

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Marlene Keeling to Alan Slobodin re: address and phone number (partial) (1 page)	09/23/1997	P6/b(6)
002. report	re: fax number (partial) (6 pages)	09/25/1997	P6/b(6)
003. form	re: Consent to be a subject (partial) (5 pages)	09/25/1997	P6/b(6)
004. list	re: address (1 page)	09/11/1997	P6/b(6)
005. letter	Pamela Stott-Kendall to Donna Shalala re: fax number (partial) (2 pages)	09/25/1997	P6/b(6)
006. letter	Marlene Keeling to Susan Blumenthal re: phone number (partial) (1 page)	07/28/1997	P6/b(6)
007. press release	re: phone number (partial) (1 page)	08/05/1997	P6/b(6)
008. letter	Marlene Keeling et al. to Michael Friedman re: phone number and address (partial) (1 page)	07/20/1997	P6/b(6)
009. paper	re: testimony of Dr. Michael Friedman (partial) (3 pages)	09/25/1997	P6/b(6)
010. petition	re: fax number, phone number, and address (partial) (3 pages)	n.d.	P6/b(6)
011. fax	From: Marlene Keeling re: phone number and fax number (partial) (1 page)	03/31/1997	P6/b(6)
012. paper	Data sheet re: fax number (partial) (1 page)	03/31/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
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013. letter	Marlene Keeling et al. to Vivian Pinn re: phone number, fax number, and address (partial) (2 pages)	08/26/1997	P6/b(6)
014. letter	Marlene Keeling to Vivian Pinn re: phone number, fax number, and address (partial) (3 pages)	06/03/1997	P6/b(6)
015. letter	Vivian Pinn to Marlene Keeling re: address and fax number (partial) (3 pages)	07/18/1997	P6/b(6)
016. report	re: fax number (partial) (6 pages)	05/28/1997	P6/b(6)

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USSW
VIRGINIA

UNITED SILICONE
SURVIVORS OF THE WORLD
VIRGINIA-COALITION

DIANE GRIFFITH
CONGRESSIONAL LIAISON

6490 SILVER RIDGE CIRCLE
ALEXANDRIA, VA 22315
Tel/Fax (703) 922-5260

Alex Klein

- we need to
look over this
and memo
Sarah.

Silicone
- ~~Q~~ either
of you
want to
review
for me
— SB

DebCar Publishing

President
Pamela Stott-Kendall
P. O. Box 030153
Fort Lauderdale, Florida 33303

Telephone: (954) 563-1215, Fax: (954) 467-1153
Internet: <http://www.bookworld.com/debcar>

October 24, 1997

Mr. Chris Jennings
Deputy Assistant to the President for Health Policies
Fax: (202) 456-5557
Pages: 1

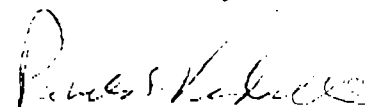
Dear Mr. Jennings,

I wanted to comment on an October 15, 1997 letter from Acting FDA Commissioner Michael Friedman who announced the agency's determination "that we do not have sufficient information to change the current regulatory position on silicone gel-filled breast implants at this time." Dr. Friedman continued to state that "five years after FDA requested safety and effectiveness data, we are not in a position to approve or deny premarket approval (PMA) applications for silicone gel-filled breast implants." Though Dr. Friedman considered an authored *Request for FDA Public Hearing* to be "mature," he did assure that "an open advisory hearing will be conducted," upon PMA submission, to provide "an opportunity for public discussion and comment."

The silicone support network of organizations is encouraged by Dr. Friedman's decision. I feel that the FDA's continued restriction of gel-filled breast implant use, which highlights the unresolved questions and concerns surrounding breast implant use, strongly supports the congressional call for an appropriate federal regulatory action on Silicone Breast Implants. Only with such a task force will we have a clear and effective regulatory resolution.

In closing, we appreciate the administration's consideration of silicone concerns affecting so large a segment of American women who are being directly affected through either cosmetic or reconstruction surgery, will succumb to breast cancer with urgent need of safe reconstruction alternatives. While the FDA's Manufacturer Device Reporting (MDR) count of breast implant injuries and illnesses steadily rises to thousands each month, another one out of every eight women will develop breast cancer.

Yours truly,


Pamela Stott-Kendall

cc: Mr. Tom Shea

August 15, 1997

Mr. Chris Jennings
Deputy Assistant to the President for Health Policies
Old Executive Office Building, Room 216
1700 Pennsylvania Avenue
Washington, DC 20502

Dear Mr. Jennings,

In follow-up of expressed concerns regarding Acting FDA Commissioner Dr. Friedman's imminent decision on the permanent status of gel-fill, breast-implant devices, I have enclosed July 18 correspondence which formed the basis of Congressman Traficant's July 21 *Dear Colleague* letter, circulated among congressional members and entitled: Inaccurate FDA Report on Breast Implant Risk; The Call for Investigation and Public Hearing. Giving reference to Dr. Friedman's testimony before a 1997 Commerce Committee meeting, this information had resulted in the enclosed, authored July 21 *Request for FDA Public Hearing*. Upon learning, unofficially, through the FDA Center for Devices and Radiological Health that such request will be denied, I again contacted Secretary Donna Shalala of Health and Human Services (August 8 correspondence enclosed). Earlier, Secretary Shalala and the House Committee on Government Oversight had received supportive documents pertinent to industry compromise of the FDA clinical-trial studies of breast implants (1992-1997) and Dr. Louise Briton's NCI breast-implant study (slated for 1998 release). At present, I am visiting in the Washington, DC, area to attend additional meeting with Congressman's Waxman's office and, hopefully, HHS officials. Clearly, the issues of FDA credibility in public-health protection and public accountability of governmental action demand appropriate investigation and intervention.

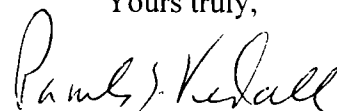
A Federal Task Force on Silicone Implants, as supported by Representatives Traficant's and Jackson-Lee's July 21 *Letter to President Clinton* which I believe has been directed in part to your attention, might well serve and satisfy this need. As in the case of the tobacco industry, over many decades profit considerations of the implant industry have obscured concern for public health protection. Seemingly, it is not until substantially large numbers of people from several generations have been seriously harmed or placed at serious risk and, consequently, public health costs have substantially soared, with substantial litigation expense attached to industry, that government begins to seek solution. With respect to the silicone industry, power exerted and exorbitant funds expended by manufacturers and plastic surgeon societies alike—in the influence, and purchase, of medical, research, congressional and media support—had encouraged many of our governmental leaders to simply look the other way. Yet, by the FDA's own count of silicone injuries and deaths (collected from implant manufactures and reported

through the MDR program) as well as growing numbers of women on disability and welfare roles, a wake-up call has sounded.

Now, the question of Dow Chemical's liability, to be established in the Louisiana class-action court case despite a bitter battle fought by Corning's parent company to evade grand-scale, financial accountability, sets the stage for bargained industry settlement as has occurred with tobacco interests. Not even Dow Chemical can afford legal exposure to continually-increasing lawsuits, filed by the thousands and already totaling some 50,000, many of which stem from the company's raw material supply of silicone to a majority of implant manufacturers. (Dow Corning was, and Dow Chemical is, named in 80% of all breast implant-related legal actions filed.) Of course, it goes without saying that greater liability will follow, should the FDA declare the gel-fill breast implant not safe for market, as a result of silicone's use in eleven-million plus (1994 statistics) men and women implanted with various devices. Undoubtedly, this eventuality is the reasoning behind the industry's persistent effort to secure FDA approval of general market for gel-fill breast implants as well as congressional support of favorable legislation.

I thank you, and the administration, for consideration of Representatives Traficant's and Jackson-Lee's *Letter to President Clinton*. I also appreciate your consideration of the overall magnitude of public health and welfare ramifications of the silicone issue. Speaking on behalf of the national, and international, support organizations, we trust that President Clinton, whom we support, will decide justly and intervene on our behalf.

Yours truly,

A handwritten signature in black ink, appearing to read "Pamela Stott-Kendall". The signature is fluid and cursive, with the first name "Pamela" being more prominent.

Pamela Stott-Kendall

cc: Secretary Donna Shalala
Congressman Henry A. Waxman

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197P-0050

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N. L. H.

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1

Divider Title: _____

LETTER TO CONGRESS

Statement of Legislative and Governmental Relief for Silicone-Implant Recipients

Prepared for:

Jan Erickson
National Organization for Women
1000 16th Street, Suite 700
Washington, DC 20036

Prepared by:

Author Pamela Stott-Kendall, *Torn Illusions*
(Reference: *Torn Illusions* has been accepted by the Food and Drug Administration for inclusion in the
FDA Center for Devices and Radiological Health Library.)
Diane Griffith, congressional liaison for United Silicone Survivors of the World (USSW)

March 18, 1997

Introduction:

Silicone implantation represents a forty-year period of human experiment without governmental or legislative intervention and regulation having required: 1) proof-of-safety submissions from manufacturers (in 1991, silicone-gel breast implants failed to prove safe when industry safety-data was finally demanded and reviewed by the Food and Drug Administration, FDA), 2) supervised clinical testing, 3) epidemiological research study, 4) and, more recently, the study of currently-injured implant recipients. To date, through the FDA's mandatory Manufacturer Device Reporting (MDR) program, silicone-gel, breast implant manufacturers have reported over 115,000 injuries and illnesses and close to 100 deaths; these MDR statistics increase at a rate of several thousand, new reports of breast implant-associated injuries and illnesses, along with several, new reports of associated death, each and every month. Despite documentation of continually-rising numbers of women harmed, and despite documentation of similar injuries, illnesses and deaths having occurred in relationship to all silicone implants of different form and use, none of these other silicone devices have undergone FDA review nor scrutiny of industrial proof-of-safety data.

In face of silicone's ongoing, unregulated human experimentation and on behalf of more than thirteen-million Americans, including women and men, who are recipients of various implanted silicone devices, and in further protection of their children exposed to second-generation silicone risks, we ask and recommend that the following congressional and governmental initiatives be introduced and implemented.

Governmental Initiatives to be Enacted:

1. Federal Task Force comprised of:

A. Knowledgeable medical experts who satisfy criteria restricting special-interest affiliation and who have conducted independently-funded, peer-reviewed, published silicone research.

implantation. In this study, 25% of women (one in four) who received these devices required additional breast-surgery due to complications occurring within five years of initial implantation. In cancer patients after mastectomies, breast-implant complications are three times more likely to occur than in cosmetic patients.

7. Continuation of Social Security, Welfare and Medicare/Medicaid benefits for silicone-related medical disabilities stemming from “toxic effects of silicone” as allowed by the ICD-9-CM classification system.

8. To reflect accurate statistics, research and data compiled by the FDA, the agency shall update and revise Consumer publications, currently being distributed to the prospective and current implant recipients, to provide all known information on silicone breast-implant risk.

Legislative Initiatives to be Enacted:

1. House Bill 366, written by United States Congressman James A. Traficant, Jr., of Ohio, cited as the “Breast Implant Accountability Act” to “require the surgical removal of silicone gel and saline fill breast implants, to provide for research on silicone and other chemicals used in the manufacture of breast implants.”

A. Explantation: Manufacturers shall pay all related medical, surgical and hospital costs of surgical removal of breast implants; explant patient may choose the physician and hospital of choice; the surgically-removed implant is the property of the explant patient; public notification “shall be published in national publications and newspapers of general circulation.”

B. Follow-up care and treatment of complications: Manufacturer is responsible for “post-operative care and treatment, including subsequent surgery to remove residual silicone, scar capsules, and granulomas, mammograms, and medication.”

C. Research shall be conducted, or contracted to be conducted, by the Secretary of Health and Human Services to determine the “physiological, neurological, and immunological effects of silicone toxicity and toxicity of other chemicals found in, or used in the process of manufacturing, breast implants.”

D. Informed consent: Physicians may not perform an implantation unless the prospective patient has first signed a consent form, prescribed by the Secretary of Health and Human Services, stating that the prospective patient has been informed of “all health risks associated with silicone oil, silica, and other chemicals used in the manufacturing of breast implants.

E. Physician services: A physician shall not refuse to treat a patient because that patient is a breast-implant recipient.

F. Organ and blood donations: “The Secretary of Health and Human Services may not make a grant... to an organ procurement organization if such organization has allowed an individual who has a breast implant in their body to donate an organ of the individual’s body”; “the Secretary of Health and Human Services may not license any entity engaged in the

collection of blood ... if such entity receives blood from an individual who has a breast implant in their body.”

2. Additional legislative protection is sought to provide health-insurance coverage, without exclusion or policy cancellation, pertaining to local and/or systemic adverse effects of silicone implantation relating to both cosmetic and reconstruction surgery.

As manufacturers fight to limit financial responsibility, and lessen settlement or court awards, to injured, silicone-implant recipients through industry litigation and bankruptcy pleadings and while health-insurance providers cancel and amend policies to exclude and/or deny silicone-related coverage, thousand upon thousands of silicone ill women, and men, turn to government-assisted support programs. FDA consultant and John Hopkins physician Dr. Norman Anderson has stated estimates projecting that 133 to 169 billion dollars will be needed for the monitoring, management and rehabilitation of breast implant victims residing in the United States alone. In time, public outcry and outrage will reach Congress; the number of silicone ill people who, after losing employment and health-insurance benefits, must rely upon government-assisted programs, both for support and medical care, grows at an alarming rate (MDR statistics). Research presented during a March, 1995 Immunology of Silicone Workshop, sponsored by the National Institute of Health, stated additional estimates projecting that less than 300,000 of an approximate, two-million American women with breast implants have reached the period of high risk for developing silicone-related disease. The FDA has acknowledged a seven to fifteen-year period of latency before symptoms and signs of implant-related illness surface.

3. Due to an established seven to fifteen-year period of disease latency associated with the development of silicone-related illness, current “statue of limitations” time-restriction on court case-filings and the discovery process, as applicable to product-liability litigation, must be revised and extended on both state and federal levels. Appropriately, in the state of New York, courts have waived “statute of limitations” restriction applicable to breast implant-related legal actions.

4. To ensure that equal distribution of financial burden rests upon those parties held responsible and not solely be delegated to governmental assistance at the public’s expense, Congress must address the larger issue of securing just compensation for injured, silicone implant recipients.

5. S. 224, written by Senator Herbert H. Kohl of Wisconsin, cited as the “Sunshine in Litigation Act of 1997,” to “amend chapter 111 of title 28, United States Code, relating to protective orders, sealing of cases, disclosures of discovery information in civil actions, and for other purposes.”

A. Protective orders and sealing of cases/settlements relating to public health and safety: An order under rule 26 (c) of the Federal Rules of Civil Procedure, restricting the disclosure of information, must not restrict the disclosure of information which is relevant to public health or safety; or “the public interest in disclosure of potential health or safety hazards is clearly outweighed by a specific interest in maintaining the confidentiality of the information or records in question”; “the requested protective order is no broader than necessary to protect private interest.”

B. Steering Committee of injured, silicone breast-implant recipients who represent the established goals of silicone informational and support networks.

C. Federal agency representatives of the National Institute of Health, Food and Drug Administration (FDA Center for Devices and Radiological Health and Office of Consumer Affairs), Health and Human Services, Center for Disease Control and Social Security Administration.

D. Representatives of major health-insurance providers.

2. Immediate guidelines set and action taken, with punitive measures adopted, by appropriate federal agencies (Federal Communication Commission and/or Food and Drug Administration) to effectively monitor, as well as to enforce, existing regulations that prevent circulation of misleading and false advertisement relating to silicone-implant use and safety.

3. Patient registry be formed to thereby total and track all silicone implant recipients, including supervised follow-up of the long-term effects of silicone implantation, pertaining, but not limited, to local, systemic, immune and neurological complications. Information collected may be utilized to establish disease-criteria relevant to silicone illness: a specific, unprecedented syndrome encompassing chronic inflammation, autoimmune/connective-tissue disorder, neurological involvement and toxic reaction that, as a syndrome, is typified by unique, yet undefined combinations of symptoms, clinical observations, laboratory findings, systemic organ/gland damage and immune dysregulation.

4. Adequate federal funding for silicone research be allocated to University-associated rheumatologists, immunologists, neurologists, toxicologists, oncologists, endocrinologists and pediatricians who satisfy criteria restricting special-interest affiliation. By this restrictive criteria, plastic surgeons, either individually or as group-organizations, will not receive federal research-funds; in addition to special-interest considerations, plastic surgery is not a diagnostic field of medicine.

5. Public-health campaign to disperse factual information on known complications and risks of silicone implantation be implemented by: 1) Health and Human Services, 2) U. S. Public Health Service, 3) Center for Disease Control, 4) and any other federal agency serving public education. For example, the public has not been informed of the FDA's own statistics stating that 71% of all breast implants rupture, or show severe gel-bleed/leakage, within ten years; 95% of these devices rupture within fifteen years, and gel-leakage occurs in 100% of all gel-filled devices from day-one of implantation. A public-health campaign, supported by these federal agencies, shall also initiate an educational program to benefit members of the medical community, in particular, those individual physicians who treat implant patients on a regular basis.

6. Due to unacceptable device failure and complication rates, the silicone-gel, breast implant ban (1992 FDA restriction of general market) shall remain in effect permanently. Recent research, (conducted by Mayo Clinic/Department of Health Sciences/Division of Rheumatology and Internal Medicine/Division of Plastic Surgery) published in the *New England Journal of Medicine* on March 6, 1997 (Vol. 6, no.10, pp. 677-719), supports a restriction of gel-fill, breast

B. Duration: No order entered in accordance with this protective provision shall continue in effect after the entry of final judgment, “unless at or after such entry the court makes a separate particularized finding of fact that the requirements” of amendments (paragraphs 1, A or C) have been met; the party seeking the entry of an order carries the burden of proof in obtaining such an order.

C. “No agreements between or among parties in a civil action filed in a court in the United States may contain a provision that prohibits or otherwise restricts disclosure of relevant information to any Federal or State agency with authority to enforce laws regulating an activity relating to such information”; information disclosed to a Federal or State agency, as described, “shall be confidential to the extent provided by law.”

D. As to evidence of serious public-health consequences resulting from a long history of court-protection of documents held secret despite warnings of health risks affecting the general public, the 1984 Stern versus Dow Corning case in California is a prime example. Attorney Dan Bolton, who represented the plaintiff, testified before a 1988 FDA Advisory Panel Review:

“I can tell you, however, that the jury saw many of these documents and determined that DOW had committed fraud, mislead the public, and disregarded the safety of women in marketing silicone breast implants. The judge in the Stern case described the Dow’s conduct as, quote, ‘highly reprehensible.’”

6. In closing, we ask that a congressional investigation and full hearing be held into the accountability of Dow Corning, Dow Chemical, Baxter Healthcare, Bristol Myers-Squibb and other silicone-implant manufacturers.

Jan This was passed with
several small amendments
Good Resolution.

BREAST IMPLANT RESOLUTION

WHEREAS, the National Organization for Women (NOW) has a longstanding policy of supporting health care, true informed consent, and safe products for women; and

WHEREAS, breast implants contain toxic chemicals, known carcinogens, and heavy metals such as aluminum and platinum, which bleeds into the body for decades at levels exceeding OSHA maximum allowable levels in the *workplace air* by 1,500%; and

WHEREAS, cancer victims have been further injured by silicone implants, and early research suggests that some children may also have silicone-related illnesses; and

WHEREAS, over one million American women, and thousands more worldwide, were told silicone breast implants were safe and would last a lifetime without any clinical, and even after 30 years of use, safety data is still inadequate; and

WHEREAS, hundreds of thousands of women have manifested a constellation of atypical illnesses, whose common link is breast implants, which are known to bleed silicone within 24 hours of insertion into the human body; and

WHEREAS, the use of breast implants continues today even though the rupture rate is as high as 71%; implant manufacturers have been found guilty of fraud with one charge upheld by the U.S. Supreme Court; and doctors and manufacturers continue to profit from women, while scientific data is still inadequate; and

WHEREAS, the Breast Implant Accountability Act (H.R. 2796), was introduced in Congress to aid victims by making manufacturers responsible for the removal recall of their ruptured or defective products; to require further research on the physiological, neurological, and immunological effects of the toxicity of silicone and other chemicals in breast implants; and to ensure that no physician refuse to treat a woman because she has breast implants.

THEREFORE, BE IT RESOLVED that the NOW work to educate women and men about the dangers of toxins in this product and as continue to empower people to accept their bodies as they are; and

BE IT FINALLY RESOLVED, that NOW support victims of silicone disease by supporting legislative intervention and avenues of relief.

