUMBER FROM GROWING. THOUSANDS ARE WATCHING OUR EFFORTS AND THE COUNTRY WILL TAKE YOUR LEAD!

MAY I INTRODUCE MY DAUGHTER, CARRIE.....

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[COMMITTEE PRINT]

102d Congress
2d Session

HOUSE OF REPRESENTATIVES

THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS

A STAFF REPORT PREPARED BY THE

HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

DECEMBER 1992

Printed for the use of the Committee on Government Operations

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FOREWORD

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC, December 31, 1992.

There has been increasing public concern about the safety of silicone breast implants since the Subcommittee on Human Resources and Intergovernmental Relations held a hearing on this topic in December 1990. During the past 2 years, there has also been new research and medical evidence of the potential risks of breast implants, as well as disclosures of evidence dating back to the 1970's. This report, which has been prepared for use by the Committee on Government Operations by members of a staff research team, provides a summary of FDA's role in the regulation of silicone breast implants.

The findings and conclusions contained in this report are those of the staff, and do not necessarily reflect the views of the members of the Committee on Government Operations.

JOHN CONYERS, Jr., *Chairman.*

LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC, December 31, 1992.

Hon. JOHN CONYERS, JR.
Chairman, Committee on Government Operations,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: I have enclosed a copy of the staff report entitled "The FDA's Regulation of Silicone Breast Implants."

The report is based on the subcommittee's 3-year investigation of the FDA's regulation of silicone breast implants, which was initiated by Chairman Ted Weiss. Because of his tragic death in September of this year, it was not possible to complete the report in time to release it as a committee report. Unfortunately, our investigation indicates that FDA continues to fail to safeguard implant patients, making it very important that this report be released in a timely manner. For that reason, it is being released as a staff report of the 102d Congress.

Thank you for your assistance.

Sincerely
DONALD M. PAYNE
Chairman, Human Resources and
Intergovernmental Relations Subcommittee.

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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.

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

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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

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

[3] Adverse reaction reports are in subcommittee files.

[4] Rogers, 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.

[5] A mixture of paraffin, petroleum jelly, and olive oil was used. See Bates, H.K., Cunny, H.C., & LaBorde, J.B. Developmental Toxicity Evaluation of Polydimethylsiloxane 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.

[6] This 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.

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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

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[7] The IND is in subcommittee files.

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

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

[10] A 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.

[12] A 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.

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for all breast implants, which would 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 were 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

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

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

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

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hardening of the breast or distortion of the shape of 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 becomes 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.

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[17] Hearing, 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.

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

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

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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 percent of glandular tissue is obscured by breast implants.[25] Mammography

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[20] Ibid.

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

[22] A 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. 123–6.

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

[24] See, 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.

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

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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 Mohney 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 that 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; however, there is considerable reason to sus-

[26] Johnson, Judith A. September 9, 1992, CRS Report, op. cit., p. 14.
[27] Described in an FDA memorandum to the file from Hoan My Do Luu, August 15, 1988, in Hearing, p. 134.
[28] Ibid, p. 134, 141.
[29] Ibid., p. 135.

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pect 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

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[30] Memorandum from Melvin E. Stratmeyer to the Director, Office of Science and Technology, Center for Devices and Radiological Health, FDA, August 9, 1983, in Hearing, p. 144.
[31] See memo in Hearing, pp. 130–133.
[32] Minutes of the November 22, 1988, meeting, p. 2; in subcommittee files.
[33] Transcript and minutes of meeting are in subcommittee files.
[34] Court documents are in subcommittee files.
[35] The 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.
[36] Ibid, p. 146.
[37] This paper was presented at the annual ASPRS meeting on May 10, 1989, and is available in subcommittee files.
[38] Memorandum 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.

chair 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 Même." [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]

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[39] Replicon and Optimam were other models sold by Surgitek. A previous model was called the "Natural Y."

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

[41] Memorandum 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 Même.

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

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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.

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

[44] See, 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.

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

[46] Hearing, testimony of Dr. Pierre Blais, pp. 40–56.

[47] Letter in subcommittee files.

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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.

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[48] Meeting transcript and minutes are in subcommittee files.

[49] The 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.

[50] Memorandum 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 implants. After the public became informed about the symp-

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[51] Memorandum from John Villforth, December 1, 1988, op. cit.
[52] Ibid.
[53] Minutes of this meeting and related documents are in subcommittee files.
[54] Hearing, testimony of Sybil Goldrich, cofounder, Command Trust Network, p. 25.
[55] July 14, 1992, memorandum from Director, Office of Training and Assistance, to Director, Center for Devices and Radiological Health; in subcommittee files.

toms 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 Heggers, 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 evaluating the dangers of silicone implants. They described a report dating back to 1964, and several reports

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[56] December 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.

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

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

[60] Letter 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.

[61] Ibid.

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

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

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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 his review of research on humans, and animal research conducted by Dr. John Heggers 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]

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[64] These 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 "humar adjuvant disease" in the medical literature, that term was no longer considered accurate by the time of the subcommittee hearing.

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

[66] Ibid., p. 92.

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

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

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

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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 Heggers 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

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[70] Goldblum, R.M., Pelley, R.P., O'Donell, A.A., Pyron, D. & Heggers, J.P. (1992). Antibodies to silicone elastomers and reactions to ventriculoperitoneal shunts, *The Lancet*, Vol. 340, pp. 510–513.

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

[72] March 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.

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

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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, FL, 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, MI, 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 incorporated within the gel mass" and a "roughly 4x6 cm irregular nodular

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[74] December 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.

[75] May 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.

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

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

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

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

[80] September 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.

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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, FL, 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 tissue could eventually cause FDA to remove silicone gel implants from the market.[87] By 1979, the president of MEC sent a

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

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

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

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

[85] October 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.

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

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

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 on 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 these 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

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[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, deCamera 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 they would have to

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[93] deCamera, 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.

[94] Dr. 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.

[95] Several 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.

[96] These letters are in subcommittee files.

remove their products from the market on January 6, 1992. un 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

[97] These reviews are in subcommittee files.

any conclusions about 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 autoimmune disease or cancer,

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

this study was criticized as inadequate in the safety informati 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 longtime 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

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

[100] Ibid.

[101] FEC printout of PAC contributions; in subcommittee files.

ASPRS, their "PlastyPac" donations "will be used to express the Society's support and gratitude to legislators who help us communicate our message on breast implants and other issues to key publics and policymakers." [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.

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[102] October 15, 1991, issue of *Breast Implant Bulletin;* in subcommittee files.
[103] This analysis is in subcommittee files.

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The ASPRS argued that women deserve "the right to ch 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

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

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Black, who was at that time an advisor to President Bush's reelection campaign, wrote a letter to Secretary Sullivan.[104] 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 conducted 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

[106] Drew, C. and Tackett, M. Op. cit.
[106] Reviewers comments and the complete PMA's are in subcommittee files.
[107] This summary is based on reviews, previously described in detail in this report, and in subcommittee files.

to their plastic surgeons for complications that they recog. 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.

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

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

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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 deCamera 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 "with fingers crossed" that studies of "contracture/gel migration" were underway.[114] He also stated that

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

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

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

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

[114] The 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,

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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 to look at the documents, but the documents were not sent to

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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 crossed 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."

[115] May 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.

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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 court room 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]

By March 1991, an FDA scientist warned the Director of the Division of Compliance that Surgitek had terminated a study that

[116] Correspondence describing this arrangement are in subcommittee files.
[117] Inspection reports and related documents are in subcommittee files.
[118] Hearing, testimony of Hoan My Do Luu, p. 159.

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 supported women's rights; the company interpreted this

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

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

[121] Hester, 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.

[122] These documents are in subcommittee files.

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

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as indicating that they were more "deviant" than small-breaste 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, CA, 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 Shown 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

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

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

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

[127] Handel, 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 of 1 or 2 on the Baker scale.

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cause 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

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

[129] Letter 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.

[130] Press release from Dow Corning in subcommittee files.

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time the implant was 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 costs with the note, "I thought we wiped out all dogs and had parts sent to W.L. [a company vice president]. My rec[commendation]—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

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[131] Hearing, testimony of Sybil Goldrich, pp. 3–10, 26.

[132] January 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.

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

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

research evidence regarding the dangers of migrating silicone and the evidence that many women have their implants replaced every 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 manufacturer's claim that it was "substantially equivalent" to silicone gel 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

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[135] For 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.

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

[137] In 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.

[138] Hearing, testimony of Maryland State Delegate Joan Pitkin, pp. 243–4.

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

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data and 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 Ander-

[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.

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son, the Acting Director of FDA's Office 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," 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 scientists 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

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

[145] A 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.

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considered one of the 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 or not 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 CRITICISMS 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 estimate of 2 million to 1 million,

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

[147] Ibid., p. 2.

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 nursed their

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

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

[150] According 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.

[151] The informed consent document is in subcommittee files.

[152] Minutes of this meeting are in subcommittee files.

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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 STATEMENTS 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 concerns 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 ominous than the

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[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.

more accurate explanation, which is that FDA has categori TDA as an animal carcinogen and potential human carcinogen, 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 or 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.

In June 1992, FDA completed its review of McGhan's response to FDA's warning letter, and concluded that, "Conditions exist where-

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[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.

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by 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.

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 avail-

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[160] Letter 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.

[161] July 15, 1992, letter in subcommittee files.

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

[163] Letter 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.

[165] Letter 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.

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ability protocol, the urgent need surgeries were permitted until cember 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, or 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

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

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

[168] Newspaper interviews are in subcommittee files.

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

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using silicone gel implants as a last resort when saline implants are not suitable.

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 re-

[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.

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leased in February 1992 were primarily from a California case volving 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

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[171] The 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.

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

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

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

[175] The FDA review is in Hearing, pp. 145–152.

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Henry Waxman, Chairman of the 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]

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

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

[178] Letter 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 [Depart 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 explanation.

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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 notably, 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 discussion of relevant informa-

tion 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

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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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Sclerodermalike Esophageal Disease in Children Breast-fed by Mothers With Silicone Breast Implants

Jeremiah J. Levine, MD, Norman T. Ilowite, MD

Objective.—To determine whether breast-fed children of mothers with silicone implants are at increased risk for the development of sclerodermalike esophageal involvement compared with children not exposed to silicone implants.

Design.—Case-control study.

Setting.—Referral-based pediatric gastroenterology clinic.

Patients.—Eleven children (mean age, 6.0 years; range, 1.5 to 13 years; six boys and five girls) referred for abdominal pain who were born to mothers who had silicone breast implants (eight breast-fed children and three bottle-fed) were compared with 17 patients (mean age, 10.7 years; range, 2 to 18 years; 11 boys and six girls) with abdominal pain who were not exposed to silicone implants.

Methods.—All children underwent esophageal manometry and upper intestinal endoscopy with esophageal biopsy and were tested for antinuclear antibody and autoantibodies to Scl-70, centromere, ribonucleoprotein, Sm, Ro, La, and phospholipid.

Results.—Six of the eight breast-fed children from mothers with silicone implants had significantly abnormal esophageal motility with nearly absent peristalsis in the distal two thirds of the esophagus and decreased lower sphincter pressure. Upper esophageal pressures and motility were normal. Compared with controls, the breast-fed children had significantly decreased lower sphincter pressure and abnormal esophageal wave propagation. These manometric abnormalities were not seen in the three bottle-fed children. There was no difference in the expression of autoantibodies in the breast-fed children compared with the bottle-fed children or controls.

