Approved: 2-24-94
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE

The meeting was called to order by Chair Sandy Praeger at 10:00 a.m. on February 15, 1994 in Room 526-S of the Capitol.

All members were present except:

Committee staff present: Norman Furse, Revisor of Statutes
William Wolff, Legislative Research Department
Jo Ann Bunten, Committee Secretary

Conferees appearing before the committee:
Gina McDonald, Executive Director, Kansas Association of Centers for Independent Living, Topeka
Senator Pat Ranson
Dr. Carol Konek, Associate Professor at the Center for Women's Studies, Wichita State University
Carrie Shearburn, El Dorado
Colleen Conte
Lori Callana, General Counsel, Kansas Medical Mutual Insurance Company
Edward J. Hund, Kansas Trial Lawyers Association
Nikki Adams, Kansas Health Information Management Association
Sharon Godfrey, Allen County Hospital, Iola

Others attending: See attached list

Presentation: Kansas Association of Centers for Independent Living

Gina McDonald, KACIL, addressed the Committee as a representative of a statewide health care reform coalition that is advocating a health care plan that will provide coverage to all Kansans as outlined in her written testimony. (Attachment 1)

During Committee discussion, Ms. McDonald noted that the 403 Commission's health care plan better addresses the needs of her coalition than any other state plan. She commented that the coalition's experience with a bill the legislature passed a few years ago that allowed rehab agencies to join the state health care system had a negative effect because as they began to negotiate with the state health insurance agents, they found out that centers for independent living, which are like small businesses, couldn't afford the premiums and in many cases were blocked out because there were too many people with disabilities. She noted there needed to be creativity to fund a single payer plan in order to make it less costly than the present situation, however, when questioned by a member if her organization had a plan for funding any type of health care reform at the state or national level, she stated they did not.

Hearing on:

SB 683 - Person licensed to practice medicine and surgery required to provide patient prior to a breast implant certain information relating to the procedure and

SB 684 - Access to medical records; limitation on fees for copies; waiver of privilege

Senator Pat Ranson, sponsor of **SB 683** and **SB 684** appeared before the Committee in support of the two bills. **SB 683** would require each physician licensed to practice medicine and surgery to inform a patient of the risks, advantages and disadvantages of a breast implant prior to the operation. The Kansas Board of Healing Arts would be responsible for the publication of a standardized summary concerning breast implants, which would be distributed to each hospital, clinic and physicians's office that performs the procedure. The bill would require this information to be supplied to the patient at least five days prior to the surgery and that the patient sign a written consent form acknowledging receipt of this information. The bill would enable the Board to revoke, suspend or limit a physician's license if these information requirements are not met. **SB 684** would entitle any person who has been a patient of a physician, medical care facility or other health care institution to obtain access to information contained in the person's medical records. The bill limits the copy fee for these records to not exceed

$.10 for each page. These provisions would not pertain to psychiatric records unless a court orders them to be opened.

Senator Ranson read a letter from Attorney General Robert T. Stephan in support of **SB 683 and SB 684**. A Task Force on Silicone Induced Disease was formed on August 13, 1993, and chaired by Dr. Carol W. Konek, Wichita State University. The task force came about as a result of a number of conversations with women in Wichita who were afflicted with silicone induced disease and were seeking assistance in trying to find answers to the problems faced as a result of silicone breast implants. (Attachment 2)

Dr. Carol W. Konek, WSU, addressed the Committee and noted that part of the issue of curtaining health costs and spreading increasing access to health care has to do with education of the public about their bodies, health solutions and beauty aids that are available to them. Unless informed consent is made mandatory, she noted that the system is perpetuated where people practice in a realm of independency, and that health consumers should not be entirely dependent on others for making reasonable informed decisions of their own well-being.

Carrie Shearburn and Colleen Conte testified before the Committee in support of **SB 683**, each telling about their experiences with silicone breast implant surgery. (Attachment 3 and 4)

Liz Dudley, R.N., Wichita, appeared in support of **SB 683**, and noted that the real issue here for the women is informed consent. It was pointed out that the women were all told by their physicians that silicone implants were totally safe and would last a life time. Ms. Dudley expressed support for **SB 684** as well. In answer to a member's question as to what would happen if this type of legislation was enacted and women still chose to have silicone breast implant surgery, Ms. Dudley stated that it would be at their risk as they would have been fully informed.

Lori Callahan, general counsel, KaMMCO, testified before the Committee as a neutral party on **SB 683** and **SB 684**. In regard to **SB 683**, Ms. Callahan noted that as a medical malpractice company, KaMMCO is concerned with language in the bill that changes common law rather than codifying it. In New Section 1 (a) the bill requires physicians to inform their patients of the "advantages, disadvantages, and risks associated with a breast implantation." She noted that this appears to be codification of common law which requires informed consent before a physician can perform breast implantation, and that language in **SB 683** is different than the common law obligation. A balloon of the bill was provided with proposed amendment. (Attachment 5)

Lori Callahan addressed three components of **SB 684** of concern as noted in her written testimony - the bill would eliminate the ability of physicians to exercise their medical judgment in attempting to best treat their patients thereby precluding access to mental health for many patients, and that the medical record copying cost provision does not include the cost of someone in the physician's office to make the copies or the physician's time to review them for psychiatric records. (Attachment 6)

Edward J. Hund, representing the Kansas Trial Lawyers Association, appeared in opposition to **SB 684** noting that the bill is really contrary to the principles and advancements of the provisions in **SB 683**. He noted that his organization has no objection to the free and open access at a reasonable cost of medical records, and two examples were given in his written testimony of the billing practices of two Wichita hospitals where excessive charges tend to deny patients access to their own records. The Kansas Trial Lawyers Association believes that the matter should be handled in a separate bill and oppose the regressive portions of **SB 684** regarding ex parte communications with physicians. (Attachment 7)

Nikki Adams, representing Kansas Health Information Management Association, and Sharon Godfrey, Allen County Hospital and member of the Kansas Health Information Management Association's executive board, appeared before the Committee in opposition to **SB 684** stating basically that the charge of $.10 a copy was not enough for copying medical records, (Attachment 8 and 9)

The meeting was adjourned at 11:10 a.m.

The next meeting is scheduled for February 16, 1994.

GUEST LIST

COMMITTEE: SENATE PUBLIC HEALTH & WELFARE DATE: 2-15-94

NAME	ADDRESS	COMPANY/ORGANIZATION
GEORGE E. COLLINS	OLATHE	K.C.D.C.
MARTHA GABEHART	TOPEKA	KCDC
Ed Hunt	Wichita	K.T.L.A.
Richard Nustan	Topeka	V
[illegible]	Wichita	State Farm Ins Co
Rosemary Sorg	Topeka	TILRC
Sandy Buschling	CLAY CENTER	
Joe Poeting	Topeka	Families Together, Inc.
Josie Torrez	Topeka	Families Together, Inc.
Christy Walka	TOPEKA	KCDC
Sharon Joseph	Overland Pk	KCDC
Wendell Lewis	Topeka	KPCDD
Jan Ray	Topeka	Ks Housing Council on DD
Vicki Adams	Wichita	HCA Wesley
Margaret Zillmyer	Topeka	SRS/DMS
Gene Stephens	DSOB - Topeka	SRS/DMS
Chip Wheeden	Topeka	KS Medical Soc.
KEITH R. LANDIS	TOPEKA	CHRISTIAN SCIENCE COMM ON PUBLICATION FOR KS
Richard Rieger	TOPEKA	KAOM
[illegible]	Topeka	Senate Staff
Sharon Huffman	Topeka	KCDC
David Herzlich	Topeka	KS Dental Assn
Alice Pratt	Topeka	KDOA