Submitted by: Disability Rights Issues Hearing
Contact: Susan Boone

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September 23, 1997

Alan M. Slobodin
Committee on Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Slobodin,

Thank you for meeting with Diane Griffith and myself on Sept. 12th regarding the request for a hearing on the FDA's regulation of silicone breast implants (see enclosed letter). As requested, I am enclosing copies of documents that reveal a pattern of undue influence by the manufacturers and a prominent Plastic Surgeons Society on the regulation and resulting inaction by the FDA in banning this harmful defective toxic product that continues today.

I will attach a cover sheet to each piece of evidence, in an attempt to disclose the importance of the document and how it fits into the cover-up of the harmful effects of silicone gel breast implants.

Respectfully,

Marlene Keeling

COO1

P6/(b)(6)

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b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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1002]

This staff report on the FDA's regulation of silicone breast implants prepared by the Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations documents the concerns in 1992 that were known at that time and have not been adequately addressed.

No breast implant has ever been approved by the FDA. Women and their children born after implantation have been experimented on with the government's knowledge.

As stated in this report in 1992, Dow Corning disclosed that the company sold implants to doctors before they were shown to be safe in animals, failed to disclose problems with the implants, and submitted fabricated information about quality control.

I left a copy of the closing arguments in the recent Dow Chemical trial in New Orleans which I hope you have had time to read. All twelve jurors answered yes to the following questions:

1. Did Dow Chemical test silicone for human use for Dow Corning? YES
2. Was Dow Chemical negligent in that research? YES
3. Did Dow Chemical conceal information about the dangers of silicone in the body? YES
4. Would a reasonable woman have considered that information when deciding to get implants? YES
5. Did Dow knowingly make misleading statements about the safety of using silicone in the human body? YES
6. Did Dow knowingly withhold information that a reasonable woman would have considered in giving an informed consent? YES
7. Did Dow Chemical conspire with Dow Corning in any wrongful act or omission in connection with silicone in the human body? YES

FRAUD WAS COMMITTED BY DOW CHEMICAL AND DOW CORNING. THEY HAVE CONSISTENTLY LIED TO THE FDA, TO THE MEDICAL COMMUNITY, TO CONGRESS, AND TO THE CONSUMER OF FAULTY DEFECTIVE TOXIC PRODUCTS.

" Rupture of the silicone elastomer envelope can result from biodegradation of the envelope by tissue enzymes.. freeing the silicone gel to escape into the prosthetic cavity and BEYOND."

"In most cases, surgeons are unable to determine by external physical examination whether a prosthesis remains intact. Roentgenographic examination also has proved incapable of discerning the status of prosthetic envelopes..."

This patent application serial No. 041886 by Plastic Surgeon and Co-inventor of the original breast implant, Dr. Frank Gerow is dated 4-23-87. It was for a breast implant with radioopaque markers that would provide a method for detecting and predicting ruptures of silicone gel beyond the envelope of the prosthesis.

In the background information of the invention of breast implants, Dr. Gerow reveals what he knew in 1987. He states:

"Usage of these directly instilled agents (paraffin, processed petroleum, and silicon fluid) now is disfavored...because their use frequently was associated with local, often intense inflammatory reactions. Additionally, migration of...silicone fluid has been associated with..potentially fatal tissue responses...Human adjuvant disease may be a systemic effect of paraffin or silicone fluid instillation and is apparently an autoimmune connective tissue disorder that manifests as mixed connective tissue disease, rheumatoid arthritis, systemic scleroderma, or systemic lupus erythematosus."

"Onset of Adjuvant Disease has been reported as early as 2 years and as many as 25 years...In some cases, remission of the disease has followed removal of the augmentation agents; and in two cases, the disease has proved fatal."

"Until recently, Adjuvant Disease had not been associated with implantation of silicone elastomer enveloped, silicone gel prostheses. However, within the last two years, there have been several reported cases where Adjuvant Disease followed implantation of these prostheses. In the only reported patient who developed Adjuvant Disease following prosthetic implantation where the prosthesis had been removed and examined, the silicon elastomer envelope was found to be ruptured; and free silicon gel was found free in the human cavity for the implant. Thus, the finding of Adjuvant Disease in a patient carrying a ruptured prosthesis combined with data establishing possible association of this disease with instillation of free silicone fluid indicates that the risk of developing Adjuvant Disease may be enhanced by rupture of silicone elastomer enveloped, silicone gel implants..."

"Additionally, escape of the silicone gel from the envelope of the prosthesis is associated with other adverse consequences including satelliting of the gel into various parts of the soft tissue around the prosthetic pocket or down into the arm. Silicone gel in the soft tissue forms dense capsules and causes pain necessitating surgical excision of the gel. Recent data also suggest that the risk of infection in the tissue surrounding the prosthesis is increased following its rupture; and free silicone gel in the prosthetic pocket together with an infection may enhance synergistically the host tissue reactions to the implant. THEREFORE, RUPTURED PROSTHESES SHOULD BE REMOVED AS SOON AS POSSIBLE; and if there is any evidence of infection or movement of the silicone gel away from the prosthetic cavity, RUPTURED PROSTHESES SHOULD BE REMOVED IMMEDIATELY."

National Cancer Institute titled "Breast Implants and Cancer". The Associated Press article quoted S. Lori Brown as stating "A report to be published Wednesday in the Journal of the National Cancer Institute gives silicone breast implants a 'clean bill of health' so far as cancer and other disease is concerned." NBC, CBS, and ABC all carried similar statements. THIS IS BUT ONE EXAMPLE OF AN FDA SPOKESPERSON ONCE AGAIN MINIMIZING THE RISKS OF THE TOXIC EFFECTS OF SILICONE.

On May 12, 1995 Dr. Samuel S. Epstein with the Cancer Prevention Coalition filed a citizen petition with the FDA requesting a medical alert be sent to women with silicone gel and Polyurethane Foam Implants (INDUSTRIAL GRADE FOAM WAS INSERTED IN WOMEN'S BODIES WITHOUT LONGTERM TESTING) warning them of their risks of breast cancer and of the need for ongoing medical surveillance. He also requested a hearing be held on this matter. To date he had received no response from the FDA.

In a peer-reviewed research article entitled "Implants Pose Poorly Recognized Risks of Breast Cancer" dated 1995, Dr. Epstein reports that evidence on the risks of breast cancer posed by implants has been withheld from the public by industry, plastic surgeons, and the FDA. He states the need to consider prophylactic removal of polyurethane implants. This recommendation is repeated in "Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review" Annals of Internal Medicine, April 1996. "Women with implants should have them removed as a prophylactic measure, preferably within 8 years of implantation, to reduce the risk for rupture or severe bleed." THE FDA CAN NO LONGER IGNORE THE NEED FOR A VOLUNTARY RECALL ON IMPLANTS EIGHT YEARS OR OLDER.

This time line is a chronology of events in the use of silicone implants over their 35 year history and involvement of undue influence by a well known Plastic Surgeon Society (supporting documents supplied upon request)..

Document ASP016958 discusses a grass-roots direct mail campaign to Dr. David Kessler and key members of congress using ASPRS non-profit mail rate and funded by the manufacturers.

The 1992 staff report to congress documents professional pro-implant lobbyists included former FDA officials who provided patient lobbyists with misleading information. This report also states that patients continue to be misled by the FDA-approved informed consent and the Plastic Surgeons attempts to change the forms.

Attached is the Mentor Adjunct Study Protocol Informed Consent which include the following statements or terms: most women implanted have had satisfactory results (not according to the PRP reports of over 100,000 adverse events), this data will be used to help determine if these implants are both safe and effective (see attached St. John's memo stating this is "an illusion" of a study), several "surveys" have shown that over 90% of women are pleased with the results, complications are uncommon, on rare occasions, causes no known problem, harmlessly, rare for an implant to rupture, FDA has required manufacturers to sponsor large-scale scientific studies, and scientific studies are continuing to determine whether women with implants have a higher rate of cancer than women without implants over a longer term. ALL DESIGNED TO MINIMIZE THE RISKS OF THE TOXIC EFFECTS OF SILICONE GEL. WHEN A WOMAN SIGNS THIS "SO CALLED" INFORMED CONSENT, SHE NO LONGER HAS ANY LEGAL RECOURSE AND MOST LIKELY WILL BE DENIED INSURANCE COVERAGE.

The 1992 Report to Congress states that the FDA's public statements about breast implants minimized the risks. The FDA continues to minimize the risks in public statements and official publications.

The FDA's official publication on Breast Implants - An Information Update dated March 1996 includes the statement on page 76 "The FDA estimates that rupture rates are generally between one to four percent". THE ANNALS OF INTERNAL MEDICINE APRIL 1996 REPORTS A 71%...FRANK RUPTURE OR SEVERE SILICONE BLEED AT EXPLANTATION.

Document ASP003001 notes PSEF (Plastic Surgeons Education Foundation) and manufacturers influence in the design of the NCI study by Dr. Louise Brinton. Document ASP035925 discusses a \$50,000 gift to NCI's research.

The most recent research released by the Journal of the National Cancer Institute was reviewed by S. Lori Brown of the Food and Drug Administration and Louise Brinton of the

You asked for research to document the spread of silicone gel to all parts of the body. The enclosed research "Breast Implants and Cancer" just recently released Sept. 17, 1997 in the Journal of the National Cancer Institute reports evidence of silicone in the implant capsule, axillary lymph nodes, arms, fingers, groin, blood, and liver. PRP REPORT #M23151 DATED 8/22/91 STAMPED FDA00019016 BY A PHYSICIAN AND PATHOLOGIST STATES "SPLEEN LOADED WITH SILICONES. THERE IS PRESENCE OF SILICA AND SILICONES IN HUMAN TISSUE AFTER IMPLANTATION OF PROSTHESES, EVEN WITHOUT OVERT RUPTURE.

Dr. Douglas R. Shanklin in a statement made before a Congressional hearing on August 1, 1995 reports finding silicone in the brain and chest cavity of a 50 year old woman who was autopsied. Dr. Shanklin summarized his experience in studying human tissues for almost ten years by saying "silicone devices are not inert in the human body. Gel filled ones leak and rupture with profound pathological and immunological consequences. Women can and do die from effects of their implants."

Spec scans are now showing reduced blood flow to the brain of many implanted women. They are being diagnosed with white lesions on the brain, atypical neurological disease, and organic brain dysfunction. Many children born to implanted mothers, are now being diagnosed with Attention Deficit Disorder. Reading through the PRP reports, the term memory loss appears repeatedly.

IT IS UNACCEPTABLE THAT THE FDA HAS ALLOWED THIS NON LIFE SAVING DEVICE TO REMAIN ON THE MARKET WITH THE GROWING BODY OF EVIDENCE OF THE HIGH RUPTURE RATE AND MIGRATION TO ALL PARTS OF THE BODY. WHILE WOMEN CAN GET THEIR IMPLANTS REMOVED, THEY CANNOT GET THE GEL REMOVED THAT HAS SPREAD THROUGHOUT THEIR ORGANS.

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. form	re: Consent to be a subject (partial) (5 pages)	09/25/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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Adjunct Study Protocol Informed Consent

002AS-01

CONSENT TO BE A SUBJECT IN THE MENTOR H/S SILICONE GEL-FILLED MAMMARY PROSTHESIS CLINICAL RESEARCH STUDY

INVESTIGATOR:

P6(b)(6)

CITY

STATE

PATIENT'S STUDY NO. (SS#):

P6(b)(6)

You are being asked to participate in the Mentor H/S Silicone Gel-Filled Mammary Prosthesis Clinical Study. This *Informed Consent* gives you information about your breast implant procedure and your participation in this study and verifies that you have received it.

To be eligible for participation in this clinical study, you must not have specific connective tissue disorders; be a candidate for breast reconstruction in which saline-filled implants are not suitable; and complete a basic screening by your surgeon. In addition, you must sign this document indicating that you have been provided with the required information. You should ask your surgeon to clarify any terms which you do not understand. Additionally, your surgeon must provide you with a copy of this document.

A. Purpose and Background of the Study

Breast implants have been used in nearly two million women for nearly 30 years. Although there are risks and complications of having breast implants, most women implanted have had satisfactory results. The Food and Drug Administration (FDA) is concerned that there is not enough information about possible health problems from the use of these devices. The FDA has called for detailed scientific studies and has allowed breast implants to be available under these studies while the data is being collected. This study will be used to collect short-term (5 year) data about possible health problems associated with breast implants. This data will be used to help determine if these implants are both safe and effective. If they are proven safe and effective, they will continue to be available. If the data from the studies does not show they are safe and effective, they will not be available in the future.

B. Device Description

The manufacturer of the implants you and your doctor have chosen is Mentor H/S. You may receive one of three different types of silicone gel-filled implants. Two of the types of implants contain both silicone-gel and saline solution and the third type contains only silicone. Your plastic surgeon will discuss the various types of implants with you and explain why a particular device may be best suited for you.

C. Procedures

1. You will talk about your procedure and participation in this study with your surgeon in advance and you should take sufficient time to think about participating.
2. If you agree to be in this study, you will first have to be examined to determine if you are a good candidate and if you are eligible. This screening may involve referral to other physicians. Follow-up visits to other physicians may also be required.
3. **Description of Operation:** The operation you will have will be performed by a surgeon using accepted standards of practice. The operation may be performed in the physician's office, or in a hospital operating room or in an outpatient surgical center. Hospitalization may or may not be required. Your surgeon will explain the particular type of implant that will be used, how and where it will be placed and the type of anesthesia to be used. He/she will also give you an overall description of the operation. This may not be a one time operation. Further procedures involving expansion/inflation of your implant or management of complications may be needed.
4. **Surgical Consent:** In addition to this Consent Form, you may have signed, or will be asked to sign a surgical consent form which addresses specific risks of the surgical procedure and risks of anesthesia.
5. **Additional Follow-Up Visits/Extra Appointments with your Surgeon:** In addition to normal visits/appointments with your surgeon (i.e., 1-2 weeks, 1 month, 6 months), there may be additional appointments which are required as part of the research. Your participation in the research will be for 5 years. The study schedule requires follow-up visits 12 months, 36 months and 60 months after your surgery. Each visit will take about 30-60 minutes. You are making a commitment to continue in the study for the duration and to complete all of these follow-up visits. If you move within 5 years, arrangements will be made with your surgeon for follow up with someone in your area.

6. **Analysis of Removed Implant:** If there is a problem resulting in a medical need to remove your breast implant, FDA requires the implant to be sent to Mentor. Mentor will store it and will ask you for permission to analyze it, a process which may alter or destroy it. The results will be sent directly to your surgeon. You will also be asked if you want the results of the analysis sent directly to you, Mentor H/S and the FDA. Mentor H/S and FDA believe there is scientific benefit to testing an explanted implant.

7. **Implant Registry:** You will additionally be asked to enroll in a breast implant registry which will allow Mentor H/S to notify you, if necessary, of important new information about your silicone gel-filled breast implant(s). Every effort will be made to keep the information in the registry confidential and will only be provided to the FDA, upon their request. However, under certain circumstances, Congress has the right to get clinical data from the FDA or a court could order disclosure of certain information which could include your clinical study records. You may object to participating in a breast implant registry. If you do object, your doctor will describe in writing how he/she will inform you of any important new information about your implants that he/she receives.

☐ I choose not to participate in this implant registry. You should also remain in contact with the surgeon to get current important information or, if you leave the surgeon, you should leave an address.

8. **Implant Identification:** Your surgeon will provide you with identification information which pertains to your implant(s) after your surgery. This will let you know what type of implant you have. This should be kept with your important papers for future reference.

9. **Second Opinions:** If any problems or complications occur during the study, you may be asked or wish to obtain second opinions. You have the right to consult a physician of your choice.

D. Benefits of Breast Implants

The major effect of breast implants is to enhance or restore the appearance of a woman's breasts. Breast implant surgery may benefit you by providing a successful surgical breast reconstruction procedure. There may be psychological benefits to having breast reconstruction with silicone gel-filled implants. Women have also reported that breast reconstruction with breast implants have been an aid in their recovery from breast cancer, and have reduced emotional stress by helping to return their body to a more natural appearance as opposed to having nothing done or using an external prosthesis. Each individual woman has her own private sense of how she wishes to look and whether she wishes to go through surgery to achieve this appearance. Several "surveys" have shown that over 90% of women are pleased with the results. However, there are insufficient controlled scientific studies to prove that these

results are long lasting. On-going studies will help evaluate whether breast implants improve a woman's quality of life.

When compared with other possible surgical treatments (i.e., flap reconstruction, etc.), breast implants have fewer surgical complications; require less surgical procedure time; are less costly; and have a shorter recovery period.

Entering in the study may also benefit other women by providing information about gel breast implants used in reconstruction, including any possible health problems associated with gel breast implants.

E. Risks

1. **Risks, Complications and Discomforts of the Operation:** Breast surgery requires an incision into the breast under anesthesia. As with any surgical procedure, there are risks such as *infection, delayed wound healing, hematoma formation (a collection of blood inside the body in and around where the incision is made), bleeding and possible reactions from anesthesia.* These complications are uncommon.

An *infection* can result from any surgery and produce swelling, tenderness, pain and fever. Almost all infections appear within a few days of the operation but on rare occasions may appear at any time after your surgery. If you get a serious infection which doesn't go away with antibiotics, your implant may have to be removed. Small *hematomas* will be absorbed by your body like any bruise but large ones may have to be drained surgically to permit proper healing. Any incision in the skin will leave a scar. Surgical techniques, under most circumstances, can minimize though not eliminate them.

2. **Risks, Complications and Discomforts of the Breast Implant(s):** Breast implants have certain specific risks and complications which may include:

a. **Capsular Contracture:** The scar tissue that forms around the implant can tighten and squeeze the implant as a natural response to having any foreign object implanted in the body making it feel firm. This firmness can range from slight to hard and the firmest ones can cause varying degrees of discomfort or pain and can also make the detection of breast cancer by mammography more difficult.

If you wish to have them softened, the scar tissue can be released or removed altogether during a surgical procedure called an *Open Capsulotomy*.

Your surgeon may recommend a technique called *Closed Capsulotomy* in which he/she will apply forceful external pressure to the breast(s) to "break up" the scar tissue. This technique is not recommended by the manufacturer, because it could result in several complications, such as breakage of the implant. However, your surgeon

may result in the best method for correcting the firmness because if it works it is quick, simple and avoids surgery, although it may be briefly painful. If your surgeon uses this technique, several complications may occur. These include **bleeding, displacement of the implant which may result in asymmetry, distortion, and breakage of the implant.**

Your surgeon will explain the possible complications as well as helping you determine your choice for correcting capsular contracture.

- b. **Calcium Deposits:** Any surgery or injury to the breast can produce small spots of calcium in the breast tissue which can be seen on X-rays (mammography). These deposits may not occur until years after implant surgery. They are benign and cause no problems but must be differentiated from the calcium that is often seen in breast cancers. An expert radiologist can usually tell a benign calcium spot from a malignant one but occasionally a biopsy may be necessary to be absolutely sure. Some patients may develop a thin layer of calcium in the scar capsule that surrounds the implant. This is almost always associated with capsular contracture but otherwise causes no known problem.
- c. **Rupture/Deflation of the Implant:** Breast implants may not last a lifetime. The shell of a silicone gel implant can break due to injury or normal wear over time, releasing the silicone gel filling. Two of the types of implants included in this study (Becker device and Combination Gel-Saline device) contain both silicone gel and saline (salt water). If the envelope containing the saline portion breaks, the saline is absorbed harmlessly by the body within hours. As the saline portion of the implant is usually small, the decrease in breast size is minor. Surgical replacement is necessary if you wish to restore your size and shape.

Gel implants can break without any noticeable symptoms. Some women have reported a burning sensation or a change in the feel or shape of the breast. You should see your doctor if you notice these symptoms or if you think for any reason, your implant may have broken. While no guaranteed method to detect breakage now exists without surgically opening the pocket containing the implant, mammography, ultrasound and physical examination can usually make the diagnosis.

The gel released as a result of rupture may be contained within the capsule surrounding the implant. If the scar envelope also tears, the gel can travel (migrate) and be squeezed into the

or tissue or into the muscle or fatty tissue next to the abdominal wall or arm. Fortunately this is uncommon. The risks from this escaped gel are unknown. See section on Unknown Risks.

- d. **Gel Bleed:** It is known that some very small amounts of silicone "bleeds" through the implant's covering or envelope. Although most of this stays in the implant pocket or is trapped in the surrounding scar, microscopic amounts of this silicone could possibly travel (migrate) to different parts of the body.