Conclusions.—A relationship appears to exist between breast-feeding by mothers with silicone implants and abnormal esophageal motility. Studies evaluating larger numbers of children are needed to determine the extent of the risk.

(*JAMA* 1994;271:213-216)

SEVERAL studies have suggested that women who have had silicone breast implants have an increased incidence of rheumatologic disorders.[1-5] A significantly greater percentage of these women have symptoms consistent with scleroderma compared with other rheumatologic conditions.[1,2,5] This finding is in contrast to the general population, among whom scleroderma accounts for only 10% to 15% of all connective-tissue disease. The pathophysiologic mechanisms regarding development of scleroderma may involve an immunologic response to substances that leak from the implant[6,7] or increased collagen biosynthesis by fibroblasts after macrophage phagocytosis of those substances.[8,9]

In scleroderma, tight, firm skin is usually present several years before visceral involvement becomes apparent; however, in some patients, visceral disease may occur in the absence of skin changes.[10] Esophageal symptoms are caused by loss of esophageal motility, which results from neuromuscular dysfunction. Esophageal motility studies in these patients reveal decreased amplitude or disappearance of peristaltic waves in the lower two thirds of the esophagus. Later in the course of the disease, dilatation and atony of the lower portion of the esophagus are seen.[11,12] Several autoantibodies to nuclei, Scl-70, centromere, ribonucleoprotein, fibrillarin, and other antigens can be demonstrated in patients with scleroderma.[13]

No studies have examined children breast-fed by mothers who have silicone implants (BFSI). Therefore, we studied esophageal function in 11 children of mothers with silicone breast implants referred to us with intestinal complaints and compared them with 17 children of mothers without implants referred for similar complaints.

SUBJECTS AND METHODS

Subjects

Clinical histories were obtained for 67 consecutive children born to mothers with silicone breast implants (56 breast-fed and 11 bottle-fed children) who were referred by their physicians or by support groups because of parental concern about possible second-generation effects (Fig 1). Recurrent abdominal pain was a significant complaint in 35 breast-fed and eight bottle-fed children. Among this group, 20 breast-fed and six bottle-fed children had additional symptoms, such as recurrent vomiting, dysphagia, decreased weight-height ratio, or a sibling with these complaints. Of these 26 children, 11 children from six families (mean age, 6.0 years; range, 1.5 to 13 years; six boys and five girls) were brought to Schneider Children's Hospital, New Hyde Park, NY, for evaluation. Eight children (mean age, 6.1 years; range, 1.5 to 9 years; five boys and three girls) had been breast-fed by mothers with silicone breast implants. The mothers had all been asymptomatic while breast-feeding, and none subsequently developed scleroderma. The mean duration of breast-feeding was 5.1 months (range, 2 to 7 months). The mean interval between the end of breast-feeding and evaluation was 5.7 years (range, 1.3 to 8.5 years). Three children (mean age, 5.3

For editorial comment see p 240.

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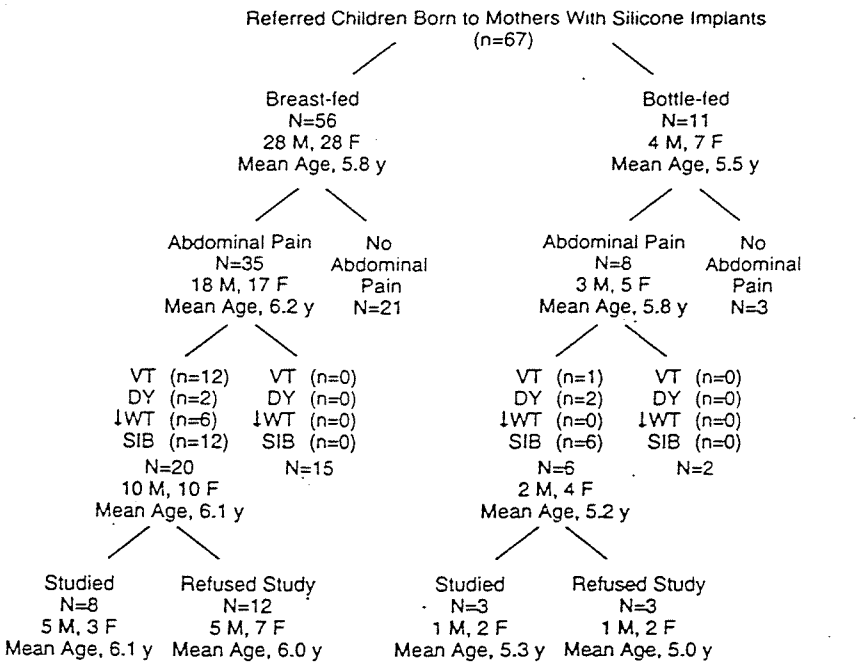

Fig 1.—Clinical examination of children born to mothers with silicone breast implants. VT indicates recurrent vomiting; DY, dysphagia; WT, weight-height ratio; and SIB, siblings with abdominal pain along with recurrent vomiting, dysphagia, or decreased weight-height ratio. The total number of patients with the foregoing symptoms is less than the sum of those with the symptoms because patients frequently had more than one symptom.

years; range, 1.5 to 13 years; one boy and two girls) had been bottle-fed by mothers with silicone implants who had been without symptoms during the pregnancy. The mammoplasties had been performed for breast augmentation in five mothers and because of a congenital deformity in one. All children underwent esophageal manometry as described herein and upper intestinal endoscopy with esophageal biopsy by means of a flexible endoscope (Olympus XP10 or XQ30, Olympus Corp, Woodbury, NY) after sedation (chloral hydrate, 75 mg/kg orally, or meperidine, 2 mg/kg, and diazepam, 0.1 to 0.2 mg/kg intravenously).[14] These investigations were done as part of the standard clinical examination of children with recurrent abdominal pain along with vomiting, dysphagia, or other symptoms suggestive of upper intestinal disease. In addition to standard light microscopy, all biopsy specimens were analyzed under polarized light by a pathologist unaware of the clinical status of the patients to determine the presence or absence of silicone crystals in the tissue.

All children also had blood samples analyzed for the presence of autoantibodies to nuclear, Scl-70, centromere, ribonucleoprotein, Sm, Ro, La, and phospholipid antigens, by standard analytic methods. The protocol to investigate autoimmune markers in children born to mothers with silicone breast implants was approved by the Human Subjects Review Committee of the Long Island Jewish Medical Center.

Control subjects were 20 consecutive children who presented concurrently with the case children to the Division of Gastroenterology because of abdominal pain associated with recurrent vomiting and/or dysphagia, and who underwent esophageal manometry and upper intestinal endoscopy as part of their evaluation. Three children were found to have achalasia with characteristic manometric findings (distinct from the manometric patterns found in the BFSI group) and were therefore excluded from the study. The remaining 17 children (mean age, 10.7 years; range, 2 to 18 years; 11 boys and six girls) were used as controls for the study. In addition, serum autoantibody testing was performed in seven of the control children.

Esophageal Manometry

Esophageal manometry was performed with or without sedation (chloral hydrate, 75 mg/kg orally) by means of a standard pull-through technique. A six-lumen esophageal catheter (Arndorfer Inc, Greendale, Wis) with radially oriented transducers spaced 5 cm apart and with three transducers in the most distal position was used with continuous water perfusion by a hydraulic capillary infusion system (a four-lumen catheter with radially oriented transducers 5 cm apart was used in patient 5; h- ageal wave propagation was dete...ned after both wet and dry swallows. The intraluminal pressures were recorded (Sandhill Scientific, Littleton, Colo). The lower and upper esophageal pressures, wave amplitude, and percentage propagation in the children were analyzed by a gastroenterologist unaware of the clinical status of the patients.

Statistics

For continuous variables, such as manometric data, results from normal controls and patients were compared by the Wilcoxon Rank-Sum Test. For qualitative variables, such as presence of autoantibodies, Fisher's Exact Test was used.

RESULTS

The results in the eight BFSI children and mean values from bottle-fed children and controls are summarized in the Table.

Clinical Symptoms

Among the eight BFSI children, three had recurrent vomiting, two had dysphagia, four had a weight-height ratio less than the 25th percentile for age, and six had symptoms suggestive of irritable bowel syndrome, with irregular bowel movements and increased intestinal gas (all children had one or more clinical indicators in addition to abdominal pain). Additional complaints included joint pains without objective arthritis (four patients) and periodic rashes (four children). Among the three bottle-fed children, one had a weight-height ratio less than the 25th percentile for age, all had symptoms suggestive of irritable bowel syndrome, two had joint pains without arthritis, and one had intermittent rashes. None of the children had Raynaud's phenomenon or skin changes suggestive of scleroderma.

Autoantibody Determinations

A positive antinuclear antibody titer was demonstrated in three BFSI patients (nucleolar pattern), and antiphospholipid IgG antibodies were demonstrated in five children (three BFSI and two bottle-fed). All autoantibodies were present in low concentrations and were nonspecific. Among the seven control children tested, one child had positive antiphospholipid IgG antibody and one had positive antiphospholipid IgM antibody (both in low concentrations). There was no significant difference in the detection of autoantibodies between the BFSI and bottle-fed children ($P>.05$), and the presence of low titers of the autoantibodies tested was not significantly different in the BFSI and bottle-fed children compared with controls ($P>.05$).

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inical and Manometric Findings in Eight Breast-fed and Three Bottle-fed Children of Mothers With Silicone Breast Implants and Controls*

Patient	Age, y	Sex	Symptoms	Sphincter Pressure, mm	Propagation, %†	Amplitude‡
1	6.5	M	ABD, ↓WT, IBS	UES, 47; LES, 20	33	33
2	6.5	M	ABD, IBS, JT, R	UES, 30; LES, 20	20	51
3	9	M	ABD, IBS, VT, JT, R	UES, 39; LES, 10	25	63
4	6.5	M	ABD, ↓WT, IBS, DY, R	UES, 55; LES, 5	23	34
5	1.5	M	ABD, ↓WT, VT, R	UES, 73; LES, 10	5	14
6	4.5	F	ABD, ↓WT, DY	UES, 20; LES, 10	20	40
7	6.5	F	ABD, IBS, VT, JT	UES, 60; LES, 10	50	41
8	8	F	ABD, IBS, JT	UES, 38; LES, 20	45	62
Total breast-fed (n=8), mean±SD	6.1	5 M, 3 F	...	UES, 45.3±17.1; LES, 13.1±5.9§	27.6±14.7§	42.3±16.3
Bottle-fed (n=3), mean±SD	5.3	1 M, 2 F	...	UES, 38.7±2.3; LES, 22.7±14.2	64.3±24.0	60.3±22.4
Controls (n=17), mean±SD	10.7	11 M, 6 F	...	UES, 42.6±35.1; LES, 24.8±11.9	53.0±16.1	50.6±18.1

*ABD indicates abdominal pain; ↓WT, decreased weight/height; IBS, irritable bowel syndrome; JT, joint complaints without arthritis; R, nonspecific rashes; VT, recurrent vomiting; DY, dysphagia; UES, upper esophageal sphincter; and LES, lower esophageal sphincter.
†Percentage of waves propagating beyond the upper one third of the esophagus after swallows.
‡Mean wave amplitude in distal esophagus.
§$P<.05$ vs control.