GUEST LIST

COMMITTEE: SENATE PUBLIC HEALTH & WELFARE DATE: 2-15-94

NAME	ADDRESS	COMPANY/ORGANIZATION
Roberta McAlister	Moline Kans	
Liz Dudley RN	Wichita, KS	Plaintiff steering committee MDL
Kay Stewart	Wichita KS	AG Task Force
Colleen Conte	Fredonia	" "
Joanne Emberg	Hutchinson	
Ray H. Bell	Topeka	Topeka AIDS Project
ALAN COBB	Wichita	Wichita Hosp. Labs
Sharon Godfrey	Iola, KS	Ks Health Info Managers Assoc
Joe Turgeon	Topeka	KCA
Bob Williams	Topeka	Ks. Pharmacists Assoc
Mary Ellen Conlee	Wichita	St Francis Reg. Med. Center
Michael R Odell	Lawrence	Health Care Coalition
Jean P. Hall	Independence, Inc. 1910 Haskell Ave. Lawrence	" " "
Sandy Strand	Lawrence	KUH

TESTIMONY TO

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

FEBRUARY 15, 1994

SENATOR SANDY PRAEGER, CHAIRPERSON

Thank you for the opportunity to address you today. My name is Gina McDonald. I am the Executive Director of the Kansas Association of Centers for Independent Living in Topeka, Kansas. Today, I am representing a statewide health care reform coalition that includes over 100 agencies.

The coalition that I represent believes that there is indeed a health care crisis in this country. According to the United States census bureau, there are more than 49 million Americans with disabilities. Of those, 34 % are not covered by private health insurance. Of people who experience significant disabilities, 43% have no private insurance. That is far above the 25% of all Americans that are not covered.

There is indeed a health care crisis when people who cannot afford enormous premiums go without health care until their situation escalates to require costly emergency room care. There is indeed a crisis when people with disabilities are promised equal rights to employment, but are afraid to accept a job because they will lose their medicaid benefits and know that they will not be covered by the company's plan.

Let me share a story with you. I know a farmer in a small town in Kansas who has three children, one of whom has a disability. He cannot get health insurance for his family because of his disabled child. Even when he tried to get coverage for the rest of the family and not include the child with the disability, he was turned down. He attempted to get Medicaid benefits for his child but was turned down because he owns land and therefore has too many assets. His options are to lie to the insurance company and not reveal that he has a child with a disability, which he will not do; get a divorce and take custody of all his land and his two non-disabled children and give his wife custody of their disabled child, who would then be eligible for Medicaid; or he can put his child in an institution where she will get health care at a cost to the state and federal government of about $100,000.00 per year. The cost to the child with the disability would be her future.

None of these options are acceptable, and none of these

Senate PH&W
Attachment #1
2-15-94

options are consistent with the promises of equal rights and inclusion that have been made to people with disabilities by both Democratic and Republican administrations. There is indeed a health care crisis when we can claim that we have the best health care in the world but not all of out citizens can afford to access it.

The coalition that I represent is advocating for a plan that will provide coverage to all Kansans.

A plan must have:

- Universal and lifetime coverage with no exclusions for pre existing conditions, no caps on services. Universal access is what we currently have and it does not work. If people with disabilities and their families are to truly have universal coverage, there can be no exclusions and no lifetime caps.

- Portability. An individual must have the option of changing jobs, or moving to a different county without fear of a change in benefits.

- Comprehensive coverage to include: long term care, acute and preventative services, community based services, prescription drugs, habilitative services and equipment, mental health coverage and durable medical equipment.

- Cost containment, affordability and community rating.

- Choice of physicians.

- Quality Assurance.

- Simplicity and efficiency

- Consumer involvement in all phases of development and implementation.

People with disabilities and their families represent a minority that continues to grow daily as society ages and technology improves. One in six Americans will have a disability at some point in their lives. If you design a package to meet the needs of people with disabilities, you will meet the needs of all Americans at all stages of their lives.

Thank you for the opportunity to speak with you today. I would be happy to attempt to answer any questions.

PRINCIPLES OF HEALTH CARE REFORM

Reflecting the Needs of People with Disabilities and All Citizens

Whereas one in every six Americans experiences a disability; and

Whereas the needs of people with disabilities provide a litmus test for the effectiveness of the health care system; and

Whereas the health care needs of people with disabilities are not currently being met;

We, the undersigned, *being organizations that advocate for the needs of people with disabilities* and/or groups with similar needs, do hereby declare our solidarity on the following basic principles that must be included in health care reform:

- Universal and lifetime coverage, with no exclusions for pre-existing conditions, no caps on services, and portability.
- Comprehensive coverage to include: long term care; acute and preventative services; community-based services; prescription drugs; habilitative services and equipment; personal assistance services; mental health coverage; and durable medical equipment.
- Cost containment, affordability, and community rating
- Choice of physicians
- Quality assurance
- Simplicity and efficiency
- Consumer involvement in all phases of development and implementation

Signed this 7th day of February, 1994.

Martha Galehart
Kansas Commission on Disability Concerns

Gina McDonald
Kansas Association of Centers for Independent Living (KACIL)

Glen Yancey
Kansas Rehabilitation Services

Ivan Rhys
Kansas Planning Council on Developmental Disabilities

Lucille Parks
Kansas Association for the Blind and Visually Impaired

Terry Larson
Kansas Alliance for the Mentally Ill

Patricia S. Sendel
Families Together, Inc.

Kay Bell
Topeka AIDS Project

Thomas W. Laing
Kansas Association of Rehabilitation Facilities

Michael R. Todd for P. Hall
Independence, Inc.

Michael Byington
Kansas Deaf-Blind Program

Marty Wooten
Southeast Kansas
Independent Living, Inc.

Jean Head
Independent Living Center of
Southcentral Kansas, Inc.

Brian M Atwell
Living Independently in
Northwest Kansas, Inc.

Ray Petty
Full Citizenship, Inc.

Thomas L. Robinson
Western Kansas Association
on Concerns of the Disabled

James W. Blume
Developmental Services of
Northwest Kansas, Inc.

Mark D Elmore
Johnson County Mental
Retardation Center

Ted Fobin
Northview Developmental
Services, Inc.

Leonard L. Laberge
Rainbows United, Inc.

Lois Reid
Achievement Services for
Northeast Kansas, Inc.

Don Pendergast
Arrowhead West, Inc.

Don L. Coldren
COF Training Services, Inc.

Judy Hearn
Kansas Elks Training Center
for the Handicapped

Thomas J. Rohleder
Futures Unlimited, Inc.

Merlee Larson
Sheltered Living, Inc.

Lottie G. Webster
Bethphage Mission of the
Great Plains, Inc.

David M. Klaus
Kansas Association of
Mental Health Centers

Barb Jones
Accessing Southwest
Kansas, Inc.

Dan O'Rourke
The WHOLE PERSON, Inc.

Bruce W. Nauer
Kansas Commission for the
Deaf and Hard of Hearing

Lisa Parlay
The ARC of Kansas

Jim Taiber
The Capper Foundation

Janet B Thompson
Cerebral Palsy Research
Foundation of Kansas, Inc.

Jay [illegible]
Occupational Center of
Central Kansas, Inc.

Linda Lock
Brown County Developmental
Services, Inc.