Silicone can also be in the body from a variety of sources and it is undetermined whether the silicone from the breast implants poses any risk. See section on Unknown Risks.

- e. **Changes in Nipple and Breast Sensation:** Any surgery on the breast, including a biopsy or breast implant surgery, can result in increased or decreased sensation of the breast and/or the nipple. This change can vary in degree and may be temporary or permanent. It may affect comfort while nursing or sexual response.
- f. **Interference with Mammography:** An implant can interfere with the detection of early breast cancer because it may "hide" suspicious lesions in the breast during an X-ray exam. It is especially important for women who are at high risk of developing breast cancer to consider this before having implants. The earlier cancer is detected, the better the chance for a cure.

Since the breast is compressed during mammography, it is possible, but rare for an implant to rupture. These problems can be reduced, but not eliminated, by making sure the mammography facility is accredited by the American College of Radiology (ACR) and asking if the personnel at the facility are experienced in performing mammography on women with implants.

Before the mammography exam, you should tell the technologist that you have implants. The technologist should take special care when compressing the breast to avoid implant rupture. Also, an experienced technologist should know how to push the implant away from the breast tissue to get the best possible views of the tissue. Even when this special technique is used, some breast tissue may be missed in the X-ray. Also, women with implants are subject to some additional radiation and higher costs because more X-ray views are needed for women with implants.

The small amount of additional radiation should not deter you from having mammograms when needed. The risk of a missed cancer is far greater than the slight amount of extra X-ray.

- g. **Cosmetic Complications:** You may not be satisfied with the appearance of your implant. *Incorrect implant size, inappropriate scar location or appearance, and misplacement of implants may interfere with a satisfactory appearance. Asymmetry (unequal breast size or shape) may occur.* The implanted breast may sag or droop (*ptosis*) over time, much like a natural breast. Very rarely the implant may change position or break through the skin, particularly if you have very thin breast tissue covering it. You may be able to feel or see wrinkles in the implant through your skin. If your implant has a valve, you may also be able to feel the implant valve with your hand. Although these complications are not dangerous, you should be aware of these possibilities when considering a breast implant operation as they can detract from the quality of the result.
- h. **Interference with Breast Feeding:** Many women with breast implants have nursed their babies successfully. Surgery that removes a great deal of breast tissue, such as mastectomy, could of course interfere with breast feeding. Any breast surgery, including breast implant surgery, could theoretically interfere with your ability to nurse your baby. Further studies will provide more information about this possible risk.
- i. **Granulomas:** These are non-cancerous lumps that can form when certain body cells surround foreign material, such as silicone. Like any lump, it should be further evaluated to distinguish it from a lump that might be cancerous and may require a biopsy.
- j. **Unknown Risks:** In addition to these known risks, there are unanswered questions about silicone gel-filled breast implants. Both rupture and "Gel Bleed" may result in the silicone going to other parts of the body. The medical complications which may occur as a result of these devices are unknown; however, there may be long-term effects which include:

Connective Tissue Disorders: There have been a few reports and substantial speculation that there could be an association between certain silicone and certain connective tissue disorders. These are a group of disorders in which the body reacts to its own tissue as though it was foreign material. These disorders can cause long-

term, serious, disabling health problems. Symptoms include pain and swelling of joints, tightness, redness or swelling of the skin, swollen glands or lymph nodes, unusual and unexplained fatigue, swelling of the hands and feet, and unusual hair loss. Generally, people who have these relatively rare connective tissue disorders experience a combination of these and other symptoms.

Some cases of these disorders have been reported in women with breast implants. Some of these women have reported a reduction in symptoms after their implants were removed. Since connective tissue diseases are rare, they are difficult to research and will require large-scale epidemiologic studies to determine if there is an association with implants. More research needs to be done to determine if women with implants have higher rates of these diseases than women without implants. To explore whether a possible link exists between breast implants and connective tissue disorders, FDA has required manufacturers to sponsor large-scale scientific studies. Final study results are expected no sooner than 1997.

Cancer: There is presently no scientific evidence that links either silicone gel-filled or saline-filled breast implants with cancer. However, the possibility cannot be ruled out. Scientific studies are continuing to determine whether women with implants have a higher rate of cancer than women without implants over a longer term.

Birth Defects: Preliminary animal studies show no evidence that birth defects are caused by breast implants. However, to rule out that possibility for humans, further scientific studies are necessary to show whether or not breast implants are associated with birth defects.

Your doctor will discuss any additional information about the risks of silicone gel breast implants and your surgical procedure. You are also encouraged to read the Product Information Data Sheet which your doctor will provide to you, upon request.

3. Non-Medical Risks:

- a. **Costs:** This study may require one or more visits, to a rheumatologist or other specialist. There may be an extra charge for these visits. All costs incurred for this study are between you and your physician. This includes costs for any additional

procedures or visits to another specialist that may be required for the operation or for participation in the study. Your operation and associated costs may or may not be reimbursed through insurance.

- b. **Insurance:** Breast reconstruction using silicone gel-filled breast implants have been covered under existing insurance policies. Neither Mentor H/S nor FDA know of any reason why existing coverage policies should not continue. It is however, your responsibility with your doctor's help, to contact your insurance company and determine the coverage available for this procedure.

- c. **Confidentiality:** Your confidentiality will be protected as much as possible throughout this study. Your medical records will be reviewed by representatives of Mentor H/S and will be made available for review as required by the FDA. Results of data collected will be reported as statistical information only.

Your Name, Date of Birth (DOB) and Social Security Number (SSN) will be listed on the clinical study forms. Disclosing your SSN is optional. If you choose not to disclose your SSN an alternative identifier will be assigned.

Under certain circumstances, your clinical records could be obtained by Congress or by a court order. While every effort will be taken to keep this information confidential, under certain circumstances this could mean public disclosure of your surgery and loss of your privacy.

- d. **Legal Risk:** If your implant needs to be removed, FDA requires the implant be returned to Mentor H/S for evaluation. This could have implications in any legal action involving your implant. Should Mentor H/S wish to do an evaluation of the implant which is removed which could alter or destroy it, you will be contacted first through your surgeon and asked whether you wish to give permission for such an evaluation.

F. Alternative Procedures

There are several alternative procedures to breast reconstruction with silicone gel-filled breast implants. These include having nothing done or wearing an external prosthesis inside your brassiere (no surgery required). Breasts can be made by transferring fatty tissues from other parts of the body such as the stomach, buttock or back (flap procedure). Although for many women saline breast implants are an alternative, you have been advised that gel implants will produce a superior result for you than will saline implants.

You may also choose to have your silicone gel breast implant procedure using another physician who is participating in a study using another brand of implant. If you choose to not participate in the study, you may not be provided with silicone gel implants by the manufacturer. Your surgeon should discuss these alternatives with you.

G. Compensation for Injury

Compensation for physical injuries, complications or medical treatment from your participation in this study is not available from Mentor H/S. If a problem occurs, medical treatment will continue to be available. Your surgeon will let you know what to do if you experience any complications while you are in this study.

H. Questions

During the course of the study, you will be advised by your physician regarding any new information about Mentor H/S breast implants which may become known during the study. You also have the right to ask questions and have them answered.

1. For questions about your procedure you should contact your surgeon, Dr. [REDACTED] at [REDACTED].

2. For questions about the study or any additional information about Mentor H/S breast implants, you may call or write to Mentor H/S at:

Mentor H/S
Adjunct Study Coordinator
5425 Hollister Ave.
Santa Barbara, CA 93111
(805) 681-6000

3. For questions regarding your participation in the study and your rights as a research subject, you may contact an independent reviewer of the research:

Independent Review Consulting (IRC)
305 San Anselmo Ave., Suite 305
San Anselmo, CA 94960
(800) IRC-3421 FAX (415) 486-0328

I. Acknowledgment

I was provided this consent form in advance (a minimum of 3 days prior to surgery when feasible) and met with my surgeon, Dr. [REDACTED] on [REDACTED] to discuss the information. All my questions have been answered to my satisfaction and I have been provided a copy of this form and Experimental Subject's Bill of Rights (in California only).



November 4, 1992

David A. Kessler, M.D.
Director
Food and Drug Administration
Rockville, MD 20857

RE: Mentor gel-filled mammary prosthesis adjunct study

Dear Dr. Kessler,

We, the undersigned, have grave concerns about the Mentor gel-filled breast implant adjunct study.

The protocol does not appear to us to be a "research study" in any familiar sense of that term: a) There is no actual goal. The study is simply open for five years to any woman who "qualify;" b) There are few exclusion criteria. In addition to the standard exclusions for any type of breast implant, women would be excluded if they merely desired augmentation, or if they had a qualifying condition and saline implants were deemed "medically unsuitable" by the surgeon; c) Inclusion criteria are very subjective and general. A woman could simply report to a surgeon that she didn't like the appearance of her breasts due to say -- ptosis -- and medically "qualify" to have reconstruction with silicone gel; d) The consent form omitted a good deal of information that we believe should be revealed (see enclosed list); and e) we have been informed by Mentor (see enclosed letter) that Institutional Review Committees may not make alterations in this consent.

We realize that many plastic surgeons have firm convictions that the silicone poses no health risk. We respect their convictions, but point out that strong convictions do not constitute scientific evidence. Not too long ago, sincere surgeons were convinced that only radical mastectomy was a suitable intervention in cases of cancer of the breast.

In your article in NEJM (June 18, 1992) you wrote: "...Restrictions on the use of silicone gel implants for breast augmentation are not based on any judgment about values. Rather, the FDA has concluded that women who desire breast augmentation are at higher risk than patients with breast cancer who have had

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ASP034225

EC- 1-92 TUE 4:17 PM ST JOHN'S HOSP

a mastectomy. Unlike patients who have undergone mastectomy, they still have breast tissue, and the presence of an implant complicates the use of mammography for the detection of breast cancer....In the end, it comes down to this: in our opinion the risk-benefit ratio does not at this time favor the unrestricted use of silicone breast implants in healthy women." The design of the Mentor adjunct "study" belies the concerns you expressed. This "study" makes these devices widely available to women who have not had mastectomies. If women are to be offered these implants outside of scientifically valid studies, we believe this offer should be restricted to the present "urgent need" population.

An FDA official (who shall remain unnamed) said to one of us (Tobias Meeker) that this adjunct protocol "is an administrative device to continue to make these implants widely available to those who have such need that the lack of established safety can be overlooked if there is a good informed consent process and the oversight of an IRB."

To assume that a good consent process (with Institutional Review Committee oversight) will protect subjects from unjustified risks strikes us as a faulty assumption. This implant is a product with unproven safety and demonstrated (but unproven) risks. Further, we are concerned that misrepresenting this "administrative device" as a legitimate scientific study misleads potential recipients, making it more difficult for them to assess risk.

We see no role for an Institutional Review Committee in this "study." We feel that we are being asked to be participants in a political solution to this highly politicized issue. Asking IRBs to behave in this manner violates their mandate and calls into question their integrity. We hope the FDA will reconsider this whole approach.

Sincerely,

Tobias Meeker, M.Div., M.A.
Director, Ethics Program

TM/jb

These persons have given permission, by signed letter, for their names to appear here: [Your Name here]

St. Jean deBailis, Center for Health Care Ethics, St. Louis Univ. Medical School, 1402 S. Grand Blvd., St. Louis, MO 63104

Tom Scoyman, St. John's Mercy Medical Center, 615 South New Ballas Road, St. Louis, MO 63141

Mr. Rose Marie Trump, St. Joseph's Regional Health Center, 100 Whittington Avenue, Hot Springs, AR 71901

Tom Shindler, Mercy Health Services, 34605 Twelve Mile Road, Farmington Hills, MI 48331-3221

Dr. Tom Tomlinson, Medical Humanities Program, Michigan State Univ. Medical School, C-201 East Fee Hall, East Lansing, MI 48824

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RESTRICTION CODES

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b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



AMERICAN SOCIETY OF
PLASTIC AND RECONSTRUCTIVE
SURGEONS INC

December 4, 1991 Telephone Conference Call 1:30 PM CST

Participants: Jon Kent, Mark Heller, Michael Reed, Dave Fellers, Bobbie Lawrie, Andrea Contreras

The purpose of the conference call was to discuss and refine the proposed actions identified during the December 3, 1991 telephone conference call.

EXECUTIVE OFFICE
448 EAST ALCONHOLA ROAD
ARUNCTON HEIGHTS, N. 60005
708/228-1900
FAX (708) 228-9151

The summit meeting goals and objectives were discussed and it was determined that this type of meeting may be better received if held in Washington, DC. The success of a summit meeting hinges on the commitment and willingness of those involved.

The letter to Dr. Kessler informing him of the activities of plastic surgeons was prepared and faxed to the participants of the call. It was determined that this type of letter was not necessary at this point in time and that a meeting with Dr. Kessler and/or his Deputy, Mike Taylor may more effectively display our continued efforts in satisfying the FDA's research concerns. A meeting between Stuart Pape, Dr. Hollis Caffee and Mike Taylor or possibly Dr. Kessler will be arranged on December 13, 1991 (alternate date December 12, 1991). The objective of this meeting is to present our list of important research areas and at the same time receive feedback as to which items on the list are of greatest importance to the FDA.

It is anticipated that the research mailing containing the identified areas of research will be distributed prior to this meeting.

A gift from the ASPRS/PSEF of \$50,000 towards the NCI's research project was discussed in great depth. An overall strategic plan in connection with this gift is needed prior to a commitment of funds. It was noted that any extreme restrictions connected to the NCI gift would be rejected. Jon Kent, Drs. Brody and Spear will meet with Nancy Taylor the week of 12/9 to engage in a substantive discussion of the NCI research project with reference to the ASPRS/PSEF gift in general terms. Another avenue (other than financial) in which ASPRS/PSEF may involve itself in the NCI project is for the members to devote their experience as plastic surgeons as it relates to their patients.

Dave Fellers informed the group of the recent Donahue program featuring implants and discussion of a new, safe implant for which a patent reportedly has been filed. A patent search will be conducted by Mike Reed and any information concerning this new implant will be distributed.

Jon Kent, Mark Heller and Michael Reed will be included in the next telephone conference call on December 10, 1991 at 7:30 PM CST.

ASP035925

Synopsis of grass-roots Direct Mail/Telephone Program

Number of pieces - 200,000 (to pre-tested lists)

Number of follow-up phone calls - 175,000

Cost for mail (with ASPRS non-profit rate) - \$162,450

Cost for phone calls - \$150,000

Manufacturer participation: Dow and Mentor have expressed a willingness to pay up to \$50,000 a piece for phone calls. McGhan participation is uncertain.

Who will now be targeted: recipient will be asked to mail pre-printed post cards, call or write:

- 1) Kessler
- 2) Key members of Congress

We have dropped the White House due to the shake-up there.

*Done!
received
from Roger
12/4/91*

✓

ASP016958

However, rather than focus on the negative statements that have been made by some critics, I believe it is very important for us to maintain a positive posture when dealing with the FDA. There is a great deal of positive activity being conducted related to the breast implant issue, and we need to make people aware of it. For instance, we can refer to the two research projects now being funded by an industry partnership.

The first is known as the "NYU Study" and seeks to replicate and expand the Deapen-Brody cancer study in Los Angeles. Our membership has contributed significant input to the selection of the researchers and the design of this project. The second project is the "Michigan Study" and will attempt to resolve once and for all the question of whether there is any cause-and-effect relationship between breast implants and autoimmune diseases. While we have not been involved in this latter project, we can urge that the FDA not take action until this and the "NYC Study" are complete. *

In addition an ASPRS resolution calling for an extensive review of the scientific literature on breast implants was approved by the AMA House of Delegates in June. The resulting informational report should be completed and distributed to the AMA House of Delegates in December. It may be published in JAMA.

Generating positive letters to the FDA and Congress at this time is very important. We continue to hear that consumer groups are very effective in generating an ongoing stream of letters to the FDA in opposition to breast implants.

Here is what we have done or are planning to counter the negative efforts:

1. Written to Dr. Kessler requesting a face-to-face meeting in Washington.
2. Preparing to initiate a grassroots letter-writing campaign that will activate ASPRS members and their staffs, other physicians, support groups and, most importantly, patients.
3. Developing a lobbying campaign that will educate members of Congress on the issue and obtain their support. This will require identifying plastic surgeons and their patients who are willing to travel to Washington and visit with their Congressmen and Senators.

4. Developing a strategic plan to pursue in the event that silicone-gel breast implants are banned or restricted by the FDA.

There are two major factors to consider. The first is the timeframe in which we must work. The letters to and other contacts with Congress and the FDA must be made immediately. The FDA staff's analysis of the PMAAs is expected to be complete by November, so action is needed NOW. The second factor is the ASPRS Annual Meeting in Seattle.

In order to utilize the convention to educate and motivate our members, we will offer you the opportunity to visit with staff about the importance of Congressional contacts and to determine whether you and/or your patients could travel to Washington, D.C. to meet with Congressmen and Senators. Special tables will be available from 9:45 am to 5:00 pm on Monday, September 23, in the Convention Center lobby, and at the ASPRS Resource Booth in the exhibit hall the rest of the week. Additionally, we will discuss this issue in more detail at the Annual Business Meeting on Wednesday, September 25.

Following the convention, an information packet will be mailed to the entire membership. A reply form will give you a mechanism to report what action you take. ASPRS will compile the information and use it as a resource to keep you informed of what strategies have been successful in responding to this issue.

The future availability of breast implants is of significant importance to a major portion of our membership. It is critical that ASPRS and its membership take the lead in responding to the inaccurate and misleading messages being spread by consumer groups. Your support in this letter-writing and Congressional-contact campaign will make a difference!

If you have any additional suggestions or ideas on how ASPRS can respond to this issue, please share them with Zan Lofgren, Director of Health Affairs, who is serving as staff project coordinator for this issue.

FDAREVIS.MEM

ASP005218

SUMMARY

The PSEF Silicone Implant Research Committee will circulate the silicone research proposals to the manufacturers for their input as to the merit and validity of the proposed projects. This effort will also assist in disseminating potential research projects which the manufacturers or other interested groups may wish to pursue.

The representatives of the PSEF and manufacturers will assemble in Washington, DC to assist Dr. Louise Brinton in composing the NCI study questionnaire.

It was agreed that the consensus conferences of various specialties are worthwhile and will be pursued. Dr. Brody will proceed with arranging the radiology, rheumatology and immunology meeting.

Dr. Kaczmarek of the FDA, outlined the differences between case control studies and cohort studies. The Hochberg study on connective tissue disease is an example of a case control study. A case control study on silicone would be favored because it more rapidly provides results.

It is important to identify a valid methodology for the study of capsular contracture from a clinical standpoint.

The establishment of a breast implant registry was discussed and no conclusion was reached except the fact that its benefits are not as "scientific" as one might hope.

In approximately 6 weeks the group will reconvene following the work to be performed concerning the NCI grant.

THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS

A STAFF REPORT PREPARED BY THE

HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS



DECEMBER 1992

Printed for the use of the Committee on Government Operations

U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON : 1993

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Report says breast-implant dangers covered up



WASHINGTON (AP) - A congressional report says women for years were misled about the safety of some breast implants. It accuses the government of failing to act and the industry of trying to cover up the problems.

Even now, Wednesday's report said, the Food and Drug Administration has played down the health risks of the implants and has not monitored their use since partially lifting a moratorium on the devices last year.

"When attention was focused elsewhere, it was business as usual at FDA," said Rep. Donald M. Payne, D-N.J. and the chairman

of the House Government Operations subcommittee on human resources.

FDA Commissioner David Kessler said the allegations in the committee's report were "ludicrous."

Asked if manufacturers were engaged in a cover-up, Kessler said, "There are investigations under way." He would not elaborate.

Kessler said, "I think it's patently clear that the action the FDA has taken over the past year has significantly affected the use of silicone gel breast implants."

Before the moratorium last January, 130,000 women a year were getting the implants, and last year that number dropped to 3,500, Kessler said.

The report said people within the FDA were long aware of problems with two kinds of breast implants: those filled with silicone gel and gel-filled implants covered with polyurethane foam.

The agency has received complaints that silicone gel leaking into women's bodies from the implants caused a host of health problems, including soreness and symptoms related to disorders of the immune system.

The polyurethane foam has its own set of problems, breaking down to toluendiamine, or TDA, a compound that causes cancer in animals, the report said.

The committee obtained company memos indicating that officials knew of the

problems in the late 1970s. Those implants were taken off the market two years ago.