Endoscopic Evaluation

No gross visual abnormalities were noted during upper intestinal endoscopy. Histologically, eight children (six BFSI and two bottle-fed) demonstrated mild chronic esophagitis with lymphocytic and/or eosinophilic infiltration of the epithelium. There were no granulomas in any of the specimens, and no crystals were identified on polarized light examination of the biopsy specimens. Among the controls, 13 of 16 had esophagitis (mild to moderate in seven and severe in six; no biopsy was performed in one child). The histologic evidence of esophagitis did not differ significantly between the BFSI and bottle-fed children. Similarly, the presence of esophagitis was not significantly different in the BFSI and bottle-fed children compared with controls ($P>.05$).

Esophageal Manometry

Six of eight BFSI children had significantly abnormal esophageal motility with nearly absent peristalsis in the distal two thirds of the esophagus. In these children, only 21% of waves (range, 5% to 33%) propagated beyond the upper one third of the esophagus (Fig 2). In addition, in some patients the waves that propagated distally were broad-based with decreased amplitude. There were no manometric abnormalities characteristic of severe esophagitis, such as simultaneous or retrograde contractions or double-peaked peristaltic waves. Upper esophageal sphincter pressure and pharyngeal and upper sphincter coordination were normal. In these children, the manometric findings after wet and dry swallows did not differ. A barium swallow in one patient (patient 6) demonstrated a dilated esophagus along with disordered peristalsis. Of the remaining two BFSI patients, one had normal lower esophageal sphincter pressure, and 45% of swallows produced an orderly, aborad progression of contraction waves with normal amplitude through the esophagus; the other had decreased lower esophageal sphincter pressure and amplitude with 50% propagation. When compared with controls, the BFSI children had significantly decreased lower esophageal sphincter pressure (mean, 13.1±5.9 mm Hg vs 24.8±11.9 mm Hg in controls; $P<.05$) and abnormal esophageal propagation (mean, 27.6%±14.7% vs 53.0%±16.1%; $P<.05$) (Table). The three bottle-fed children of mothers with silicone implants had lower esophageal sphincter pressure and esophageal propagation that were not significantly different from those of controls (lower esophageal sphincter pressure: mean, 22.7±14.2 mm Hg vs 24.8±11.9 mm Hg in controls, $P>.05$; esophageal propagation: mean, 64.3%±24.0% vs 53.0%±16.1%; $P>.05$). Upper esophageal sphincter pressure and mean wave amplitude were not significantly different in the BFSI children compared with the bottle-fed children and controls.

Follow-up esophageal manometry in three BFSI patients (patients 3, 5, and 6), conducted a mean of 10 months after the initial manometry and during long-term ranitidine therapy, did not demonstrate any improvement in the motility abnormalities, although clinically the children had fewer episodes of abdominal pain.

COMMENT

Although our patients did not meet the clinical criteria for systemic sclerosis, the esophageal abnormalities present, involving only the distal two thirds of the esophagus with almost absent peristalsis and decreased lower esophageal sphincter pressure and without simultaneous or retrograde contractions, are characteristic of this disorder.[15] The similarity of the esophageal lesions among the BFSI patients, contrasted with the controls, suggests that a relationship may exist between breast-feeding by mothers with silicone implants and the abnormal esophageal motility. The absence of crystals in esophageal tissue several years after exposure (ie, breast-feeding) may indicate that crystals were never present, or may be a result of the long period between potential exposure and evaluation. It is unclear whether the silicone itself, other by-products released by the implants, or immunologic factors, such as immune cells or antibodies, may have contributed to the esophageal dysmotility.

Although severe esophagitis can lead to esophageal dysmotility, the motility disturbances typically include simultaneous or retrograde contractions as well as double-peaked waves,[16] none of which were demonstrated in our patients. In addition, the motility disturbances seen in children with esophagitis are seen only in those patients with severe esophageal inflammation by biopsy,[15] whereas our patients had only mild chronic inflammation. These differences suggest that the dysmotility noted in our patients is distinct from the motility abnormalities caused by esophagitis. The persistence of the motility abnormalities at follow-up in three patients, despite continued treatment for esophagitis, also suggests that the dysmotility is not secondary to esophagitis. Finally, the presence and severity of esophagitis on histologic examination was not significantly increased in the BFSI children compared with either the bottle-fed or the control children and therefore is an unlikely explanation for the differences in esophageal motility.

In our study, the bottle-fed children of mothers with silicone implants had manometric findings similar to those of control children and distinct from those of the BFSI children. This suggests that the esophageal disorder seen in the BFSI children may be related to direct esophageal exposure to substances released into breast milk from women with silicone implants, while bottle-fed children are not so exposed.

One potential confounding variable

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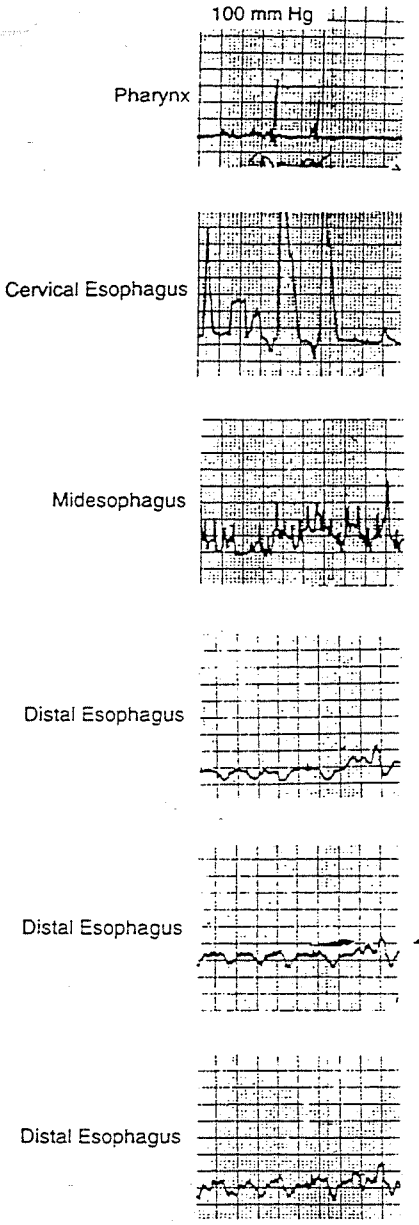

Fig 2.—Esophageal wave propagation after wet and dry swallows in a patient breast-fed by a mother with silicone breast implants. The coordination between pharyngeal contraction and wave propagation into the cervical esophagus was preserved, but no peristaltic contractions propagated into the distal esophagus. Chart speed, 2.5 mm/s; amplitude, 2.5 mm Hg/mm.

may be the differences in age between patients and controls. The greater age of the control children may result from the fact that symptoms of dysphagia or significant vomiting warranting extensive evaluation are less common in young children. In our study there was no difference in the findings between the younger and older patients among the BFSI children. In addition, the follow-up manometric findings in three of the patients suggest that the abnormality did not improve with increasing age.

The relationship between breast implants and the subsequent development of scleroderma in the women with implants remains controversial, with several studies suggesting an association[1,2,5] and others not.[17,18] In the women with implants who developed scleroderma, a latent phase of 2 to 20 years has been described from mammoplasty to onset of symptoms. In addition, several women have developed atypical scleroderma with neither Raynaud's phenomenon nor specific autoantibodies.[1,2,5] The children in this report also did not have Raynaud's phenomenon, nor did they express high levels of specific autoantibodies; furthermore, the presence of autoantibodies was not significantly different in those with manometric abnormalities and those with normal motility.

The possibility that BFSI children may develop sclerodermalike esophageal disease suggests that these children may constitute another group of patients at risk for developing disease related to exposure to breast implants. Several studies have demonstrated increased macromolecular uptake across the intestine in human newborns compared with older children and adults.[19] In addition, immune function in response to antigen exposure is immature in the infant.[20] Although these results will need to be verified by larger studies, it is possible that substances leaking from the implant or immunologic factors may be transmitted through breast milk and taken up across the immature intestinal barrier of the breast-feeding infant. The interaction between these factors and the immune system may lead to immunologically mediated damage, resulting in the sclerodermalike esophageal dysmotility.

In this study, the eight BFSI children were from four families, raising the possibility that the demonstrated esophageal dysmotility was caused by an inherited factor, not by silicone exposure. However, the familial occurrence of scleroderma is extremely rare.[21] The probability of finding four such families is low, although some genetic contribution to susceptibility cannot be excluded.

The long-term outcome of these esophageal abnormalities is unknown, although four of the children had decreased weight-height ratios, suggesting that the symptoms in some cases may have affected their overall health. Our experience with three children who were reexamined at a mean of 10 months and did not demonstrate any improvement in motility suggests that the problem may persist for extended periods. The true incidence of this disorder among breast-fed children is unknown and cannot be estimated from our study because of selection bias. Studies examining greater numbers of children are needed to confirm these results and to determine the long-term outcome of these children.

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Dow Corning cuts silicone risk by reducing number of customers

By David Lawder
Reuters News Service

DETROIT — Dow Corning Corp., the world's largest silicone producer, is taking stricter control of medical uses for its products after being stung by $2 billion in liabilities from silicone-gel breast implants this week.

The joint venture between Dow Chemical Co. and Corning Inc. yesterday said it now sells silicone to only 12 select medical products companies to limit liability.

The Midland, Mich.-based company previously had up to 40 customers that made medical products. In some cases, it did not know where the soft, highly elastic rubber ended up.

"It's a risk-avoidance strategy," said Judy Mason, Dow Corning's marketing manager for medical products. "Our materials were in some of the non-Dow Corning mammary implants as well, so that was the sensitizing issue that came along."

On Monday, Dow Corning agreed to contribute $2 billion to a $4.75 billion settlement of litigation over the safety of silicone-gel breast implants, which the Food and Drug Administration banned for most uses in 1992.

Bristol-Myers Squibb Co. and Baxter International Inc. also contributed $1.5 billion and $556 million to the settlement, respectively.

The company now will sell silicone only for medical products that come in contact with human tissues for less than 30 days.

The implants, which can rupture and leak liquified silicone into body tissues, have been blamed for triggering immune system disorders and other ailments, including a hardening of breast tissues that disguises tumors.

More than 1 million U.S. women are estimated to have received the implants since Dow Corning developed them in the early 1960s.

The settlement will provide between $150,000 and $2 million to tens of thousands of women with diagnosed illnesses caused by the implants. A fund will be set up to pay new claims over the next 30 years.

Dow Corning's medical products sales are small, but it was forced to take an after-tax charge of $415 million in 1993 to cover uninsured liabilities, leading to a loss of $287 million for the year.

Dow Corning is continuing to weed out risky uses of its silicone after halting breast implant production in 1992 and silicone sales for other long-term medical implant uses last year.

The company now will sell silicone only for medical products that come in contact with human tissues for less than 30 days and do not have to bear a lot of pressure, Mason said.

Acceptable products range from silicone tubing for diagnostic equipment to silicone catheters.

Customers who have been operating for five years must buy at least $100,000 worth of silicone a year, Mason said. "That's a big commitment for fabricators."

Dow Corning chose this strategy after struggling with the temptation to abandon the medical silicone business.

"During the heat of the mammary implant crisis, certainly the question was raised about whether a medical materials organization made sense," Mason said.

"We believe strongly that it does make sense, but to keep it that way, we needed to do a careful scrutiny of our customers and their applications."

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SILASTIC® MSI
Brand

Mammary Implant H.P.

