Approved: February 17, 1994

MINUTES OF THE SENATE COMMITTEE ON FINANCIAL INSTITUTIONS AND INSURANCE.

The meeting was called to order by Chairperson Richard Bond at 9:07 a.m. on February 15, 1994 in Room 529-S of the Capitol.

All members were present.

Committee staff present: William Wolff, Legislative Research Department
Fred Carman, Revisor of Statutes
June Kossover, Committee Secretary

Conferees appearing before the committee: Senator Pat Ranson
Jack Jonas, Director, Midwest Cancer Foundation
Dr. P. N. Kim, Medical Director, Midwest Cancer Foundation
Norma Richards, Wichita, KS
Barbara Scritchfield, Technician, MCF Cancer Screening Van
Dr. Carol Konek, Wichita, KS
Janice Crabtree, Sterling, KS
Jill Hartford, Wichita, KS
Liz Dudley, Wichita, KS

Others attending: See attached list

Senator Praeger made a motion, seconded by Senator Steffes, to approve the minutes of the meeting of February 10 as submitted. The motion carried.

Chairman Bond announced that **SB 622** will not be heard today as scheduled, but will be continued on Monday, February 21. A subcommittee consisting of Senators Praeger, Steffes, Lee, Hensley and Bond will be appointed to consider **SB 622**.

The chairman opened the hearing on **SB 640**, relating to insurance coverage for mammograms. Senator Pat Ranson appeared before the committee to explain that the Midwest Cancer Foundation, located in Wichita, provides access to mammograms at a reasonable cost, and to introduce the conferees. Senator Ranson also presented a letter from United States Senator Nancy Landon Kassebaum. (Attachment #1.)

Jack Jonas, Midwest Cancer Foundation, provided background information on MCF and explained the need for this legislation. (Attachment #2.) In response to Senator Lawrence's question, Mr. Jonas identified Cigna and Blue Cross/Blue Shield as insurance carriers with whom they have experience some degree of difficulty.

Dr. P. N. Kim, Medical Director, MCF, explained the importance of early detection of breast cancer and stated that the goal of the MCF Mobile Screening Van is to make diagnosis at an early stage and that there is presently no technology, other than mammography, for breast cancer screening.

Norma Richards, Wichita, KS, explained her experience with the mobile van and stated that because of early detection, her cancer was cured without the need for radiation or chemotherapy.

Barbara Scritchfield, Chief Technician, testified that theirs is strictly a screening operation and, in answer to Senator Praeger's question, stated that a three-step follow-up procedure is executed for every abnormal mammogram, and this includes a report to the patient's physician. Senator Petty inquired whether prostate screening is also available with the van and Ms. Scritchfield replied that blood is drawn and sent to the lab; resources are available for both men and women.

Senator Steffes inquired about the quality of the equipment used and was advised that the mobile screening van has the newest and highest quality equipment in Wichita.

Written testimony was presented by Pamela Tapp Byl, MN, RN, Kansas State Nurses Association (Attachment # 3), and Betty Dicus of the American Cancer Society (Attachment #4).

Since a fiscal impact study is required by statute, Chairman Bond announced that the hearing on **SB 640** will be continued pending receipt of the impact study.

Hearing was opened on **SB 682**, concerning insurance coverage for breast implant removals and related conditions. Dr. Carol Konek, Wichita State University, presented a brief oral history of the problems being experienced with silicone breast implants and requested the committee to give serious consideration to this legislation.

Janice Crabtree, Sterling Kansas, appeared before the committee in support of **SB 682**, and presented her personal history with breast implants and her difficulties with her insurance carrier. (Attachment #5.)

Jill Hartford, presented written testimony from Connie Masters, who is too ill to appear before the committee. (Attachment #6.)

Liz Dudley, RN, presented graphic photographs of victims of silicone breast implant procedures and Silicone Induced Disease and testified to the need for removal of the implants and difficulties experienced with insurance carriers. Chairman Bond asked how the $4 billion settlement agreed to by manufacturers of silicone breast implants would be accessed by Kansans and was advised by Ms. Dudley that the amount received by any one victim would depend on how many claims and filed, and that settlement is expected to take from 4 to 6 years.

Written testimony was presented by Senator Ranson (Attachment #7), Cynthia Steward (Attachment #8), Linda Thomas (Attachment #9) and by Pamela Tapp-Byl, RN (Attachment #10).

Chairman Bond and Senator Ranson agreed that there are language problems in **SB 682**, which will need to be corrected. This legislation will also require a fiscal impact study since the bill contains mandates; therefore, hearing on **SB 682** was continued pending completion of the required study.

The committee adjourned at 10:00 a.m.

The next meeting is scheduled for February 16, 1994.

GUEST LIST

SENATE

COMMITTEE: FINANCIAL INSTITUTIONS AND INSURANCE   DATE: 2/15/94

NAME	ADDRESS	ORGANIZATION
Terry Leatherman	Topeka	KCCI
Michelle Peterson	Topeka	Ks Gov Consulting
Linda Thomas	Lane	
Janice Crabtree	Sterling	
Joanne Embry	Hutchinson	
Geradine G. Asber	Hutchinson	
Glennys Joan Knackstedt	Windom	
Catherine Campbell	Topeka	
Norma Richards	Wichita	MCF
Shelby Smith	"	MCF
P. N. Kim	"	MCF
Barbara Switchfield	"	MCF
Bill Sneed	Topeka	HIAA
Pam Terp Byl	Topeka	KSNA
Rich Guthrie	KC	Health Midwest
Sue Bond	Overland Pk	
Robin Walker	Topeka	SRS
Colleen Conte	Fredonia	STD
Roberta McAlister	Moline KS	
Betty Dicus	Topeka	ACS
Connie Tinzanic	Topeka	Am. Cancer Soc.
Jay Beatti	Topeka	Dept of Admin
Carrie Shearburn	El Dorado	Survivor

GUEST LIST

SENATE

COMMITTEE: FINANCIAL INSTITUTIONS AND INSURANCE DATE: 2/15/94

NAME	ADDRESS	ORGANIZATION
Lee Barfield	2555 Chaibon Ct	A.G. Task Force
Kay Stewart	1036 Post Oak Rd	AG Task Force
Liz Dudley RN	752 N. Stagecoach	Plaintiff Steering Committee
Carol Ann Ladd	[illegible] President	Attorney General's
BARBARA CARTER	4533 SE 85th Terr	Tech Task A.A. TASK FORCE

CY LANDON KASSEBAUM
KANSAS

COMM
LABOR AND HUM URCES
FOREIGN RELA...NS
INDIAN AFFAIRS

United States Senate

WASHINGTON, DC 20510-1602

February 14, 1994

Honorable Pat Ranson
Senator
Kansas Senate
Topeka, Kansas 66612

Dear Pat:

I am pleased to learn that you and several other senators have introduced Senate bill 640, an act relating to insurance coverage for mammograms.

When the Midwest Cancer Foundation was founded some years ago, I agreed to serve as honorary chairman because I believe that care and concern for current cancer patients as well as prevention and early detection of cancer are very important goals. When MCF launched their mobile mammography van, I felt this was the realization of one of their major goals--prevention of cancer. Women in the workplace would now be able to have a mammogram in convenient setting.

The insurance companies' refusal to reimburse for mammograms performed by the KDHE and HCFA certified mobile facility has seriously hampered the Midwest Cancer Foundation's efforts to continue to detect breast cancer. I sincerely hope that Senate bill 640 will be successful in rectifying this situation.

Warmest regards,

Nancy

Nancy Landon Kassebaum
United States Senator

NLK:ss

Senate 4141
2/15/94
Attachment #1

Van Schedule
March 1993 through December 1993

Company	# of visits	Education sessions
Albertsons/Public screenings	2	
Argonia Sch. Dist.	1	
Beech Aircraft Corp.	1	Mgmt. Dinner
Belle Plaine/ Public screenings	1	
Cheney Sch. Dist.	1	
Coleman Company Inc.	1	
Conway Springs Sch. Dist.	1	
El Dorado Sch. Dist.	1	x
Excel Corporation	1	x
Friends Health Fair	1	
Koch Industries Inc.	3	
Larksfield Place	2	
Learjet	2	
Love Box Company	2	
MetLife	1	x
Multimedia Cablevision	1	
NCR	1	
Prairie State Bank/Public	1	
Rec. Veh. Products	1	x
Rent-A-Center	2	
Richardson's Pharmacy/Public	1	
Sedgwick County Fair/Public	1	
Sedgwick Plaza	1	
St. Mark Health Fair	1	
Udall Sch. Dist./Public	1	
Towne East/Public	1	
Wichita Mall/Public	1	
City of Wichita	1	
Emprise Bank (South)	1	
Emprise Bank (Downtown)	1	
Emprise Bank (West Douglas)	1	
Belle Plaine	2	
Pres. Church/Kingman	1	x
Sterling/Pres. Manor Health Fair	1	
Derby Schools	1	
TOTAL		

March through December, 1993, a total of 743 females have been screened for breast cancer. Eighty-three were found to be abnormal. Eleven of these were biopsied with five mastectomies performed.

In the same time frame, a total of 582 men have had the PSA (Prostate Specific Antigen) blood test. Of the 582 performed, ten were abnormal with two biopsied and one found to be malignant.

We had 133 mammograms performed at KPL (Wichita/Hutchinson). Statistics are at AIH in Kansas City.

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Updated 2/4/94

Midwest Cancer Foundation Screening Van
3243 E. Murdock * Suite 400 * Wichita, KS 67208 * 316-681-1131

Foundation wants to make mammograms easier to get

By Julie Wright
The Wichita Eagle

TOPEKA — Only three in 10 women get mammograms as regularly as they should, and the Midwest Cancer Foundation of Wichita is campaigning to increase that number.

Last spring, the nonprofit foundation began taking a large van equipped with mammography equipment to Kansas employers. The goal is to make it easier and cheaper for women to get mammograms — breast X-rays designed to detect abnormalities, including cancer.

Women can duck out of work and have a mammogram done in the foundation's van in 15 to 20 minutes.

The van also provides a blood test to screen for prostate cancer in men. Between March and December of 1993, 743 women and 582 men were screened at workplaces in various Kansas cities.

Foundation officials consider the project a big success, with one exception: Some insurance companies aren't paying for the tests unless they have been ordered by a physician. Others say they don't want to pay for "mass screenings" but won't say what a mass screening is.

The result is that some women are faced with paying the $55 fee out of their own pockets, which makes the test much less attractive.

Sen. Pat Ranson, R-Wichita, has introduced a bill to change that. But

LEGISLATURE 1·9·9·4

at least one insurance company representative cautions that the bill could amount to sidestepping the professional judgment of physicians.

"We've always taken the position, if it's medically necessary, we pay for it," said Brad Smoot, a lobbyist for Blue Cross and Blue Shield of Kansas. "That's kind of a general principle of health care. And the person we rely on to make that determination is the physician."

Ranson's bill would not allow insurance companies that pay for mammograms to pick and choose who does the test.

Her bill would require that insurance companies that pay for mammograms and prostate-specific antigen testing pay for any test conducted by a provider that is certified by the state Department of Health and Environment and the federal Health Care Financing Administration. The foundation's van meets both of those standards.