Documents from Medical Engineering Corp. ordered the destruction of lab beagles who were developing "such adverse reactions as hemorrhage, possible pneumonia of the lung and hyperplasia of lymphoid tissue of the large intestines," the report said.

The company's president wrote in long-hand across the top of one of these documents "sacrifice dogs ASAP" and ordered "no organs of dogs in freezer."

The report said women have been misled for at least 15 years about the implants' safety. It said manufacturers made safety claims that could not be backed up.

The report added that plastic surgeons did not question the companies and the FDA was slow to demand that the manufacturers scale back their claims.

The report attributed the FDA's slow response largely to lobbying efforts by plastic surgeons and manufacturers, as well as being kept in the dark about possible health problems appearing in the companies' own studies.

Silicone gel breast implants are available in controlled clinical studies to women who need reconstructive surgery after breast cancer, and on a much more limited basis to women wanting them for purely cosmetic reasons.

JAMES A. TRAFICANT, JR.

17th DISTRICT, OHIO

COMMITTEE:

TRANSPORTATION AND
INFRASTRUCTURE

SUBCOMMITTEES

RANKING DEMOCRAT: PUBLIC BUILDINGS
AND ECONOMIC DEVELOPMENT

AVIATION

COMMITTEE:

SCIENCE

SUBCOMMITTEE:

SPACE

Congress of the United States

House of Representatives

Washington, DC 20515-3517

August 18, 1997

SILICONE IMPLANT ILLNESS: AN ATYPICAL DISEASE

Dear Colleague:

Prior to the August recess, information touting the safety of silicone breast implants was again distributed to Members. This time, quotes from scientific journals were used to conclude that there is "no connection between implants and connective tissue disease," ("Silicone Breast Implants and the Risk of Connective-Tissue Disease," New England Journal of Medicine, June 22, 1995, emphasis added). I would like to provide additional insight on the industry-funded studies printed in these journals.

There has been overwhelming scientific criticism of the epidemiological data collected through industry-funded projects. The prime criticism is that the studies avoided reporting silicone implant illness as the atypical disease it is, and tried to fit the illness in a known illness category, such as connective tissue disease. When that failed, industry sang the praises of implant safety.

In truth, it is now readily recognized in the scientific community that breast implant-associated illness is an atypical, unprecedented syndrome, and does not conform to the established criteria for connective tissue disease.

The expert panel consensus of an April 17, 1997 National Institutes of Health Workshop on Atypical Rheumatic Disease and Silicone Breast Implants acknowledged evidence of atypical, systemic illness and called for unbiased research.

Testimony before the first National Science Panel, convened by Judge Samuel Pointer in Birmingham, Alabama on July 22-24, 1997 offered compelling evidence of the still undefined and not categorized "new" illness associated with silicone breast implantation.

According to the April 1996 issue of the *Annals of Internal Medicine*, these these industry-funded, epidemiological studies had many faults, including the fact that "sample size was inadequate...study methods inappropriate for detecting atypical syndromes...poor choice of comparison group...inadequate duration of follow-up or information gathering techniques that may have biased the detection of implant or clinical syndromes."

World renown epidemiologist, UCLA's Dr. Sander Greenland, whose testimony before the National Science Board in July, referred to the studies' "misuse of data," and numbers "so small [they are] fractions of true report."

Silicone implant-related illness is an atypical disease not unlike Gulf War Syndrome, caused by physical exposure to chemicals and toxins. I encourage you to get all of the facts and decide for yourself. For further information, please feel free to contact me or Kimberly Harris Bliton at x5-5261.

Respectfully,

James A. Traficant, Jr.
Member of Congress

2446 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-5281

125 MARKET STREET
YOUNGSTOWN, OH 44503
(216) 743-1914

5555 YOUNGSTOWN WARREN ROAD
SUITE 503
NILES, OH 44446
(216) 652-5649

109 WEST 3RD STREET
EAST LIVERPOOL, OH 43820
(216) 383-5821



CONGRESS OF THE UNITED STATES
 HOUSE OF REPRESENTATIVES

Some flowers are roses.

My mother's name is Rose.

Therefore, my mother is a flower.

If you have some doubts about that logic, read on.

July 30, 1997

Dear Colleague:

Over the past few weeks, there has been an exchange of 'Dear Colleague' letters about the safety of silicone gel breast implants. I think an examination of the scientific literature demonstrates that claims to the contrary are not supported by credible research.

A 1997 review found that "88 published works in the scientific literature fail to support an association between silicone gel breast implants and systemic diseases. . . . Comprehensive epidemiologic studies have concluded that there is **no connection between breast implants and the known connective tissue diseases** or between implants and breast carcinoma." Review of the Possible Health Implications of Silicone Breast Implants, *Cancer*, May 1, 1997, (emphasis added).

That finding was confirmed by a just-published study by the Danish Cancer Society. A review of more than 2,500 Danish women did not find statistically significant difference in the incidence of connective tissue disorders between women with silicone gel breast implants and those without. ("Connective Tissue Disease and Other Rheumatic Conditions Following Breast Implants in Denmark," *Annals of Plastic Surgery*, July, 1997).

One of the largest studies on this subject was recently completed by the Mayo Clinic of women in Olmstead County, Minnesota. "At a mean follow-up of 7.8 years, there was **no association between breast implants and connective tissue or rheumatic disease.**" ("Risk of Connective Tissue Disease and Other Disorders After Breast Implantation," *New England Journal of Medicine*, June 16, 1994, emphasis added). A similar conclusion was reached in the follow-up of the nurses' health study by Harvard University. After 14 years of follow-up, researchers found **no association between implants and connective tissue diseases.** ("Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms," *New England Journal of Medicine*, June 22, 1995, emphasis added).

Reviewing these latter two studies, the American College of Rheumatology found that they "provide compelling evidence that silicone implants expose patients to **no demonstrable additional risk for connective tissue or rheumatic disease.** Anecdotal evidence should not longer be used to support this relationship in the courts or by the FDA." (Statement, American College of Rheumatology, October 22, 1995, emphasis added).

Unfortunately, those who stand to reap financial windfalls have relied on anecdotal evidence that is not supported by scientific review. Many women suffer from connective tissue disorders. And it is not surprising that some women with breast implants have those disorders. But to conclude that breast implants are the cause of connective tissue disorder is to make a seriously flawed assumption.

I urge you to keep in mind the facts and the science when reviewing claims about the supposed health risks of silicone gel breast implants.

Sincerely,

Greg Ganske
 Member of Congress

Congress of the United States

Washington, DC 20515

July 21, 1997

INACCURATE FDA REPORT ON BREAST IMPLANT RISK: THE CALL FOR INVESTIGATION AND PUBLIC HEARING

Dear Colleague:

We would like to provide additional insight on information that was recently circulated to Members regarding Food and Drug Administration Commissioner Michael Friedman's testimony (as Lead Deputy Commissioner), before the Commerce Committee, on the safety of silicone gel breast implants. It is precisely because of this misunderstanding that a Federal Task Force on Silicone Breast Implants is needed. After reviewing the following information, we encourage you to co-sign our letter to President Clinton.

1) In his statement, Commissioner Friedman stated: *"My perception of how the agency has moved over the past several years is one of progressive revelation."*

In truth, the FDA's 1992 clinical trials of gel-fill breast implants have been conducted by the implant manufacturer Mentor, and are to be analyzed by an industry-paid consultant, plastic surgeon Dr. Gary Brody. Though the FDA has long acknowledged a 7- to 15-year period of latency in association with the development of implant-related disease, these clinical "studies" have been designed merely for a 5-year period; an accurate occurrence of disease onset will, conveniently, be missed.

2) Commissioner Friedman contended: *"There were concerns initially that somehow silicone was contributing to breast cancer or obscuring the ability to detect breast cancer. In fairly short time, that concern was shown not to be a valid concern."*

This statement is false. No new research has refuted the data reporting a 41 percent false-negative breast cancer test rate — despite the recommended, two-view mammography screening — in women with breast implants. In fact, only 67 percent of malignancies in breast implanted women are diagnosed by mammography. According to research data presented to the 1992 FDA Panel Review of Breast Implants, all breast implants, including the less obstructive saline-filled devices, obscure up to 80 percent of all breast tissue during mammography screening.

As to the implant's contribution to breast cancer, no new research has refuted earlier findings of a higher incidence of invasive lesions and involvement... (Hayes, *Plastic and Reconstructive Surgery*, 1988; Silverstein, *Archives of Surgery*, 1988; Schmidt, *Proceeding of the Annual Meeting of the American Society of Clinical Oncology*, vol. 7, 1988; *Torn Illusions*, Chapter IX, p. 152). In addition, we cite the FDA's own 1990 *Federal Register* publication: "Other silicone implants (besides breast implants)...have been documented to produce sarcoma and other forms of carcinoma in humans." Apparently, Dr. Friedman may have neglected to inform the Commerce Committee of a great deal of evidence linking implants to a wide range of serious health risks.

3) Commissioner Friedman asserted: *"There is a third area...and that is local complications, reoperation rates, failure rates and so forth...In the New England Journal of Medicine...really good solid information that was provided with a large enough sample to give us confidence."*

This is misstated. What this cited study (the "new" Mayo research; *New England Journal of Medicine*, March 6, 1997) really reported was that 25 percent of women (1 in 4) who receive breast implants require additional breast surgery due to complications occurring within 5 years of implantation. In cancer patients following mastectomies, breast implant complications are 3 times more likely to occur. As to implant failure rate, former FDA Commissioner Kessler cites the Robinson study (the largest explant study ever conducted), which reports a 71 percent rupture rate, including gross gel leakage, within 10 years and a 95 percent rupture rate within 15 years of implantation.

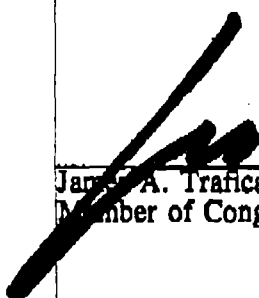
4) Commissioner Friedman claimed: *"It is not possible to demonstrate that we can identify a subgroup of women who suffer from autoimmune disorder..."*

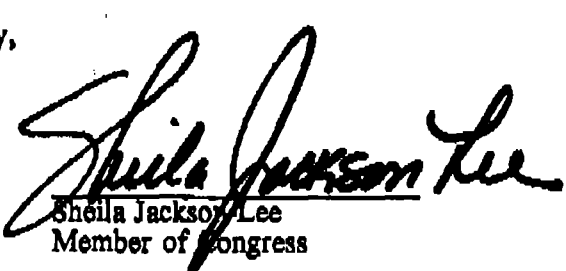
This statement is inaccurate. These women are more than a subgroup (several thousand statistics published monthly by the FDA Manufacturer Device Reporting) and not afflicted with classical connective tissue disorder. Independently-conducted, peer-reviewed, published reports show strong evidence of systemic as well as atypical connective tissue disease, including major organ, gland and neurological involvement in silicone recipients. This study, by far, outweighs the data reported by industry-funded studies, which were highly criticized for faulty means and methods. Of late, 7 studies support health risks associated with implantation. For example, in studies conducted on implant recipients, Harvard Medical School reports high levels of silicone in the liver; UCLA School of Public Health reports various, associated neurological conditions and a higher than expected rate of cancer; and Louisiana State and Tulane University report high counts of anti-polymer antibodies in patients exhibiting disease.

Out of respect for the thousands of women who have suffered debilitating conditions from silicone poisoning and have repeatedly been told it's "all in your head," we respectfully request that you obtain all the fact on this issue.

Should you have any questions, need further information, or wish to co-sign the letter to President Clinton requesting the formation of a Federal Task Force on Silicone Breast Implants, please contact Kimberly Harris Bliton (Mr. Trafficant, x55261) or Jennifer Leach (Ms. Jackson-Lee, x55316).

Respectfully,


James A. Trafficant, Jr.
Member of Congress


Sheila Jackson-Lee
Member of Congress

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES**How Safe Are Breast Implants?****Let's Ask the Experts at the FDA.**

July 16, 1997

Dear Colleague:

Some of our colleagues have been seeking signatures on a letter to President Clinton calling for the formation of a task force to investigate silicone gel breast implants. I would certainly welcome research on this subject if done in a balanced manner that does not presuppose its conclusion.

There is already a growing body of evidence on the safety of silicone gel breast implants. Earlier this year, Dr. Michael Friedman, Lead Deputy Commissioner of the Food and Drug Administration, testified before the Commerce Committee. When asked about breast implants, he said:

"My perception of how the agency has moved over the past several years is one of progressive revelation. There were sets of questions that were unanswered at a point in time and that each moment we have gotten more and better information.

"You recall, sir, how there were concerns initially that somehow silicone was contributing to breast cancer or obscuring the ability to detect breast cancer. In fairly short time, that concern was shown not to be a valid concern.

"... I share your perspective at this time that in general, looking at large populations of patients in well-done trials, it is not possible to demonstrate that we can identify a subgroup of women who suffer from autoimmune disorder because of silicone. . . .

"There is a third area that I know you are concerned about as well, sir, and that is local complications, reoperation rates, failure rates and so forth, not because those are such systemic serious problems, but they are very important local problems to some women. Information may help them make informed choices about what to do, and as you know, in the New England Journal. . . there was a fine article also from the Mayo Clinic, from the Rochester section of Minnesota, where they looked at local failure rates, and that was the first really good solid information that was provided with a large enough sample to give us confidence.

"So I see this as moving progressively toward providing us with the information that we need.

"I can tell you, sir, that we are looking at this issue internally within the agency and reevaluating exactly what the position should be now that it is driven by the data, and we have the ability now to make those sorts of judgments, whereas several years ago there were really was none of this information developed (emphasis added)."

For a good review of this issue, please read Dr. Marcia Angell's article in the New England Journal of Medicine which is attached.

Sincerely,

Greg Ganske
Member of Congress

Congress of the United States

Washington, DC 20515

February 18, 1997

Dear Colleague:

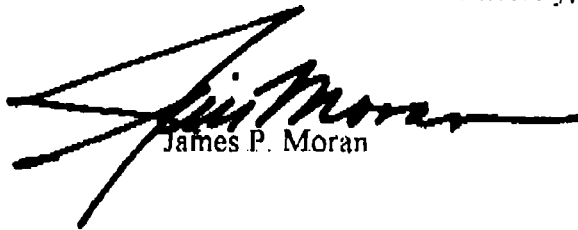
We would like to invite you and your staff to a very important briefing concerning silicone breast implants on Monday, February 24th at 10:00 a.m. in 2168 Rayburn. The briefing will feature Dr. Arthur E. Brawer, a board-certified rheumatologist who will discuss common medical problems associated with breast implants. Dr. Brawer has 20 years experience as a practicing physician and has published two peer-reviewed articles on the subject of breast implants.

As you may know, 440,000 women are now involved in negotiations with the major implant manufacturers, including Dow Corning, in one of the largest class action suits in history. One hundred and fifteen thousand of these women have documented illnesses stemming from silicone exposure. Dow Corning, 3M, Bristol Myers, and Baxter manufactured silicone implants from 1964 to 1994. Many women who received those implants now suffer from autoimmune disorders, including neurological problems, lupus, scleroderma, and other ailments. These are severe and debilitating illnesses which can result in financial ruin, destroyed careers, divorce, and even death. Families are devastated as they see beloved mothers, sisters, and daughters suffer from these debilitating illnesses.

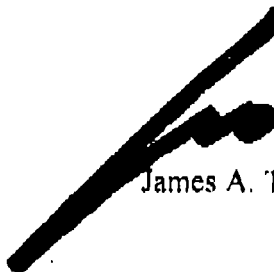
This briefing will provide valuable information on the types of ailments Dr. Brawer has seen and what, if any, conclusions can be drawn from the number of women with health problems who have breast implants.

Many of you are probably contacted by women who have such implants, or are considering having them removed. In order to better address the concerns of these constituents, we urge you to attend this important, informative briefing. To register for the briefing call Kristin King in Congressman Moran's office at 5-4376 or Kimberly Harris Bliton in Congressman Traficant's office at 5-5261.

Sincerely,



James P. Moran



James A. Traficant, Jr.

Congress of the United States
House of Representatives
Washington, DC 20515-3517

January 10, 1997

BREAST IMPLANT GLOBAL SETTLEMENT COLLAPSES!

SUPPORT THE "BREAST IMPLANT ACCOUNTABILITY ACT"

Dear Colleague:

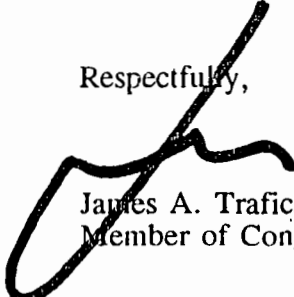
On October 10, 1995, the \$4.23 billion global breast implant settlement collapsed, closing the door on 440,000 women who desperately need medical treatment. Of those 440,000 women who qualified for funding under the settlement, an estimated 75 percent of the women still have ruptured or leaking implants in their bodies with no financial means to pay for surgical explantation. While a few women will be fortunate enough to win exorbitant law suits, as evidenced by the recent \$10 billion Nevada case, this practice will eventually bankrupt the manufacturers, leaving hundreds of thousands of women with no recourse. As a result, I have introduced H.R. 366, the "Breast Implant Accountability Act," to provide a fair solution for all parties involved, and invite you to join me by cosponsoring the legislation.

The "Breast Implant Accountability Act" does the following:

- * Requires silicone breast implant manufacturers to notify breast implant recipients that funds will be provided for the surgical removal of breast implants which were implanted before January 1, 1994. Patient participation is completely voluntary; explantation will be performed only at the request of the individual.
- * Allows the notice recipient to select the physician and hospital or surgery center for the explantation procedure. The provision would prevent manufacturers from forcing women to travel great distances or to one central location for the explantation.
- * Ensures that the explanted breast implants become the property of the individual from which it was removed. ~~The implant shall be given to the individual~~ in an appropriate condition.
- * Requires further research on the physiological, neurological and immunological effects of silicone on the human body. Individuals in the class action suit shall be included in the research, should they volunteer.
- * Requires all future implant candidates to be informed of the health risks of implants and to sign a consent form stating that she has read and understands the risks involved.
- * Prohibits the donation of blood and organs by individuals with breast implants.

As with any faulty product that threatens the health or safety of consumers, the manufacturer should issue a recall of the product. The fact is, per woman, the cost of explantation provided for under H.R. 366 is generally far less than the settlement award. If you support a fair and equitable solution for your constituents, without bankrupting the manufacturers, I urge you to cosponsor H.R. 366 by contacting me or Kimberly Harris Bliton at x55261.

Respectfully,



James A. Traficant, Jr.
Member of Congress

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Divider Title: _____

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005. letter	Pamela Stott-Kendall to Donna Shalala re: fax number (partial) (2 pages)	09/25/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

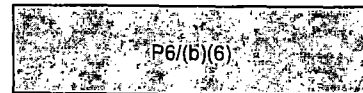
C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



DeeCar Publishing

[005]

President
Pamela Stott-Kendall
P. O. Box 030153

Fort Lauderdale, Florida 33303

Telephone: (954) 563-1215; Fax: (954) 467-3882
Internet: <http://www.bookworld.com/deecar>

August 8, 1997

The Honorable Donna Shalala
Secretary of the Department of Health and Human Services
200 Independence Avenue SW, Room 615F
Washington, DC 20201
Fax: (202) 690-7203

Dear Madam Secretary,

In April, I had forwarded a copy of my authored book, *Torn Illusions*. A validated medical/legal exposé on silicone implants, the book has been accepted for inclusion in the FDA Center for Devices and Radiological Health Library and reviewed by the U. S. Department of Justice, both Civil and Criminal Divisions, at the request of Attorney General Janet Reno.

Later, on June 30 after a cordial meeting with Dr. Susan Blumenthal, I had then forwarded additional correspondence and documentation of serious, industry compromise of the FDA clinical-trial studies and Dr. Louise Briton's National Cancer Institute study of breast implants, which are together slated for release of findings in 1997. However, beyond these concerns, a quite urgent situation has developed with regard to the FDA under the direction of Acting Commissioner, Dr. Michael Friedman. In this respect, I have enclosed copies of recent correspondence to Bob J. Nash, Assistant to the President and Director of Presidential Personnel, and Congressman James A. Traficant, Jr., pertaining to Dr. Friedman's testimony before a 1997 Commerce Committee meeting, as well as a July 21 copy of demand for FDA public hearing. As of June, it has been the agency's stated intention to make an imminent decision, in the interim of replacement FDA Commissioner appointment, on the status of gel-fill devices, "by the end of summer." According to Dr. Friedman's Commerce Committee testimony, such a decision would be issued in blatant disregard of agency-held data and agency-known research findings which, in evidence of unacceptable, associated risks, preclude general marketing of the gel-fill, breast implant device. At best, it is my opinion that Dr. Friedman's testimony reflects a lack of scientific awareness and an unwillingness to acknowledge much relevant, agency-collected information. A public hearing is thereby warranted.