Gel-Filled Design By Dow Corning Wright

Nos. 4,455,691; 4,472,226; 4,965,430 and Others Pending

Description

The SILASTIC® MSI Mammary Implant H.P. is a silicone gel-filled breast implant made with a micro structured silicone envelope. The silicone envelope consists of medical grade high performance (H.P.) silicone elastomer with an integral surface micro structure and a fluorosilicone barrier layer laminated to the inner surface of the envelope. The product nomenclature "MSI" stands for Micro Structured Implant. The product nomenclature "H.P." indicates the implant is fabricated from SILASTIC® brand medical grade high performance silicone elastomer which exhibits greater resistance to tear propagation than conventional silicone rubber. The fluorosilicone coating within the envelope provides an effective barrier to significantly reduce gel bleed. The envelope is filled with transparent silicone gel.

This implant is available in a range of product sizes, providing the surgeon with versatility in satisfying specific patient requirements. Except for special order products, the unit volume in cc's, implant style, and company name are embossed in the envelope seal patch for easy identification.

For service and information, contact your authorized sales representative or:
Dow Corning Wright
5677 Airline Road
Arlington, TN 38002
U.S.A.
Toll free 1-800-238-7117. Outside the United States, contact your closest Dow Corning International Office.

INDICATIONS

Breast contour reconstruction and/or size augmentation following mastectomy procedures.

Unilateral or bilateral mammary augmentation or reconstruction to surgically correct various congenital defects or anomalies such as amastia, hypomastia, hypoplasia, or for cosmetic purposes.

CONTRAINDICATIONS

A mammary implant should not be used with a patient who:

- Has a history of immunological responses or sensitization to foreign materials.
- Demonstrates psychological instability, displays a lack of understanding, or inappropriate motivation or attitude.
- Is not willing to accept the possibility of multiple surgeries for revision.
- Demonstrates inadequate or unsuitable tissue; e.g. radiation damage to tissue, ulceration, compromised vascularity, or has a history of compromised wound healing.

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- May experience compromised vascularization because of implant placement.
- Demonstrates physiologic or anatomic anomalies that might result in significant post-operative complications.
- Has an active infection.

Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship.

PRECAUTIONS

1. SILASTIC® brand medical grade silicone elastomers made exclusively by Dow Corning Corporation are among the least reactive implant materials available. However, surgical glove powder, drape and sponge lint, dust, talc, skin oils and other surface contaminants deposited on an implant by improper handling may evoke foreign body reactions; e.g. excessive fluid, fibrous tissue buildup, and/or infection. There should be strict adherence to clean, aseptic techniques to prevent contamination of the implant and possible complications. Surgical gloves and instruments should be rinsed free of lint, tissue debris, etc. before handling or contacting the implant.
2. Pre-existing infection should be treated and resolved before implantation of the implant.
3. It is recommended that before implantation the prosthesis be carefully examined to assure product integrity and cleanliness.
4. The surgical approach and incision size should be evaluated by the surgeon in line with the stresses which will be placed on the implant. Certain surgical approaches may result in higher stresses on the implant during insertion and may result in more difficult insertion of the implant.

   The surgeon should select an incision size and location which allow for creation of a well-defined, dry pocket; allow for insertion of the implant without distortion; and allow for ready digital access to the pocket to ensure flat implant placement and smoothing of the implant surface.
5. The surgeon should select an implant size, implant style, pocket location, and pocket size appropriate for the patient frame size (i.e., the implant diameter is not too large for the breast and chest wall dimensions) and tissue coverage (especially when there is a limited breast tissue coverage and/or limited subcutaneous fat). The submuscular plane may be preferable in patients with minimal, thin, and/or poor quality overlying tissue.

   The pocket size created by the surgeon should be of sufficient size to allow the implant to lie flat in the pocket.
6. Dow Corning Wright does not endorse or recommend the introduction of drugs around the implant. The action of drugs, such as vitamins, anti-inflammatory steroids, and antibiotics, in conjunction with the breast implant has not been adequately tested by the manufacturer. The risks of such usage are unknown.
7. When the surgeon treats a hematoma or serous fluid accumulation by aspiration, or performs a biopsy, care should be taken to avoid damaging the implant. These procedures present possible risk of implant puncture.
8. Microwave diathermy of a patient with a SILASTIC® MSI Mammary Implant H.P. is not recommended. Microwave diathermy, under normal conditions, does not appear to alter gel-filled implants. However, incidents of tissue necrosis and skin erosion with subsequent exposure or extrusion of the implant have been reported following microwave diathermy of patients with gel-filled implants.

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9. This implant is intended for single patient use. **DO NOT REUSE IN ANOTHER PATIENT.**

10. The American College of Radiology has stated that mammography may be more difficult to perform and less effective on implanted breasts. This is because the silicone is more radiopaque to X-rays than normal breast tissue, which may possibly obscure any small malignant tumors, and because breast tissue may be compressed by the implant which may render it more difficult to detect small tumors. Factors which may affect the radiographic outcome include submammary or subpectoral implant placement, the presence and degree of capsular contracture, and a patient's anatomy as well as technical factors such as foreign body halo, the degree of tissue compression during mammography and film screen versus xeroradiography.

    The American College of Radiology recommends that to perform high quality mammography only "dedicated" or specially designed equipment be used by the mammographer. It is preferred that the mammographer have experience with the most current radiologic techniques for implanted patients that will show more breast tissue and as little implant as possible. Special diligence and use of extra tangential images customized to each patient have been reported to be beneficial when performing mammography on an implanted patient. This will increase the cost as well as increase the radiation exposure for the patient. All patients should be provided this information and be advised to inform referral physicians and radiographers of the presence of an implant.

11. Implant Life Expectancy: It is not possible to predict the life expectancy of an implanted mammary prosthesis. Performance of the implanted prosthesis is not related solely to the design, materials of composition or fabrication of the prosthesis, but also relates to the surgical procedure with its possible attendant medical complications and consequences and to the specific medical condition, physiological, anatomical, biological and behavioral aspects of the patient. Most patients have had implants with no revisions; others have required multiple revisions.

    NOTE: It has been reported upon removal of conventional gel implants that some have contained particulates. These have included material of varying size, texture, and coloration. Analysis has revealed many to contain triglycerides, lipids, or steroid-type compounds. These are postulated to slowly move through the silicone elastomeric shell from the surrounding tissues. The degree of such diffusion of biologicals appears to be patient-specific.

12. Animal experiments studying the micro structured surface of the SILASTIC® MSI Mammary Implant H.P. indicate a differing local tissue response dependent upon implantation site. SILASTIC® MSI micro structured implant samples placed on fatty tissue beds of rats were found to develop thinner capsules with a greater degree of capsule architecture disruption than similar implants placed in a non-fatty tissue plane. The clinical relevance of this in humans is unknown.

WARNINGS

1. Do not insert a damaged implant or attempt to repair a damaged implant.

2. The silicone mammary prosthesis should be implanted without any alterations to its original design or fabrication. Meticulous care must be taken to avoid pinching the

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prosthesis with instruments and avoid contacting the implant shell with any sharp or pointed objects such as needles or surgical instruments. Any cut, puncture, scratch, or other compromise of the envelope integrity, whether inadvertent or intentional, will expose the silicone gel and will render the implant unusable. If the implant should accidently rupture during insertion or be nicked with an instrument or suture needle, remove the damaged implant and any exposed gel and replace with a new, intact, sterile implant. A surface scratch or partial penetration in the shell may be enough to eventually cause subsequent rupture. Do not try to repair the implant or leave it in the surgical pocket. When inserting and positioning the implant, care should be taken to ensure the unit is flat with a minimum of surface wrinkling and to avoid excessive manipulation or undue handling with sharp, pointed or blunt objects, including retractors. Avoid extensive stretching of the envelope during insertion as it may result in a local bulge in the implant shell.

3. Do not introduce or make injections of drugs or other materials into the implant. Injections through the implant shell will compromise product integrity.

ADVERSE REACTIONS AND COMPLICATIONS

Thousands of women per year have had cosmetic or reconstructive surgery with implantation of mammary prostheses. Complications or adverse reactions have been reported. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different.

Possible risks, adverse reactions and complications associated with surgery and the use of the mammary prosthesis should be discussed with and understood by the patient prior to surgery. The adverse reactions and complications most likely to occur with the use of this product are listed below. **IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH THIS INFORMATION PRIOR TO SURGERY.**

A SILASTIC® MSI Mammary Implant H.P. is composed of alloplastic materials. Therefore, it is subject to possible reactions and complications including those listed herein. The patient should not be led to unrealistic expectations as to the performance or cosmetic results that the surgery and prosthesis can provide. The patient should be informed that the life expectancy of any implant is unpredictable, and that successful results cannot be guaranteed.

1. ***Asymmetry***
   Asymmetry may be attributed to pre-existing anatomic asymmetry, incorrect choice of implant shape or size, surgical technique, contracture of the fibrous capsule, seroma or hematoma, breast dysplasia developing post-operatively, discrepancy in muscle development between sides, or rupture of the implant. In the event of rupture of an implant, it is recommended that the implant be removed promptly.

2. ***Ptotic Breast***
   It is possible that, like the non-augmented breast, the augmented breast may become ptotic over time. Variability in skin elasticity and muscle tone may contribute to this result.

3. ***Breast and Nipple/Areola Sensation***
   It is reported in the medical literature that some patients undergoing breast surgery experience a significant decrease in sensation or hypersensitivity of their nipple/areolar complex, and in some cases, the breast area in general. With more extensive breast

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surgery there is a greater probability that the patient will experience changes in sensation to breast skin and/or nipple complex. The return of sensation varies among patients. In a few instances, it has taken as long as several years for sensation to return. There are also reports of permanent loss of nipple or breast sensation, and of cold, itchy breast areas following implantation.

4. ***Pain***
Breast region pain of varying intensity and duration has been reported as an expected occurrence following breast implant surgery. In addition, there have been reports of pain in association with excessive capsule contracture.

5. ***Interruption of Surgical Incision Wound Healing***
Causes cited include infection, fluid accumulation and lack of drainage, hematoma, too tight a closure, too large an implant for the pocket, contamination of suture line, abscess of sutures, improper support, pressure against the wound, i.e. improperly fitted wired brassiere, trauma, use of anti-inflammatory steroids in the pocket, placement of the prosthesis in injured areas (i.e., burned, irradiated, scarred tissue). Exposure or extrusion of the implant may occur.

6. ***Skin Sloughing/Necrosis***
Skin breakdown may be attributed to inadequate circulation due to thinness of the skin flap overlying the implant or too large an implant relative to the pocket size. It may also be attributed to trauma to the skin intra-operatively, the use of anti-inflammatory steroids, or skin deterioration or breakdown. Implant exposure and/or extrusion may result. Unresolved skin breakdown may necessitate removal of the implant. Early compromise in skin circulation necessitating post-operative implant removal has been reported in the medical literature where subcutaneous placement of the prosthesis was used for reconstruction of congenital amastia, subcutaneous mastectomy, and cancer mastectomy.

7. ***Incorrect Size, Inappropriate Location of Scars, and Misplacement or Migration of Implants***
These complications are usually iatrogenic in origin. Any surgeon performing this type of breast surgery should be familiar with the currently acceptable techniques for measuring the patient, determining implant size, and performing the surgery. Since the implant generally cannot be repositioned following closure, surgical revision may be required if the implant is misplaced or displaced.