The Senate Financial Institutions and Insurance Committee will consider the bill Tuesday.

Ranson thinks it's a matter of people taking responsibility for their own health.

Two key reasons women don't have mammograms as frequently as they should are the test's cost, which usually is more than $100, and the time it takes to have the mammogram, said Paik Nyon Kim, foundation president.

"The van serves those who would not take time from work to go to a hospital or clinic setting, making it convenient, and is cost-effective for the employee, employer and insurance group," Kim wrote in a letter to Ranson.

Experts have begun to disagree about the usefulness of mammography and about how often it should be performed.

From 1987 through 1993, the National Cancer Institute and the American Cancer Society recommended that women in their 40s have mammograms every one to two years and that women over 50 have them every year. However, studies have failed to prove that mammograms saved lives of women in their 40s.

In December, the National Cancer Institute changed its formal guidelines for breast-cancer screening and dropped the recommendation that women under 50 have regular mammograms.

But just days earlier, the American Cancer Society and several other medical groups called a news conference to say that women in their 40s should continue to get regular mammograms as a screen for breast cancer.

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Hearing Before the Senate Committee on Financial Institutions and Insurance on Senate Bill No. 640
February 15, 1994

The mission of the Midwest Cancer Foundation (a not-for-profit foundation), is to make Mammography and PSA testing available at the worksite at a reduced cost.

To accomplish this, we have invested $250,000 in a state-of-the-art equipped mobile van that meets the high accreditation standards of HICFA.

Our X-Ray technicians and radiologists also are fully accredited to HICFA standards.

We are here today to share with you our first ten months operation experience, challenges, successes, and frustrations.

A major challenge has been raising the funds to cover cost of the van, equipment, and personnel.

We are happy that two major grants have been approved to assist with the cost of the van and equipment. As a result, our fees are often under normal fees, i.e., $55 for a mammogram and $45 for PSA.

We are still experiencing a shortfall in operational budget,

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Attachment #2

primarily because we have been frustrated by obtaining support from several major insurance companies.

The Midwest Cancer Foundation is approved as a provider for a majority of insurance companies, nevertheless, we find it difficult to gain approval for our services, i.e., one major carrier states that they do not approve mass screening and consider mobile mammography as mass screening even though our experience shows that we can only serve 30 clients a day and our average participation for a company is approximately 10%. If we were booked solid for one year we could not accommodate more than 5,000 screenings.

In spite of the challenges from insurance companies, we have signed up 65 major corporations for participation including such large companies as Beech, Learjet, Koch Industries, Rent-A-Center, NCR, and over 38 school districts, to name a few.

To date, we have screened 850 women for mammography with results of 89 recommended for diagnostic screening of which 11 required biopsies and 5 required mastectomies. One breast cancer is diagnosed out of each 170 screenings with the cost of $9,350. On the PSA, 636 have been tested, resulting in 2 biopsies and the discovery of 1 malignancy.

We are not experts in the legislative initiatives, however, we do know and understand cancer and how early detection can save

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lives. We also know that only 33% of women follow the suggested guidelines in obtaining mammograms by the standards of the American Cancer ~~Foundation~~ Society and the ~~National Association~~ American College of Radiology.....common sense tells us that if we make screening accessible at the workplace, requiring approximately 15 to 20 minutes of time, that more women will participate and more lives will be saved because of the early diagnosis.

We would think that insurance companies would applaud and support our efforts, particularly when considering that the cost of treating one metastatic breast carcinoma is $300,000 at minimum which is equal to the cost of screening 5,500 women with mammogram. This says nothing about the heartache and total destruction of the family that often occurs with cancer.

Some insurance officials have implied that it is cheaper for them to pay the cost of breast cancer treatment for a few women than to pay the screening of many. These comments seem neanderthal when considering the emphasis that major companies are placing on wellness programs today.

We urge you to assist us in obtaining the unqualified support of insurance companies for this project. We have provided each of you with a packet of information that gives greater detail of our efforts and we will be pleased to answer any questions you may have at this time. We thank you for the opportunity of appearing before you today.

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KSNA
the voice of Nursing in Kansas

KSNA & You
A Powerful Match

FOR MORE INFORMATION CONTACT:
Terri Roberts J.D., R.N.
Executive Director
700 SW Jackson, Suite 601
Topeka, Kansas 66603-3731
913-233-8638
Date: February 15, 1994

S.B. 640 Relating to Insurance, Mammogram Coverage

Chairperson Bond and members of the Senate Financial Institutions and Insurance Committee my name is Pamela Tapp Byl M.N., R.N. I am a Clinical Nurse Specialist and Clinical Director of a local women's health center that performs over 600 mammograms a month. I represent Kansas State Nurses Association and speak in support of SB 640.

As you may know, in 1980 the American Cancer Society (ACS) evolved criteria for the development of the Cancer Related Health Check-up. Each recommended cancer screening test was chosen on the basis of four criteria having been met:

1) There must be good evidence that the test or procedure is effective in reducing mortality or morbidity;
2) Medical benefits must outweigh risks;
3) The costs must be reasonable relative to benefit; and
4) The test or procedure must be practical or feasible for application in existing health care settings.

Mammography and pap smears were two such cancer screening tests that met these criteria. Similarly, screening for prostate cancer can now easily be performed through use of the Prostate-Specific Antigen Test (PSA).

The Kansas legislature in 1988 enacted SB 668 and mandated that insurers provide coverage for screening mammography and pap smears. No doubt many women's lives have been saved in the State of Kansas due to this legislation, but problems still exist which present barriers to the implementation of screening guidelines and early detection of cancer.

Because the original mammography legislation did not stipulate the ages of women to be covered or how frequently the exam should be cone, women, especially older women who are most likely to get breast cancer, have relied upon their physicians to refer for these procedures--and while healthcare providers generally agree on the importance of mammography, there is continued lack of universal agreement among professional provider organizations regarding screening guidelines. The 1992

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Mammography Attitudes and Usage Study has revealed that as women age and they begin to see their physician more frequently, they are less likely to be referred for a mammogram.

The U.S. Department of Health and Human Services National Strategic Plan for Early Detection and Control of Breast and Cervical Cancers recommends that professional associations coordinate their efforts to establish a set of consensus guidelines, that quality assurance regulations be enacted, and that consistent messages regarding these guidelines be communicated to women and providers.

Primary care providers and screening centers do not work in isolation, but are influenced by their practice settings and by reimbursement patterns. Pap tests, PSA tests, and mammography referral could be increased significantly if Kansas adopts consensus guidelines and ties reimbursement to quality. KSNA along with the American College of Radiology and many other professional medical associations endorse ACS screening guidelines for breast, cervical and prostate cancer and believe that these tests will not reach their full potential until a uniformly high standard of care is mandated.

We urge your favorable passage. Thank you.

a:94legislation/orange/sb640/la

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AMERICAN CANCER SOCIETY®
KANSAS DIVISION, INC.

THERE'S NOTHING MIGHTIER THAN THE SWORD

TESTIMONY OF BETTY DICUS, TOPEKA
CHAIRMAN OF THE BOARD
AMERICAN CANCER SOCIETY, KANSAS DIVISION, INC.

SENATE FINANCIAL INSTITUTIONS AND INSURANCE COMMITTEE
FEBRUARY 15, 1994
SENATE BILL 640

Mister Chairman and Members of the Committee:

My name is Betty Dicus and I currently serve as Chairman of the Board of Directors for the American Cancer Society, Kansas Division, Inc. We thank you for the opportunity to appear before you in support of Senate Bill 640.

Last year, an estimated 182,000 women nationwide were diagnosed with breast cancer. Over 46,000 died, making breast cancer the second major cause of cancer death in women. During that same year, an estimated 165,000 men were diagnosed with prostate cancer in the United States. There were 35,000 deaths from the disease, ranking it as the second leading cause of cancer death in men. This legislation would encourage screening for both breast and prostate cancers.

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Attachment #4

1315 SW ARROWHEAD ROAD • TOPEKA, KANSAS 66604-4020
(913) 273-4114 • FAX (913) 273-1503

The American Cancer Society advocates accessibility to cancer screening tests for all individuals. By diagnosing these malignancies at an earlier stage, they can be treated more successfully, with a better chance of patient survival. To assist you in considering this legislation, I have attached to my testimony a copy of the American Cancer Society's guidelines relating to screening for breast and prostate cancer. Additional data regarding incidence, treatment, and mortality for these diseases is available, should you require further information.

This is an excellent opportunity for the Legislature to encourage Kansans to take responsibility for their health by accessing recommended screening examinations. On behalf of the American Cancer Society, I request your favorable consideration of Senate Bill 640.

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AMERICAN CANCER SOCIETY
KANSAS DIVISION, INC.

1315 SW Arrowhead Road
Topeka, KS 66610

EARLY DETECTION OF CANCER SCREENING GUIDELINES

BREAST CANCER

The American Cancer Society recommends that women have a screening mammogram by age 40; women 40 to 49 should have a mammogram every 1-2 years; asymptomatic women age 50 and over should have a mammogram every year. In addition, a clinical physical examination of the breast is recommended every three years for women 20 to 40, and every year for those over 40. The Society also recommends monthly breast self-examination as a routine good health habit for women 20 years or older. Most breast lumps are not cancer, but only a physician can make a diagnosis.

Besides its effectiveness in screening asymptomatic women, mammography is recognized as a valuable diagnostic technique for women who have findings suggestive of breast cancer. Once a breast lump is found, mammography can help determine if there are other lesions too small to be felt, in the same or opposite breast. Since a small percentage of breast cancers may not be seen on a mammogram, all suspicious lumps should be biopsied for a definitive diagnosis, even when current or recent mammography findings are described as normal.

PROSTATE CANCER

Every man 40 and over should have a digital rectal examination as part of his regular annual physical checkup. In addition, the American Cancer Society recommends that men 50 and over have annual prostate-specific antigen blood testing. If either result is suspicious, further evaluation in the form of transrectal ultrasound should be performed.

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JANICE L. CRABTREE
STERLING, KANSAS

At the young age of 23 I was given the diagnosis of advanced fibroid cyst disease and told I needed to have a double mastectomy with reconstruction of silicone breast implants. I was told it would save my life. I had this procedure done and now 17 years later I am battling with my insurance company over coverage for the removal and testing of silicone breast disease.

I went for a consultation in July 1993, with a micro-vascular plastic surgeon in Houston, Texas to discuss the removal of my breast implants which were both diagnosed as ruptured and leaking silicone into my body which was making me ill. I had many symptoms of arthritis, memory loss, fatigue, swelling of joints and muscles, rashes, chills, muscle weakness, etc. I requested that he send a letter along with diagnostic codes and procedures to my insurance company explaining what his examination revealed, and any additional information that my insurance company would need for authorization of my surgery. He did so immediately. Four weeks later the surgeon's office notified me that my insurance company had informed them that they would not even consider my request for surgery without me first sending in a nude photograph of my breasts including my face to make sure I was the patient. They stated that this was necessary in order for them to tell if I really had breast implants and really needed to have surgery.