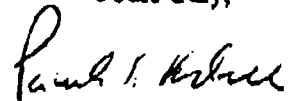
Today, the concern has grown even more serious and extremely urgent. This morning, I learned through communication with the FDA Center for Devices and Radiological Health that the demand for public hearing will go without consideration and that the crucial, gel-fill device decision—one to invoke significant public, as well as governmental and congressional, reaction and repercussion—will be made next week. As it happens, I plan to arrive in Washington, DC

on Tuesday, August 12, to attend a second, follow-up meeting with Congressman Waxman's office. (Congressman Waxman, Ranking Minority Leader, House Committee on Government Oversight, had received the same documents earlier forwarded to your attention.) These examples of industry compromise of science will not go without notice and accountability. With congressional signature and support, Representatives Traficant's and Jackson-Lee's *Letter to President Clinton*, in call of a Federal Task Force on Silicone Implants, has been received by the White House.

By these just concerns, I respectfully request, upon my arrival in Washington, a meeting with you. I sincerely appreciate timely consideration, for under your authority, Health and Human Services should be fully apprised of so important an FDA directive seemingly delivered in rush and rash manner. The scientific verdict is not yet in. On July 22-24, I attended the National Science Panel convened by Judge Samuel Pointer (MDL 924 consolidation of all federally-filed breast implant cases) in Birmingham, Alabama. This convening of unbiased experts has only begun; two other panel meeting are to be held. On April 17, I had attended the NIH-sponsored Workshop on Atypical Rheumatic Disease and Silicone Breast Implants. The expert panel's consensus supported concern and called for unbiased research study into the implant-associated, atypical illness with the definition of disease criteria in its description. Further, preliminary findings of Baylor's breast-implant research project have produced "disturbing" results (FDA notification). The FDA is called upon to act in a responsible manner.

I thank you, and my contact telephone number is (703) 922-5260, directed to Diane Griffith of Alexandria, Virginia.

Yours truly,



Pamela Stott-Kendall

cc: Dr. Michael Friedman

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
006. letter	Marlene Keeling to Susan Blumenthal re: phone number (partial) (1 page)	07/28/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

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July 28, 1997

Dr. Susan J. Blumenthal
Director, Office of Women's Health
U. S. Public Health Service
200 Independence Avenue S. W., Room 712 E
Washington, D.C. 20201

Dear Dr. Blumenthal,

Thank you for sending the information regarding the IOM Study on the Safety of Silicone Breast Implants. I have some questions regarding this study including the following: Who is included in the "Working Group"? Are any implant-injured consumers, silicone-support network members, or clinicians familiar with this "new" disease included in this working group? Can we trust the Institute of Medicine of the National Academy of Science to be free of bias from the manufacturers and industry? Can we get a copy of the House of Representatives report as mentioned in the background information? Why are only "classic" auto-immune symptoms mentioned (implant-injured consumers have non-classic symptoms)? Why does the language read "access to silicone breast implants has been severely limited, leaving breast cancer patients with few health choices" (the mantra of the industry-funded Y-Me group)?

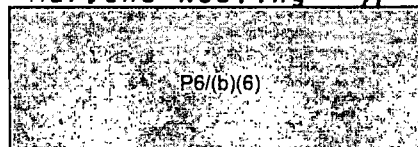
To bring you up to date on our activities, we now have a petition circulating in congress for signatures asking the White House for a Federal Task Force on the Silicone Breast Implant Issue. This prompted a July 16 "Dear Colleague" letter by Representative Greg Ganske, M.D. (Plastic Surgeon) to which we have replied with a rebuttal letter.

I am enclosing a copy of my letter to Dr. Michael Friedman asking for a full-panel formal public review after learning of his comments before a 1997 congressional, Commerce Committee meeting as quoted by the Ganske letter.

I plan to be in Washington, D.C. the week of Sept. 8-12. Can we arrange a meeting at that time with your office? We need your help to hold the FDA accountable.

Respectfully,

Marlene Keeling
Marlene Keeling



Diane Griffith
6490 Silver Ridge Circle
Alexandria, VA 22315
(703) 922-5260

May 8, 1997

The Honorable Donna Shalala
Health & Human Services
200 Independence Avenue, SW
Room 615F
Washington, DC 20201

Dear Madam Secretary:

I am respectfully requesting an appointment with you for Marleen Keeling of Houston, Texas; Pamela Stott-Kendall, author of Torn Illusions, of Ft. Lauderdale, Florida and myself for June 6, 1997. The purpose of this meeting is to discuss the crisis of silicone breast implants.

I am the founder of the Virginia Coalition for Breast Implant Victims and the congressional liaison for the United Silicone Survivors of the World. As a dedicated advocate, I am working with many congressional offices, The White House Office for Women, the Food and Drug Administration, the National Institute for Health and the National Organization for Women.

Please contact me at the number listed above as soon as possible to confirm an appointment.

Sincerely,

A handwritten signature in cursive script that reads "Diane Griffith".

Diane Griffith
Congressional Liaison
USSW

Diane Griffith
USSW - United Silicone Survivors of the World
6490 Silver Ridge Circle
Alexandria, VA 22310
(703) 922-5260

November 7, 1996

Dr. Susan J. Blumenthal
Director, Office of Women's Health
U.S. Public Health Service
200 Independence Avenue, S.W.
Room 712 E
Washington, D.C. 20201

Dear Dr. Blumenthal,

I am writing on behalf of the millions of women and children who have suffered near fatal illnesses and disabilities from silicone poisoning. As a result of illness due to silicone, we have lost our homes, careers, credit ratings, marriages, families, and our potential for contributing to our communities and country. Many of us live in despair, illness, and poverty because we bought from corrupt companies a product that cost eleven cents to manufacture and has now ruined our lives. We depended on public policies requiring research and promoting health and safety, and those policies have failed us. We deserve a federal task force and Congressional attention to address that failure by demanding research and public education and redress for the victims.

We ask that a national task force comprised of knowledgeable experts from the medical community, a victims' steering committee, and interested federal agencies be convened to establish the criteria for breast implant safety studies. Silicone manufacturers should not be dictating or influencing the criteria for safety studies, nor should they be permitted to manipulate the outcome. For example, the Mayo Clinic and Harvard Nurse Studies are considered biased, flawed and ethically questionable by leading medical authorities. Instead, medical experts and the following federal agencies should be consulted and assigned responsibilities within their purviews.

We ask that the FDA assume the responsibility it has shirked thus far. Certain basic questions should have been asked, and the FDA never asked them. The agency never asked Dow, or any other manufacturer, to test silicone over a long term in humans. It never requested a study of silicone's immunological effect on the body. It never asked for the establishment of a registry of women who had received the implants, a procedure that would have enormously simplified the basic research on the subject. The FDA did next to nothing until public opinion and mounting lawsuits forced it into action. Even then, after twelve years of negligence, it took another four years to hold its first public hearings on the subject. When the FDA finally reported findings to Congress

in 1992, it glossed over the crisis and grossly misrepresented research findings.

We ask that funding for research and medical care be earmarked specifically for silicone-related problems and disorders. There is a desperate need for solid, scientific information that can be respected by the public and reliably referred to by government agencies, medical and research organizations. We need studies that are independent of funding and manipulation by manufacturers or others who have a vested interest. Funding should be made available to rheumatologists, immunologists, neurologists, endocrinologists and pediatrics, but NOT to plastic surgeons. Plastic surgery is not a diagnostic field of medicine and prevention, and plastic surgeons only stand to gain financially from continuing the unsafe practice of silicone implantation.

We ask that silicone manufacturers or Medicaid/Medicare be required to make funds immediately available for women needing explantation of silicone breast implants. There is no disagreement that the products can be faulty. The FDA has acknowledged that 72% of all implants rupture in the first ten years, and 95% rupture after fifteen years. As a result, women with breast implants end up requiring an average of four further surgeries. Ruptured implants in symptomatic women need immediate medical attention.

We ask that the Department of Health and Human Services and the Center for Disease Control take and active interest in silicone-related disorders. More than 440,000 women have come forward to acknowledge concern about the silicone problem. Many more women are part of a vast silent majority due to the stigma placed on the embarrassing issue of breast implants. We urge HHS, including the U.S. Public Health Service, the Centers for Disease Control and any other relevant federal agency, to implement public education campaigns to inform women with aging implants and their doctors about the symptoms of toxic poisoning and fungus growth.

We ask that the Social Security Administration and medical insurance companies recognize that thousands of women are partially or totally disabled as a result of silicone diseases. Women are consistently denied medical care and insurance coverage for silicone-related disorders and explantation. Federal intervention is needed to remedy the destructive cycle in which the silicone-induced disease escalates, a woman loses her job (and thus her health insurance) because she is too ill to work, and her financial resources are exhausted by treatments not covered by any insurance. Medicaid/Medicare must expedite all current claims, as well as immediately updating their "listings" of addressed illnesses to include silicone-related disorders.

We ask that the Federal Communications Commission be required to monitor and enforce regulations on false and misleading advertising. Advertising of silicone products, particularly breast implants, has glorified the products and denied the risks, thus misinforming consumers. Even some government publication are misleading, in this manner, and should be withdrawn from distribution.

In addition to the above requested initiatives of federal agencies, USSW will ask

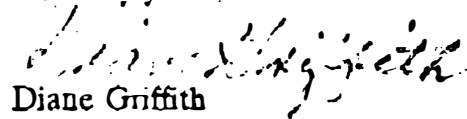
that Congress address the larger issues of public health, safe medical practice, and a resolution to the problem of just compensation for victims.

We ask that a congressional investigation and hearing be held regarding Dow Chemical and Dow Corning. We ask that they be held responsible for suppressing evidence from and lying to the FDA and Congress, and conspiring to commit fraud. Dow has consistently avoided responsibility through a 30-year cover-up. It has refused to acknowledge many unpublished studies indicating the danger of silicone breast implants in humans. A full scale investigation with sworn witnesses, detailed hearing reports, and corrective legislation must ensue.

We ask that members of Congress address the states' statutes of limitations on discovery as they apply to breast implants. Silicone manufacturers still deny a link between silicone breast implants and disease. The FDA concluded that it can take at least 7-15 years for symptoms to manifest. The manufacturers are using the discovery statutes of limitations to avoid legal responsibility. Statutes of limitations, as applied to breast implants, should be waived or amended in each state in order to give all women the right to a fair trial. The state of New York has already authorized an extension of the statute of limitations for personal injury or death caused by silicone signed into law 7/21/93. Or, there may well be a national solution that can be developed for the statute of limitation problem.

The foregoing represents our most major and urgent concerns for silicone victims. Undoubtedly, many more needs will be identified as we progress. USSW solicits your advice and assistance in helping us to find relief for the millions of Americans who have been let down by their government and misled by manufacturers and the medical profession. Remember, women's lives are at stake here.

Sincerely yours,


Diane Griffith
USSW Congressional Liaison

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
007. press release	re: phone number (partial) (1 page)	08/05/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

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PRESS RELEASE

[007]

WHO: United Silicone Groups
WHAT: CONGRESS ASKS PRESIDENT for FEDERAL TASK FORCE on SILICONE BREAST IMPLANTS, CO-AUTHORED BY CONGRESSWOMAN SHEILA JACKSON LEE
WHEN: August 6, 1997, 10:00 AM
WHERE: Room 207, NORTHWOODS Presbyterian Church, 3320 FM 1960
 For more information contact:
 Ron Cole P6(b)(6) (Phone # for PRESS ONLY)
 UNITED SILICONE SURVIVORS OF THE WORLD
 1960 HOUSTON CHAPTER
 PEGGY PARDO P6(b)(6) (Phone # for PRESS ONLY)
 BREAST IMPLANT INFORMATION EXCHANGE - CHICAGO

Y-ME, a breast cancer support group FUNDED in part by MANUFACTURERS of Implants, filed a CITIZEN PETITION on September 19, 1996, asking for the RESTRICTIONS to be eased on SILICONE GEL BREAST IMPLANTS. The FDA will make this important DECISION by the end of the summer and will rely upon the soon-to-be released MENTOR Adjunct Study (Documents reveal that a physician at St. Johns Hospital in Missouri called this study an "ILLUSION").

CONGRESSMAN Greg Ganske, M.D. (Plastic Surgeon) sent a misleading "Dear Colleague" letter to members of CONGRESS quoting Dr. Michael Friedman, Acting FDA Director, as implying breast implants are safe. DOCUMENTS that show ASPRS (Plastic Surgeons) attempting undue influence aimed at the FDA and others will be available.

Documents will show Dr. J. E. Woods, author listed on two recent MAYO Clinic breast implant studies, was acknowledged to be biased by MAYO, and that SPECIAL INTEREST GROUPS funded these studies, after they were originally rejected by the FDA.

Similarities have been found to COVER-UP and PR activities in the TOBACCO INDUSTRY and the DOW COVER-UP, as reported by long-time employee JOHN SWANSON, as well as the "TUSKEGEE EXPERIMENT", recently revealed. Women have been experimented upon for over twenty years with the FEDERAL GOVERNMENT'S knowledge. The purpose of this press conference is to expose the ASPRS' questionable activities and failure to alert women as to the DANGERS of these implanted devices.

ADDITIONALLY, good photo opportunities will exist with WOMEN SEVERELY INJURED by LEAKING, RUPTURED, & DEFECTIVE BREAST IMPLANTS who support this GRASS ROOTS effort to hold both the FDA and the ASPRS accountable for their FAILURE to PROVIDE FOR the SAFETY of these WOMEN.

BARBARA HASENOUR

P6(b)(6)

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008. letter	Marlene Keeling et al. to Michael Friedman re: phone number and address (partial) (1 page)	07/20/1997	P6/b(6)

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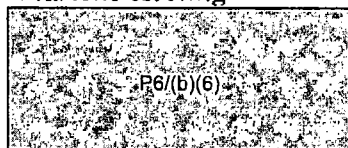
C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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[006]
Marlene Keeling

Pamela Stott-Kendall
P. O. Box 030153
Fort Lauderdale, FL 33303
Telephone: (954) 563-1215
Fax: (954) 467-3882

Diane Griffith
6490 Silver Ridge Circle
Alexandria, VA 22315
Telephone: (703) 922-5260
Fax: (703) 922-5269

July 21, 1997

Dr. Michael Friedman
Acting FDA Commissioner
Food and Drug Administration (FDA)
9000 Rockville Pike, Bldg. 611F, Rm. 2803
Bethesda, MA 20892
Fax: (301) 443-3100 (Federal Express delivery)

Dear Dr. Friedman,

By this notice, we request a full, formal public hearing on the status of silicone-gel breast implants, regarding standing, agency-filed petitions #97P-0050/CP1 and #98P-0337, as necessitated by the following information: 1) your public address before a 1997 congressional, Commerce Committee meeting, as cited by Congressman Greg Ganske in a July 16 *Dear Colleague* letter, in assurance of breast implant safety, inaccurately, without fair, required report of contradictory research-data, held in the agency's possession, stating otherwise and with disregard of FDA responsibility toward, and compliance with, public-health safety demands; 2) the comments of a *Wall Street Journal* article, dated March 6, 1997, which quoted a "top FDA official" as stating that "it might be time to reconsider putting the devices [gel-fill breast implants] back on the market"; 3) a June 6, 1997 *Los Angeles Times* article to have quoted plastic surgeons who report, "There is some possibility that the moratorium will be lifted"; 4) FDA failure to provide informed-consent and disseminate public health information on breast-implant risks through agency-published, consumer-pamphlet information and consent forms signed by prospective gel-fill implant recipients; and 5) attachments reporting documentation of special-interest involvement, on the part of the industry (including manufacturers and a prominent society of plastic surgeons), in the FDA clinical-trial studies of gel-fill breast implants and Dr. Louise Britton's National Cancer Institute (NCI) study of breast implants, both slated for 1997 release. In light of this information and supportive attachments (submitted to HHS Secretary Donna Shalala and appropriate, congressional oversight committee), public opinion raises valid questions as to agency integrity in matters of public health protection and further demands the suspension of the FDA's stated intention to make an imminent decision, "by the end of summer," on the permanent status of gel-filled devices, especially in the interim of presidential appointment of a replacement FDA Commissioner to assume accountability of agency directives issued.

We request that the public hearing be comprised of:

1. Implant-injured consumers as well as their children born after the mothers' implantation and exposed, through pregnancy and breast-feeding, to silicone-implant toxins. This testimony shall not exceed twenty minutes and shall be limited to five-minute presentation.

II. Clinicians who have treated 100 or more women with breast implants and researchers who have completed published, silicone-related research. All of these participants will sign and acknowledge "conflict-of-interest" statements. On this segment, five physicians are to be selected by the Y-Mc organization, and another five will be selected by the silicone-support network of injured implant recipients.

III. Manufacturer representatives who will answer public questions regarding the scientific criticism of faulty design, means and methods of industry-funded research projects, including Mentor's FDA clinical trials, the contribution of funds to NCI while the institute conducted a breast implant study and the selection of an industry-paid consultant, Dr. Gary Brody, to analyze and report on the FDA's clinical study of gel-fill breast implants. Representing the American Society of Plastic and Reconstructive Surgeons (ASPRS), which is the society documented (attachments) to have collaborated with Dr. Louise Britton on the NCI study of breast implants, Dr. Brody testified before a 1992 FDA Panel Review that his society's (ASPRS) sole contribution to the study of implant safety consisted of a one-day convening for debate in San Monica, California. Moreover, the ASPRS had repeatedly refused FDA Review Panel requests to initiate a patient registry in the follow-up of implant patients. Dr. Brody not only lacks a research background necessary to analyze clinical-trial data, but is also disqualified by special-interest bias. His removal from clinical-trial involvement, and interpretative further requested.

IV. Scientists of the FDA Center for Devices and Radiological Health, who will make a public statement regarding current research-data pertaining to device failure and complication rates and any other pertinent research-data information.

V. In consideration of the FDA's public omission of research data showing silicone implant risks, a medical expert of our choice to review scientific evidence presented to the July 22-25 Science Trial held before Chief Judge Samuel Pointer of the Multi-District Litigation (MDL) consolidation as well as a review of research presented before two National Institutes of Health-sponsored Workshops: a March, 1995 Immunology of Silicones Workshop and an April 17 Workshop on Atypical Disease and Silicone Breast Implants.

An immediate public hearing is requested in fulfillment of Federal guidelines and the 1976 Medical Device Act empowering the FDA to act responsibly in matters of public health protection. An experimental device which: 1) failed to prove safe through required manufacturer-submission of safety data, still lacking; 2) causes several thousand, new occurrences of gel-fill related illnesses and injuries each month, including several, additional related deaths, as reported by manufacturers through the FDA's mandatory Manufacturer Device Reporting Program; 3) includes silica, a substance having established cause-effect relationship to human illness, in its composition; and 4) exhibits a 71% rupture and gross gel-loss, failure rate within 10 years: gel-fill breast implants must not be returned to general market availability in defiance of current research and reason—and in avoidance of large-scale, credible study of second-generation risks which has yet to be conducted. In the meantime, the saline-fill breast implant is available for general market as a viable replacement, despite its own experimental, not FDA-approved use, to satisfy the "public health need" of breast implants by

cancer-reconstructive patients until a truly safe alternative might be devised, tested, FDA approved and then marketed. However, to satisfy informed-consent requirements, prospective recipients of saline-fill implants must be notified that the outer, silicone shell of this device includes a 30% silica component.

Should the FDA choose not to act in a responsible manner and not face public accountability, the public must call upon other Federal options. Your timely response is anticipated and appreciated.