Dr. Stanley Ulm Jr.
Wyandotte Developmental
Disabilities Services

Tom L. Klaus
Tri-Valley Developmental
Center, Inc.

Willie B Gray
Lakemary Center, Inc.

Laura Sauder
Starkey, Inc.

Alice M Hackney
Nemaha County Training
Center, Inc.

Edward Hummel
STEPS, Inc.

Jack Sturman
Tri-Ko, Inc.

William V. Fleming
AARP Kansas State
Legislative Committee

1-4

STATE OF KANSAS

OFFICE OF THE ATTORNEY GENERAL

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

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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

Senate PH&W
Attachment #2
2-15-94

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.

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

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-

Please Turn to Page B8, Column 6

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.

24

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.

FRIDAY, MARCH 20, 1992 B1

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

HEALTH

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

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

Please Turn to Page B5, Column 5

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.

2-7

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 vot ed to dismantle its 1,400 nuclear 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.

Congress, feeling an urge to ... nd, ... y'

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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 — gett 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."

2-8

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.

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2-9

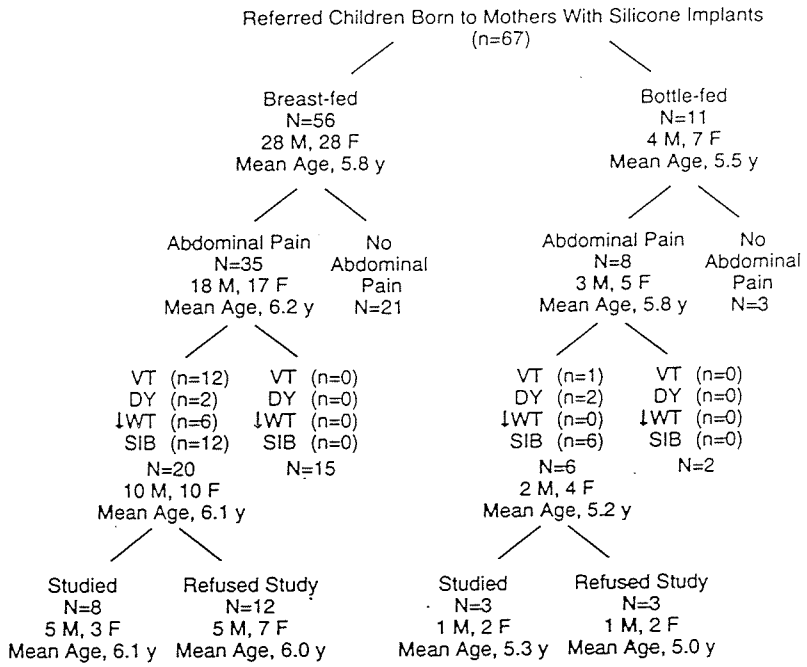

Fig 1.—Clinical examination of children born to mothers with silicone breast implants. VT indicates recurrent vomiting; DY, dysphagia; WT, weight-height ratio; and SIB, siblings with abdominal pain along with recurrent vomiting, dysphagia, or decreased weight-height ratio. The total number of patients 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 ($P>.05$).

2-10

linical 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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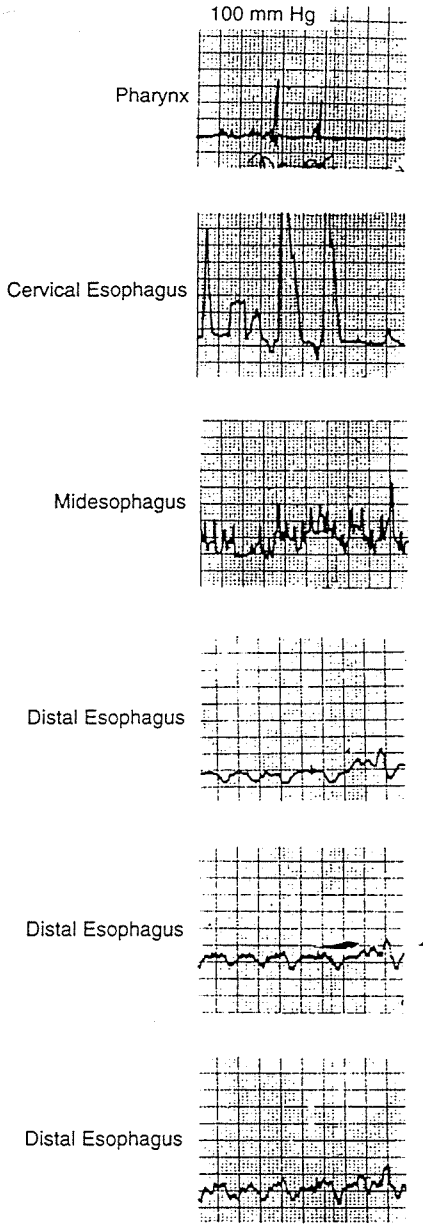

Fig 2.—Esophageal wave propagation after wet and dry swallows in a patient breast-fed by a mother with silicone breast implants. The coordination between pharyngeal contraction and wave propagation into the cervical esophagus was preserved, but no peristaltic contractions propagated into the distal esophagus.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

2-12

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.

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

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."

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 request 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 physician 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, 2-16

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 Center 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. Oppenberger, ~~[illegible]~~ an immunologist. He is not even a pediatrician.

2-17

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.

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.

2-19

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

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,

2-21

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

FAX MEMO

PAGES 1 DATE 11-6-92
TO Evelyn McCormick
FROM Sharron Watson
CO.
PH 316-321-1970 FAX 316-221-1079
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

ST. FRANCIS REGIONAL MEDICAL CENTER
WICHITA, KANSAS

SPECIALITY CLINICS

PCN REFERRAL

DATE: 2-9-94

PATIENT: Rachel Sylvanus

DATE OF BIRTH: 2-20-88

PATIENT ID NUMBER: 00100 64 34 349

PATIENT ADDRESS: 620 N 1st Milvane 67110

PCN PHYSICIAN: Dr Philip Christensen

PCN PROVIDER #: Ch 503884

REFERRAL TO: Dr Jovanovich Levine

REASON FOR REFERRAL: Upper Endoscopy; Manometry 90 Dx R/o GERD

Phillip L. Christensen, M.D.

(PHYSICANS SIGNATURE)

Attn Jerry Simpson - Topeka M.A

2-24

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 PH&W
Attachment #3
2-15-94

Cover Story

Carrie Shearburn

...e 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.

3-2

COLLEEN CONTE (MRS. RICHARD)
AGE 58
FORMER RESIDENT OF CALIFORNIA. CURRENTLY LIVING IN KANSAS.
STATUS - WIDOW.

I HAVE ENDURED SIX (6) SURGERIES ON MY BREASTS, BEGINNING IN MARCH OF 1988 TO MARCH OF 1992. I AM TOLD I MUST HAVE ANOTHER SURGERY. SIX YEARS OF PAIN, HUMILIATION, FINANCIAL RUIN, DISFIGUREMENT, MUTILATION AND PAIN, PAIN, PAIN.

PRE-1988 MY LIFE WAS FULL, BEAUTIFUL, FAMOUS, RESPECTED, BEFORE I MADE THE AWFUL MISTAKE OF BELIEVING THE PROMISE OF GREEDY DOCTORS.