8. ***Wrinkles, Folds, or Knuckles in Implant Shell***
Some surgeons have indicated that in some patients "wrinkles," "folds," and/or "knuckles" in the implant shell may occur and be visible and/or palpable beneath the overlying tissue. "Wrinkles" and/or "folds" are a possible clinical outcome, especially if one or more of the following conditions exists:

1) The patient is thin (i.e. little or no subcutaneous fat) or is small-framed.

2) There is no breast tissue or breast tissue is sparse.

3) The overlying tissue is of poor quality, e.g. a post-partum patient with slack, less elastic skin or a mastectomy reconstruction patient.

4) The implant is placed in the subcutaneous position.

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5) The implant is of generous base dimensions and volume relative to the patient's frame size and size of the pocket which is created.

6) Fibrous capsule contracture is present.

"Wrinkles" or a rippling of the implant shell may be most commonly seen in the infraclavicular region. "Folds" with associated "knuckles" at the ends of the folds are most commonly reported in the lateral to medial inferior region of the implanted breast but may also be observed in the other regions as well.

Surgical revision may be desired by some patients exhibiting "wrinkles"or "folds." For some patients, these features have been reported to diminish with time. There have been reports of "folds" leading to thinning and erosion of the overlying tissue. In such cases, implant removal will likely be required.

9. ***Palpable Implant***

Palpable implants have been reported by some surgeons. It may be more readily observed in a patient with a large implant relative to pocket and/or patient frame size, when there is thin or tight overlying tissue, when the implant is placed in the subcutaneous position, and/or when contracture occurs.

10. ***Capsule Formation and Contracture***

The post-operative formation of a fibrous tissue capsule around the mammary prosthesis is a normal physiologic response to the implantation of a foreign object. Capsule formation occurs in all patients. However, each patient's capsule will vary in degree, ranging from thin to heavily thickened.

Contracture of a fibrous capsule may occur, independent of its thickness, resulting in discomfort, pain, excessive breast firmness, a palpable prosthesis, wrinkles and/or folds in the prosthesis shell, and/or displacement of the prosthesis. The presence and degree of capsular contracture may effect the diagnostic value of mammographic procedures. Reported causative factors of capsular contracture include infection, hematoma, lack of drainage, implant volume, diabetes mellitus, patient's immune system, implant type, gel bleed, trauma, foreign body reaction, inadequate pocket dissection, and implant placement. The medical literature documents that correction may require surgical intervention. In some patients, even with further surgery and treatment by their surgeon, breast firmness may recur.

Dow Corning Wright cannot warrant the integrity of the implant if closed capsulotomy is performed. Integrity of the implant envelope cannot be assured if the surgeon should choose to perform this procedure because unknown or abnormal force will be applied to the implant. Such abnormal trauma or stress to the breasts could result in prosthesis rupture with extravasation of gel into surrounding tissue.

The chance of excessive capsular contracture for all augmented patients will increase with time and may necessitate reoperation. Patients who have undergone reconstructive breast surgery stand a high chance of the need for reoperation at some future date to correct excessive capsular contracture.

11. ***Implant Rupture/Gel Extravasation***

Rupture of implants has been reported both intra- and post-operatively. Rupture may result from the following: intra- or post-surgical trauma; excessive stresses or manipulation as may occur during normal living experiences including routine and purposeful or

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accidental trauma as in vigorous exercise, athletics, and intimate physical contact; mechanical damage before or during surgery, or other unknown causes at the site of implantation, including so-called spontaneous rupture. Excessive manipulation of the implant shell during use as may be experienced during the performance of routine manual massage or manual exercise of the implanted breast may also produce long-term fatigue of the envelope, resulting in rupture.

If the surgeon should choose to perform manual compression of the breast (closed capsulotomy), he/she should be aware that it may lead to implant rupture due to weakening of the envelope from the forces the implant may experience. The patient should be adequately informed of the possibility of implant rupture with the use of this technique and of the necessity to remove a ruptured implant should that occur. Dow Corning Wright is not responsible for the integrity of the implant if a closed capsulotomy is performed.

Medical reports state more frequent intra-operative rupture occurs with the use of too small an incision for introduction of the prosthesis.

Upon loss of shell integrity, gel may be released from the implant envelope. If left in place, complications such as enlarged lymph nodes, scar formation, inflammation, granulomatous foreign body reaction, presence of foamy histiocytes, silicone mastopathy, nodule formation, or other difficulties may result. Migration of the silicone gel to adjacent or other tissue may occur.

It has been reported that if the gel material becomes inter-mixed with body fluids, the consistency of the resultant gel/body fluid mixture may become less viscous than the original gel; hence possibly more difficult to remove. In the event that a ruptured prosthesis is suspected, Dow Corning Wright recommends prompt removal of the envelope and gel. The long-term physiological effects of uncontained gel are not completely known.

12. ***Infection***
When infection is associated with an implant site, an appropriate regimen of treatment should begin. If an infection is encountered and not brought under control, it is recommended that the implant be removed. Occasional latent infections of unknown etiology have also been reported.

A specific infection-related event, Toxic Shock Syndrome, has been referenced, or speculated upon, in rare case reports involving mammary prosthesis implantation.

13. ***Hematoma***
Meticulous hemostasis during surgery is the principal measure for prevention. Clinical literature documents that hematomas are a possible precursor to infection and increased fibrosis. If evacuation is the chosen treatment, every precaution should be taken to not damage the prosthesis. This procedure presents possible risk of implant damage, including puncture.

14. ***Serous Fluid Accumulation***
Serous fluid accumulation occurs occasionally in association with the surgical placement of any mammary prosthesis and may be accompanied by swelling and pain at the surgical site. This condition is reported to occur more frequently with surface-textured implants as a part of a normal wound healing in response to a non-smooth surface. This condition may also occur as the result of trauma. If aspiration is the surgeon's treatment

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of choice, every precaution should be taken to not damage the prosthesis. This procedure presents possible risk of implant puncture.

Prolonged persistent serous fluid accumulation may necessitate removal of the implant.

15. ***Calcification***

Physicians have reported so-called "calcification" of the tissue surrounding the implant. This mineralization is referred to in the medical literature as heterotopic ossification. The etiology of "calcification" is unclear. In some instances, heavy "calcification" resulting in local discomfort and breast firmness may require removal of the implant and the "calcified" capsule.

16. ***Implant Gel Bleed***

Gel bleed is the passage of small quantities of silicone through the elastomeric shell of the implant. In vitro bleed tests demonstrate that this bleed phenomenon is significantly reduced in the Dow Corning Wright SILASTIC® II and SILASTIC® MSI Mammary Implant H.P. As a result, the envelopes of the implants will be relatively dry feeling.

The detection of small quantities of silicone in the tissue adjacent to the intact, conventional gel-filled implant and detection of small quantities of silicone in axillary lymph nodes has been reported in the medical literature. Some cellular reaction around the implant may be expected as a normal foreign body response.

Some doctors believe that silicone bleed from mammary implants may appear in breast milk. However, a study reported to the medical community indicates that milk samples from implanted and non-implanted mothers show no difference in silicone content.

17. ***Immune Responses***

There have been reports of suspected immunological responses to silicone mammary implants. Many of the case reports suggest systemic illness with joint pain, myositis, fever, and lymphadenopathy being most frequently mentioned. Additional symptoms claimed include, for example, localized inflammation and irritation at the implant area, fluid accumulation, rash, general malaise, swelling of joints, weight loss, scleroderma, chronic arthropathy, morphea, keratoconjunctivitis sicca, pyrexia, skin lesions, arthralgia, and alopecia. Some reports in the medical literature refer to various combinations of such symptoms as so-called silicone-induced human adjuvant disease.

A review of the published experimental findings and clinical experience shows that convincing evidence does not exist to support a causal relationship between exposure to silicone materials and the acquisition or exacerbation of a variety of rheumatic and connective tissue disorders. A causal relationship between mammary implants and rheumatic/connective tissue disorders such as scleroderma, scleroderma-like disorders, and other rheumatic/connective tissue disorders remains to be established.

If an immunological response is suspected and the response persists, removal of the prosthesis is recommended along with removal of the surrounding capsule tissue. Such patients should not be re-implanted.

18. ***Tumorigenesis***

During the past 28 years of clinical use, the medical literature generally indicates that the silicone mammary prosthesis is not tumorigenic. There have been case reports

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of ordinary breast cancer associated with the presence of mammary implants, as would be expected on statistical grounds alone. A retrospective epidemiologic study of patients with mammary implants was conducted in Los Angeles, California, by Deapen, Pike, Casagrande, and Brody. This study of over 3,100 subjects concluded that the incidence of ordinary breast cancer in women with mammary implants is no greater than statistically expected for that population. No cancers of the breast other than carcinomas were found.

Malignant sarcomas in animals (rats) associated with implanted silicone gel are to be expected on the basis of solid-state tumorigenesis or the so-called Oppenheimer effect which applies to all relatively stable alloplastic materials. Available evidence demonstrates that the induction of sarcomas (solid-state tumorigenesis) as seen in animals either does not operate in man or is, at most, a rare event. There is no evidence that silicone materials can induce breast malignancies of any type.

INSTRUCTIONS FOR USE

A. Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process.

B. The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the mammary prosthesis.

C. **Surgical Procedures**
Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Some of the surgical and implant sizing variables that have been identified as being important include:

1) Patient frame size (e.g., the implant diameter is not too large for the breast and chest wall dimensions).
2) Tissue coverage of the implant (especially when there is limited breast tissue coverage and/or limited subcutaneous fat).
3) Surgical plane of placement (the submuscular plane may be preferable in patients with minimal, thin, and/or poor quality overlying tissue in order to minimize palpation, visibility, and/or erosion of any "wrinkles" or "folds" in the implant, if they should occur).
4) Size of implant pocket (create a pocket of adequate size and symmetry so that the implant may be placed flat and the surface of the implant adequately smoothed to assure a minimum of wrinkling at the surface).

Each surgeon must, of course, evaluate the appropriateness of the procedure based on his or her own training and experience.

Various factors must be considered by the surgeon in determining the proper size and shape of the implant used with a particular patient. The SILASTIC® MSI Mammary Implant H.P. is available in many standard sizes. It is advisable to have more than one size mammary implant in the operating room at the time of the surgery to allow the surgeon flexibility in determining the appropriate size implant to be used. Prior to use, the prosthesis should be carefully examined for structural integrity and cleanliness. A back-up implant should be available in the event of implant damage/rupture or contamination. A damaged or contaminated implant should not be used.

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D. **Packaging**

The sterile mammary implant is contained pre-cleaned in a film wrap, enclosed in a double sealed blister package to provide enhanced assurance of sterility. Product is considered sterile as long as the package integrity has not been compromised. If package integrity has been compromised, resterilization is required before use of the implant.

Non-sterile Special Order SILASTIC® MSI Mammary Implant H.P. units are supplied pre-cleaned, packaged in a film wrap, and labelled as non-sterile.

Two patient labels to record pertinent data, e.g. catalog number, product volume, lot number, etc., are supplied. These labels should be filled out and made a part of the patient's permanent records.