Yours truly,

James S. Vatal
Deane Griffith
Marlene Keeling

Attachments: (five)

July 21 *Letter to the President* (Congressman Traficant and Congresswoman Jackson-Lee); July 16 *Dear Colleague* letter (Congressman Ganske); July 18 letter to Congressman Traficant (Kendall); June 27 letter to Dr. Michael Friedman (Kendall); and June 30 letter to Secretary Donna Shalala (Kendall).

cc: President Bill Clinton
Secretary Donna Shalala, Health and Human Services
Director Susan Blumenthal, Health and Human Services
FDA Director Bruce Burlington
Senator Edward M. Kennedy
Representative James A. Traficant, Jr.
Representative Sheila Jackson-Lee
Representative Gene Green
Representative Henry A. Waxman

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
009. paper	re: testimony of Dr. Michael Friedman (partial) (3 pages)	09/25/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
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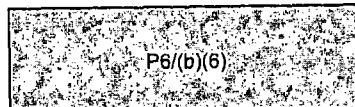
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FROM THE TESTIMONY OF DR. MICHAEL FRIEDMAN ON
APRIL 23, 1997

[009]

DR. MICHAEL FRIEDMAN "FDA'S PRIMARY MISSION FOR 90 YEARS HAS BEEN TO PROMOTE AND PROTECT THE PUBLIC HEALTH"

Our response: The FDA has allowed the experimentation on women to continue for over 20 years in spite of over 100,000 adverse events reported following implantation of silicone gel breast implants. Our silicone support organization has presented to members of congress this book full of appalling PRP reports which should have long ago raised a red flag and caused grave concern.

"OUR DIVERSE ACTIVITIES INCLUDE...REVIEWING, APPROVING, AND MONITORING THE MAUFACTURE AND USE OF...MEDICAL DEVICES,... MONITORING CLINICAL INVESTIGATIONS"

We have documents showing that St. John's Hospital in Springfield, Missouri sent Dr. David Kessler a letter, dated November 1992, stating that the Phase II Mentor Study did not appear to be a research study in any familiar sense of the term. A doctor at the FDA subsequently, stated that the Memtor Study was an administrative device to make the devices available to those who have such need that the lack of established safety can be overlooked if there is good informed consent process. The St. John's Hospital documents quote one of the surgeons who hoped to do those studies, "This protocol was designed to give the illusion of a study and does not meet criteria that we normally expect of clinical study."

"I KNOW YOU SHARE OUR VIEW THAT ALL AMERICANS EXPECT AND DESERVE THE ASSURANCE THAT THE MEDICAL DEVICES THEY USE ARE SAFE AND REALLY WORK...THE ASSURANCE THAT FDA IS VIGILANT AND ACTIVE, EVERY DAY, IS SO FUNDAMENTAL TO OUR EXPECTATIONS OF PUBLIC HEALTH PROTECTION THAT IT IS ALMOST TAKEN FOR GRANTED. BECAUSE OF THE PROTECTIONS IN THE FOOD AND DRUG LAWS, AMERICANS DO NOT WORRY ABOUT THE SAFETY OR EFFECTIVENESS OF LITERALLY THOUSANDS OF PRODUCTS THEY USE EVERY DAY.."

Twenty years ago, the public had not heard the term "grandfathered" medical devices and did not understand its implications. The public had no other option but to put its blind trust in the FDA to protect them.

"MEMBERS OF THE SUBCOMMITTEE (ON HEALTH AND THE ENVIRONMENT) AND OTHERS IN CONGRESS CRITICALLY REVIEWED THE AGENCY'S PERFORMANCE."

What were the congressional conclusions and how could the continued market availability of these dangerous devices been allowed to continue?

"PLEASE KNOW THAT THE AGENCY, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND THE ADMINISTRATION ARE COMMITTED TO

WORKING WITH CONGRESS ON BIPARTISAN LEGISLATION THAT WILL HELP US DO OUR JOB OF PROMOTING AND PROTECTING PUBLIC HEALTH AS WELL AS WE CAN"

How can concerned consumers promote and encourage the passage of bipartisan legislation to prevent a repeat occurrence of an omission of responsibilities by the FDA?

"SOUND EVIDENCE OF MEDICAL EFFICACY IS A CRUCIAL COMPONENT OF THE AGENCY'S RISK BENEFIT ASSESSMENT FOR A NEW PRODUCT OR NEW USE OF AN ALREADY-APPROVED PRODUCT."

In over twenty years there has never been sound evidence of the medical efficacy or safety of breast implants and now there is mounting evidence of a 70% or higher rupture or severe gel bleed rate. Gel breast implants are not life saving devices and are not a public health need - they are a public health hazard. Safety and efficacy should not be "negotiable" doctrines.

"IN OTHER WORDS, FDA SHOULD REVIEW THE DATA TO DETERMINE THE MAGNITUDE OF BENEFITS AND TOXICITIES. THIS BEST CASE SCENARIO WILL OCCUR, HOWEVER, ONLY IF THE AGENCY HAS AN EFFECTIVE SUPPLEMENTAL APPLICATION PROCESS AND ONLY IF INDUSTRY SUBMITS THESE APPLICATIONS. THESE REQUIREMENTS FOR WHAT CONSTITUTES APPROPRIATE EVIDENCE OF EFFECTIVENESS MUST BE CLEAR AND REASONABLE".

The manufacturers have never submitted applications that have been approved by the FDA. The PMA process has completely broken down in the case of breast implantation. Therefore, it seems that undue political pressure on the part of industry and special interest groups has taken place.

"ONE OF THE THEMES THAT RUNS THROUGHOUT THE AGENCY'S EFFORTS TO IMPROVE ITS PERFORMANCE IS THE IMPORTANCE OF INVOLVING ALL STAKEHOLDERS BOTH IN DEFINING THE PROBLEMS THAT EXIST AND IN DEVELOPING APPROPRIATE SOLUTIONS. THIS MODEL OF PUBLIC PARTICIPATION, REFLECTED IN SO MANY OF THE INITIATIVES I HAVE BEEN DISCUSSING, IS MOST CLEARLY DELINEATED IN THE PROCEDURES THE AGENCY HAS PROMULGATED FOR THE ISSUANCE AND USE OF AGENCY GUIDANCE DOCUMENTS. CONCERNS ABOUT THE ABSENCE OF PUBLIC INPUT ON GUIDANCE DOCUMENTS AND THE INAPPROPRIATE APPLICATION OF SUCH GUIDANCE WERE RAISED IN A CITIZEN'S PETITION FILED BY THE INDIANA DEVICE MANUFACTURERS COUNCIL AND WERE SUBJECT OF A HEARING CHAIRED BY CONGRESSMEN SHAYS AND MCINTOSH. THE PURPOSE OF GOOD GUIDANCE PRACTICES IS TO ENSURE THAT (1) AGENCY GUIDANCE DOCUMENTS ARE DEVELOPED WITH ADEQUATE PUBLIC PARTICIPATION (2) GUIDANCE DOCUMENTS ARE READILY AVAILABLE TO THE PUBLIC."

The appointment of a Federal Task Force, as requested in an August 1, 1997 congressional letter, is needed in this case to ensure that women injured by silicone

gel implants are included in decision making processes which remain heavily influenced by industry interests.

"WHEN THE DEVICE LAW WAS PASSED, CONGRESS SAW FIT TO PROVIDE FOR CIVIL MONEY PENALTIES AND RECALL AUTHORITY...JUST LAST YEAR, CONGRESS PASSED PESTICIDE LEGISLATION THAT INCLUDED A PROVISION FOR CIVIL PENALTIES."

Women with ruptured leaking implants, many of whom lack funds for removal, need to have these civil penalties enforced before their health deteriorates further. A recall needs to be declared on implants eight years or older as stated in "Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review" Annals of Internal Medicine, April 1996... women with implants should have them removed as a prophylactic measure, preferably within 8 years of implantation, to reduce the risk of rupture or severe bleed.

"THE TWO PILLARS OF FDA'S SUCCESS, AND THE REASONS WE HAVE THE CONFIDENCE OF THE AMERICAN PUBLIC, ARE OUR INDEPENDENT PUBLIC HEALTH COMMITMENT AND SCIENTIFIC EXPERTISE. IN THE END, IT IS THE FDA'S INDEPENDENCE THAT GIVES THE AMERICAN PEOPLE CONFIDENCE IN THE AGENCY'S DECISIONS. THEY KNOW THAT WHEN FDA APPROVES A DRUG, THAT APPROVAL IS MADE FREE OF COMMERCIAL INTERESTS. WHILE WE RECOGNIZE THAT IT IS IMPORTANT TO WORK WITH INDUSTRY AND CONSUMERS TO BRING THE BEST EXPERTISE TO BEAR ON PROBLEMS, WE MUST NOT OVERLOOK THE IMPORTANCE OF MAKING REGULATORY DECISIONS IN AN ENVIRONMENT WITHOUT BIAS OR VESTED INTEREST."

Women now disabled after being implanted with silicone gel breast implants, supported by collected evidence showing the dangers of implants, feel that these devices have been allowed to remain on the market as a direct result of undue scientific bias in the medical community and vested interest of the plastic surgeon societies. We challenge the statement that the FDA acted independently.

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
010. petition	re: fax number, phone number, and address (partial) (3 pages)	n.d.	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

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#97P-0050
CITIZEN PETITION

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, rm 1-23
12421 Parklawn Dr.
Rockville, MD. 20857

The undersigned submits this petition to request the Commissioner of Food and Drugs to revoke the implantation of silicone gel breast implants for Cancer Victims and women who previously had implants due to the following reasons:

(1) No studies have ever been accepted by the FDA that show their safety or effectiveness. No breast implant has ever been approved by the FDA. They were "grandfathered" into the Medical Device Reform Act of 1976

(2) Excessive Rupture Rate - over 70% after 10 years had either frank rupture or severe gel bleed

(3) Severe bleed or rupture is the same physiologically as silicone injection which was banned in the 1960's because of migration and health related problems.

(4) Silicone implants are not life saving devices, they interfere with mammography, may impede the early detection of Cancer, and may rupture during mammography

(5) Animals with silicone implantable devices showed reduced natural killer cell counts to fight off returning Cancer, but counts went back to normal when implant was removed

(6) In July of 1994, a National Cancer Institute investigator confirmed the carcinogenicity of silicone gel which was indicated earlier in a Dow study that was buried and never disclosed except thru discovery. An FDA Task Force recommended a medical alert be issued to all breast implanted women in 1988, based on the Dow study when examined. Nothing was ever done.

(7) When ruptured or with severe gel bleed into surrounding tissue, upon explantation additional breast tissue may have to be removed causing further mutilation to Cancer victims.

(8) The risk of repeat breast surgeries due to capsular contracture (hardening of the breast) reported to be as high as 100% in non-ruptured breast implants

(9) Insurance companies now recognizing the toxic effects of silicone (ICD Code 989.83) and some companies are now refusing to insure women with breast implants

(10) The risk of passing silicone, silica, or its components, or antibodies to future generations thru the placenta and in Mother's milk

(11) No long term research has been done on the new "atypical" disease seen in an alarming number of breast implanted women including Demyelinating Neuropathy, Peripheral Neuropathy, Fibromyalgia, Chronic Fatigue, Organic Brain Syndrome (Cognitive Dysfunction), Sjogren's Syndrome, etc. These statistics on diagnosed diseases are now deposited with the class action which should be available thru the Freedom of Information Act.

(12) There are now over 1,300 published peer-reviewed research articles regarding the general biology of mammary silicone prosthesis associated diseases, silica, and silicosis.

PHOTOCOPY
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Leonard Keeling

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Feb-15-97 03:13 PM

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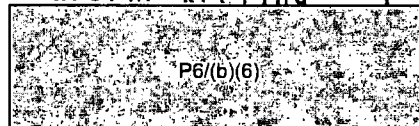
We further petition the FDA to issue a recall on all silicone gel and polyurethane breast implants eight years or older to reduce the risk of rupture and severe gel bleed. Plastic Surgeons should warn women with aging implants before these records are destroyed. Women have never been given true informed consent.

Resources:

- (1) The FDA's Regulation of Silicone Breast Implants December 1992 (ISBN 0-16-039937) Congressional Review
- (2) Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review, Annals of Internal Medicine, 15 April 1996, Dr. David A. Kessler (Co-author)
- (3) Silicone is a Potential Carcinogen, International Journal of Occupational Medicine, Vol. 4, Number 1, Jan-Mar 1995
- (4) Implants Pose Poorly Recognized Risks of Breast Cancer, International Journal of Occupational Medicine and Toxicology, Vol. 4, Page 315-342, 1995
- (5) Scleroderma-like Esophageal Disease in Children Breast-Fed by Mothers with Silicone Breast Implants, JAMA, Jan 19, 1994, Vol. 271, Number 3
- (6) Medicode Publications, 5225 Wiley Post Way, Suite 500, Salt Lake City, Utah 84116-2889 (1-800/999-4600)

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Marlene Keeling
Marlene Keeling



NAME (signature) ADDRESS & PHONE
GROUP AFFILIATION/ IF ANY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, rm 1-23
12421 Parklawn Dr.
Rockville, Md. 20857

The undersigned submits this additional information as requested by Gloria Ortega, Dockets Management Branch. See previously submitted petition received by the FDA on January 27, 1997.

ENVIRONMENTAL IMPACT - I request an environmental assessment under Sec. 25.31. I believe that there will be a positive environmental impact when silicone gel implants are totally removed from the market because there will be less toxic waste to dispose of when implants are removed. I believe women and their children will experience less toxic poisoning and environmental injury when gel implants are no longer placed in their bodies or when silicone, silica, or its components are passed in the placenta or in breast milk.

ECONOMIC IMPACT

Revoking the implantation of silicone gel implants will help balance the budget and reduce the deficit. Less money will have to be paid out when former hard working productive women implanted with silicone gel become disabled, lose their insurance, or can no longer care for themselves and their families. This should have a favorable economic impact on the individual considering gel implants in long term health care savings. Just because there is insufficient data does not mean that a new "atypical" disease does not exist, it simply means that the long term studies have not been done looking for the toxic effects of silicone in the human body. We do not know the frequency of complications or the severity of disease, because a national registry was never mandated. Because of the latency period of systemic symptoms of all organs of the body, doctors and women have been slow to recognize that their disease may be related to their implants. However, most implant women do not need epidemiological studies to know that something has gone tragically wrong.

A possible negative impact to the economy might be a loss of income for the Plastic Surgeons who have come to depend on the easy money generated by breast implants, the repeat surgeries that they require, and the high cost of explantation when rupture or severe gel bleed occurs. I do not feel that women are given true risk ratios or accurate information in order to make an informed choice or to give an informed consent. It is a conflict of interest for an unethical Plastic Surgeon to advise a patient on elective surgery. When choice may damage a woman's health and that of her unborn children, they must be protected. Women can only truly have choice, when they have all the facts. The facts are not in.

PHOTOCOPY
PRESERVATION

Safety and efficacy still has not been proven. We do not know the severity of the complications from leakage and rupture which may include "atypical" autoimmune and neurological disease, chemical toxicity, cancer, and organ involvement. Breast Cancer patients may be even more vulnerable and at risk due to weakened immune systems due to chemotherapy and radiation.

Of course women will still be able to choose saline filled/silicone shell implants or reconstruction and the Plastic Surgeons can still enjoy an adequate income. It is time to face up to this egregious conduct by the manufacturers and this heinous national tragedy being done to women in the name of greed.

The physical insult to a woman's body from breast cancer should not be followed up with the physical insult of implanting a dangerous toxic foreign body with such a high defective rate, both rupture and contracture. This is contrary to public health. In support of this conclusion, I submit the following findings in the literature regarding the risk of silicone gel-filled breast implants as compiled within the FDA in 1990:

FIBROUS CAPSULE CONTRACTURE RISKS/PROBLEM ASSESSMENT

Fibrous capsular contracture - the formation of a constricting fibrous layer around the prosthesis - is the most common complication associated with mammary augmentation and reconstruction. Capsular contracture may result in disfigurement, excessive breast firmness, discomfort, pain, displacement of the implant, and psychological trauma (Refs. 1-18). Attempts to prevent or treat it (by compression techniques) may result in rupture of the implant envelope, leading to gross leakage of the silicone gel into body tissues with possible toxic effects. (Refs. 19,22,24,26,27,28,30-44, 47-56). Surgical removal of the implant with its surrounding capsule and placement of a new implant may only be a temporary correction (Ref.13). Therefore, the number of repeat surgeries a patient may face is unknown. The risks associated with each repeated operation are significant.

TREATMENT CONCERNS

Methods of treating the established fibrous capsular contracture include closed compression (nonsurgical external compression to rupture the contracted capsule) and open capsulotomy (surgical removal of the implant with its fibrous capsule and its replacement with a new implant). Implant rupture as a result of external compression is well documented (Refs. 28,32-34,50,56) and the recurrence of capsular contracture following this technique is high (Ref.27). The number of repeat surgeries that a patient may face in a lifetime to release contracted fibrous capsules is unknown. FDA believes that the risks associated with repeat surgeries for treating capsular contracture are significant.

CLINICAL ENDPOINTS

There are numerous reports of complications related to silicone leakage and migration resulting from breast implant rupture. Clinical symptoms include implant deflation, gel disappearance, breast deformities, asymmetry, ulceration, pain, enlarged lymph nodes, palpable masses, and respiratory distress (Refs.26, 34-41,59,77,94,122,143).

ETIOLOGICAL FACTORS

Rupture of the implant is reported to be due to mechanical factors such as damage before and during surgery, intra and postsurgical trauma, stresses or manipulations as may be experienced during normal living experiences including exercise, athletic events, physical contact, routine manual massage of the breast, performance of closed capsule compression to treat capsular contracture or other unknown reasons (Ref.1,21,26,34-41,50).

Macro leakage of silicone may or may not be accidental (Refs. 53,185,187). It has been shown that closed or external capsulectomy to treat contracture may exert 15-20 lb. manual pressure on the prosthesis which may cause the silicone envelope to weaken and/or rupture (Refs.43-44). There have been numerous reports of complications following closed capsulectomy with rupture and extravasation of gel out of the surgical pocket necessitating surgical removal of the gel within or away from the breast area (Refs.27-28, 32, 34,37-41,44,47,49-55). When an implant ruptures, gel may be released and spread into tissues away from the breast area causing enlarged lymph nodes, silicone granulomas, lump formation and other unknown complications (Ref.38,50-61). The degree of gel cohesiveness of the prosthesis plays an important role in the salvage of implant rupture. Soft, fluid gel can transmit pressure to weaken areas of the thin silicone envelope with expansion and rupture. Once migrated, it is very difficult to retrieve soft gel allowing for other possibly more severe problems. Firm gels, on the other hand, if released would not flow and would be easier to remove during revision. Nevertheless, correlation between gel cohesiveness and gel retrieval in case of implant rupture has not been evaluated. In any case, it is most important that explantation is performed as soon as rupture is suspected.

The thickness of the silicone envelope is another possible cause for the implant to rupture when subject to physical stresses such as manipulation, vigorous exercise, trauma, drugs, etc. at the site of implantation. Case reports indicate that the periphery of the mammary implants appeared to be the site of failure. Small incisions to introduce the mammary implant, along with folds in the sac, may cause strain and wear of the shell. Imperfections at the edge and capsular contracture which induce sharp folds

may precipitate shell perforation. "Thin shell" mammary implants from various manufacturers were reported to develop edge perforation and rupture at a significant faster rate than "thicker shell" (Ref.43a). There have been no well controlled studies to identify the role that physical, mechanical and chemical characteristics of silicone envelope and gel may play in the immediate or long-term rupture of the implant.

Silicone degradation is another possible cause of breast implant failure based on the analysis of explanted mammary prostheses (Refs.43a-b, 45a-b). Schmidt (Ref.43a) critically examined removed implants and reported that the sac of both inflatable and gel-filled mammary implants were perforated and suggested wear and degradation as a mode of implant failure. There is evidence of the degradation of other implanted silicone devices such as heart valves, finger, and toe joint prostheses, etc. (Refs.45a,80,81,121, 122,130).

MAGNITUDE OF RISK/INCIDENCE OF IMPLANT RUPTURE

Leakage and migration of silicone ruptured breast implants have been documented in numerous reports: local migration in breast parenchyma (Refs.38,59), into the regional lymph node (Ref.61), into the upper arm, the chest and shoulder (Ref.59), into the chest and abdominal walls (Ref.34) and as far as the groin (Refs.34,60).

Silicone leakage may be difficult to assess due to the long latency period involved. It is reported that many ruptured implants do not result in physical disfigurement immediately but result in deposition and distant migration of silicone gel in the body with consequential granuloma and lymphadenopathy years later (Ref.57,61,94,118,122,123,143). A survey of published case reports indicates that silicone granulomas and lymphadenopathy are observed 5 to 20 years following augmentation mammoplasty. Implant failure due to rupture was reported both in gel and saline filled mammary prostheses (Ref.42-43,46).