I was humiliated! For a brief moment I knew what a rape victim must feel like. I felt my privacy invaded, all for a problem that I never really asked for 17 years ago. I trusted my doctor then, I trusted the manufacturers of these breast implants. 17 years ago nobody was handing the patients pamphlets from the manufacturers telling us of hazards that may be experienced from these devices. I was told by my doctor that my implants would last the rest of my life. Now I was being asked by my insurance company to produce a nude photograph of myself to make sure I really needed this surgery? I have asked myself many times since this occurred what is wrong with our health care system that an insurance company can not take a through medical report from a specialist who has personally examined me as the proper documentation in order to make a determination of medical necessity.

I was also referred by my insurance company to a 1-800 phone number for certification of my hospitalization. It was explained to me and my husband that it would be necessary for me to undergo some extensive testing prior to my surgery to determine the extent of damage that the leaking silicone

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had caused with my immune system and my nervous system. They also needed to determine if my lungs had suffered any damage from the silicone and if they were strong enough to undergo the 10 - 14 hour surgery that I was facing. It turns out that this 1-800 number is what my insurance company calls the Wichita Preferred Physicians Association, better known to you and I as the Wichita Medical Society. It seems that they make the determination for my insurance company whether or not hospitalization is medically necessary. Of course they determined that mine was not, and after doing some investigating on my own, I find out that they allowed a retired general surgeon and a family practice physician to make this determination for my benefits. Neither one of these doctors had had any prior experience with silicone breast disease. I requested that they have the same type of specialist that had examined me in Houston review my doctor's medical information, and I was told that would not be necessary because disallowing hospitalization for medical testing of silicone breast disease was a national consensus. This is news to me, news to the specialists that examined me and treated me, and most of all, this is news to the other women in this state who are also suffering from these problems. How do you fight an insurance conglomerate? How do you get them to change their opinion, especially when you know it is wrong? I need your help today! Please don't allow them to make me a victim again.

I am the consumer, I pay my premiums in good faith and I am basically being told that my insurance company will determine the type of health care I receive, not my physician. I have a tremendous problem with this.

Since my surgery in September 1993, my insurance company has taken the last 4 1/2 months to review my claims. I have received a multitude of questionnaires, claim summaries stating that all of my claims have been suspended for review, I am told now that some of my claims have been sent to senior review which is their home office in Des Moines , Iowa, and that they are requesting a company by the name of Health Care Excellence in Naperville, Il. to audit my hospital bill for possible billing errors.

I believe all of this is being done as a stall tactic. They have had these claims in house since the middle of October and they are just now getting around to having them reviewed and audited?

If I conducted my business in this type of delay manner, I am sure I would loose my good credit standing, have all of my utilities shut off and be considered a bad risk.

I believe in this day and age of big business, my insurance company is more interested in profits and dividends for

their investors than the needs of me the patient. This was confirmed for me last night when I was watching the Winter Olympic games and I saw my insurance company, The Principal Financial Group as a prime time advertiser of the Olympics. I believe the tag line on their commercial was "we take care of our people." I don't think so. You are looking at one subscriber that definitely has not been taken care of in a fair and proper manner.

I want my physician to set the quality standards for my medical care, not my health insurance company!

PLEASE HELP US TODAY! DO NOT LET THIS CONTINUE TO HAPPEN TO THE WOMEN OF KANSAS WHO ARE SICK FROM THEIR IMPLANTS. HOLD THESE INSURANCE COMPANIES ACCOUNTABLE FOR THE WAY THEY DO BUSINESS IN OUR STATE. Thank you for your time.

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'I caught it in the nick of time'

Breast implants a nightmare for Sterling woman

By Sara Peterson-Davis
The Hutchinson News

STERLING — Two years ago Jan Crabtree developed arthritis in her hands. Thinking it was just another part of growing older, she ignored it.

Then it spread to her hips and legs, and with it came fatigue, pain, digestive problems, insomnia and short-term memory loss.

"It got to the point that I couldn't remember how to use the phone," said Crabtree, who eventually had to quit her job because she became so disabled. "I would get in the car and forget how to get to the grocery store."

After hearing several other women describe the same symptoms on a television news magazine, Crabtree realized her problems might be the result of a ruptured breast implant.

When she approached doctors about the possibility that her implants might be causing her health problems, they dismissed the notion as ridiculous.

"I was told it was just a group of hysterical women who didn't know what they were talking about," Crabtree said.

Last month, the 41-year-old wife and mother traveled to Houston Methodist Hospital to have her breast implants removed.

When surgeons went in to remove the implants during a 10-hour surgery, they discovered that the silicon pouches had not only ruptured but that the silicon filling had entered Crabtree's chest cavity.

"The implants were black," said Crabtree, who had the implants put in 17 years ago after undergoing a double mastectomy. "The silicon was like taffy on the surgical instruments."

Photo by Sandra Watts

'We've been through a lot together,' Janice Crabtree says to her husband Steve Wednesday morning at their home in Sterling. Crabtree is recovering from a 10-hour surgery she underwent at the Houston Methodist Hospital in Houston about six weeks ago to remove silicon breast implants that had ruptured.

Before her surgery, Crabtree's physical condition deteriorated so far that she couldn't tie her shoes because of the arthritis in her hands or open a car door because she was so weak. Her short-term memory loss was so severe that she would write notes to remind herself of things and then lose the notes.

She eventually left her position at Sterling College.

"I got frightened and didn't want people to have to watch me," she said.

As her conditions worsened, Crabtree joined a support group and got in contact with Wichita attorney Mark Hutton, who is representing women suffering the side effects of ruptured silicon implants.

From Hutton she heard about Dr. Bernard Patten, a Houston doctor specializing in treating women suffering the side effects of ruptured implants.

Because she had a strong immune system, Crabtree said, doctors told her she had been able to fight the effects of the silicon for a long time. They also told her that like many women, her implants probably began leaking between 10 and 15 years after they were inserted.

Compared to other implant victims receiving treatment from Dr. Patten, Crabtree said, she was still in relatively good health. Some of the women she met at the hospital had developed lupus, permanent nerve damage, severe rashes and even gangrene.

"I caught it in the nick of time," Crabtree said.

Not wanting to take a chance on silicon implants, Crabtree underwent trans-flap surgery, a procedure where fat and muscle is taken from a woman's abdomen and used to sculpt new breasts. By using tissue from the patient's body, the risk of rejection is nil.

"It's really a miracle that this surgery (trans-flap) is available. This was actually a bonus," Crabtree said.

Since she has had her implants removed, Crabtree has seen her physical problems subside. She sleeps better, she has felt her arthritis pain lessen and her memory has returned.

Doctors told Crabtree that she will probably experience a full recovery in a year.

Since she became ill and has undergone surgery, Crabtree has become a vocal critic of silicon implants and an advocate to have them banned. If states won't ban the implants, Crabtree believes doctors should be required to fully inform women about all the potential risks with implants.

Next January, Crabtree plans to testify before the Kansas Legislature about implants.

"After reading the literature, I can't imagine women keeping them," she said. "I didn't ask nearly enough questions."

Crabtree is alarmed by the number of women — especially young women — who continue to get breast implants despite the literature and news reports.

"You shouldn't wait until you have a problem," she said. "You shouldn't trade good health for good looks."

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I am Connie Masters, a breast implant victim of 9 years. I have undergone numerous outpatient testing by over 20 local physicians and specialists and extended $20,000.00 for this purpose. As a result of my medical problems being undiagnosed, untreated and misdiagnosed, my health rapidly deteriorated and I sought treatment by a specialist in Houston, Tx, Dr. Bernard Patten. Dr. Patten requested my immediate need for hospitalization faxing my insurance provider, Blue Cross/Blue Shield, 12 pages of my patient history illustrating multiple auto immune diseases, severe weight loss, and documenting that I "looked like I had aids." Blue Cross denied my admittance and I personally had to come up with $18,500.00 cash payment before I could be admitted to the hospital.

Recently I was denied in my application for state disability being informed that "although medical evidence revealed I had complex syndromes, multiple symptoms, and chronic conditions", "these conditions are not severe enough to keep me from working."

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I recently had to turn to medicaid as primary insurance provider. Medicaid is denying medical services for my necessary medical treatment. I write to the Topeka SRS agency with requests for assistance. They do not answer. I call the same agency continually. They evade my questions or do not respond at all. It is a constant struggle to gain any assistance with what seems to be discriminating, lethargic agencies.

I would most importantly like to bring to your attention that my 5 year old daughter is a 2nd generational victim of silicone exposure and toxicity who suffers with multiple and complex symptoms and chronic conditions. My daughters primary insurance provider is medicaid, and Unfortunately, she is traveling down the same "misfortunate medical path of blindness" that I have. In the past year, my daughter has seen 18 physicians and specialists in the state of Kansas who were unable to diagnose or treat her illness. She has gone through painful extensive testing and surgery. In July of 1993 I began requesting medical services and assistance through Medicaid to take my daughter to a pediatric physician, Dr. Jeremiah Levine in New York, who specializes in my daughters illness and to date is the only phipician in the U.S. treating and diagnosing her illness. In November 1993 Medicaid denied assisting me with treatment by Dr. Levine in New York. However, the Medicaid Medical Director, Dr. Jerry Simpson,

informed me of medicaids approval for my daughter to be seen by pediatric physicians at K.U. Medical Center in Kansas City, Kansas Who Were dealing with and treating my daughters illness. When I inquired with Dr. Simpson the names of such physicians, he could not offer any Doctor's names specifically but stated he Knew they existed. My call to Dr. Jane Scott (K.U. pediatric director) confirmed such qualified physicians dealing in my daughters illness did not exist at K.U. Medical Center. I was willing to take my daughter to K.U. to be evaluated as medicaid had informed me if she could not be treated at K.U. and K.U. would give her a medical referral to Dr. Levine in New York - I could then get medicaid assistance. Medicaid referred to K.U. as a "stepping stone" to treatment by Dr. Levine. In the past 2 months my daughter has been evaluated by 8 pediatric K.U. physicians at K.U. Medical Centh in Kansas City. The evaluating K.U. specialists have given Dr. Jerry Simpson, Medicaid medical director, a referral for my daughters medical necessity to be treated by Dr. Levine in New York. Dr. Simpson has again denied my request and denied her referral by K.U. specialists. Dr. Simpson recommended I instead take my daughter to yet another K.U. physician, Dr. Eugene Berger, an immunologist. He is not even a pediatrician.

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On a February 1, 1994 meeting with Wichita SRS Officials the real reason for denial of my daughters treatment was exposed: it is an issue of money and not an issue of my daughters declining health.

Another obstacle factor of my daughters treatment denial may be related to the fact of the regulating Topeka Medicaid Director being one of many prior plastic surgeons who have irreversibly polluted the bodies of women and children worldwide with a pollutant called silicone and as a result have a complex of guilt and future liability in professing medical treatment for this toxic disease.

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The University of Kansas Medical Center

Gastroenterology Section
FAX: (913) 588-6319

Rayna Grothe, M.D.

K.U. Children's Center
K.U. Children's Center Foundation
(913) 588-6354

February 4, 1994

Dr. Jerry Simpson
Topeka Medicaid
Fax# 913 296 4813

Re: Sylvanus, Racheal
KU#: 9324633
Date of dictation: 1/28/94

Dear Dr. Simpson:

I was asked to evaluate Rachael Sylvanus in the pediatric gastroenterology clinic on 1/11/94 for evaluation of chronic abdominal pain. Her history was remarkable for pain of 6 to 8 months duration. Also, there was a history of difficulty swallowing meat.