E. **Recommended Procedure for Opening Package**

1. **Sterile Product**

   a. Firmly hold the outer package blister so that the outer cover is pointing away from the person opening the package.

   b. Grasp outer cover film and peel back completely to end seal.

   c. Drop sterile inner package into sterile field.

   d. When implant is needed, open inner package in the same manner as the outer package.

   e. Lift the sterile wrapped implant from the inner blister well.

   f. Remove wrap and implant is ready to use. Note that foreign body reactions can be caused by drape and sponge lint, glove powder, talc, fingerprints, and other surface contaminants. Care should be taken to prevent contamination of the SILASTIC® MSI Mammary Implant H.P. If the implant is contaminated, it should be cleaned and resterilized per the instructions in Section F before it is used. Handling of the sterile implant should be minimized.

   g. Voids may occasionally be observed within the gel of SILASTIC® MSI Mammary Implants. These voids may form during the manufacturing process and consist of FREON® (dichlorodifluoromethane), the carrier gas used for sterilization. Data is on file that demonstrates that the gas is not cytotoxic. These voids are harmless to the patient and will generally dissipate with time. The use of product with bubbles within the gel does not endanger the patient or compromise the safety of the implant.

2. **Non-Sterile Product.**

   a. Open package under clean conditions.

   b. Remove the implant from wrap and sterilize per the instructions in Section F.

F. **To Clean and (Re)Sterilize Mammary Implants**

NOTE: THIS PRODUCT IS FOR SINGLE PATIENT USE ONLY.

1. **To Clean**

Should the sterile implant become contaminated before use, scrub thoroughly, but gently, with a clean soft-bristled brush in a hot water-soap solution to remove possible surface contaminants. Use a non-oily, mild soap.

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Do not use synthetic detergents or oil-based soap as these soaps may be absorbed by the implant and may subsequently leach out to cause a tissue reaction. Rinse thoroughly in hot water; follow with thorough rinses in distilled water. Be careful when removing the implant from the basin that it is not re-contaminated with floating particulates. (Re)sterilize as follows:

2. **To Sterilize (non-sterile product) or (Re)Sterilize**
Each institution should establish the efficacy of its sterilization procedure by appropriate methods. If resterilization of sterile product or sterilization of non-sterile SILASTIC® MSI Mammary Implant H.P. is required, the following steam autoclave techniques have been effective and are provided as a guide. Do not sterilize the implant in the package and/or wrap supplied.

   a. Wrap the unit in a suitable lint-free wrapping material for autoclave use and place in a clean open autoclave tray.

   b. Standard Gravity Sterilizer—**STERILIZE THIRTY (30) MINUTES AT 250°F, 15psi (121°C, 1 kg/cm^2 or 1.03 Bar).** Pressure differential during steam autoclaving may cause small bubbles in the gel. The bubbles will not affect the function of the implant and will dissipate with time.

   c. High Speed Instrument (flash) Sterlizer—**STERILIZE FIFTEEN (15) MINUTES AT 270°F, 30psi (132°C, 2 kg/cm^2 or 2.07 Bar).**

   d. **DO NOT USE A PREVACUUM HIGH TEMPERATURE STERILIZER WHICH RAPIDLY EVACUATES THE STERILIZER CHAMBER THEN PULSES (VACUUM/STEAM) TO ACHIEVE A FAST CYCLE TIME AS THIS TYPE UNIT WILL CAUSE THE SILICONE GEL TO BUBBLE EXCESSIVELY AND THE IMPLANT TO SWELL. IF THE STEAM STERILIZATION PROCESS INCLUDES A VACUUM CYCLE WHICH CANNOT BE BYPASSED OR AVOIDED, RESTERILIZATION OF THE PRODUCT USING THAT STERILIZATION PROCESS IS NOT RECOMMENDED. DO NOT STERILIZE BY ETHYLENE OXIDE AS THE RESIDUAL STERILANT MAY CAUSE ADVERSE TISSUE REACTION.**

   e. Avoid repeated sterilizations.

   f. After sterilization, the center of the implant may retain heat even though the surface is cool. Be sure the implant has thoroughly cooled throughout before implantation. This may be accomplished by gently kneading the unit in sterile water or saline and allowing adequate time for cooling. Note that the mammary prosthesis may be easily ruptured while still hot from the autoclave. Care must be used during handling to avoid damage.

REFERENCES

Literature references are available upon request to:
Dow Corning Wright
Marketing Department
P.O. Box 100
Arlington, TN 38002
U.S.A.

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WARRANTY

Dow Corning Wright warrants that reasonable care in selection of materials and methods of manufacture were used in fabrication of this product. Dow Corning Wright shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this product. The foregoing warranties, as conditioned and limited, are in lieu of and exclude all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise.

Dow Corning Wright neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Dow Corning Wright intends that this mammary implant product should be used only by physicians having received appropriate training in plastic surgery techniques.

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

SILASTIC®—This registered trademark is the brand name for Dow Corning's silicone elastomer products, materials and related products. Only Dow Corning and its subsidiaries may identify its products with the trademark SILASTIC®. The word is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's material. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

DOW CORNING WRIGHT
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ARLINGTON, TN 38002
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CURRENTLY UNDERSTOOD RISKS OF SALINE-FILLED BREAST PROSTHESES

1. Fibrous Capsular Contracture

Fibrous capsular contracture, the formation of a constricting fibrous layer around the prosthesis, is the most common risk associated with breast augmentation and reconstruction. Capsular contracture may result in excessive breast firmness, discomfort, pain, disfigurement, and displacement of the implant. This condition occurs most commonly within the first few months following surgery. Degrees of capsular contracture have not been quantitatively defined. The rate of clinically significant contracture has been cited as between approximately 3 and 45 percent.

Although several etiological factors have been suggested, including hematoma, infection, foreign body reaction, and radiation, no single factor has been demonstrated to be the sole cause of contracture. The etiology of contracture is not understood.

2. Deflation

Deflation of the device results from partial or total loss of the contents due to puncture, rupture or other failure of the shell, or a faulty valve. Deflation results in the loss of shape of the prosthesis, which may cause deformity of the breast and require surgical intervention to correct.

3. Infection

Infection, a risk of any surgical implant procedure, is associated with the use of silicone inflatable breast implants. As in any implantation procedure, compromised device sterility and surgical techniques may be major contributing factors to this risk. Other factors specifically related to breast implants have been identified which may increase the risk of infection associated with this device. Burkhardt et al. have concluded from their studies that *Staphylococcus epidermidis*, which has been cultured from uninfected breast glands, may cause subclinical infections of the periprosthetic area if the ductal system is disrupted during the surgical procedure. It has been suggested that this may also contribute to the early development of capsular contracture.

4. Interference With Early Tumor Detection

Several reports have suggested that the presence of silicone inflatable breast implants may interfere with standard mammography procedures used to screen patients for breast cancer. The presence of the implant can produce a shadow on the radiograph that may reduce visual clarity of a significant portion of the breast. Furthermore, there is greater reduction of transmission of X-rays through the saline filler than through tissue. In addition, the presence of the implant compresses overlying breast tissue, particularly fat, creating a denser organ with less radiographic contrast. Compression obliterates the fine trabecular pattern of the breast, making architectural distortions difficult to see in a radiograph.

The risk of interference with early tumor detection could potentially affect a large number of patients, because most recent predictions indicate that approximately 10 percent of women in the United States will develop breast cancer during their lifetime.

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Admn #5-73
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Attm# 6

Informed consent can be crucially important when you seek any medical need. As a consumer, as a patient, you may make the assumption the physician has placed your safety, and your welfare as their foremost concern, because physicians have been entrusted as guardians of our health-care - they have sworn an oath to do no harm. However, my assumption that all physicians would behave responsibly, and thus place my safety, and my welfare as their first and foremost concern, has been a devastating assumption for my health.

The silicone gel breast implant was my third medical device injury to occur from a medical fraud. My first two injuries resulted from an inter uterine device (IUD), manufactured by A.H. Robins, the Dalkon Shield. Each of the failed medical devices, I used, had been marketed as being safe when the manufacturers, in fact, knew otherwise, but the manufacturers are not alone in their negligent behavior; physicians have been negligent as well by encouraging the use of these defective devices, and withholding information of the possible side effects.

I unknowingly used the I.U.D. device twice, because my physician chose to withhold pertinent information I had every right to know; his apathy resulted in my being injured twice by the same device; thus resulting in a hysterectomy I shouldn't have needed.

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However, I did not learn of my physician's betrayal, and negligence, until fifteen years later, in 1986, when A.H. Robins filed bankruptcy, and I obtained my medical records. This physician, and the surgeon who implanted the breast device, had both assured me of the safety of these, in fact, defective medical devices. The first surgeon, according to my medical records, knew my inflammation, and bleeding was caused from the IUD, he noted it in my medical records; this physician chose to let me suffer infections, bleeding, and pain.

October 16, 1974, I had surgery to replace lost breast tissue, and to correct the appearance of my sagging breasts; the surgeon assured me that the implants were safe, they had been used for many years without complications. He stated the device would make it easier to detect tumors; he said it would last a lifetime, and this was a one time surgery. However, contrary to what this surgeon told me, I began having difficulties.

November 11, 1975, I had surgery to alleviate a painful contracture of the left breast; the surgeon told me the contracture was a rare occurrence, and he said it was unlikely to re-occur, but the contracture problem did re-occur; what I did not realize then was that the contracture of the breast, though extremely painful, was only the begining of the intense pain, illness, and internal destruction that I, and thousands of other women would be subjected to from exposure to this deleterious device.

I had the silicone implants, and capsules removed, May 8, 1992; the **right** implant was ruptured, and had ruptured as early as 1975. The removing surgeon was dismayed by my decision not to put in more implants; he was more concerned about what he viewed as the possible psychological difficulties I might suffer from loosing breast tissue, and/or the implants, but my illness had become overwhelming. I felt it was more important to hopefully regain my health, than to have my breasts. I would never have had the implant surgery had I known I would be taking any risk; the deceit of the manufactures, and the misinformation given to me by the implanting surgeon, has destroyed my health, and destroyed my life. I feel betrayed; I was betrayed.

Consumers need and deserve the protection of stringent informed consent guidelines, guidelines that will protect consumers from the type of charlatan who places profit above public safety. The medical manufacturers, the pharmaceutical industry, and some physicians are unconscionably aloof to the human suffering they create; profit has first priority, but then again some physicians are merely inept.

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My resulting medical status from using the defective medical devices:

Dalkon Shield - two surgeries, and loss of female organs.

Silicone gel breast implants, one set, 18 year exposure - three surgeries, deformity, loss of tissue, Chronic pulmonary dysfunction, pulmonary fibrosis, Atypical Scleroderma, Sjogren's Syndrome, Fibromyalgia, Axonal Neuropathy, myalgia, myositis, dry eyes, acne necrotia, TMJ, myopathy secondary to silicone implants, rheumatic symptoms secondary to silicone implants, nodules on my thyroid gland that have to be watched closely, breast adjuvant disease, migraine headahes.

I have esophageal problems, I choke; my muscles, and nerves twitch, or sometimes I have severe spasms; I have headaches, and I suffer from chronic fatigue, I have chemical sensitivities - I have had violent reactions to some drugs, I have neurological problems, short term memory loss - I loose words, I get lost, I can't remember names, i.e., I wanted to call my oldest son, but I couldn't recall his last name; I can no longer run, hike, or walk for long periods of time; I can not sit for to long, such as working at a desk, or traveling, because of bowel functioning problems, my joint problems, as well as my internal organ problems, adversely affects literally everything I do.