I AM A FORMER "MISS CALIFORNIA" IN THE "MISS UNIVERSE" PAGEANT, ACTRESS, PRODUCER, WRITER. I OWNED TWO HOMES, ONE IN LOS ANGELES (BEVERLY HILLS), ONE IN PALM SPRINGS, CALIFORNIA. I OWNED THREE BOUTIQUES THAT DEPENDED ON MY PERSONAL ATTENTION. I HAVE TWO SONS AND TWO ADOPTED DAUGHTERS. ALL OF THEM DEPENDED ON MY STABILITY, FINANCIAL AID, WISDOM AND A SAFE HAVEN WHEN NEEDED. MY REPUTATION AND PERSONAL APPEARANCES AIDED MANY CHARITIES AND NEEDY ORGANIZATIONS. I HAVE BEEN CHOSEN 9 TIMES OVER THE YEARS BY MOTION PICTURES ASSOCIATIONS TO RECEIVE AWARDS FOR MY PHILANTHROPIC WORK AND ACCOMPLISHMENTS. MY FRIENDS AND ACQUAINTANCES NUMBERED IN THE THOUSANDS. I WAS ENGAGED TO MARRY THE ACTOR "CORNEL WILDE". I HAD IT ALL AND ONLY SOUGHT TO KEEP FIT. IN MY FORMER WORLD, MAINTAINING OUR BODIES AND FACES WAS AS NECESSARY AS MAINTAINING OUR CARS AND HOMES. WE HAD TO TRUST OUR DOCTORS. BUT, BIG REPUTATIONS DID NOT ALWAYS MEAN "GOOD DOCTORS', IMPLANTS HAD NEVER OCCURED TO ME. THAT YEAR (1988) MY WEIGHT WAS LOW, AGE AND GRAVITY CATCHING UP. DR. DONALD WEISMAN TOLD ME THE IMPLANT SURGERY WOULD RESTORE MY BREAST TO PRIOR BEAUTY AND THE SURGERY WAS TOTALLY SAFE. A QUICK RECOVERY WAS ALSO PROMISED. I DID NOT WANT BIGGER BREASTS. MY BOSOM WAS ALREADY FAMOUS. (WHEN PEOPLE EXPECT YOUR BODY AND FACE TO STAY THE SAME ALL YOUR LIFE, IT PLACES UNREAL RESPONSIBILITIES).

NO ONE WARNED OR PREPARED ME FOR THE MANY THINGS THAT NOT ONLY COULD GO WRONG, BUT 98% OF THE TIME, DO GO WRONG: FROM MARCH 10, 1988 TO THE PRESENT, I LOST EVERYTHING I HAD BUILT, ACQUIRED, CREATED. MEDICAL BILLS, LOSS OF INCOME, LOSS OF SELF RESPECT, LOSS OF REPUTATION FOR DEPENDABILITY, CAPABILITIES, LOSS OF HEALTH AND ENERGY. I BECAME A RECLUSE, INVALID, TOTALLY ABSORBED AND PREOCCUPIED WITH PAIN/UGLINESS.

IN 1988, I WAS IN THE BEST OF MY PRIME, MONEY, HOMES, SOLID REPUTATION, HAPPY FUTURE TO LOOK FORWARD TO. MY CHILDREN, FRIENDS AND FAMILY LOVED ME AND RESPECTED MY JUDGEMENT. (I AM NOW RARELY CONSULTED ON ANYTHING). MY FIANCE CORNEL WILDE ADORED ME AND DEPENDED ON ME. BY 1989 I WAS IN SO

Senate P H & W
Attachment #4
2-15-94

MUCH PAIN, CORNEL DID NOT TELL ME HAD BEEN DIAGNOSED WITH "LEUKEMIA". HE PUT OFF HIS OWN TREATMENT, TO HELP ME. AS A RESULT, HIS TREATMENT CAME TOO LATE AND HE DIED OCTOBER 16, 1989.

IN MY BUSINESS AND SOCIAL WORLD, GOOD LOOKS AND HEALTH ARE EXPECTED! MY BODY HAD BEEN HEALTHY AND ALMOST MAINTENANCE FREE MOST OF MY LIFE. A BATH AND POWDER WAS ALL I NEEDED TO BE NEAT, FRESH AND EFFICIENT. I NEVER GAVE A SECOND THOUGHT TO MY BODY. IT SIMPLY WAS! GOOD FORTUNE HAD BEEN MINE. I WAS ATHLETIC (TOOK PART IN MANY SPORTS EVENTS), LOVED THE SUN. I READ CONTINUALLY, ANOTHER JOY LOST.

IN OTHER SIMPLIER WORDS, I HAD BEEN TOTALLY BLESSED WITH GOOD HEALTH, GOOD LOOKS, GOOD MIND, GOOD LIFE AND THE ENERGY TO USE THESE QUALITIES.

NOW I HAVE HEART DISORDERS (TACCACARDIA), LUNG PROBLEMS (COUGHING-HYPERVENTILATING), AUTO IMMUNE MYASTHENIA GRAVIS (SWALLOWING DISORDER), CHOKING, HEARING LOSS, PARTIAL BLINDNESS, EXTREME SENSITIVITY TO LIGHT (PHOTOPHOBIA), JOINTS HURT, BONES ACHE, MUSCLES HURT AND UNDEPENDABLE, BRAIN FUNCTION IS SPORATIC, SOMETIMES GOOD, MOSTLY SLOW. BLOOD PRESSURE SO LOW, CANNOT STAND AT TIMES. EXTREME SLEEP DISORDERS. MY STANDARD OF LIVING IS BARELY ACCEPTABLE. BUSINESS REPUTATION IS IN SHREDS, CHILDREN ARE EMBARRASSED (THOUGH SUPERFICIALLY SYMPATHETIC) ABOUT MY CONDITION. PARENTS ARE ANGRY AT ME FOR GETTING INTO THIS MESS. FRIENDS BEGAN TO SHUN ME. I LEFT CALIFORNIA AND MOVED BACK TO KANSAS AFTER GOING ON NATIONAL TV TO EXPOSE THIS SHAMEFUL SURGERY.

SO, AT AGE 58, I AM ILL, DEPRESSED, BROKE AND ALONE. I AM AN EMBARRASSMENT AND BURDEN TO MY FAMILY.

KaMMCO

KANSAS MEDICAL MUTUAL INSURANCE COMPANY
AND
KANSAS MEDICAL INSURANCE SERVICES CORPORATION

TO: Senate Public Health and Welfare

FROM: Lori Callahan, General Counsel

RE: S.B. 683

DATE: February 15, 1994

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

KaMMCO appreciates the opportunity to testify as a neutral party on S.B. 683. As a medical malpractice company, KaMMCO is concerned with language in the bill that changes common law rather than codifying it.

Initially, in New Section 1(a) the bill requires physicians to inform their patients of the "advantages, disadvantages, and risks associated with a breast implantation". This appears to be codification of common law which requires informed consent before a physician can perform breast implantation. The problem is that S.B. 683 uses language different from the common law obligation.

The common law provides that except in emergency situations, a physician has a legal obligation to make a reasonable disclosure to the patient of: (a) the nature of the suggested or recommended treatment, (b) the possible consequences of such treatment, and (c) the dangers of such treatment which are within the physician's knowledge. This disclosure is required by law so the patient will have a basis to make an intelligent informed consent to the proposed treatment. Stovall v. Harms, 214 Kan. 835, 842, (1974). The physician's legal obligation is limited, however, to those disclosures which a reasonable medical practitioner would make under similar circumstances. The facts and circumstances of each case determine whether a reasonable disclosure, under which an informed consent may rest, has been made. The Kansas Supreme Court has said it is not willing to extend a physician's duty to disclose to such an extreme that the physician must make the patient aware "not only of the known risks but also of each infinitesimal, imaginative, or speculative element that would go into making up such risks." Charley v. Cameron, 215 Kan. 750,756 (1974).