Rachael was breast fed and at the time, Rachael's mother had breast implants which were ruptured.

At the time of the evaluation, I felt that the pain was most consistent with GE reflux and/or gastritis. We initiated routine screening tests, including stool heme tests which were negative, stool for O&P and stool culture which are still pending, CBC, sed rate, AST ALT, bilirubin, amylase and lipase, BUN and creatanine which were essentially within normal limits except for a sed rate of 24.

Since this visit, I have spoken with Dr. Jeremiah J. Levine who is in the Division of Pediatric Gastroenterology & Nutrition at Schneider Children's Hospital at Long Island Jewish Medical Center, Long Island Campus of the Albert Eienstein College of Medicine, New Hyde Park, New York. Address: Schneider Children's Hospital, Room 229, Albert Eienstein College of Medicine, New Hyde Park, New York 11042.

Dr. Levine indicated to me that he had done some blood work on Rachael indicating abnormal antibodies and autoantibodies levels felt to represent autoimmune markers in children born to mothers with silicone breast implants.

Also, I reviewed with Dr. Levine his most recently published article of sclerodal like esophageal disease in children breast fed by mothers with silicone breast implants in the Journal of the American Medical Association, January 19, 1994, Volume 271, No. 3, Page 213. In this study, 11 children were referred for evaluation of abdominal pain who were born to mothers who had silicone breast implants. All children underwent esophageal manometry and upper intestinal endoscopy with esophageal biopsy and had various autoantibodies tests accomplished. Dr. Levine found that 6 of 8 breast fed children from mothers with silicone implants had abnormal esophageal motility with absent peristalsis in the distal 2/3 of the esophagus and decreased lower sphincter pressure. It is not clear to me what the correlation with endoscopy biopsies were. The manometric abnormalities, however were not seen in the bottle fed children, just the children who were breast fed.

Senate H+H 2/15/94
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This information leads me to believe that there may be some type of association with silicone exposure in the newborn breast milk and autoimmune disease later on in life. Again, I do not have the knowledge to comment on this possible association. I, however would suggest that Rachael follow-up with Dr. Levine in regards to the autoantibody level and possible endoscopy and manometry. I did discuss with Rachael's mother that an EGD could be performed here, however I do not perform esophageal manometry at The University of Kansas Medical Center. Also, I am not in a position to make comments concerning esophageal disease and possible silicone exposure. I, therefore feel the most efficient, as well as thorough approach to handling this possible issue is to have Rachael evaluated by the individuals who are studying this issue in a very research oriented scientific matter.

Also, I recommend that a barium swallow and upper GI be done prior to initiating endoscopic or manometric studies.

Rayna Grothe, MD
Pediatric Gastroenterology

RG:cc

cc: Connie Masters
Dr. Nancy Olson
Dr. Jane Scott/CRU
Dr. Levine
Dr. Clay Shaw
Dr. Helen Lovell
Dr. David Palmer

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6-6

JANUARY 9, 1994

Ms. ROBIN WALKER
DEPT. OF TOPEKA SRS
915 HARRISON STREET
TOPEKA, KS. 66612-1570

RE: STATEMENT IN TELECONFERENCE ON 2-1-94 WITH WICHITA SRS OFFICE.

Dear Ms. Walker:

I would like to inquire about a statement you made in a recent 2-1-94 teleconference consisting of yourself, Dr. Jerry Simpson, Dot Laekly, and included Wichita SRS officials Galen Bright, Mark Stuckey, and Keith Massie that I attended with my father, Hershel Masters. In this teleconference I inquired about out-of-state medical services and travel expense assistance by SRS for an El Dorado Kansas woman, Carrie Shearburn, of Butler County who had been seeing the same Houston Texas physician Dr. Bernard Patten for over a year for the same medical diagnosis that I was seeing Dr. Patten for in the association of silicone adjuvent breast disease. I inquired with you why SRS has been assisting Ms. Shearburn with out-of-state medical sevices related to my same disease and I am having extreme difficulty in obtaining authorization for the same medical services. You informed me you had checked into Ms. Shearburn's medical treatment and that she was not being treated for silicone adjuvent breast disease by Dr. Patten. Enclosed copy of a November 10,1992 letter faxed to Evelyn McCormick of the Topeka SRS office contradicts your statement regarding Ms. Shearburn's diagnosis by Dr. Bernard Patten. It is obvious that Ms. Shearburn is, in fact, being treated for the same illness by Dr. Patten that I am. Like Ms. Shearburn, I have been diagnosed with other severe illnesses such as autoimmune diseases, neurological disorders, muscular disorders, gasteroentology disorders and other health problems that should be the focus of authorization for my out-of-state medical service assistance instead of the singular focus of silicone breast disease which your organization views as "still in the experimental stage." As I have stated to you Robin, in one of many conversations,

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I have expended over $20,000 in medical expenses in seeing over 20 Kansas physicians and specialists in an attempt to diagnose and treat my illness for over a year and a half, while my illness progressively and rapidly deteriorated. It was only out of desperation and last recourse that I sought treatment out-of-state. I have appealed your decision to deny my treatment for out-of-state medical travel expenses for my December appointment with Dr. Patten. I have an April 7th 1994 appointment with Dr. Patten and Dr. Ray Verm in Houston, Tx. My PCN appointed DR. Robert Haskins has sent this proir referral by fax to your office this day to request out-of-state medical services. Dr. Haskin's office has also contacted Ms. Sherry Steuber to initiate my medical file for authorization. If you perceive this April appointment to again be denied by SRS services please contact me as soon as possible. Thank you for your time and attention to this ongoing controversy.

Respectfully submitted,

Connie S. Masters

Connie S. Masters
620 N. 1st
Mulvane, Ks. 67110

316-777-4246

cc: Ms. Donna Whiteman
Dr. Jerry Simpson
Mark B. Hutton, attorney

7141 2/15/94
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FAX MEMO

PAGES 1 DATE 11-10-92 913-296-4813
TO EVELYN MCCORMICK
FROM SHARRON WATSON
CC
PH# 316-321-1970 FAX# 316-685-1099
501 6012

Evelyn Mc Cormick
Fax # 913-296-4813

The reason Carrie was sent to Baylor Clinic, no one in the State of Kansas had the expertise to diagnose women with neurol muscle disease caused by chemical exposure.

This facility specializes in the diagnosis and treatment of women with silicone associated diseases. There is no such facility in Kansas. There are many others across the country with the expertise but Baylor was the closest.

No doctor in Kansas could find a diagnosis but after treatment at Baylor, Carrie has a diagnosis of myasthenia gravis and silicone adjacent breast disease. The anti-body level is so high she needs a thymectomy. That needs to be done by a certain protocol set up by Dr. Patton and his surgeons. The work up has shown she has a thymus gland in multi areas and a procedure using a endoscope would be indicated. Using this technique will require less hospital time, less recovery time and would not entail a major chest operation. This procedure is not available in Kansas, nor is the follow up treatment. If you need any further information or plan not to approve, please contact Mark B. Hutton, Attorney as soon as possible.

She is scheduled to be admitted November 13, 1992 and to have surgery on November 16, 1992.

Sharron Watson

Sharron Watson, Mother

cc: Mark B. Hutton, Attorney
Fax # 316-686-1077

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ST. FRANCIS REGIONAL MEDICAL CENTER
WICHITA, KANSAS

SPECIALITY CLINICS

P C N REFERRAL

DATE: 2-9-94

PATIENT: Rachel Sylvanus

DATE OF BIRTH: 4-20-88

PATIENT ID NUMBER: 00100 64 54 349

PATIENT ADDRESS: 620 N 1st Mulvane 67110

PCN PEYSICAN: Dr Phillip Chrisman

PCN PROVIDER #: Ch. 503884

REFERRAL TO: Dr Jovanovich Levine

REASON FOR REFERRAL: Upper Endoscopy; Manometry 90 day Referral

Phillip L. Chrisman M.D

(PEYSICANS SIGNATURE)

Attn Jerry Simpson: Topeka M.A

Fax 2/15/94

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STATE OF KANSAS

OFFICE OF THE ATTORNEY GENERAL

2ND FLOOR, KANSAS JUDICIAL CENTER, TOPEKA 66612-1597

ROBERT T. STEPHAN
ATTORNEY GENERAL

MAIN PHONE: (913) 296-2215
CONSUMER PROTECTION: 296-3751
TELECOPIER: 296-6296

TESTIMONY BEFORE SENATE COMMITTEES
FINANCIAL INSTITUTIONS AND INSURANCE
AND PUBLIC HEALTH AND WELFARE
Attorney General Robert T. Stephan
February 15, 1994

Dear Chairpersons Bond and Praeger and
Members of the Committees:

I regret that I am unable to attend the committee hearings today, but, because I had a previous commitment in Liberal, I cannot be with you. I want to speak in support of Senate Bills 682, 683 and 684.

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

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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.

At the very least, individuals should have the right to receive their medical records expeditiously and at negligible cost. Silicone Induced Disease should be subject to the same insurance coverage that is accorded to other diseases covered by insurance policies in this 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 the Senate Bills heretofore referenced. At the most, they codify existing case law, common sense and decency to 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.

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Thank you for your consideration of Senate Bills, 682, 683 and 684 which will assist all who suffer from Silicone Induced Disease.

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Breast Implants Raise More Safety Issues

THE WALL STREET JOURNAL

THURSDAY, FEBRUARY 4, 1993

Research Links Silicone Version To New Diseases

By THOMAS M. BURTON
Staff Reporter of THE WALL STREET JOURNAL

In the year since a national debate erupted about the safety of breast implants, a growing number of medical researchers are linking silicone-gel implants to a number of never-before-seen diseases of the human immune system.

Their conclusions will almost certainly affect the course of litigation over liability involving silicone implants. Manufacturers face an estimated 2,000 complaints in a consolidated federal court proceeding in Alabama and nearly 1,000 state lawsuits just in California. In a Texas state court late last month, implant maker Bristol-Myers Squibb Co. lost a $25 million verdict; it plans an appeal.

Researchers say the illnesses – some very serious – that they have detected mimic traditional diseases known generally as autoimmune illnesses, in which the body's immune system attacks its own tissue. But the ailments differ both in their symptoms and in laboratory results.

"The disease is a disease unto itself," says Gary Solomon, associate director of the rheumatic diseases department at New York's Hospital for Joint Diseases Orthopaedic Institute. "I had been skeptical" about a disease-silicone link, he says. "But after seeing five or six patients, I was convinced."

Chronic Fatigue

Dr. Solomon says his patients with silicone implants suffered chronic fatigue, inability to swallow, hair loss and rashes on their upper chests. These women, he says, have featured a "constellation of lab findings" not consistent with any previous diseases. Many tested positive for antinuclear antibodies, entities that attack the body's own tissue.

If borne out through continued research, findings like Dr. Solomon's would have immense significance medically and legally. Some of the findings have been published, others not.