Silicone leakage is second to capsular contracture for accountable failures of silicone mammary prostheses (Ref.56). The rate of these incidences may be under-reported since the appearance of migrated silicone is indistinguishable by physical or radiographic examination from neoplasia (Refs. 33,52,57,196b). Therefore, palpable masses observed in patients with breast implants should be excised and examined histopathologically to identify cases of silicone leakage and migration (Ref.57)

There are few studies that have examined the incidence of rupture of silicone gel-filled prostheses in animals. Vistnes et al. (Ref.53) reported that silicone gel-filled prostheses elicit inflammatory response with resultant capsule formation at implant sites in rats. Silicone droplets

were identified at distant sites demonstrating migration of silicone from ruptured implants. However, there are a number of studies which showed fibrous capsule formation following subcutaneous implantation of synthetic polymers in experimental animals (Refs.111-117.161.186b).

The term implant failure in breast augmentation has been poorly defined (Refs.3,105,162,169,171,194). Well-controlled studies have not been performed to assess the rate of prosthesis rupture, and the number of revisions involved in cosmetic or reconstructive augmentation mammoplasty. Reported statistics vary and only reflect personal experiences of investigators (Refs.11,163-164,168-169,194,196c). The cases reported are often incomplete and are used only to identify clinical end points, latency period involved. Therefore, specifically designed large scale retrospective clinical studies are required to adequately assess the incidences, rate, causes and prevention of implant rupture/failure as well as the risks involved in breast augmentation.

GEL BLEED: CLINICAL END POINTS

In addition to the potential rupture of the implant as discussed above, all types of silicone breast implants are reported to "bleed" micro amounts of silicone through the intact silicone elastomer shell into surrounding tissues (Refs.7,9,45,65,71-75,162). Clinical symptoms related to granulomas and lymphadenopathy are reported to be the result of gel bleed. The diffused silicone can react locally forming a fibrous capsule (Ref.71) or migrate to distant locations resulting in granulomas and lymphadenopathy (Refs.57,72,78,122,143). In order to demonstrate that the implanted silicone breast prostheses leak silicone gel through intact membrane, researchers have used scanning electron microscopy (SEM) and energy dispersive analysis of X-rays (EDAX), transmission electronic spectroscopy (TES) etc. to quantitatively assess the presence and amount of element silicon (Si) in the tissues adjacent to the prostheses, and in axillary lymph nodes of patients with explanted intact prostheses (Refs.45a,57,69,70-71). Histopathology was also performed and silicone oil droplets have been identified by transmission electron spectroscopy in multinucleated giant cells, macrophages in fibrous capsules near breast prostheses (Refs.45,71).

ETIOLOGICAL FACTORS

"Bleeding" of silicone in patients implanted with gel-filled prostheses have been documented by numerous investigators (Refs.45,65,69-74,78). Baker et al. (Ref.65) demonstrated continuous leakage of silicone gel from intact breast implants by simply placing intact silicone gel-filled breast prostheses on cardboard paper with or without pressure for a period of one week.

The exact mechanism of the transgression of silicone

through the shell is not known but is postulated that leakage of silicone gel through an intact implant may be due to the high permability of silicone rubber in silicone gel since both are chemically similar in composition differing only in degree of cross linking and the presence of reinforcing silica filler (Ref.7). Silicones, which are used for medical purposes, are homopolymers such as polydimethylsiloxane or co-polymers, dimethyl, diphenyl, and dimethyldiphenylsiloxane. The silicone polymers are compounded into silicone rubber stocks by adding reinforcing fillers such as fumed silica or silicone aerogels via blending them together on a rubber mill. The rubber stock is then dispersed in solvent and used in the preparation of mammary prosthesis. Depending on the extent of cross linking and the amount of silica present as fillers one can obtain silicone of different viscosities or as fluid, gel, or solid (Ref.196d). Chemically, polydimethylsiloxane with solubility coefficient (d-7.3) is lipophilic and non-polar. Animal studies indicate that silicone has a high affinity for circulating lipids and steroids such as progesterone and estrogens (Ref,159). Case reports in the literature have identified the presence of silicone in the fibrous capsules around prostheses and presence of biological materials inside the intact prosthesis (Refs.45a,65,69-75,78). These data suggest that silicone gel and/or its components may diffuse out of the envelope and migrate into the fibrous capsule. Diffusion of the gel out and the uptake of lipids, steroids, or other biological materials in through the intact silicone membrane should be evaluated. Possible interaction between lipid soluble biological materials and silicone may play an important role in implant failure in humans, and carcinogenic potential of the device in animals (Ref.160)

MAGNITUDE OF RISK/RATE OF INCIDENCE

Silicone gel bleed through the intact envelope of breast implant is a serious risk associated with implantation of all silicone gel-filled breast implants, regardless of design. Gel bleed may result in deposition and migration of free silicone in the body leading to capsular contraction, silicone granuloma, lymphadenopathy and other unknown toxic effects (Refs.21,57,72,78,122,143).

SILICONE MIGRATION

Migration of silicone has been reported via the lymphatics and circulatory system (Refs.34,36,38,41,45a-b,50,57,59,60,68,72,76,122,143). Subcutaneous injections of silicone fluid into rats and mice elicit foreign body reactions in the vicinity of the implants and at distant sites including kidney, spleen, liver, adrenal glands, ovaries, and pancreas (Refs.53,62,112).

In humans, numerous reports described silicone granulo-

mas or lymphadenopathy in distant organs such as axillary lymph nodes, liver, kidney, and even the brain which demonstrate silicone migration in patients that underwent augmentation mammoplasty 5-20 years earlier (Refs. 26,38,50,57-61, 68,72-77,122,143,197). Others have reported that malignant lymphoma (Refs. 118,120), and metastatic carcinoma (Refs. 119,122-125,131,145) have been observed concurrently with silicone granulomas. Calcification of the fibrous capsule (Refs.45a,178-180,190,196) has also been suggested as a form of foreign body reaction to silicone breast implants.

AUTOIMMUNE DISEASE - IMMUNOLOGICAL SENSITIZATION

Immunological sensitization may be a serious risk associated with the implantation of a silicone gel-filled breast prosthesis. Although it was previously believed to be chemically "inert", silicone is capable of eliciting a cellular immune response that can be demonstrated by the migration inhibition technique.

Although primarily composed of silicone, breast implants also contain silica as a filler in their envelopes and gels (Refs.7,186a-b,196d). In addition, phagocytic cells may convert silicone to silica (Refs.82,92). Silica's presence is noteworthy, as it can potentially induce the development of silicosis (Refs.82,92), causing harmful granulomas, fibrosis, and other harmful sequelae. In addition, silica is immunologically active, and may act as an immunological adjuvant which can potentiate the development of autoimmune diseases induced by mycobacterial or other antigens present in resident microorganisms (Ref.181).

An association of tuberculosis, silicone implants and the subsequent development of connective tissue disease has been reported and closely corresponds to an animal model of "adjuvant disease" (Ref.181). Since mycobacterial infections can lie dormant for many years, caution must be exercised when considering the implantation of these devices in people with a history of mycobacterial infection or a positive tuberculin test.

INTERFERENCE WITH EARLY TUMOR DETECTION

The presence of silicone gel-filled breast implants may interfere with standard radiographic diagnosis of breast cancer. The silicone envelope and gel are radiopaque and thus may reduce the ability to see clearly through the implant. Furthermore, the implant compresses breast tissue, making it more difficult to identify some of the early changes caused by carcinoma (Refs.97-99),

Recent clinical reports (Refs.95,101) showed that augmentation mammoplasty with silicone gel-filled implants dramatically reduces the ability of mammography to visualize breast tissue. In summary, augmentation patients with

breast cancer presented with more advanced disease; they had a higher percentage of invasive lesions and positive axillary nodes, resulting in a worsened prognosis.

CALCIFICATION

Calcification is the deposition of mineral salts in the fibrous capsular tissue surrounding the breast prosthesis. The mineral salts are predominantly calcium hydroxylapatite. However, zinc and calcium hydrate phosphate have recently been identified at the tissue prosthesis interface (Ref. 178). These particular salts have never been reported in any other mineralization process related to human pathology. The major risk associated with calcification may be the interference with early tumor detection and diagnosis which can delay treatment and impact on the clinical course of cancer patients. Many times calcification is associated with capsular contracture which can result in breast firmness and pain (Refs.18,176,177,178).

OCCURRENCE RATE

It is difficult to identify the rate of occurrence or magnitude of risk of calcification. One report indicates a rate of about 33% (Ref.178). Another report (Ref.180) indicates that calcification occurs in almost all patients injected directly with silicone.

HUMAN CARCINOGENICITY

Carcinogenicity has been a widely discussed topic related to the injection of silicone in augmentation mammoplasty since the early 1950's (Ref.68,129,133,134,143,162). Although relatively purer medical grade silicone is now produced, long-term complications related to silicone migration including calcification, lymphadenopathy, granulomas, and cancer remain as significant risks associated with the implantation of silicone gel-filled breast implants (Refs.26, 43,57-58,95,118,122-128,143-145,177,179-180,184,193,197). A survey of the literature indicates numerous case reports of carcinoma following augmentation mammoplasty. In view of the possible migration of silicone via the reticulo-endothelial system to distant sites in the body, cancer incidences of other target organs need to be investigated.

In lifetime bioassays, silicone and other polymers (polyurethane, polytetrafluoroethylene) have been reported to induce from 0 to 50% incidences of cancer, predominantly sarcoma, at site of implants following subcutaneous implantation in rats and mice (Refs.107,111,132,153-160,186a,190). However, it should be noted that silicone polymers are known to contain macromolecules by peroxide crosslinkages, additives, catalysts (platinum) and fillers (solid or fumed silica)(Refs.7,186b,196d). In addition, it has been pointed out (Ref. 160) that silicone gel, being lipophilic, selec-

tive binds progesterone and other lipids. The affinity of liquid silicone for progesterone is 50 times more than for estrogens. Possible uptake of high concentration of hormones at the implant site was postulated to be the cause of increased cancer incidences found in animal studies (Ref. 159).

On August 1987, FDA was presented with partial results of a 2 year-rat-bioassay (1985-1987) conducted by Dow Corning. The data indicated that "original" and "responsive" silicone gels, MDF-0193 and Q7-2159A, implanted subcutaneously in rats induced pronounced increases in the incidences of sarcoma. The dose used in the Dow Corning rat study is in the order of magnitude to the amount of gel to which the human body is exposed, in augmentation mammaplasty. In the Dow Corning study, metastasis was recorded in a number of cases.

Sarcomas have been reported to be associated with polyurethane, another polymer, at the implant site and remote from the implant site (Ref.153-158). Both polyurethane and silicone are known to degrade and migrate via blood to other parts of the body (Refs.147,153a-b,157-158). Other types of implants (bone plates, screws, plastic plompage in the lungs, vascular graft, injected silicone) were reported to produce sarcoma and carcinoma in humans (Refs.108,109,135-139) and animals (mice,rats,rabbits,dogs)(Refs.107,108,153-160,186a).

The following factors should be considered for explaining why there may not be as much human sarcoma data:

1. The transport of silicone through lymphatics and blood to target organs is a slow process. Cancers or other complications may not be thought to be associated with breast implants due to distant sites and long latency period involved (Refs.108,122,129,143,186a).
2. The time to tumor observed in rats is approximately 2/3 of a lifetime. Insufficient time has elapsed to result in statistically significant number of human cancer reports related to augmentation mammaplasty (Ref.108).
3. There is insufficient well controlled epidemiological studies to determine the risk of cancer as a result of silicone implant leakage and migration in humans.

Aside from the question of causation, there are numerous breast cancer case reports on augmented women who had a higher percentage of invasive lesions and more positive lymph nodes resulting in worsened prognoses compared to non-augmented women (Ref.95,100,101). The possibility of worsened diagnosis due to implant presence is disturbing and deserves further study (Refs.95-102,196b).

HUMAN TERATOGENICITY

Because young women constitute the majority recipients

of the silicone gel-filled mammary implants in augmentation mammoplasty, the potential hazard to the unborn which may arise from exposure of the mother to the silicone mammary implants before and/or during pregnancy may be serious.

DEGRADATION OF POLYURETHANE COVERED BREAST PROSTHESES

The question of safety of Polyurethane Covered Breast Prostheses has been raised due to PU's degradation with time and its unknown fate in vivo (Refs.146-148, 152, 203). A review of the pre-clinical literature on polyurethane reveals that polyesterurethane foams are produced from toluene diisocyanates (TDI) and 2,4 diamino toluene (TDA)(Refs.204-209). There is ample evidence that polyurethanes, TDI and TDA induced both sarcomas and carcinomas at sites of implantation, liver, and breast cancers in lifetime bioassays in rats and mice (Refs.153a,154,205-206,212). Both the EPA and the FDA have considered 2,4 TDA as suspected human carcinogen based on the results of 1978 NCI bioassay (Ref.212). 2,4 TDA is also known to be a male reproductive toxin in humans and animals (Refs.220-223). Two primary concerns are noteworthy:

1. Difficulty with removal of the prosthesis due to fragmented PU shell and capsular tissue ingrowth (Refs.146-152).
2. Difficulty in treating delayed pain and infection probably due to chronic inflammatory reaction produced by PU degradation products or fragments (Refs.146,149,151,152, 213-214).

Fragmentation, disappearance of the polyurethane coating, and a marked foreign body response (capsular contraction, infection, fever, pain, extreme fatigue, and arthritic-like symptoms) are recognized reactions to polyurethane coated mammary prostheses in humans(Ref.146-152,213-217). Data in experimental animals showed that polyurethane coated silicone implants degrade within 6 to 12 months after implantation (Refs.203-204). Risk characterization of the degradation of polyurethane implants in humans has not appeared in the open literature although polyurethane foam was expected to degrade within one to two years (Ref.204). PU-coated prostheses share 20-25% of the market of mammary prosthesis.

There is no human evidence on cancer associated with the use of polyurethane foam covered breast implants. One possible explanation (among many others) for the lack of human evidence is that polyurethane foam, once implanted in biological environment would become fragmented. According to this hypothesis, one can envision the hydrolytic cleavage of PU foam into smaller fragments with minimum yield of TDA. The fragments can be removed by scavenger cells and may be excreted by hepatobiliary and/or pulmonary and GI routes.

**PHOTOCOPY
PRESERVATION**

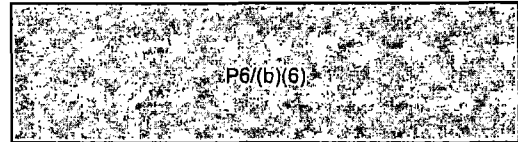
The bioavailable dose of TDA in patient will then be extremely small.

DISCUSSION OF RISKS AND BENEFITS

FDA has weighed the probable risks and benefits to the public from the use of the silicone gel-filled breast prosthesis and believe that the studies discussed above present evidence of significant risks associated with the use of the device.

Note: I will supply the list of reference sources upon request.

Marlene Keeling
Marlene Keeling



Attachment: Silicone Gel-filled Breast Implants in Women:
Findings at H-1 MR Spectroscopy, Radiology December 1996.
(over 50% of breast implanted women in this study were found
to have silicone in the liver)

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P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[011]

TO:

FAX:

FROM: MARLENE KEELING FAX:

P6/(b)(6)

PHONE:

P6/(b)(6)

DATE: MARCH 31, 1997

RE: NATIONAL INSTITUTE OF HEALTH MEETING APRIL 4, 1997

Dear Breast Implant Friend,

Diane Griffith, USSW Congressional Liaison, has secured a meeting with the National Institute of Health. We have the Shanna Swan study "Disease Occurrence in Silicone Breast Implanted Women: Estimates from the Sample of Domestic Claimants". This random sample of 2,994 was drawn by the court from the first 191,400 claims and shows a 5.5% increased incidence of scleroderma in breast implanted women than in the general population.

I have designed a statistical data gathering sheet that should not take over 10 minutes to complete for each participant. No name will appear on the sheet, only an identifier and state code. The individuals name, address, and telephone number will be known only by the support group leader and the state leader (we need to be able to verify the data by documents showing rupture or disease if needed by the NIH). The state leader will number the participants consecutively from their state.

This is our opportunity to attempt to get the NIH to address this important health issue. We will attempt to point out that they can save millions of research dollars by using the statistics that are already compiled on 450,000 women within the MDL.

You can help by trusting your support group leader and your state leader, with information which will ultimately be available to the manufacturers thru the MDL or when your case comes up for trial.

Once you receive a copy of this from your state leader, please return by 5:00 P.M. Wednesday, ~~March~~ ^{APRIL} 2nd. We also have an appointment with the Office ~~for~~ Women in the Executive Offices connected to the White House and with the chairman of the Commerce Committee.

Your help will make a difference.

~~FOR~~

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

EXAMPLE

	1	2	3	4	5	6	7	
BI #1 TX	IDENTIFIER /STATE	BI #1 TX	BI #2 TX	BI #3 TX	BI #4 TX	BI #5 TX	BI #6 TX	BI #7 TX
1 3	YEAR OF BIRTH	1942	1949	1934	1946	1960	1959	1949
SETS 1977 1979*	# OF IMPLANTS	3 Sets	2 Sets	1 Set	1 Set	1 Set	1 Set	1 Set 3 Sing
HS GEL MG DL*	YEAR(S) IMPLANTED	1977 1979*	1983 1993	1974	1984	1988	1991	1979 1979*
	TYPE OF IMPLANTS	HS Gel MG DL*	CX DL MG Sa	DO Gel	BR DL	CX DL	MG Gel	Gel Gel *
1994	YEAR EXPLANTED	1995	1994	1996	1994	1994	Still	1994
12	# OF BREAST SURGERIES	12	3	2	2	2	1	8
NO	PERIPHERAL NEUROPATHY	No	No	Yes	No	No	No	No
NO	DEMYELINATING NEUROPATHY	No	Yes	No	No	No	No	No
YES	ATYPICAL NEUROLOGICAL	Yes	Yes	Yes	No	Yes	No	No
YES	ORGANIC BRAIN SYNDROME	No	No	Yes	No	No	No	No
NO	LUPUS OR LUPUS LIKE	No	Yes	No	No	Yes	No	Yes
NO	FIBROMYALGIA	No	Yes	No	No	No	No	No
YES	ATYPICAL CONNECT- IVE TISSUE	Yes	No	Yes	No	Yes	No	No
	MIXED CONNECT- IVE TISSUE	No	No	No	No	Yes	No	No
NO	SCLERODERMA	No	No	No	No	No	No	No
NO	ESOPHAGEAL REFLUX	No	No	No	No	No	No	No
YES	GASTRO-INTESTINAL DYSMOTILITY	Yes	No	No	Yes	Yes	No	Yes
NO	CHRONIC FATIGUE	Yes	Yes	No	Yes	Yes	No	Yes
NO	SJOGRENS SYNDROME	No	No	No	No	No	No	No
YES 1994*	CANCER OR MGUS YEAR & TYPE	NO	no	No	No	No	No	No
1993 ME GEL No	COMMENTS	*1993 ME Gel No Photo- sensi- tivity		Hasimo- to's Disease Carpel tunnel syn-	No mon- ey for diag- nosis	Poly- myosi- tis MS	Spas- tic colon	*1980 Gel No *1981 Gel no **
NDOME- TRIAL ANCER NO ONLY	RUPTURE YES/NO	No 1 Only	No No	Yes	No	No	No	No

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

AB. VIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU
(polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan)