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Since removal of the Breast implants the severe swelling of my head, neck, and underarms, has subsided; my eyes have not swollen shut since the removal of the breast implants, May 8, 1992. I still have some morning swelling of my eyes in varying degrees; my chest, neck, and entire head remain tender, and sensitive to touch, but the worst of the swelling has ceased. I am taking medications for pain, which gives me some relief from the constant pain, but it's like having a perpetual, vacillating flu; I hurt, I ache everywhere, there is nothing that I can do that is not painful, or difficult.

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PH + (W)
3-16-94

STATE OF KANSAS

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TOPEKA

SENATE CHAMBER

COMMITTEE ASSIGNMENTS
CHAIR: PUBLIC HEALTH AND WELFARE
JOINT COMMITTEE HEALTH CARE DECISIONS FOR THE 90's
MEMBER: FEDERAL AND STATE AFFAIRS
FINANCIAL INSTITUTIONS AND INSURANCE
CORPORATION FOR CHANGE
KANSAS HEALTHY KIDS CORPORATION
JOINT COMMITTEE ON CHILDREN AND FAMILIES

TESTIMONY ON SB 816

By Sandy Praeger

House Public Health and Welfare Committee
March 16, 1994

Thank you, Madam Chair and Committee members for the opportunity to testify on behalf of SB 816. Before giving you my reasons for supporting SB 816, I would like to call the committee's attention to the components of health reform that have already passed in Kansas or will hopefully pass this session.

Kansas insurance reform has expanded portability, guaranteed issue to members of group plans, eliminated the preexisting condition exclusions and compressed rates for small employee groups (fewer than 25 employees). This year we hope to expand that rate compression to group plans of 50 or fewer employees and portability to all policies, groups and individuals. We have also recommended legislation that will reduce the waiting period in the Kansas Uninsurable Health Plan from 1 year to 90 days.

We have worked on cost containment measures such as universal claims forms, a system for collecting and analyzing health data and a uniform standard for utilization review. SB 759, which you heard testimony on yesterday, will provide us with a managed care system for delivering services to our Medicaid population which can control costs and provide better quality care.

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Kansas has the distinction of being the first of the pilot states participating in the EACH/PCH project to have a rural network certified. This program can maintain and improve access to quality care in rural areas.

These are just the highlights of the steps we have taken already in Kansas to improve access, provide affordable coverage and control costs in our health care delivery system.

SB 816 will be the important next step. It establishes a LEGISLATIVE oversight committee, with legislative membership and public/private sector advisory committees. The committee would have the authority to hold public hearings and introduce legislation. The duties of the committee are spelled out in Sec. 3. They are very similar to the duties envisioned by the 403 Commission. The difference is that the committee guiding health reform and making recommendations for responses to federal reform mandates would be legislatively-driven, and not driven by a new bureaucracy as created by the 403 Commission plan. The advantage to this approach is that as legislation is introduced the legislators who have been involved in the committee will help shepherd the necessary legislation through the process.

This is a general overview of the bill. I would be happy to respond to questions.

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KANSAS AMI
KANSAS ALLIANCE FOR THE MENTALLY ILL
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913-233-0755 • FAX 913-233-4804

Testimony

March 16, 1994

To: House Public Health & Welfare Committee

From: Terry Larson, Executive Director,
Kansas Alliance for the Mentally Ill

RE: Senate Bill 816

There is nothing intrinsically wrong with this bill, and we will do nothing to impede its progress. We applaud the inclusion of consumers and would sincerely hope a conscientious effort would be made to include several consumers of mental health services, especially persons with severe and persistent mental illnesses.

Our objection to the bill is that it appears to represent another delaying tactic. The Commission on the Future of Health Care, chaired by Dr. Bill Roy, was charged with developing a plan. Through numerous town meetings and many thousands of hours of work by commission members and their staff, we saw democracy at its best. The Commission went to the communities and received input from Kansas citizens representing a broad array of personal and public interests. The Commission's findings and recommendations have now been relegated to the back burner without so much as even a legislative hearing.

However, if nothing else is going to happen in Kansas this year with respect to health care reform, we hope you do support SB 816.

In the meantime, whatever plan is or is not adopted, we ask that the Kansas legislature begin now to explore the current discrimination in health insurance regarding certain diseases of the brain known as mental illnesses. In Kansas, mental illness coverage is included in the state mandated mental health benefits replete with limits which are not applicable to other diseases of the brain such as Parkinson's and multiple sclerosis. We support continuation of the mental health mandate in all health insurance for Kansans, but we know that mental illnesses do not belong under mental health but should be included with all other physical diseases.

Thank you.

PHWC
3-16-94
Attm #8

TESTIMONY ON S.B. 816, TO ESTABLISH A KANSAS HEALTH REFORM

LEGISLATIVE OVERSIGHT COMMITTEE

Walter H. Crockett, Kansas AARP, March 16, 1994

Kansas AARP supports this legislation as the best we are likely to get at this time. But we had expected much more.

For more than four years, Kansas AARP has followed the activities of the legislature as it struggled with the issue of health care reform. We have attended every public meeting of the House Committee on Public Health and Welfare, of the Senate Committee on Public Health and Welfare, of the Joint Committee on Health Care Decisions for the 90's, of the Kansas Commission on Health Care, Inc., and of various non-governmental organizations, including our own, which examined in detail the crisis in health care in our state and nation. We studied dozens of proposals for dealing with that crisis. We had expected to see a bill before this legislature like the one in Missouri, providing reforms in health care that would take effect whatever action the Federal government takes. Such a program would blend with federal legislation when it passes or would initiate reform in Kansas if it does not.

Kansas AARP met with the leadership of the Kansas Commission on Health Care, Inc. and with Secretary Harder, before their health care reform bills were introduced, to determine whether their proposals satisfied our criteria for health care reform. We are at a loss to understand how the legislature could allow the Kansas Commission on Health Care to conduct meetings and public hearings for 27 months and then not even hold a public hearing on the bill it proposed. We urge this committee to recommend that House Bill No. 3075 at least receive public hearings before this session ends.

Far from proposing health care reform, the present bill merely sets up a legislative committee to keep track of whatever action the federal government takes. Our organization uses ~~uses~~ five critaria to evaluate proposals for health care reform: universal coverage of all Kansans; comprehensive benefits, including preventive care as well as assistance with long-term-care and prescription drugs; cost containment; fair and affordable financing; and consumer involvement in governing the health care system. The present bill provides only some measure of consumer involvement.

We have heard it said that there is no interest in Kansas in health care reform. Our own assessment diverges greatly from that judgment. AARP is proud to have 365,000 members in Kansas. Our State Legislative Committee annually asks members of AARP chapters and of Kansas Retired Teachers Association units to indicate which issues they want the Committee to support in the coming legislative session. The opinions of a random sample of AARP members in Kansas who do not belong to AARP chapters and RTA units are also obtained. Health care reform was at the top of concerns among our members. I have appended to my testimony the 1994 Facts and Legislative Priorities of Kansas AARP. Please note that health care reform takes first place in the priorities of the State Legislative Committee.

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If the present bill is the best this legislature can produce, then we have no alternative but to support it. But we deeply regret that our state should lead all those in our region in the depth of its inquiries into health care reform, but then lapse into inaction when the time came to do something about it.

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3-16-95
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KANSAS STATE LEGISLATIVE COMMITTEE

The AARP State Legislative Committee (SLC) decides and promotes the legislative objectives to be sought by the Association in each state legislative session. Composed of volunteers from the AARP membership across the state, the Committee works on behalf of not only AARP members, but all older persons and the state community.

Each year, the State Legislative Committee in Kansas selects legislative priorities based on the needs of the state's residents, using guidelines developed by the AARP National Legislative Council. SLC members work with legislators to promote passage of legislation beneficial to Kansas's older population.

The Kansas SLC participates responsibly in the legislative process from discussion of concern, to a bill's conception, to its signing into law and the translation of its intent into administrative procedures and regulations. The SLC volunteer "citizen lobbyists" are assisted by AARP legislative staff. Technical support for the state legislative program is provided by the AARP Public Policy Institute and by AARP program volunteers.

***AARP established AARP/VOTE to inform voters about issues important to older people. Because AARP/VOTE works closely with the State Legislation Department in educating various audiences on public policy issues, the VOTE Coordinator is an ex officio member of the SLC.*

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Most State Legislative Committees have recognized that they need additional volunteers to help promote the AARP legislative program to lawmakers, legislative staff, executive branch officials and other organizations. This need to strengthen the AARP presence in the state capital city has prompted many SLCs to create a Capital City Task Force (CCTF).

The primary role of the CCTF is to help the SLC promote and defend AARP legislative interests before the state legislature. The SLC may also rely on CCTF members to monitor and participate in the regulatory and rulemaking processes of the state. The duties of Task Force members range from testifying before legislative committees to preparing legislative updates to researching issues.

To ensure appropriate policy oversight of the CCTF's activities, the SLC Chair designates a SLC member to coordinate the group. Capital City Task Force members belong to AARP and reside close to the Capitol.

AMERICAN ASSOCIATION OF RETIRED PERSONS

AARP was founded in 1958 as a voluntary nonprofit and nonpartisan organization to help improve the quality of life of not only its members, but all older people. It is dedicated to helping its members meet the challenges of pre-retirement and retirement living and achieve a dynamic maturity of independence and purpose.

In Kansas, more than 365,079 individuals belong to the American Association of Retired Persons. AARP volunteers serve their communities through a variety of programs, from free tax counseling to support for newly widowed persons. The Association also offers a variety of educational and advocacy programs for older workers, who make up one-third of AARP's total membership.

AARP, the largest membership organization of older Americans, totals more than 33 million nationwide. There are more than 4,000 local AARP chapters.

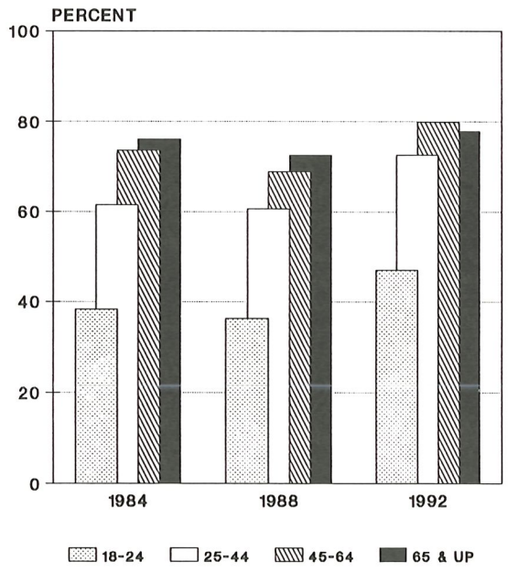
AARP initiatives marshal Association resources to address health care concerns; a variety of older worker issues; economic security matters, particularly for low-income older Americans; the status of minority elderly and issues relating to mid-life and older women. The Association is also emphasizing protection for mid-life and older consumers on a broad range of issues including personal financial security, housing and utility regulation.

OLDER VOTERS

Older people are generally eager to participate in all facets of political life. Older persons are often involved in registering voters, assisting voters in traveling to polls and actually conducting poll operations on election day. They believe in the Eisenhower adage, "Politics should be the part-time profession of every citizen."

The voter turnout graph illustrates the participation rate of four age groups of Kansas voters in elections held between 1984 and 1992.