It has been nine months since the Food and Drug Administration sharply curtailed the implants, allowing them only in limited clinical trial settings, mostly for reconstruction and breast-cancer patients. An estimated one million women in the U.S., and more overseas, have gotten silicone breast implants over three decades, either for cosmetic reasons or following surgery for breast cancer.

The FDA last April said it had concerns about the devices' safety but found that no conclusive causal link had been shown between the implants and autoimmune diseases like scleroderma, rheumatoid arthritis and systemic lupus.

Potentially Fatal

However, like Dr. Solomon, Alan J. Bridges of the University of Wisconsin asserts that "even people who were skeptical are saying there's just too much scleroderma" in women with implants. Scleroderma is a potentially fatal immune-system illness featuring leathery hardening of the skin; it can attack internal organs, as well.

"I believe there is a subgroup of women who will develop a disease if they have these things in long enough," says Dr. Bridges, a rheumatologist and associate professor of medicine. He has seen 150 patients with silicone implants and notes "some clinical and immunologic differences" from typical connective-tissue diseases. Such afflictions are a subset of autoimmune diseases that strike joints and tissues near joints, among other areas of the body.

Manufacturers continue to insist there isn't any proof that silicone causes diseases. And some physicians concur, noting that there haven't been large clinical trials comparing implant recipients to women without implants. Noel R. Rose, chairman of immunology at Johns Hopkins Univer-

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HEALTH

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.

Research Is Linking Silicone-Gel Implants To Some New Diseases

Continued From Page B1

sity, says he awaits such trial results before he will be convinced. Any such trials would take several years.

A study sponsored by Dow Corning Corp., the first manufacturer of silicone implants and the maker of much of the silicone gel in other companies' devices, is now under way at the University of Michigan to examine whether silicone may cause scleroderma. Aside from such questions, it has been clearly documented that women can become severely disfigured when their breast tissue hardens around the implants or when implants burst.

On the legal front, Salvatore Liccardo, a plaintiff lawyer, estimates that 2,000 cases have been filed or soon will be in the consolidated federal court proceeding in Birmingham, Ala. Lawyers say more than 80% of the cases filed name Dow Corning, Midland, Mich., a joint venture of Dow Chemical Co. and Corning Inc., as a defendant.

Other companies named in many of the lawsuits, lawyers say, include Minnesota Mining & Manufacturing Co. and Baxter International Inc. In other suits, defendants include implant makers Mentor Corp. and McGhan Medical Corp., a unit of Inamed Corp.

A number of researchers have found "anecdotal" evidence in their patients' symptoms and lab tests that links silicone and autoimmune illness. But such anecdotal findings are given less weight by researchers, although many medical professionals have found the specifics, especially lab results, particularly compelling in these cases.

"Reasonable people are not asking whether silicone causes disease, but how often," says Eric Gershwin, chief of rheumatology and allergy at the University of California at Davis. Dr. Gershwin has examined children who nursed from mothers with silicone breast implants and concluded that they, too, may get sick from the devices.

Silicone "may cross into the breast milk and not turn up for a number of years," he says. "We've seen a number of children who've had disease that we feel is possibly related to nursing with silicone implants." He reports examining babies and children with what he describes as "atypical autoimmune diseases."

At Baylor Medical College in Houston, other doctors tell of a woman whose silicone implants ruptured while she was under treatment at another Houston hospital. The Baylor doctors who treated her say the woman developed badly disfiguring scleroderma precisely where the escaping silicone had flowed.

An FDA researcher, Lori A. Love, studied 13 women with silicone who developed an extremely rare, and sometimes fatal, illness called myocitis. The women's symptoms and antibody patterns differed from traditional myocitis, Dr. Love found. For instance, they had a high incidence of unexplained falling, a shawl-patterned rash on their backs and distinctive neck rashes.

Other doctors at Baylor described women with implants who became sick, then had the devices surgically removed. Bernard M. Patten, an associate professor of neurology at Baylor who testified at FDA hearings last year, now says he has seen more than 500 women with implants who suffer from various diseases.

THE WALL STREET JOURNAL.

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MARKETPLACE

Marketing: *AT&T continues to offer credit cards with no annual fees* **Page B5.**

Who's News: *Air Products readies top spot for Harold Wagner* **Page B8.**

Women Find It Difficult to Get Breast Implants Removed

By JOAN E. RIGDON
Staff Reporter of THE WALL STREET JOURNAL

HEALTH

When Cynthia K. Buford decided to enlarge her breasts with silicone-gel implants in 1983, her doctor quickly scheduled surgery and billed her insurance.

But when she decided to get the implants removed after black goo began leaking from her nipples recently, Ms. Buford got a rude shock. Plastic surgeons, demanding cash up front, issued stern warnings about potential disfigurement. One doctor told her to imagine "a very huge fat lady and look at the skin under her arms. That would give" her an idea of what her breasts would look like if she didn't replace the implants after removing them, Ms. Buford recalls. "I came home and cried for three weeks."

In the end, she sought help at a county hospital, which demanded a down payment of $525 on a charge card. The total bill: more than $4,000. (A spokeswoman says the hospital normally asks for the whole fee up front because the surgery is considered cosmetic and shouldn't be funded with taxpayer money.)

Women are finding that it was much easier to get implants than it is to get rid of them. While Esther Rome, a member of the Boston Women's Health Book Collective, says "it's impossible to document" the scarcity of doctors willing to remove implants, she adds that "it seems fairly widespread."

Replacement Implants

Getting the procedure performed is also emotionally draining. Many plastic surgeons predict deformity or encourage women to get replacement implants even if they don't want them. Most also say the procedure isn't medically necessary, so insurance companies are refusing to pay for it. (Some women have persuaded their insurers to pay by bypassing their surgeons and obtaining letters from family doctors and rheumatologists instead.)

Under fire from angry women, one implant maker is offering financial aid to those who want their implants removed. This week, Dow Corning Corp., which is getting out of the silicone implant business, increased its financial aid offer to $1,200 a woman, up from $1,000 in February. (Dow Corning is a joint venture of Dow Chemical Co. and Corning Inc.) Other breast-implant makers declined to comment on the issue of financial assistance or said they haven't decided whether to offer it.

But financial aid is small consolation to women who can't find doctors willing to perform the procedure. Many plastic surgeons are reluctant because they fear lawsuits from other patients: Removing implants is tantamount to admitting they're not safe. Critics charge that the implants can cause or trigger a variety of diseases, ranging from muscle pain to chronic immune disorders.

Even doctors who are willing to extract implants say they are being discouraged from doing so by insurers. One plastic surgeon says his insurance company, Doctor's Co. of Sonoma, Calif., advised him against performing a large number of removals. "They didn't want me to be a potentially higher risk person . . . because it's such a lethal issue right now," the surgeon says. Doctor's Co. says it doesn't charge members more if they perform implant removals.

Stray Silicone

Removing implants can require more surgery than putting them in, because if the implants have ruptured, stray silicone must be scooped out. Polyurethane-covered implants can be especially difficult to remove if the polyurethane has mingled with scar tissue or surrounding muscle tissue.

Women's health groups have been steering women toward a few surgeons who also remove and study scar tissue to see if it

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Dow Corning Says It Will Stop Making Silicone Implants

By STEPHEN POWER
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON—Saying their decision to stop manufacturing breast implants was "strictly business," Dow Corning Corp. officials continued to defend the safety of the devices.

The company, as expected, announced it will stop making silicone gel breast implants and offered to pay as much as $1,200 a patient toward the cost of removing the company's implants. Dow Corning is a joint venture between Dow Chemical Co. and Corning Inc.

Keith McKennon, Dow Corning's chairman and chief executive officer, rejected suggestions that the withdrawal reflected fears the implants may have injured the many women who received them. He also said that the withdrawal won't force any employee layoffs and that women who accept the company's offer to remove implants won't be required to sign agreements releasing the company from liability.

"I made the decision on a business basis only, not on a safety basis," Mr. McKennon said at a news conference. "We continue to receive lawsuits. That's no mystery."

Dow Corning also will finance a $10 million research effort to "answer those remaining questions women may have about the implants," Mr. McKennon said. He said the company will cease providing silicone gel for other implant makers except where it is bound to do so under existing contracts. Dow Corning's "long-term interest is not to be in the business," he said, adding he is unsure how long the company will be contractually bound to make the gel.

Dr. Sidney Wolfe, director of health research for Public Citizen, a Washington-based consumer group, said Dow Corning's offer of $1,200 to help women remove implants might be "inadequate." The cost to remove breast implants runs from several hundred to several thousand dollars, depending on the surgeon's fee and any complications.

Dr. Wolfe also complained that Dow Corning and the Food and Drug Administration failed to determine the safety of implants before they were marketed.

"These products should have been tested before they hit the market," said Dr. Wolfe, a leading crusader against implants. "This whole fiasco has been made possible by the complicit consent of three parties: the manufacturers, the plastic surgeons and the FDA."

He called on the two remaining silicone-gel implant manufacturers, Mentor Corp. of Santa Barbara, Calif., and the McGhan Medical unit of Inamed Corp. of Carpinteria, Calif., to stop making the implants. "If McGhan and Mentor were responsible, they would follow suit and get out of the business," he said.

Officials of Mentor and Inamed were not immediately available for comment.

Separately, a federal court judge in Bridgeport, Conn., granted a temporary restraining order sought by an attorney suing Dow Corning on behalf of a woman with implants. The order directs the company not to destroy any implants or implant components it holds in inventory until a hearing can be held March 30.

Women Are Facing Obstacles in Removal Of Breast Implants

Continued From Page B1

has reacted with the silicone. One such surgeon, Dr. Lu-Jean Feng of Cleveland, has performed almost 100 implant removals on women from all over the U.S. But Ms. Rome of the Women's Health Book Collective says that so far she has searched unsuccessfully for a plastic surgeon in the Boston area who will remove and study scar tissue along with implants or send the tissue and implants to other researchers.

Some surgeons may be reluctant to remove implants for fear they will anger their colleagues or hurt their practices. One Texas woman, who traveled to Florida to have her implants removed in 1990, says her plastic surgeon told her he didn't want to remove too many implants in too short a time because "that would imply there was something wrong with them." The woman, a medical records worker, declines to be named.

Dr. Charles Plows, a member of the American Medical Association's Council on Ethical and Judicial Affairs, says there's no policy on how quickly surgery should be performed on women who want to remove their implants. In general, "valid concerns by patients should be investigated," he says.

The American Society of Plastic and Reconstructive Surgeons says it "applauds" Dow Corning's decision to offer financial aid to women seeking implant removal and encourages members to "further minimize" costs for patients who don't have insurance. It says it will help to arrange doctor visits for women who have lost touch with their plastic surgeons.

Nonetheless, for many women, the quest for removal has become an odyssey. Ms. Buford, whose gel implants were covered with polyurethane foam, says she decided to have them removed after she developed knots in her breasts and "black stuff" began leaking from her nipples. The first plastic surgeon she consulted encouraged her to get replacements.

A second surgeon, Dr. Richard Burkett of Dallas, "told me I would want another set because I was going to look so disfigured" without implants. After comparing the likely result to a fat lady's arms, Dr. Burkett called her at home to repeat his warning that "I would not look right" without implants, Ms. Buford says. Dr. Burkett declined to return several phone calls seeking comment.