Thus, the language in S.B. 683 which requires information on the advantages, disadvantages and risks differs from common law and current practice which requires information on the nature of the procedure, the possible reasonable consequences of the procedure and the possible reasonable dangers of such a procedure which are within the physician's knowledge. This difference is critical.

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Senate P H & W
Attachment 4
2-15-94

Advantages and disadvantages of a medical procedure include not only medical issues but social and personal aspects as well. This is especially true with breast implantation where the majority of patients chose the procedure for augmentation purposes rather than medical necessity. Thus, to change informed consent for one procedure including facets which are not within a physician's knowledge (social and personal advantages and disadvantages); not requiring that only reasonable elements be disclosed; and further excluding disclosure of the nature of the procedure and the reasonable medical consequences of such a procedure appears dangerous.

Secondly, S.B. 683 does not clarify that if the physician gives the physician's own list of advantages, disadvantages and risks, whether that also meets the requirements of New Section 1(a) as does meeting the three requirements under (c).

Finally, under S.B. 683 it is not clear that providing the information required thereunder meets the requirements of informed consent. In other words, a physician could meet all of the requirements of the statute and still be sued for not informing the patient. This would be true especially if the patient felt the Board of Healing Arts' information was not accurate. The physician would then be liable for damages for following the statute and providing the information developed by the Board of Healing Arts. This does not appear consistent with the goals of the bill. We, therefore, propose an amendment to New Section 1. This amendment clarifies the physician may comfortably follow the statute without civil consequences.

We appreciate the opportunity to testify and raise these questions.

Session of 1994

SENATE BILL No. 683

By Senator Ranson

2-4

AN ACT concerning the healing arts act; requiring persons licensed to practice medicine and surgery to provide information to certain patients concerning breast implants; amending K.S.A. 65-2836 and repealing the existing section.

Be it enacted by the Legislature of the State of Kansas:

New Section 1. (a) Before a person licensed to practice medicine and surgery operates on a patient to insert a breast implant, the person licensed to practice medicine and surgery shall inform the patient of the advantages, disadvantages and risks associated with a breast implantation.

(b) The board of healing arts shall:

(1) Provide a standardized written summary in layman's language that:

(A) Contains all the information on breast implantation generally contained in the information sheet for the breast implant; and

(B) discloses side effects, warnings and cautions for a breast implantation;

(2) update as necessary the standardized written summary; and

(3) distribute the standardized written summary to each hospital, clinic and physician's office and any other facility that performs breast implantations.

(c) A person licensed to practice medicine and surgery satisfies the requirements of subsection (a) of this section if:

(1) The person licensed to practice medicine and surgery provides the breast implantation patient with the standardized written summary described in subsection (b) of this section;

(2) the patient receives the standardized written summary five days before the breast implantation operation; and

(3) the patient signs a statement provided by the board of healing arts acknowledging the receipt of the standardized written summary.

(d) In the event of any claim by the patient against the person licensed to practice medicine and surgery, it shall be conclusively presumed that any patient who receives the information set forth in subsection (c) of this section shall have been fully informed regarding the procedure and given an informed consent to the same.

e ~~(d)~~ This section shall be part of and supplemental to the Kansas healing arts act.

Sec. 2. K.S.A. 65-2836 is hereby amended to read as follows: 65-2836. A licensee's license may be revoked, suspended or limited, or the licensee may be publicly or privately censured, or an appli-

cation for a license or for reinstatement of a license may be denied upon a finding of the existence of any of the following grounds:

(a) The licensee has committed fraud or misrepresentation in applying for or securing an original, renewal or reinstated license.

(b) The licensee has committed an act of unprofessional or dishonorable conduct or professional incompetency.

(c) The licensee has been convicted of a felony or class A misdemeanor, whether or not related to the practice of the healing arts.

(d) The licensee has used fraudulent or false advertisements.

(e) The licensee is addicted to or has distributed intoxicating liquors or drugs for any other than lawful purposes.

(f) The licensee has willfully or repeatedly violated this act, the pharmacy act of the state of Kansas or the uniform controlled substances act, or any rules and regulations adopted pursuant thereto, or any rules and regulations of the secretary of health and environment which are relevant to the practice of the healing arts.

(g) The licensee has unlawfully invaded the field of practice of any branch of the healing arts in which the licensee is not licensed to practice.

(h) The licensee has engaged in the practice of the healing arts under a false or assumed name, or the impersonation of another practitioner. The provisions of this subsection relating to an assumed name shall not apply to licensees practicing under a professional corporation or other legal entity duly authorized to provide such professional services in the state of Kansas.

(i) The licensee has the inability to practice the branch of the healing arts for which the licensee is licensed with reasonable skill and safety to patients by reason of illness, alcoholism, excessive use of drugs, controlled substances, chemical or any other type of material or as a result of any mental or physical condition. In determining whether or not such inability exists, the board, upon reasonable suspicion of such inability, shall have authority to compel a licensee to submit to mental or physical examination or drug screen, or any combination thereof, by such persons as the board may designate. To determine whether reasonable suspicion of such inability exists, the investigative information shall be presented to the board as a whole, to a review committee of professional peers of the licensee established pursuant to K.S.A. 65-2840c and amendments thereto or to a committee consisting of the officers of the board elected pursuant to K.S.A. 65-2818 and amendments thereto and the executive director appointed pursuant to K.S.A. 65-2878 and amendments thereto, and the determination shall be made by a majority vote of the entity which reviewed the investigative information. Information

5-1

KaMMCO

KANSAS MEDICAL MUTUAL INSURANCE COMPANY
AND
KANSAS MEDICAL INSURANCE SERVICES CORPORATION

TO: Senate Public Health and Welfare

FROM: Lori Callahan, General Counsel

RE: S.B. 684

DATE: February 15, 1994

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

KaMMCO appreciates the opportunity to testify as a neutral party on S.B. 684. As a liability carrier for Kansas physicians, there are three components of this bill we would like to address.

Initially, Section 1(a) of the bill, lines 12-18, sets out an entitlement for patients to all of the information contained in that patient's medical records. Currently, the law provides that the medical record is the property of the physician not the patient. This allows the physician to utilize medical judgment when determining whether to release medical information to a patient. As the bill recognizes by its exception of psychiatric records from this entitlement, some medical information is too hazardous for a patient to know. Many patients, whether for cost or other reasons, will not seek psychiatric care for their mental problems. Primary care physicians, obstetricians, gynecologists and plastic surgeons become the patient's only source of mental treatment. Due to the mind-body connection, it is imperative physicians be free to treat and make note of the mental conditions of their patients in order to treat the physical conditions. S.B. 684 eliminates the ability of physicians to exercise their medical judgment in attempting to best treat their patients thereby precluding access to mental health for many patients.

Secondly, this provision only applies to physicians and hospitals, rather than all health care providers, including chiropractors, podiatrists, and others. There does not appear to be justification for the creation of this mandate on one class of health care providers but not on others.

The next component of the bill establishes medical record copying costs at 10¢ per page. The issue of medical record copying costs was studied extensively for three years in the area of worker's compensation. As a result, on July 1, 1993, a schedule of medical fees, including medical record copying costs, was adopted and became law in Kansas. A copy of this schedule is attached hereto. We would suggest that the committee consider reference to this fee schedule rather than adopting a statutory amount which must be legislatively revised in order to keep up with inflation.