VOTER TURNOUT GRAPH



Source: Census Bureau

1994 KANSAS LEGISLATIVE PROGRAM

PRIORITIES

- Promote comprehensive health care that:
  — covers all Kansans, ensuring a continuum of care across an individual's lifetime
  — provides a comprehensive set of benefits including:
    - preventive, physical and mental health care;
    - long-term care covering: home, community-based and nursing home care;
    - all prescription drugs
  — addresses the special health needs of rural Kansans
  — provides choice of health care providers
  — ensures quality care and research
  — controls costs
  — ensures fair and equitable financing
- Promote suitable, safe and affordable housing for all Kansans with attention to the special needs of persons frail, disabled or elderly
- Provide a fair and equitable tax system to support essential services
- Assure the protection of all Kansans and their property (e.g., greater emphasis on victims' rights; improved consumer protection from fraud; reduced availability of handguns/ automatic weapons)

SUPPORT ITEMS

- Monitor the action of the Kansas Commission on the Future of Health Care, Inc. using AARP's principles of health care reform as guidelines
- Promote coordinated transportation system recognizing the needs of elderly and disabled persons
- Support Citizens Utility Ratepayers Board (CURB) in its efforts to represent consumers
- Protect the integrity of public and private pensions and seek to improve benefits for KPERS members

SL1003KS(1093)

KANSAS

State Legislative Committee

1994 FACTS & LEGISLATIVE PRIORITIES

AARP

American Association of Retired Persons

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KANSAS MEDICAL SOCIETY
623 SW 10th Ave. • Topeka, Kansas 66612 • (913) 235-2383
WATS 800-332-0156 FAX 913-235-5114

March 16, 1994

To: House Committee on Public Health and Welfare

From: Jerry Slaughter
Executive Director

Subject: SB 816; Concerning the Health Care Reform Legislative Oversight Committee

The Kansas Medical Society appreciates the opportunity to appear today as you consider SB 816, which would establish the Health Care Reform Legislative Oversight Committee.

Unfortunately, the issue of health care reform has become as politically charged in Kansas as it now is in Washington. In retrospect, this is not surprising since so much is at stake for everyone involved: patients, insurance companies, health care providers, government and employers, to name a few of the huge array of persons and entities affected. The polarization which is occurring makes it difficult to create a spirit of collaboration towards solving the problem. We strongly believe that reform efforts will fail unless a more inclusive, and less divisive, attitude begins to work its way into the broad debate.

It is ironic that almost everyone agrees on the core issues: universal coverage, portability, affordability, simplicity, fairness and personal responsibility. The areas of disagreement are principally on how best to achieve the commonly held goals, not whether we should strive for them. The speed with which we should enact reform measures is as contentious as is the issue of what the reformed system should look like, and who should pay for it. Should we become a "fast-track" state and implement sweeping reforms before the federal government acts, or should we move forward cautiously and be ready to incorporate federal dictates as they are enacted? In truth, many of the states that took aggressive steps are now having to delay implementation of key reforms because they are finding that until the Congress acts there are just too many unanswered questions about financing, benefits, federal programs such as Medicare and Medicaid, etc. Some of these states are also finding that it is more expensive and complex to implement reforms than they had imagined.

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3-16-94
Attm # 10

What does all this mean for Kansas? We believe it means that we should continue to work on reforms that are within our ability to effect, irrespective of federal action. Examples are the positive steps that the Legislature has taken to make insurance available to "uninsurable" individuals; the incremental approach to implementing community rating, and the efforts to make insurance more available and affordable to small businesses. Our efforts to establish a comprehensive database will serve us well, for we must have reliable data upon which to build the foundations of reform. The move to consolidate all acute care Medicaid services into a managed care program, if properly funded and planned, can improve access and restrain spending growth for the over 200,000 Kansans covered under this federal/state program.

Beyond that, we must now create a process for achieving consensus on which direction our specific reforms should take, in the context of our unique problems, and federal actions which will be forthcoming. We believe that SB 816 contains a viable vehicle for moving Kansas forward. The key decisions on health care reform will center around financing (who pays and how much?), and the goal of universal coverage (employer vs. individual mandates). Since these are issues that can only be decided by the Legislature, then it follows that our process for developing solutions must be legislatively driven. Only then can "ownership" be established for legislators who must ultimately make the tough votes. The ability of the Oversight Committee to utilize advisory panels assures that there will be input from a wide spectrum of individuals and organizations, which we feel is very important to the process.

We support the process of planning and development which is contemplated in SB 816. It should position Kansas to move forward at an appropriate pace with solutions that fit our needs and meet forthcoming federal requirements.

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~~pg 2 of 2~~

KANSAS DEPARTMENT OF SOCIAL AND REHABILITATION SERVICES
Donna L. Whiteman, Secretary

House Public Health and Welfare Committee
Testimony on Senate Bill 816
Health Care Reform Legislative Oversight Committee

March 16, 1994

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The SRS Mission Statement:
"The Kansas Department of Social and Rehabilitation Services empowers individuals and families to achieve and sustain independence and to participate in the rights, responsibilities and benefits of full citizenship by creating conditions and opportunities for change, by advocating for human dignity and worth, and by providing care, safety and support in collaboration with others."

****

Madam Chairman and members of the committee, thank you for this opportunity to testify on the Kansas Health Care Reform Legislative Oversight Committee, which is to oversee federal and state law on health care reform for Kansas.

SRS is pleased to see attention being brought to the health care needs of all Kansans. We are especially interested in plans that assist in assuring access to effective quality care for Medicaid beneficiaries. We continue to struggle with this issue as we are asked to cover more of the population with fewer dollars. The FY 1988 to FY 1992 Medicaid expenditures doubled. For FY 1995 Medicaid expenditures are projected to increase by 10 percent.

The Department of Social and Rehabilitation Services would support the oversight and examination of federal health care reform by this legislative committee, and the development of a central contact agency for health care reform. If this legislation is passed it would place Kansas in a positive position for health care reform at the federal level.

We are pleased with the appointment of the Secretary of Social and Rehabilitation Services to the oversight committee and the addition of consumers of health care to each subcommittee.

In summary, we are very interested in supporting any legislative action that assures our clients are provided access to quality health care in a cost-effective manner through health care reform.

Robert L. Epps
Commissioner
Income Support/Medical Services
(913) 296-6750

PNeW
3-16-94
Attm #11

KANSAS COMMISSION ON DISABILITY CONCERNS
1430 SW Topeka Blvd
Topeka, KS 66612-1877
(913)296-1722 (V) 296-5044 (TTY) 296-1984 (Fax)

TESTIMONY PRESENTED TO HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE

by

Sharon Joseph, Chairperson
March 16, 1994

Senate Bill 816

Madam Chair, members of the committee, thank you for this opportunity to testify today in opposition to Senate Bill 816. This bill does not adequately address the issue of guaranteeing comprehensive health care reform for people with disabilities residing in this state.

The Kansas Commission on Disability Concerns (KCDC) believes that all people with disabilities are entitled to be equal citizens and equal partners in Kansas society. The purpose of KCDC is to involve all segments of the Kansas Community through legislative advocacy, education and resource networking to ensure full and equal citizenship for all Kansans with disabilities.

It is with this purpose in mind that I come before you today to urge your support of the involvement of people with disabilities in the development and implementation of health care reform in Kansas. Please consider the following three facts when you consider any health care reform bill before you:

1. *One in every six Americans experiences a disability.*

2. *The needs of people with disabilities provide a litmus test for the effectiveness of the health care system.*

3. *The health care needs of people with disabilities are not currently being met.*

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With these three facts before you, please take a closer look at Senate Bill 816 and ask yourself the following questions:

① *Does the bill guarantee adequate representation from consumers with disabilities on each of the subcommittees assigned to the oversight committee?*

? ?

② *Does the bill require that public hearings be held to provide consumers with disabilities the opportunity to actively participate in the process of deciding on the future of their health care?*

? ?

③ *Does the bill require the oversight committee take the needs of people with disabilities into consideration when making recommendations on the future of health care for Kansas?*

The answer to all three of these questions is a resounding ***NO!!!*** The fact is, although you will find words such as "**cost containment**", "**residents of underserved areas**", "**insurance**", "**employer**", "**provider**", and even "**consumer**"; not once will you find the word "**disability**" mentioned in this bill.

With nearly half a million individuals with disabilities residing in this state, representing approximately one fifth of the total population, it is imperative that we be given the opportunity to fully participate in the policy-making and implementation process of health care reform. Involvement of people with disabilities must be allowed in order to ensure that the future health care needs of **ALL** citizens will be considered when drafting a health care plan for Kansas.

KCDC cannot support a proposal that does not guarantee this involvement and would encourage you to examine the real intent of any proposal that excludes people with disabilities from the policy-making process.

Thank you again for this opportunity to speak before you today. I would be glad to attempt to answer any questions you might have at this time.

PH&W 3-16-94 Attm #12-2 pg 2 of 2

KANSAS ASSOCIATION OF CENTERS FOR INDEPENDENT LIVING

3258 South Topeka Blvd. ~ Topeka, Kansas 66611 ~ (913) 267-7100 (Voice/TT)

Gina McDonald
Executive Director

TESTIMONY TO
HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE
MARCH 16, 1994
REPRESENTATIVE JOANN FLOWERS, CHAIRPERSON

Member agencies:

ILC of Southcentral Kansas
Wichita, Kansas
(316) 838-3500 V/TT

Independence, Inc.
Lawrence, Kansas
(913) 841-0333

Independent Connection
Salina, Kansas
(913) 827-9383

LINK, Inc.
Hays, Kansas
(913) 625-6942 V/TT

Resource Center for
Independent Living
Osage City, Kansas
(913) 528-3105 V/TT

ILC of Northeast Kansas
Atchison, Kansas
(913) 367-1830 V/TT

The WHOLE PERSON, Inc.
Kansas City, Missouri
(816) 361-0304 V
(816) 361-7749 TT

Topeka Independent
Living Resource Center
Topeka, Kansas
(913) 267-7100 V/TT

A.S.K., Inc.
Dodge City, Kansas
(316) 225-6070 V/TT

SEK Independent Living
Parsons, Kansas
(316) 421-5502 V
(316) 421-6551 TT

Thank you for the opportunity to testify today. My name is Gina McDonald. I am the Executive Director of the Kansas Association of Centers for Independent Living (KACIL). KACIL is an advocacy organization that promotes the rights of people who experience disabilities.

I have also been working with a coalition of over 100 agencies concerned about health reform and how it will or will not impact people with disabilities.

I am speaking today in opposition to Senate Bill 816. There is already a 12 member Joint Committee on Health Care Decisions for the 1990's. This committee is comprised of an equal number of Republican and Democratic members. The committee proposed in S.B. 816 would be Republican dominated.

The 403 Commission has already accomplished many of the proposed activities of the new committee. For example, Section 3 (3) mandates that the new committee will consider all health care financing and delivery options now in effect... and (6) mandates that it develop plans for health care cost containment. Both of these mandates have already been accomplished by the 403 commission. Furthermore, the Bill prepared by the 403 Commission would have established a Kansas Health Care Commission, which would have been a more appropriate body to perform many of the tasks proposed by the new committee.

Senate Bill 816 offers no concrete solutions to the health care crisis in Kansas, and many of us believe it is a stall tactic to delay significant health reform. People with disabilities need reform now. We don't need another study to determine that we cannot afford health insurance, and when we can, it does not cover our pre existing conditions. We need meaningful changes to the system today.

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