Devastated, Ms. Buford waited weeks before consulting another plastic surgeon, Dr. Diane Gibby of Dallas, who told her that surgery would make her flat-chested, not disfigured. "She's the one who started making me feel good about myself again," Ms. Buford says.

But there was another obstacle: Dr. Gibby required $5,000 in cash up front, Ms. Buford says. Unable to pay and no longer covered by insurance, she sought treatment at Parkland Memorial Hospital, a county hospital in Dallas. Her doctor required $1,500 up front but later settled for a $525 down payment made with her American Express card.

Other women say they had to travel long distances for treatment. Patti Scher, a former nursing director who lives in Charlotte, N.C., flew with her husband to Cleveland so she could be operated on by Dr. Feng.

Ms. Scher says that before her implants were removed, she suffered fatigue, blurred vision and night sweats that made her so weak she had to quit her job. Normal errands became Sisyphean tasks. "My family would have to be fed off of whatever I was able to get in the grocery cart in the first two aisles, because I couldn't master the rest," she says. Now, several months after surgery, she says she is feeling healthier.

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Trial in killings to open

GAINESVILLE, Fla. — Residents for the first time will hear details of the grisly mutilation murders of five college students more than three years ago when a career criminal goes on trial in the killings today.

Danny Harold Rolling, a 39-year-old drifter from Shreveport, La., is charged with five counts of first-degree murder, three of sexual battery and three of armed burglary.

The state is seeking the death penalty.

The crimes terrorized this college community in late August 1990 and for months after, and now residents will get their first close look at the evidence collected against Rolling.

More logging may be OKd

WASHINGTON — The Clinton administration, with environmentalists' blessing, is asking a judge to ease a court order so logging can resume in forests that are home to the northern spotted owl.

Twelve environmental groups that won the Northwest logging injunction in 1991 have agreed they will not challenge the request to release a small amount of federal timber for sale, Assistant Agriculture Secretary Jim Lyons said Monday. But Lyons, who oversees the Forest Service, said it marked the first real sign that the government could begin moving some logs from national forests to the mills without violating a series of environmental laws.

Kazakhstan aid to triple

WASHINGTON — President Clinton and Kazakhstan President Nursultan Nazarbayev signed agreements Monday to triple U.S. aid to the former Soviet republic and encourage development of its vast oil reserves.

The announcement of the i crease in U.S. aid came two month after Nazarbayev's government vo ed to dismantle its 1,400 nuclea warheads and become a nuclear-free state.

Standing at Clinton's side in the East Room of the White House, Nazarbayev said he looked forward to the "increased contribution that American business can make to the development of the economy of Ka-

Breast implant makers OK settlement terms

Associated Press

BIRMINGHAM, Ala. — Three major manufacturers of silicone breast implants agreed Monday to pay more than $3.7 billion of a proposed $4.75 billion settlement with thousands of women who claim the surgery harmed or threatened their health.

Some women with health problems from implants could receive up to $2 million each under the agreement, and others who aren't ill could be covered for medical examinations and implant removal, attorneys said.

The settlement must win final approval from the companies involved, then be reviewed by a plaintiffs' advisory committee, and approved by U.S. District Judge Sam Pointer in Birmingham. No date for a settlement hearing was set.

Pointer is overseeing the negotiations between about 20 corporations and attorneys representing hundreds of thousands of implant recipients.

The proposal was welcomed by women like Joy Bryan of Lexington, Ky., who had her implants removed in 1991. She sued over symptoms including joint pain, memory loss, seizures and hair loss.

"It helps to ease the pain of the wrong that has been done to the women of this country," said Bryan.

Opponents of the proposed settlement said lawyers would take too much of it and payments to women wouldn't be large enough.

Gail Armstrong, a spokeswoman for the National Plaintiffs Breast Implant Coalition in Dallas, said a previous order in the case allowed lawyers to take 6 percent of the settlement.

"Everyone wins except the women. The lawyers, the experts, doctors, the companies, everybody gets a slice of the pie. Women get the leftovers," Armstrong said.

Lawyers said the agreement would allow implant recipients to opt out of the class action and sue for damages on their own. The agreement also would allow women who have implants from now-bankrupt companies to participate in the settlement.

Stanley Chesley, a plaintiffs' lawyer, said it was impossible to say how many women may be affected by the settlement since many may not come forward until the agreement is advertised.

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It's a c

Associated Press

NEW YORK — One couple sipped champa other was taking the pl and a third was signin

The check-in line fo left Monday as 31 coup a romantic high — get atop the Empire State Valentine's Day.

"It's so great, so ro thused Laura Lee DiBi before she became Mrs. vello.

After exchanging "I vellos tiptoed off to a ing their half-full cham es, careful not to distu being exchanged a few Ogie Shentov and Lu kova.

And they kept comin new couple every 15 veritable parade of De and Cary Grants ("An member"), Meg Ryan Hankses ("Sleepless Fay Wrays and King

Yes, indeed. Love wa Not to mention the f judge, music, champa and wedding rings wer tesy of a neighborho group.

The wedding windmi near the top of the E Building came courtesy management and the Partnership, a business ples responded to a n offering the free wedd

Of course, love was on Valentine's Day, and really high rooftop in

■ In Valentine, Neb., were married by a ma truly wears her heart o — and back and chest Mary Galloway's red blouse was a clear favo newlyweds.

■ Twenty-eight couple ried in Philadelphia named Goodheart and s a city councilman who round of applause when "Makin' Whoopee."

Preliminary Communication

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.

From the Divisions of Pediatric Gastroenterology and Nutrition (Dr Levine) and Rheumatology (Dr Ilowite), Schneider Children's Hospital, Long Island Jewish Medical Center, Long Island Campus of the Albert Einstein College of Medicine, New Hyde Park, NY.

Reprint requests to Pediatric Gastroenterology and Nutrition, Schneider Children's Hospital, Room 229, Albert Einstein College of Medicine, New Hyde Park, NY 11042 (Dr Levine)

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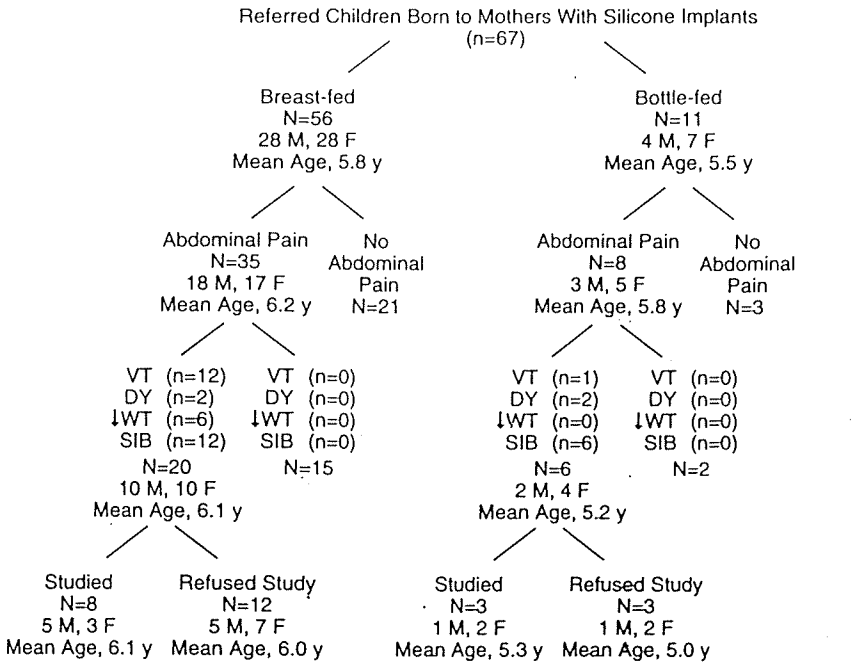

Fig 1.—Clinical examination of children born to mothers with silicone breast implants. VT indicates recurrent vomiting; DY, dysphagia; WT, weight-height ratio; and SIB, siblings with abdominal pain along with recurrent vomiting, dysphagia, or decreased weight-height ratio. The total number of patients 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). Esophageal wave propagation was determined 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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Clinical 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, mm‡
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,[16] 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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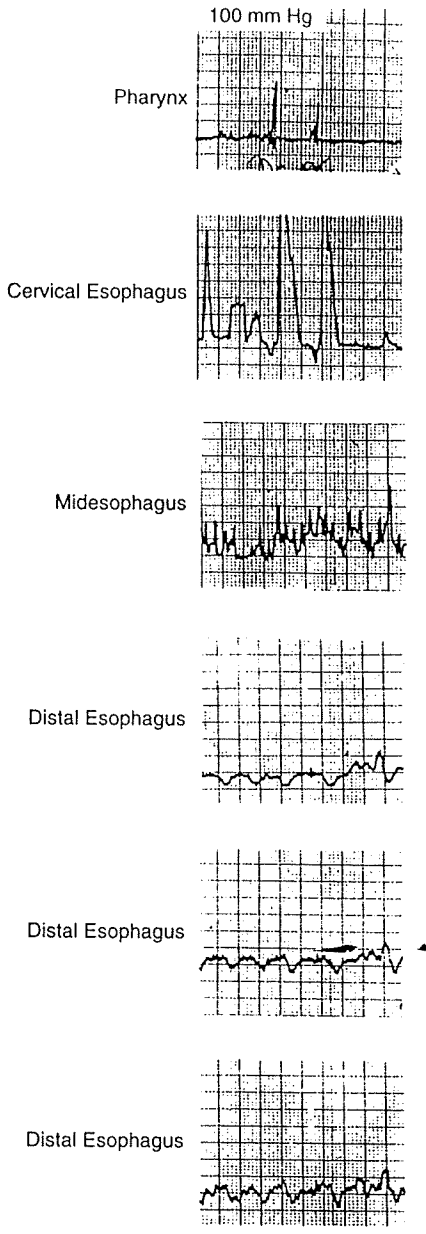

Fig 2.—Esophageal wave propagation after wet and dry swallows in a patient breast-fed by a mother with silicone breast implants. The coordination between pharyngeal contraction and wave propagation into the cervical esophagus was preserved, but no peristaltic contractions propagated into the distal esophagus.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

We thank Howard Trachtman, MD, for his critical review of the manuscript, David Gold, MD, for his review of the manometric data, and Kathryn Moschetti, RN, MSN, for her care and concern for the children.