Senate P H & W
Attachment #6
2-15-94

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Additionally, the medical record copying cost provision in S.B. 684 does not include the cost of someone in the physician's office to make the copies or the physician's time to review them for psychiatric records, which are specifically excluded in the bill from release.

Finally, Section (b) of the bill further clarifies current law by specifically allowing ex parte communications with the physician once the patient has filed suit putting their medical condition in issue. Whether ex parte communications between attorneys and treating physicians are allowed under Kansas' current physician-patient privilege statute has been extensively debated in the past. To date, the Kansas Supreme Court has consistently upheld that once an individual files a lawsuit, that the physician-patient privilege is waived. If such was not allowed, physicians, as the defendant in the suit, would not be allowed to speak with their own attorney. In 1992, the Kansas legislature considered a proposal which would have precluded these ex parte communications. That legislation was killed. The Legislature found that ex parte communications decrease litigation costs by allowing interviews with the physicians which are much easier to schedule and are less expensive than depositions. It is also recognized that these communications result in the elimination of nonessential parties and witnesses as well as the early evaluation and settlement of claims. The Legislature also noted that it was unfair to preclude a defense attorney from meeting with the treating physician when the plaintiff's attorney had an unrestricted opportunity to do so.

We, therefore, support efforts to further clarify this important provision of the law.

We appreciate the opportunity to testify on S.B. 684.

WORKERS COMPENSATION

SCHEDULE OF MEDICAL FEES

July 1, 1993

DIVISION OF WORKERS COMPENSATION
KS DEPT OF HUMAN RESOURCES
800 SW JACKSON ST STE 600
TOPEKA KS 66612-1227

229

6-3

DEPOSITIONS/TESTIMONY & REPRODUCTION OF MEDICAL RECORDS SECTION

1. **DEPOSITIONS/TESTIMONY:** In determining the dollar price of medically related depositions or testimony rendered on behalf of employees receiving benefits under the Kansas Workers Compensation Act, the following guideline shall be used:

   A health care providers time for giving a deposition or testimony shall be reimbursed at the health care providers usual and customary charge not to exceed, however, $300.00 per hour plus an allowance of $75.00 for 15 minutes increments thereafter.

2. **INDEPENDENT MEDICAL EXAMINATIONS (IME) AND OTHER SPECIAL EXAMINATIONS AND/OR REPORTS:** In determining the dollar price of any necessary IME's and other special examinations and/or reports rendered on behalf of employees receiving benefits under the Kansas Workers Compensations Act, the following guidelines shall be used:

   A health care providers time for the rendering of an IME or other special type of examination and/or report shall be reimbursed at the health care providers usual and customary charge not to exceed, however, $275.00 per hour plus and allowance of $68.75 for 15 minute increments thereafter.

3. **REPRODUCTION OF MEDICAL RECORDS:** Reimbursement for the reproduction of an employee's medical record is to be at the health care providers usual and customary charge not to exceed, however, the following:

1st 10 pages:	$15.00
11 - 50 pages:	$25.00 ($15.00 for the 1st 10 pages plus $10.00 for 11-50 pages)
above 50 pages:	$25.00 plus $0.35 per page

4. **CANCELLATION OF A DEPOSITION/TESTIMONY:** Whenever a deposition/testimony is to be canceled, more than two working days notice is required to avoid a charge. If notice is less than two working days, a $150.00 charge is allowable.

5. **ITEMIZATION OF CHARGES:** All bills submitted for payment shall be itemized and shall include the respective CPT Code for proper reimbursement.

TESTIMONY

of the

KANSAS TRIAL LAWYERS ASSOCIATION

regarding Senate Bill 684

February 15, 1994

The Kansas Trial Lawyers Association requests unfavorable consideration of Senate Bill 684 and offers the following information in support of its opposition to this bill.

EX PARTE COMMUNICATIONS

Upon the filing of a medical malpractice lawsuit, a defense attorney will be permitted to talk privately with physicians and other health care providers who have rendered treatment to the plaintiff. These communications will take place outside of a deposition or trial and will be unattended by either the plaintiff or by the plaintiff's attorney. Under the AMA's Principles of Medical Ethics IV, "A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law."

Section 5.05 of the current opinions of the Judicial Council of the AMA (1984) states: "The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree . . . The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law." At common law there was no physician/patient privilege. The only statutory enactment dealing with the subject is K.S.A. 60-427. In the context of our Rules of Evidence, it then states under subsection d: "There is no privilege under this section in the action in which the condition of the patient is an element or factor of the claim or defense of the patient . . ."

However, these sames Rules of Evidence proscribe <u>how</u> the information subject to privilege may be disclosed, such as an application for an order for records, request for production of records, or oral testimony by deposition.

This bill allows a defense attorney in a malpractice case to circumvent rules of evidence and the ethics of the physicians who are not parties to the action and gives them the right to speak to those physicians without any authorization from the patient and without the presence of either the patient or the patient's attorney.

Senate P H & W
Attachment 4
2-15-94

This becomes particularly problematic in medical malpractice cases where the attorney may not only represent a defendant in the malpractice action, but also represent the treating physician or represents the treating physician's insurance carrier. There are safeguards in judicial proceedings for the objection to irrelevant material. They are not present in an ex parte communication. There are irrelevancies that can be discussed which would promptly be excluded in an evidentiary proceeding (a discussion of a sexually transmitted disease, infidelity, drug or alcohol treatment, emotional problems, impotence) which could be disclosed. The problem is not only for the patient, but also for the doctor, because the doctor without an appropriate authorization may release information which is covered by federal law such as those dealing with alcohol and drug abuse. There are even cases in other jurisdictions of civil actions which have been brought by patients against doctors for the breach of confidence or complaints of an unethical act of releasing information without authorization or court order.

In medical malpractice actions, defense counsel should not be entitled to conduct unauthorized private interviews with nonparty treating physicians, but should be limited to discovery devices in the discovery rules of the Rules of Civil Procedure. Procedures set forth in discovery rules should be the sole means by which a defendant can obtain information to which the plaintiff had waived his privilege by bringing suit unless plaintiff voluntarily agrees to a private interview of a treating physician. Public policy should dictate that practice and procedures in litigation should not allow for unnecessary breakdown of trust and confidentiality embodied in the physician/patient relationship, and therefore a physician should not engage in ex parte conferences with a legal adversary of his patient.

In effect, by allowing ex parte communications, defense counsel, being the only individual trained in the intricacies of the law and possessing a vested interest in obtaining as much information regarding the plaintiff as possible and obtaining favorable testimony, bears the burden of policing the propriety of these communications. The potential for abusing that responsibility far outweighs any potential benefit.

Furthermore, the damage suffered by plaintiff as a result of ex parte communications is immeasurable and often irreparable when the treating physician is subsequently allowed to testify against the interest of the plaintiff at trial. It will be virtually impossible for a trial court in hindsight to determine whether or not the ex parte communications was proper and within the bounds of legitimate discovery and that the physician was not improperly influenced. By utilizing formal discovery provided in the statute, plaintiff's counsel will always be on notice and will have an opportunity to attend any conferences and object to discovery tactics believed to be inappropriate.

Conclusion

Because plaintiff's treating physician is not educated in the intricacies of discovery in litigation, and defense counsel has a vested interest in obtaining as much information regarding plaintiff as possible, allowing defense counsel unfettered access to plaintiff's treating physician is akin to letting the fox guard the hen house.

PATIENT'S ACCESS TO THEIR MEDICAL RECORDS AT A REASONABLE COST.

Section 1.(a) and (c) provide in effect unrestricted access to their medical records at the reasonable price of 10¢ per page. There is an exception involving psychiatric records, presumably where the disclosure of these records would be harmful to the patient. Under current practice, most hospitals and physicians require a patient to contact an attorney who must present a written and properly executed release along with a request to obtain medical records. In Wichita, the Sedgwick County Medical-Legal Code provides for a ceiling on reproduction of physician's medical records. This code provides for a basic service charge of $15 or actual retrieval fee plus 30¢ per page for copy expense. Hospitals recently however have taken the position that they aren't bound by this code and have begun charging prices ranging from 50¢ per page to $1.00 per page. These charges are billed by a copying service designated by the hospital. For example, Wesley Medical Center has contracted with PMS, Inc., of Waco, Texas, who charges $1.00 per page plus chart and authorization review, search and retrieval, postage, and postage and handling. Attached please find an invoice documenting these charges. Smart Corporation is the copy service for St. Joseph's Medical Center in Wichita. Attached is a charge for 50¢ per page plus retrieval, shipping and handling, and sales tax.

The billing practices of two Wichita hospitals merit some review because the excessive charges tend to deny patients access to their own records. The Kansas Trial Lawyers Association however believes that the matter should be handled in a separate bill and that the regressive portions of the bill regarding ex parte communications with physicians require its opposition.

Respectfully submitted,

Edward J Hund

EDWARD J. HUND
For the Kansas Association
of Trial Lawyers

7-3

PMS Inc.

RELEASE OF MEDICAL INFORMATION

OSPITAL: Wesley

ATE: 10/21/93

INVOICE

No. 66616

PLEASE REMIT YELLOW COPY & PAYMENT UPON RECEIPT TO:

PMS, Inc.
P.O. BOX 2605
Waco, Texas 76702-2605
Phone (817) 776-3260 • TAX ID# 74-1827932

REQUESTOR INFORMATION

CO. NAME: Cordry, Hund, & Hartman
ATTN: Edward J. Hund
ADDRESS: PO Box 47528
CITY, STATE, ZIP Wichita, KS 67201-7528

PATIENT INFORMATION

PATIENT NAME: Williams, Mona Lee
SS #: 513-20-4649
MR #: 930420746
OTHER:

BILLING INFORMATION

SEARCH AND RETRIEVAL	21	$	15.00
CHART AND AUTHORIZATION REVIEW	15.00	$	10.00
PHOTOCOPY CHARGE 112 PAGES @$1.00 PER PAGE	39.20	$	112.00
PHOTOCOPY CHARGE (MICROFILM) ____ PAGES @$2.00 PER PAGE	5.90	$	
MISCELLANEOUS $ 10.10 Pd 10.10	10.10	$	
SUB-TOTAL		$	137.00
SALES TAX (WHERE APPLICABLE)		$	
POSTAGE AND HANDLING Ent		$	5.90
TOTAL CHARGES		$	142.90
PREPAYMENT CREDIT (Check #_____)		$	(- 0
TOTAL BALANCE DUE		$	142.90

THANK YOU FOR YOUR PROMPT REMITTANCE. NO STATEMENT WILL BE MAILED.

A Service Charge of 1½% per month (18% per annum) will be charged on all accounts not paid in 30 days.
To insure proper credit to your account, please detach this invoice and return the yellow copy with remittance.

7-4

Data Documents 09-532840-01 3Z10 12

STAPLE HERE

Smart Corporation

P.O. BOX 2826
TORRANCE, CA 90509-2826
FEDERAL TAX I.D. NO. 95-3313004

Questions? Call the Customer Service Center at (310) 618-1992
Hours: 6:00 AM - 4:30 PM Pacific Time

INVOICE

No. B437309
(HOME OFFICE USE ONLY)

PLEASE SEE REVERSE SIDE FOR IMPORTANT INFORMATION

SOLD TO

Requested by: Donald C. Tinker, Jr
Account Name: Robbins ET al
Address: 700 Mkt. Centre 155 N. Market
City: Wichita State: KS Zip: 67202

CHARGES EXCEEDING $50.00 MUST BE PRE-APPROVED

Approved By
Position
Amount Date
Time Phone

INVOICE DATE	SITE NUMBER	AREA NUMBER	REP NUMBER
5/18/93	47	17100	7043

Basic Fee		12/10
Per Page Fee	Micro ___	Paper .50
Page Count	Micro ___	Paper 717

Copies From: St. Joseph Med Ctr
Patient Name: Black (Last) Virginia (First)
Insured Name:
Employer Name: DOB 8/27/38

☐ Claim # ☐ Policy #
☐ Plan # ☐ Certificate #
☐ Case # ☐ Provider #
☐ File # ☐ Subscriber #
☐ SS # ☐ Group #
☐ ID # ☐ Control #

(1)	Photocopy Charge.... (Basic + Per Page Fees)	365.50
(2)	Facility's Retrieval/ Search Fee.....	5.00
(3)	Shipping/Handling....	20.00
(4)	Sub Total..... (Add lines 1, 2, 3)	390.50
(5)	Sales Tax..... (% x line 4)	19.13
	TOTAL CHARGES (Add lines 4 and 5)	409.63
	Minus Payment.....	( )
	BALANCE DUE	

☐ Payment Enclosed

Check No. ☐ Facility Kept Payment

Check No.

☒ Attorney ☐ Subpoena ☐ Disability / Social Security
☐ Insurance ☐ Worker's Comp. ☐ Other

WHITE CUSTOMER COPY - RETURN WITH PAYMENT

Remit to: Smart Corporation
P.O. Box 2826
Torrance, CA 90509-2826

7-5

KHIMA
Kansas Health Information Management Association

▲ P.O. Box 2308 Topeka, Kansas 66601 ▲

Date: February 11, 1994

To: Sandy Praeger, Chairperson, Senate Public Health and Welfare

From: Nikki Adams, A.R.T., Past Pres., Kansas Health Information Management Association

Re: Senate Bill No. 684 AN ACT relating to medical records; concerning the limitation of fees for copies of medical records.

Senator, thank you for the opportunity to appear before you this morning. My name is Nikki Adams. I am representing the Kansas Health Information Management Association (KHIMA). KHIMA is a professional organization of 610 members with the responsibility of maintaining the medical record.

The Kansas Health Information Management Association is opposed to setting a fee for copies of medical records. I would like to share with you information regarding actual hospital costs associated with supplying copies of patients' medical records.

DIRECT LABOR COSTS:

* Open mail - larger hospitals receive 1,000+ requests per month
* Validate the authorization to ensure the patient's confidentiality.
* Retrieve the medical record and make the appropriate copies.
* Invoice the receivable, address the envelope, and mail the copies.
* Re-file the medical record.

INDIRECT COSTS:

* Equipment rental - copier and/or fax machine.
* Equipment supply costs - toner, paper, routine maintenance.
* Overhead - accounting & purchasing departments' services, usage of hospital computers for software support.
* Administrative oversight - supervisory, hospital legal counsel.
* Postage, freight, microfilm conversion costs.
* Off site medical record storage and retrieval costs.

A recent survey by KHIMA showed that the average charge for copies by many acute care hospitals in Kansas is $.49 per page. Recent national surveys indicate that actual medical record copying costs range from $.83 per page to $1.00 per page. At the present time the average Kansas hospital is not charging enough to even cover the costs.

As Past President of the Kansas Health Information Management Association, I and my colleagues are opposed to the regulation of these charges out of concern for the impact this would have on increasing healthcare costs.