References

1. Spiera H. Scleroderma after silicone augmentation mammoplasty. *JAMA*. 1988;260:236-238.
2. Varga J, Schumacher HR, Jimenez SA. Systemic sclerosis after augmentation mammoplasty with silicone implants. *Ann Intern Med*. 1989;111:377-383.
3. Brozena SJ, Fenske NA, Cruse CW, et al. Human adjuvant disease following augmentation mammoplasty. *Arch Dermatol*. 1988;124:1383-1386.
4. Sergott TJ, Limoli JP, Baldwin CM Jr, Laub DR. Human adjuvant disease, possible autoimmune disease after silicone implantation. *Plast Reconstr Surg*. 1986;78:104-114.
5. Bridges AJ, Conley C, Wang G, Burns DE, Vasey FB. A clinical and immunologic evaluation of women with silicone breast implants and symptoms of rheumatic disease. *Ann Intern Med*. 1993;118:929-936.
6. Goldblum RM, Pelley RP, O'Donell AA, Pyron D, Heggers JP. Antibodies to silicone elastomers and reactions to ventriculoperitoneal shunts. *Lancet*. 1992;340:510-513.
7. Reiser KM, Last JA. Silicosis and fibrogenesis: fact and artifact. *Toxicology*. 1979;13:51-72.
8. Lugano EM, Dauber JH, Elias JA, Bashey RI, Jimenez SA, Daniele RP. The regulation of lung fibroblast proliferation by alveolar macrophage in experimental silicosis. *Am Rev Respir Dis*. 1984; 129:767-771.
9. Vargas A. Shedding of silicone particles from infected breast implants. *Plast Reconstr Surg*. 1979; 64:252-253.
10. Rodnan GP, Fennell RH Jr. Progressive systemic sclerosis sine scleroderma. *JAMA*. 1962;180: 665-670.
11. Garrett JM, Winkelmann RK, Schlegal JF, Code CF. Esophageal deterioration in scleroderma. *Mayo Clinic Proc*. 1971;46:92-96.
12. Klein HA, Wald A, Graham TO. Campbell WL, Steen VD. Comparative studies of esophageal function in systemic sclerosis. *Gastroenterology*. 1992; 102:1551-1556.
13. Reimer G. Antibodies against nucleolar, and mitochondrial antigens in systemic sclerosis (scleroderma). *Rheum Clinic North Am*. 1990;16:169-183.
14. Caulfield M, Wyllie R, Sivak MV, Michener W, Steffen R. Upper gastrointestinal tract endoscopy in the pediatric patient. *J Pediatr*. 1989;115:339-345.
15. Flick JA, Boyle JT, Tuchman DN, Athreya BH, Doughty RA. Esophageal motor abnormalities in children and adolescents with scleroderma and mixed connective tissue disease. *Pediatrics*. 1988; 82:107-111.
16. Cucchiara S, Staiano A, DiLorenzo C, et al. Esophageal motor abnormalities in children with gastroesophageal reflux and peptic esophagitis. *J Pediatr*. 1986;108:907-910.
17. Goldman JA, Lamm SH, Cooper W, Cooper L. Breast implants are not associated with an excess of connective tissue disease. *Arthritis Rheum*. 1992; 35(suppl):S65. Abstract.
18. Dugowson C, Daling J, Koepsell T, Voigt L, Nelson J. Silicone breast implants and risk for rheumatoid arthritis. *Arthritis Rheum*. 1992;35(suppl): S66. Abstract.
19. Sanderson IR, Walker WA. Uptake and transport of macromolecules by the intestine. *Gastroenterology*. 1993;104:622-639.
20. Lawton AR, Cooper MD. Development and function of the immune system. In: Stiehm ER. *Immune Disorders in Infants and Children*. 3rd ed. Philadelphia, Pa: WB Saunders Co; 1989:1-14.
21. Gray RG, Altman RD. Progressive systemic sclerosis in a family. *Arthritis Rheum*. 1977;20:35-41.

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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5. **Human Carcinogenicity**

Carcinogenesis has been widely discussed as a reputed risk secondary to implantation of any material. Evidence from the literature indicates that in animal studies, different forms of silicone have been associated with various types of cancer. Cases of several types of cancer in humans have been reported in association with various forms of implanted silicone.

6. **Human Teratogenicity**

Teratogenesis includes the origin or mode of production of a malformed fetus and the disturbed growth processes involved in the production of a malformed fetus. Studies using silicone fluid in animals have been minimal, and yield contradictory and inconclusive results. Prolonged contact with the silicone membrane and its components might present a potential risk of teratogenicity in humans.

7. **Adverse Immunological Effects and/or Connective Tissue Disorders**

Adverse immunological effects and/or connective tissue disorders may be a serious risk associated with the implantation of a silicone inflatable breast prosthesis. These problems have been discussed related to the use of silicone gel-filled prostheses and silicone injections in augmentation mammaplasty. There are clinical reports of several patients who have undergone augmentation mammaplasty with silicone gel-filled breast prostheses and who have presented with connective tissue disorders. Because the silicone inflatable breast prosthesis may contain a similar elastomer rubber shell, prolonged contact with this prosthesis presents a potential risk of adverse immunological effects and/or connective tissue disorders in humans.

8. **Calcification**

Calcification of the fibrous capsule surrounding the implant involves the deposition of mineral salts in the capsule and may compromise interpretation of mammographic films and contribute to diagnostic errors or delays in diagnosis of cancerous lesions.

9. **Biological Effects of Silica**

Amorphous (fumed) silica is bound to the silicone in the shell and may be fibrogenic. Fumed silica and the silicone shell each elicit cellular responses in rats. The biological effects of silica present a potential risk.

I have read this and have had my questions answered as a prerequisite to being implanted with saline-filled silicone implants.

_____ _____

Signature Witness

Date:_____

Source: Food & Drug Administration Letter

AHH
2/15/94
7-14

My name is Carrie, I could be your daughter, your son's wife, your grandchildren mother.

At the age of 16, on the advice of my physician and a specialist I received a set of silicone breast implants to correct a birth defect. Living through the birth defect was a nightmare, living through the cure is my greatest hope.

I was your typical farm girl growing up in rural Kansas USA. The decision my mom and dad made to correct my birth defect was not an easy decision, they thought looking like all the other girls would allow me a full life. The specialist assured them that the implants would last a life time and that he had implanted women for years and had no complaints or problems.

Let me tell you what this specialist did not tell my parents:

1. Silicone gel in its original form began as transformer coolant. They simply changed the label to read "Medical Grade Silicone".

2. Silicone implants have a life of 4 to 7 years.

2. Less than 1/2 oz. of silicone mixed with fluids in the human body then has a contact surface area capable of contaminating 147 acres of land.

3. All implants leak gel some as soon as 24 hours of implantation.

4. Breast Implants interfere with mammography.

Because my parents were not informed their daughter has A-Typical Myasthenia Gravis, silicone human adjuvant breast disease, Toxic Chemical Poisoning, Lung Disease, Altzhelmer like Disease from Brain Damage, to put it mildly my life has been shortened. The final blow is my three children have been exposed to the silicone in my body and it may also shorten their lives.

There are 1 million women and the children they will conceive and nurse who were not informed, there are 60,000 little boys with testicular silicone implants who were not informed, there are 100,000 men with penial silicone implants who were not informed.

Informed Consent would give all of us the right to decide our futures. Informed Consent will save thousands from being expermintal guinea pigs like me and my three children.

Ladies and Gentlemen Please read "THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS" **WE ALL NEED TO BE INFORMED FOR YOU MAY SAVE THE ONES YOU LOVE**

Senate 7141
2-15-94
7-15

Cover Story

Carrie Shearburn

.ie Watson

Carrie may not live long enough to see her eldest child graduate. Her baby might not either.

When she was 16, on the advice of her physician and a specialist, Carrie had silicone breast implants inserted in her body to correct a deformity. Living through the deformity was a nightmare. Living through the cure is her greatest hope. There are no guarantees.

She was a typical farm girl growing up in rural Kansas USA. At age eight, she drove the tractor on her family's farm.

"My brother steered, I shifted," she laughs.

She made average to good grades in school and showed some talent with numbers. Once she heard a phone number, she never had to look it up again. She could even remember the numbers of her childhood buddies. She earned a music scholarship. But she chose marriage over college and went to night school later.

Made of good pioneer stock, she valued her self-sufficiency. When things go wrong on a farm, you fix it, you hold it together with bailing wire, or you work harder. She and her husband worked, went to night school, raised two kids. When the marriage failed and finances got tough, she worked three jobs. It wasn't in her to ask her parents for help.

Looking back now, Carrie can see the early signs of trouble. She would forget simple instructions at work. She'd have to look things up. She couldn't remember being asked to do something. As the trouble became worse, it was not just an annoyance anymore. It was costing her her job; one job after another. Her memory was failing. She and her husband would fight over things he said he told her and she'd swear he didn't. She was in a wreck and didn't remember it happening. She'd promise to do something for the kids; they'd count on it, she'd forget. Her parents couldn't understand, they thought she was on drugs.

"My dad..." Carrie trails off, beginning to cry. She'd always worked to make him proud.

"Some days I'd wake up and I'd forget I had kids," says Carrie sobbing. Talking about the kids is the roughest part.

Her body was acting weird, too. She was always exhausted, even after a night's sleep. She would have "the flu" for months on end. Rashes would "bloom" from her neck across her face. Her joints would ache. Her muscles hurt. Sometimes it would be so painful to walk that she would have to crawl to take care of her sick baby. Doctors didn't have a clue.

After years of wondering if she was losing her mind, wondering if she could withstand another day of torturous pain, it was Carrie, herself, who discovered that her implants were sabotaging her body.

She was home sick watching TV, something she was usually too busy to do when she was well. A talk show was on about the adverse effects of breast implants. Carrie immediately recognized the symptoms the guests on the stage were describing, but it was when an audience member stood up that Carrie almost panicked.

"They're not telling you the half of it," the woman said. "They aren't telling you that you have passed this on to your kids!"

Carrie was terrified, but she knew she had to be calm, to get information; not fly off the handle. She called the manufacturers of her implants for their side of the story. The lady on the phone reassured her. Studies had been done that show implants are safe. There are other factors that cause the symptoms.

Another sick day, another talk show. This time Donahue. There was just too much to be coincidence. It was months before Carrie could find a doctor to address her concerns about the implants.

"It was the happiest day of my life, " she says. "It wasn't my fault. I wasn't going crazy. It was the implants!"

She wanted them removed but had no job, no money, no insurance. She was on welfare and had to ask her folks for help. She found an attorney who now handles more than 350 breast implant cases. He helped her find doctors who would donate their time and let her make payments to pay for the other costs of surgery.

The implants are out now, but the damage continues. Today Carrie suffers from Myasthenia Gravis, a degenerative muscle/nerve autoimmune disease, adjuvant breast disease, joint pain, skin rashes and Alzheimer's-like symptoms from brain damage. Her two older children wake up with headaches and have severe cramping and constipation. Her youngest, she breast fed (her doctor said it was safe), threw up blood and had blood in his stools. The prognosis for children who suffer from Silicone Toxicity, from breast feeding or passed on through the placenta, is not known.

Through her attorney, Carrie learned of other women in the Wichita area who are going through the same nightmare. They began to get together for lunch, to compare notes, to reassure each other. It helped, but it wasn't enough. They are pressing on. Called "Survivors" of silicone implants, these women have risked ridicule to come out of the closet to help other survivors and to save others from making an uniformed decision that could be life threatening to them and to their children. More than 100 women attended their first meeting in Wichita.

They have their work cut out for them. Insurance companies won't pay for taking implants out. Families are failing under the financial strain. Medical facilities are withholding records.

The survivors are asking that the FDA require silicone gel (and probably saline) implants to be recalled, and that insurance companies be required to pay for taking implants out with no questions asked.

"We can safely say that none of us wanted to file law suits and be privately invaded," the Survivors wrote in their first newsletter, "but when your medical needs exceed $130,000 a year, then find out your children are afflicted with toxic substances, you need to know your rights. . . Our greatest hope is that you are not one of us!"