Senate PH&W
attachment #8
2-15-94

& REPRODUCTION OF MEDICAL RECORDS SECTION

1. **DEPOSITIONS/TESTIMONY:** In determining the dollar price of medically related depositions or testimony rendered on behalf of employees receiving benefits under the Kansas Workers Compensation Act, the following guideline shall be used:

   A health care providers time for giving a deposition or testimony shall be reimbursed at the health care providers usual and customary charge not to exceed, however, $300.00 per hour plus an allowance of $75.00 for 15 minutes increments thereafter.

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1st 10 pages:	$15.00
11 - 50 pages:	$25.00 ($15.00 for the 1st 10 pages plus $10.00 for 11-50 pages)
above 50 pages:	$25.00 plus $0.35 per page

4. **CANCELLATION OF A DEPOSITION/TESTIMONY:** Whenever a deposition/testimony is to be cancelled, more than two working days notice is required to avoid a charge. If notice is less than two working days, a $150.00 charge is allowable.

5. **ITEMIZATION OF CHARGES:** All bills submitted for payment shall be itemized and shall include the respective CPT Code for proper reimursement.

ALLEN COUNTY HOSPITAL
101 South First Street
Post Office Box 540
Iola, Kansas 66749
316-365-3131

KHIMA RURAL HOSPITAL RESPONSE TO SENATE BILL NO. 684

My name is Sharon Godfrey. As a member of the Kansas Health Information Management Association's executive board and as a Health Information Services Department Director in a 49 bed rural hospital, I would like to respond to Senate Bill No 684.

The issue raised in Senate Bill No. 684 is one limiting the amount charged by health care providers for the copying of medical records in conjunction with the release of information function. The limit specified is 10 cents per page. This will have a major impact in the hospital setting due to the actual cost of copying these records being 60 cents per page and higher.

The cost of release of information is not limited to the cost of the copy paper. There are many labor intensive processes that must occur to insure proper release of confidential medical information.

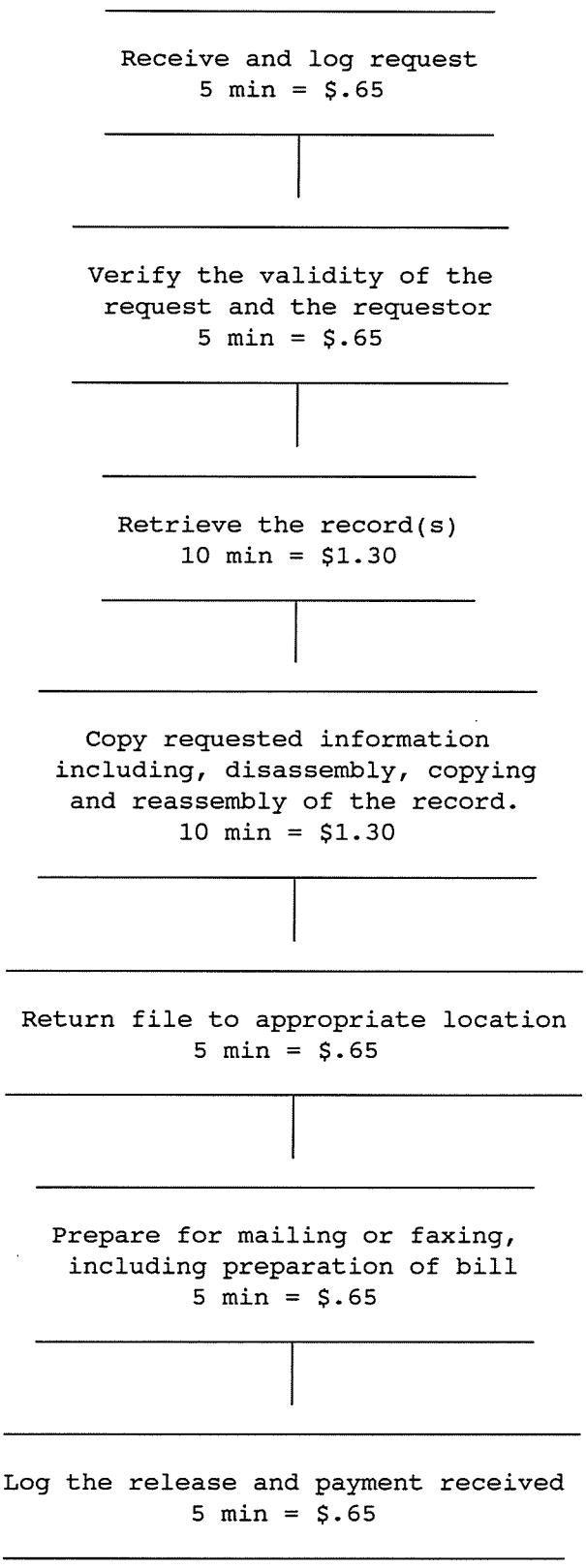
The cost per page for the actual supplies is approximately $.05/page. This does not include any expenses incurred in the mailing or faxing of the information. The labor costs = $.13 / minute, as broken down in the attached flow chart.
The cost for a release of 10 pages would be: $6.34 or 63.4 cents per page.

RURAL ISSUES:
The smaller hospital will have increased labor costs, for example:

1. The copier may be smaller and slower.
2. The copier may not be located in the department.
3. Fax machine may not be available, in the dept or in the facility.
4. Clerks have multiple duties, with release of information being only one.

Senate P H&W
Attachment #9
2-15-94

FLOW CHART OF PROCESSES FOR APPROPRIATE RELEASE OF CONFIDENTIAL MEDICAL INFORM N



Total time = 45 minutes @ $.13/minute = Total labor cost of $5.85
Total supply cost = 10 pages @ $.05 = Total supply cost $0.50
Total cost $6.35

9-2

BREAKDOWN OF COSTS:

Copier rent/maintenance contract		
$350.00/month @ 15,000 copies/month	=	2.33 cents
Copier toner		
#250.00/month @ 15,000 copies/month	=	1.67 cents
Additional maintenance expense		
$750.00/year at 180,000/year	=	.4 cents
Paper per sheet	=	.5 cents
Total supply cost per copy	=	4.90 cents

Staff time:

Avg salary, release of information clerk + benefits = $7.80 / hr
= $ .13/minute

TIMES FOR PROCESSING RECORD REQUESTS:

Receive and log request: 1 - 10"		Avg 5 min
Verify the validity of the request/requestor 5 - 15"		Avg 10 min
Retrieval of records		Avg 10 min
incomplete	5 min	
complete - recent	5 min	
complete - purged	25 min	
complete - microfilm	30 min	
complete - off site storage	60 min	
Disassemble, copy, and reassemble record		Avg 10 min
1-5 pages	7 min	
6-10 pages	10 min	
11-25 pages	15 min	
26-50 pages	20 min	
Return file to appropriate location		Avg 5 min
incomplete	3 min	
complete - recent	3 min	
complete - purged	15 min	
complete - microfilm	10 min	
complete - off site storage	45 min	
Prepare for mailing or faxing, billing		Avg 5 min
Log the release and payment received		Avg 5 min

Total cost for a 10 page request:

Paper/copy expense	10 @ 4.9	.49
Receive and log request	5 @ .13	.65
Verify validity	5 @ .13	.65
Retrieval	10 @ .13	1.30
Copy the record	10 @ .13	1.30
Return the file	5 @ .13	.65
Prepare for mailing or faxing	5 @ .13	.65
Log release and payment	5 @ .13	.65
Total cost		6.34