Editors note: More information is available from Survivors, P.O. Box 780801, Wichita, KS 67278-0801. Their next meeting is June 30, 6:30 p.m., at John Knox Presbyterian Church (9th and Armour) in Wichita.

FEBRUARY 15. 1994

TO WHOM IT MAY CONCERN:

IN OCTOBER 1977 IN GREAT HEALTH .I HAD SILICONE IMPLANTS PUT IN TO HOPEFULLY HELP MY SELF ESTEEM.

I WAS TOLD BY THE DOCTOR THAT THEY WERE SAFE AND WOULD LAST A LIFETIME. I WAS NEVER TOLD ANY OF THE DANGERS OF SILICONE OR OF ANY TESTING DONE ON ANIMALS AND I WAS NEVER SHOWN THE PACKAGE INSERT.

WITHIN TWO YEARS OF HAVING THE IMPLANTS I BEGUN HAVING SEVER HEADACHES AND LUNG INFECTIONS THAT COULD NOT BE TREATED WITH ANTIBIOTICS. CHRONIC FATIGUE AND JOINT PAIN. I WOULD GET THESE RASHES AND BLISTER ON MY BODY ESPECIALLY IN THE CHEST AREA. MY HEALTH CONTINUES TO GO DOWN HILL.

DOCTORS HAVE DIAGNOSED ME WITH MANY DISEASES AND I HAVE DECREASED BRAIN ACTIVITY WHICH CAUSES ALZHEIMER'S LIKE SYSTEMS. DOCTORS SAY THEY ARE CAUSED FROM SILICONE ASSOCIATE DISEASE.

MY PLASTIC SURGEON SAID IT WAS MEDICALLY NECESSARY FOR ME TO HAVE THE IMPLANTS REMOVED . HE WROTE A LETTER TO MY INSURANCE COMPANY STATING ALL OF MY SURGERY PROCEDURES WERE MEDICALLY NECESSARY. HOWEVER THEY ONLY PAID A ABOUT 1/4 OF MY 4.500.00 BILL.

I ALSO HAVE HIGH TREATMENT BILLS WHICH IS NOT ALL COVERED. WE ARE IN THE PROCESS OF PUTTING OUR HOUSE ON THE MARKET TO HELP PAY FOR MY MEDICAL TREATMENTS.

PLEASE HELP US.

THANK YOU

CYNTHIA K. STEWARD
1036 POST OAK RD.
WICHITA. KS 67206

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Attachment #8

LINDA THOMAS

40121 PLEASANT VALLEY RD.

LANE KS 66042

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Attachment # 9

October 16, 1974, I had surgery 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, but 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 device.

June 4, 1991, I was told by a plastic surgeon that I had a rupture of the left breast implant; he also told me it was nothing to be concerned about; I saw this same surgeon again when the Food and Drug Administration announced it's moratorium on breast implants. He told me the moratorium was purely political, and it was nothing to be concerned about; he said that silicone gel breast implants would not be off the market very long, and recommended that I see a rheumatologist for my various health complaints.

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I found another surgeon willing to assist me in getting the implants removed, because I had the symptoms of silicone poisoning. He sent my insurance company, Blue Cross/Blue Shield of KS, a letter for preaproval for the surgery, but there were weeks of foot dragging by my insurance, and no response to my surgeon's calls; he was concerned that he might upset the insurance company if he called too often. When I called my insurance, I was told that they were still determining the medical necessity of the procedure.

Absolutely frustrated, and extremely ill, I called the Insurance Commissioners office. The individual I spoke to felt it sounded like an emergency to him, and my surgery was approved that day.

For years I've paid for health insurance believing I was adequately protected, but when I needed my health care coverage, I found myself not only very ill, but I had to fight for every cent of the coverage I needed; coverage I thought I had paid for to protect myself from unexpected illness, or injury.

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I've heard that since my insurance approved my implant removal request, other injured women have not been as fortunate with their insurance assisting them in removing this hazardous device from their poison stricken bodies. I find the insurance companies attitude curious, since we now know, the silicone gel filled device was fraudulently marketed, and this implant device can contain as much as 95% liquid silicone, and it is contained in a very thin, permeable silicone elastomer shell, that is not much thicker than an ordinary condom; liquid silicone injections were outlawed by the Food and Drug Administration many years ago. Thus, is it not reasonable to assume that liquid silicone delivered into the body, regardless of how it is transported into the human body, is dangerous?

(Even though silicone injections were outlawed many years ago by the FDA, some physicians have continued injecting silicone.)

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.

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Because of my unusual neurological difficulties, I went to Houston TX, to see a neurologist with knowledge of this disease, Dr. Bernard Patten. I had attempted to obtain pre-approval weeks in advance of my appointment, because of my symptoms I was certain Dr. Patten would hospitalize me. My health insurance again give me the run around; my insurance responded after I again called the Insurance Commissioners office; my insurance requested that Dr. Patten list what tests he wanted run, but Dr. Patten could not give that information before seeing me.

12-8-92, I flew to Houston for my appointment with Dr. Patten on the 9th. After the examination, Dr. Patten stated he wanted to admit me to the hospital for further testing. My insurance was again notified for pre-approval, and again the run around ensued; I sat in a hotel room all week, finally my insurance approved me for one day; I was in the hospital nine days. My insurance wanted Dr. Patten to list up front all the tests he was going to run, but he explained that what I needed would be determined by what each test indicated I needed, and he could not tell them what I needed before the fact. I did not know that my insurance refused to approve me for more than one day until I checked out of the hospital on the afternoon of the 22nd of December, 1992. I had to fight my insurance for a year before getting them to pay my hospital bills in Houston; they maneuvered, manipulated, and they were caught in an outright lie--they stated they paid what Blue Cross allowed in Texas; they did not. It has been a tremendous strain on my health, and my family, but the maneuvering to keep from paying my medical claims did not end there.

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Dr. Patten had given me a prescription for Gamma Immune treatments. I gave the prescription to a local neurologist, Dr. Samuel Lehman; Dr. Lehman made arrangements with an oncologist, Dr. David L. Lee, to give me the prescribed treatments. Dr. Lee's office stated they had to obtain pre-approval for the treatments; pre-approval was given, and I received my last infusion 2-22-93. However, I received a letter dated April 6, 1993, from my insurance addressed to Dr. Lee, stating my insurance was reveiwing the medical necessity of this treatment; **this had already been pre-approved!** I was told by someone on Dr. Lee's staff, that this behavior by B.C. & B.S., ad been a ongoing problem; I didn't ask for details of the situation. Meanwhile, I'm extremely ill, and I had to straighten out this outrageous, and unnecessary mess.

Another problem I had with my insurance, and it's a difficulty any consumer may unexpectedly find themselves having to contend with, is the Caps (cost limitation). My insurance has set limits on what health care providers can charge, which wouldn't be a problem, if they would work this out between themselves. However, the consumer is the one to have this unexpected cost burden dumped on them. Consumers are not told what these limits are, so even if all your

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deductible have been met, you may still, unexpectedly find yourself deeply in debt. This is an undue burden on consumers who can not work, or for someone on a fixed income. I personally have nearly exhausted my savings; I need more surgery due to my injuries from the defective medical devise that injured me, but at present I can't afford to pay the deductible; I can not work, and because of the early onset of my illness, I am not eligible for benefits. I have been seriously injured by the negligence, and fraud of someone else, but the burden of my medical expenses has been placed on me, and my family.

I fortunately obtained my surgical records from the 1974, breast surgery, before important information was destroyed. I called medical records, and 2-12-92, I sent a written request for my records. The records were in storage, and I was told it would take a week to retrieve them. I waited a week, and I called back to see if they had retrieved my medical records; they had. At the time I was seriously ill, and having extreme difficulty walking, but I sensed it was imperative I pick those records up immediately. My instincts were correct, because my written request was returned March 27, 1992, stating they could not identify this patient. I sent a second records request for the same medical records sometime later; I received from them one page from my medical records with an attached statement that the one page was all they could find.

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The silicone gel breast implant was my third medical device injury to occur from a 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. A recent example I can use to illustrate my concerns, is in 1985, plastic surgeons were <u>required</u> to give women the package insert that accompanied the breast implant device. Physicians were to give this package insert to women containing information on the potential health risks, but physicians either didn't bother to give women the information, and those who did give women the information, expressed their personal bias, thus misleading women to believe the device was actually safe.

Consumers need and deserve the protection of informed consent, because medical manufacturers, and <u>some</u> physicians are aloof to the human suffering they create; profit has priority, but some physicians are merely inept.

I unknowingly used the I.U.D. device twice, because my physician <u>chose</u> 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.

The assumption that all physicians will in act in the consumers best interest has proven to be an erroneous assumption, and consumers deserve protection from these few.

My resulting medical status from using the defective medical devices:

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

Silicone gel breast implants, one set, 18 year exposure - 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 headaches.

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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.

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. I remain seriously ill.

I wish to thank you for allowing me to share with you, my situation, my story, my thoughts, concerns and wishes.

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the voice of Nursing in Kansas

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FOR MORE INFORMATION CONTACT:
Terri Roberts J.D., R.N.
Executive Director
700 SW Jackson, Suite 601
Topeka, Kansas 66603-3731
913-233-8638
Date: February 15, 1994

S.B. 682 Concerning Insurance, Coverage for Certain Breast Implant Removals and Related Conditions

Chairperson Bond and members of the Senate Financial Institutions and Insurance Committee my name is Pamela Tapp Byl M.N., R.N. I am a Clinical Nurse Specialist and Clinical Director of a local women's health center that performs over 600 mammograms a month. I represent Kansas State Nurses Association and speak in support of SB 682.

Kansas State Nurses Association was recently contact by the Wichita Area Support Group for Silicone Breast Implant with a membership of over 200 women who have an illnesses directly related to silicone implants and obviously women throughout the state are dealing with the effects of silicone related diseases.

The facts related to the FDA's regulation of silicone breast implants are illuminated in the Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations:

1. The FDA ignored warnings about the need to regulate breast implants for more than 12 years.

2. Scientists have been concerned about the risks of connective tissue/autoimmune disorders since 1975.

3. Physicians, engineers, and employees of implant manufacturers have been concerned about breakage and leakage of silicone gel implants since the 1970's.

4. FDA ignored their own scientists' advice to reject manufacturers PMA applications in 1991

5. Professional pro-implant lobbyists included former FDA officials and provided patient lobbyists with misleading information.

6. Manufacturers have never provided proof of safety to the FDA.

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7. FDA officials and manufacturers prevented the 1991 FDA breast implant advisory committee from considering crucial safety information.

8. FDA concerns about cancer led to the removal of breast implants covered with polyurethane from the market in 1991.

9. The 1992 FDA advisory panel lacked crucial information about interference with mammography and other problems.

10. 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.

11. Patient have been misled about he safety of breast implants for at last the last 15 years.

For whatever reason women chose to have breast implants, be it for cosmetic enhancement or breast reconstructions following cancer, they assumed that a surgical implant device was safe and certainly would not lead to disease. It is reasonable to expect insurers to cover removal of these devices when in fact they have been found to be linked to disease in a significant number of women.

We urge your favorable passage. Thank you.

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