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

EXAMPLE

	1	2	3	4	5	6	7	
BI #1	IDENTIFIER	BI #8	BI #9	BI #10	BI #11	BI #12	BI #13	BI #14
TX	/STATE	TX	TX	TX	TX	TX	TX	TX
1942	YEAR OF BIRTH	1945	1947	1947	1949	1952	1949	1941
3	# OF IMPLANTS	5 sets	7 sets	5 sets	1 set	1 set	1 set	1
SETS	YEAR(S)	1976	1975	1981	1987	1981	1977	1990
1977	IMPLANTED	1977*	1976*	1981*				
1979*	TYPE OF IMPLANTS	PU	HS Gel	DO	DO DL	BA	HS	MG DL
HS GEL		PU	CX PU	DO				
MG DL*	YEAR EXPLANTED		1992	1987		1994	1992	1994
1994	# OF BREAST SURGERIES	8	10	9	2	3	2	2
12	PERIPHERAL NEUROPATHY	no	yes	yes	no	no	yes	yes
NO	DEMYELINATING NEUROPATHY	no	yes	yes	no	no	yes	yes
NO	ATYPICAL NEUROLOGICAL	yes	yes	yes	no	no	yes	yes
YES	ORGANIC BRAIN SYNDROME	no	yes	yes	no	no	no	no
YES	LUPUS OR LUPUS LIKE	no	yes	no	no	no	yes	yes
NO	FIBROMYALGIA	yes	yes	yes	yes	yes	yes	yes
NO	ATYPICAL CONNECT-IVE TISSUE	yes	yes	yes	no	no	yes	n
YES	MIXED CONNECT-IVE TISSUE	no	yes	no	no	no	yes	no
NO	SCLERODERMA	no	yes	no	no	no	no	yes
NO	ESOPHAGEAL REFLUX	yes	yes	yes	no	no	yes	yes
NO	GASTRO-INTESTINAL DISMOTILITY	yes	yes	yes	no	no	yes	yes
YES	CHRONIC FATIGUE	yes	yes	yes	yes	yes	yes	yes
NO	SJOGRENS SYNDROME	no	yes	yes	no	no	no	yes
NO	CANCER OR MGUS YEAR & TYPE	no	yes	no	no	no	no	no
YES								
1994*	COMMENTS	*1978 MG SA Yes *1982 HS Gel No *1992	*1979 BA PU Yes *1983 HS DL Yes *1984	*1983 DO No *1984 DO No				
1993								
ME GEL								
No								
ROOME-								
TRIAL								
CANCER								
NO								
ONLY								
	RUPTURE YES/NO	Yes Yes	Yes Yes	Yes Yes	No	Yes (1)	yes	No

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGill)

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

XAMPLE

	1	2	3	4	5	6	7
BI #1 TX	IDENTIFIER /STATE	BI #15 TX	BI #16 TX	BI #17 TX	BI #18 TX	BI #19 TX	BI #20 TX
	YEAR OF BIRTH	1935	1922	1953	1926	1946	1955
SETS 1977 1979*	# OF IMPLANTS	2 sets	1 set	1set	1 set 1 Sing.	1 set	1 set
HS GEL MG DL*	YEAR(S) IMPLANTED	1976 1977	1968	1985	1967 1991	1975	1991
	TYPE OF IMPLANTS	DO HS	DO	BR	DO	DO	BR
1994	YEAR EXPLANTED	1994	1995	1997	1992	1991	1997
12	# OF BREAST SURGERIES	5	2	2	7	2	7
NO	PERIPHERAL NEUROPATHY	yes	no	yes	yes	yes	no
NO	DEMYELINATING NEUROPATHY	yes	no	yes	yes	yes	no
YES	ATYPICAL NEUROLOGICAL	yes	no	yes	yes	yes	yes
YES	ORGANIC BRAIN SYNDROME	no	no	no	yes	yes	no
NO	LUPUS OR LUPUS LIKE	yes	no	yes	yes	yes	no
NO	FIBROMYALGIA	yes	yes	yes	yes	yes	yes
YES	ATYPICAL CONNECT- IVE TISSUE	yes	yes	yes	yes	yes	yes
	MIXED CONNECT- IVE TISSUE	yes	yes	yes	yes	yes	yes
NO	SCLERODERMA	yes	yes	no	no	no	no
NO	ESOPHAGEAL REFLUX	no	no	yes	yes	yes	no
YES	GASTRO-INTESTINAL DYSMOTILITY	yes	no	yes	yes	yes	no
NO	CHRONIC FATIGUE	yes	yes	yes	yes	yes	yes
NO	SJOGRENS SYNDROME	yes	yes	no	yes	yes	yes
YES 1994*	CANCER OR MGUS YEAR & TYPE	no	yes*	no	no	no	no
1993 ME GEL No	COMMENTS		Soft tissue back				
NDOME- TRIAL CANCER NO ONLY	RUPTURE YES/NO	no	yes	yes	yes	no	no

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

ABB IATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(Mag)

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

EXAMPLE

	1	2	3	4	5	6	7
IDENTIFIER /STATE	BI #22 TX	BI #23 TX	BI #24 PA	BI #25 AR1	BI #26 AR2	BI #27 FL13	BI #28 FL14
1942 3	1957	1963	1947	1944		1964	194
SETS 1977 1979*	# OF IMPLANTS 1 set	1 set 1 sing.	1 set	1 set	1 set	2 sets	1 set
HS GEL MG DL*	YEAR(S) IMPLANTED 1989	1981 1986	1990	1976	1984	1985 1996	1985
	TYPE OF IMPLANTS BR	3M DL BR DL	BR PU	DO	BR DL	DL	Gel
1994	YEAR EXPLANTED 1996	1995	1993	1993	1991	1996	1991
12	# OF BREAST SURGERIES 2	5	2	2	2	2	4
NO	PERIPHERAL NEUROPATHY yes	yes	yes	no	no	no	yes
NO	DEMYELINATING NEUROPATHY no	yes	no	no	no	no	no
YES	ATYPICAL NEUROLOGICAL no	yes	yes	no	yes	yes	no
YES	ORGANIC BRAIN SYNDROME no	no	no	no	yes	no	no
NO	LUPUS OR LUPUS LIKE yes	yes	no	yes	yes	no	yes
NO	FIBROMYALGIA yes	yes	yes	yes	yes	yes	yes
YES	ATYPICAL CONNECT- IVE TISSUE yes	no	yes	no	yes	yes	yes
NO	MIXED CONNECT- IVE TISSUE yes	yes	yes	no	no	yes	no
NO	SCLERODERMA no	no	no	no	no	no	no
NO	ESOPHAGEAL REFLUX yes	yes	no	no	no	yes	yes
YES	GASTRO-INTESTINAL DYSMOTILITY yes	yes	no	yes	yes	yes	yes
NO	CHRONIC FATIGUE yes	yes	yes	yes	yes	yes	yes
NO	SJOGRENS SYNDROME no	no	no	no	no	no	no
YES 1994*	CANCER OR MGUS YEAR & TYPE no	no	no	no	no	no	no
1993 ME GEL No	COMMENTS						
DOOME- TRIAL CANCER NO ONLY	RUPTURE YES/NO no	no no	no	yes	yes		

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan) ME

NATIONAL INSTITUTE OF HEALTH DATA SHEET
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AFTER IMPLANTATION

EXAMPLE

	1	2	3	4	5	6	7
BI #1	IDENTIFIER	BI #29	BI #30	BI #31	BI #32	BI #33	BI #34
TX	/STATE	FL 01	FL 02	FL 03	FL 04	FL 05	FL 06
19	YEAR OF	1943	1949	1948	1943	1946	1955
3	BIRTH						1933
SETS	# OF	1 set	1 set	1 set	2 sets	1 set	1 set
1977	IMPLANTS		1 sing.				2 sets
1979*	YEAR(S)	1972	1979	1966	1983	1990	1980
HS GEL	IMPLANTED		1980				1971
MG DL*	TYPE OF	DO Gel	3M Gel	Gel	DL	Gel	3M Gel
	IMPLANTS						Gel
1994	YEAR	1994	1992	1994	1991	1991	still
	EXPLANTED						1994
12	# OF BREAST	2	4	2	7	2	2
	SURGERIES						3
NO	PERIPHERAL	yes	yes	yes	yes	yes	no
	NEUROPATHY						yes
NO	DEMYELINATING	no	yes	no	no	yes	no
	NEUROPATHY						yes
YES	ATYPICAL	no	yes	yes	yes	yes	no
	NEUROLOGICAL						yes
YES	ORGANIC BRAIN	no	yes	no	no	yes	no
	SYNDROME						no
NO	LUPUS OR	no	yes	yes	yes	yes	no
	LUPUS LIKE						yes
NO	FIBROMYALGIA	yes	yes	yes	yes	yes	yes
							yes
YES	ATYPICAL CONNECT-	yes	yes	yes	yes	yes	no
	IVE TISSUE						yes
	MIXED CONNECT-	no	no	yes	yes	no	no
	IVE TISSUE						yes
NO	SCLERODERMA	no	no	no	yes	no	no
							no
NO	ESOPHAGEAL	no	yes	yes	yes	yes	no
	REFLUX						no
YES	GASTRO-INTESTINAL	yes	yes	yes	yes	yes	no
	DISMOTILITY						no
NO	CHRONIC	yes	yes	yes	yes	yes	yes
	FATIGUE						yes
NO	SJOGRENS	yes	yes	no	yes	yes	no
	SYNDROME						no
YES	CANCER OR MGUS	no	no	no	no	no	no
1994*	YEAR & TYPE						
	COMMENTS						
1993							
ME GEL							
No							
NDOME-							
TRIAL							
ANCER							
NO							
ONLY							
	RUPTURE		yes	yes	yes	no	yes
	YES/NO						yes

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

ABL -VIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan) ME

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

XAMPLE

	1	2	3	4	5	6	7
BI #1	IDENTIFIER	BI #36	BI #37	BI #38	BI #39	BI #40	BI #41
TX	/STATE	FL 08	FL 09	FL 10	FL 11	FL 12	FL 15
1942	YEAR OF BIRTH	1943	1948	1921	1939	1943	1933
3	# OF IMPLANTS	1 set	1set	1set	2 sets	2 sets	1 set
SETS	YEAR(S) IMPLANTED	1990	1976	1975	1985 1996	1977 1980	1977
1977	TYPE OF IMPLANTS	MG DL	Gel	Gel	Gel SA	SA Gel	Gel
1979*	YEAR EXPLANTED	1995	1991	still	still	1991	1994
HS GEL	# OF BREAST SURGERIES	2	2	1	2	2	2
MG DL*	PERIPHERAL NEUROPATHY	no	yes	yes	no	yes	yes
	DEMYELINATING NEUROPATHY	no	yes	yes	no	yes	yes
	ATYPICAL NEUROLOGICAL	no	yes	yes	no	yes	yes
	ORGANIC BRAIN SYNDROME	yes	no	yes	no	no	no
	LUPUS OR LUPUS LIKE	no	yes	yes	no	no	yes
	FIBROMYALGIA	yes	yes	no	yes	yes	yes
	ATYPICAL CONNECT-IVE TISSUE	yes	yes	yes	no	no	yes
	MIXED CONNECT-IVE TISSUE	no	yes	yes	no	no	no
	SCLERODERMA	yes	yes	yes	no	no	no
	ESOPHAGEAL REFLUX	no	no	yes	yes	yes	yes
	GASTRO-INTESTINAL DISMOTILITY	yes	no	no	no	yes	yes
	CHRONIC FATIGUE	yes	yes	no	yes	yes	yes
	SJOGRENS SYNDROME	no	yes	no	no	yes	yes
	CANCER OR MGUS	no	no	no	no	no	no
1994*	YEAR & TYPE	no	no	no	no	no	no
	COMMENTS						on S.S. disab
1993							
ME GEL							
No							
COME-							
RIAL							
CNCER							
NO							
ONLY	RUPTURE YES/NO	NO					No
							Yes

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan) ME

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

AMPLE

		1	2	3	4	5	6	7
I #1	IDENTIFIER	BI #43	BI #44	BI #45	BI #46	BI #47	BI #48	BI #49
TX	/STATE	IL 1	IL 2	IL 3	IL 4	IL 5	IL 6	IL 7
19	YEAR OF							
3	BIRTH	1953	1931	1937	1941	1953	1951	1952
	# OF							
SETS	IMPLANTS	1 set	1 set	1 set	1 set	2 sets	1 set	1 set
1977	YEAR(S)					1990		
1979*	IMPLANTED	1989	1971	1989	1987	1992	1990	1974
HS GEL	TYPE OF					ME Gel		
MG DL*	IMPLANTS	ME Gel	DO Gel	BR Gel	CX DL	SA	CX Gel	DO Gel
	YEAR							
1994	EXPLANTED	1993	1992	1989	1994	1993	1995	1994
	# OF BREAST							
12	SURGERIES	2	3	7	2	5	2	2
	PERIPHERAL							
NO	NEUROPATHY	yes	yes	yes	yes	yes	yes	yes
	DEMYELINATING							
NO	NEUROPATHY	yes	no	no	no	no	no	no
	ATYPICAL							
YES	NEUROLOGICAL	yes	yes	no	yes	yes	yes	yes
	ORGANIC BRAIN							
YES	SYNDROME	yes	yes	no	yes	yes	yes	no
	LUPUS OR							
NO	LUPUS LIKE	yes	yes	no	no	yes	no	no
	FIBROMYALGIA							
NO		yes	yes	yes	yes	yes	yes	yes
	ATYPICAL CONNECT-							
YES	IVE TISSUE	yes	yes	yes	yes	yes	yes	yes
	MIXED CONNECT-							
	IVE TISSUE	yes	yes	yes	no	yes	yes	yes
	SCLERODERMA							
NO		no	no	yes	no	no	no	no
	ESOPHAGEAL							
NO	REFLUX	yes	yes	yes	no	no	yes	no
	GASTRO-INTESTINAL							
YES	DISMOTILITY	yes	yes	no	no	yes	yes	yes
	CHRONIC							
NO	FATIGUE	yes	yes	yes	yes	yes	yes	yes
	SJOGRENS							
NO	SYNDROME	yes	yes	no	yes	yes	yes	yes
YES	CANCER OR MGUS							
1994*	YEAR & TYPE	no	no	no	no	no	no	no
	COMMENTS							
1993		Lung				Lung		
ME GEL		disease				disease		
No								
NDOME-								
TRIAL								
CANCER								
NO								
ONLY	RUPTURE							
	YES/NO	no	yes	no	yes	no	no	yes

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS
 IATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan) ME

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
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AMPLE		1	2	3	4	5	6	7
I #1	IDENTIFIER	BI #50	BI #51	BI #52	BI #53	BI #54	BI #55	BI #56
TX	/STATE	IL 8	IL 9	IL 10	IL 11	IL 12	IL 13	IL 14
1942	YEAR OF BIRTH	1949	1939	1938	1939	1932	1943	1951
3	# OF IMPLANTS	1 set	2 sets	1 set	2 sets	2 sets	2sets	1 set
SETS	YEAR(S)		1978		1989	1989	1981	
1977	IMPLANTED	1976	1979	1972	1990	1990	1985	1988
1979*	TYPE OF IMPLANTS	DO Gel	SA Gel	HS DL	DL MG Gel	ME Gel	MG Gel	MG Gel
HS GEL								
MG DL*								
1994	YEAR EXPLANTED	still	still	1984	1993	1995	1993	still
	# OF BREAST SURGERIES	1	2	3	7	3	5	1
12	PERIPHERAL NEUROPATHY	yes	yes	yes	yes	no	yes	yes
NO	DEMYELINATING NEUROPATHY	yes	yes	yes	no	no	no	yes
NO	ATYPICAL NEUROLOGICAL	yes	yes	yes	no	no	yes	yes
YES	ORGANIC BRAIN SYNDROME	yes	yes	yes	yes	yes	yes	yes
YES	LUPUS OR LUPUS LIKE	yes	yes	yes	no	yes	yes	yes
NO	FIBROMYALGIA	yes	yes	yes	yes	yes	yes	yes
NO	ATYPICAL CONNECTIVE TISSUE	yes	yes	yes	yes	yes	yes	yes
YES	MIXED CONNECTIVE TISSUE	yes	yes	yes	no	no	yes	yes
NO	SCLERODERMA	no	no	no	no	no	no	no
NO	ESOPHAGEAL REFLUX	yes	yes	no	no	yes	yes	yes
NO	GASTRO-INTESTINAL DISMOTILITY	yes	yes	yes	no	no	yes	yes
YES	CHRONIC FATIGUE	yes	yes	yes	yes	yes	yes	yes
NO	SJOGRENS SYNDROME	yes	yes	yes	no	no	yes	yes
NO	CANCER OR MGUS							
YES	YEAR & TYPE	no	yes 1992*	no	no	no	no	no
1994*	COMMENTS			Thyroid problems				
1993								
ME GEL								
NO								
CONCERNIAL								
NO								
ONLY	RUPTURE YES/NO	yes	yes	yes	no	no	yes	no

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan) ME

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
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EXAMPLE

	1	2	3	4	5	6	7
BI #1	IDENTIFIER	BI #57	BI #58	BI #59	BI #60	BI #61	BI #62
TX	/STATE	IL 15	IL 16	IL 17	IL 18	IL 19	IL 20
19	YEAR OF BIRTH	1957	1942	1939	1951	1953	1949
3	# OF IMPLANTS	1 set	3 sets	1 set	1 set	1 set	1 set
SETS	YEAR(S) IMPLANTED	1991	1988 1989*	1977	1971	1974	1972
1977	TYPE OF IMPLANTS	BR	PU GEL	DO Gel	DO Gel	DO Gel	DO Gel
1979*	YEAR EXPLANTED	1996	1992	1992	1996	1996	1994
HS GEL	# OF BREAST SURGERIES	2	7	3	2	2	2
MG DL*	PERIPHERAL NEUROPATHY	yes	yes	yes	no	no	yes
	DEMYELINATING NEUROPATHY	yes	yes	yes	no	no	yes
1994	ATYPICAL NEUROLOGICAL	yes	yes	yes	no	no	yes
	ORGANIC BRAIN SYNDROME	yes	yes	yes	yes	yes	yes
12	LUPUS OR LUPUS LIKE	yes	yes	no	yes	no	yes
NO	FIBROMYALGIA	yes	yes	yes	yes	yes	yes
NO	ATYPICAL CONNECTIVE TISSUE	no	yes	yes	yes	yes	yes
YES	MIXED CONNECTIVE TISSUE	yes	no	no	no	yes	no
YES	SCLERODERMA	no	no	no	no	no	no
NO	ESOPHAGEAL REFLUX	yes	yes	no	no	no	yes
NO	GASTRO-INTESTINAL DYSMOTILITY	yes	yes	yes	no	no	yes
YES	CHRONIC FATIGUE	yes	yes	yes	yes	yes	yes
NO	SJOGRENS SYNDROME	yes	yes	no	no	no	yes
NO	CANCER OR MGUS	no	no	no	no	no	no
YES	YEAR & TYPE						
1994*	COMMENTS						
1993							
ME GEL							
NO							
NDOME-							
TRIAL							
ANCER							
NO							
ONLY	RUPTURE YES/NO	no	yes	yes	yes	yes	yes

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

AB. VIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan) ME

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		1	2	3	4	5	6	7
BI #1	IDENTIFIER	BI #64	BI #65	BI #66	BI #67	BI #68	BI #69	BI #70
TX	/STATE	IL 22	IL 23	IL 24	IL 25	IL 26	IL 27	IL 28
1942	YEAR OF BIRTH	1947	1947	1944		1949	1948	1943
3	# OF IMPLANTS	1 set	1 set	1 set	4 sets	1 set	2 sets	1 set
SETS								1 sgl.
1977	YEAR(S) IMPLANTED	1981	1987	1985	1980		1976	
1979*					1981*	1974	1994	1976
HS GEL	TYPE OF IMPLANTS		CX Gel	PU Gel	HS SA		BA Gel	
MG DL*					CX DL*	HS Gel	SA	ME Gel
	YEAR EXPLANTED	still	still	1993	1995	1995	1994	1996
1994								
12	# OF BREAST SURGERIES	1	1	2	9	3	3	5
	PERIPHERAL NEUROPATHY	yes	yes	yes	yes	no	yes	no
NO								
	DEMYELINATING NEUROPATHY	no	yes	yes	no	no	yes	no
NO								
	ATYPICAL NEUROLOGICAL	yes	yes	yes	yes	no	yes	no
YES								
	ORGANIC BRAIN SYNDROME	yes	yes	no	yes	yes	yes	yes
YES								
	LUPUS OR LUPUS LIKE	yes	no	no	no	no	yes	no
NO								
	FIBROMYALGIA	yes	yes	yes	yes	yes	yes	yes
NO								
	ATYPICAL CONNECT-IVE TISSUE	yes	yes	yes	yes	yes	yes	yes
YES								
	MIXED CONNECT-IVE TISSUE	no	no	yes	no	no	yes	no
NO								
	SCLERODERMA	no	no	no	no	no	no	no
NO								
	ESOPHAGEAL REFLUX	yes	no	yes	yes	yes	yes	no
NO								
	GASTRO-INTESTINAL DISMOTILITY	yes	no	no	yes	no	yes	no
YES								
	CHRONIC FATIGUE	yes	yes	yes	yes	yes	yes	yes
NO								
	SJOGRENS SYNDROME	yes	yes	yes	yes	no	no	yes
NO								
	CANCER OR MGUS YEAR & TYPE	no	no	no	no	no	no	no
YES								
1994*								
	COMMENTS							
1993								
ME GEL								
NO								
DOME-								
RIAL								
NCER								
NO								
ONLY								
	RUPTURE YES/NO		no	no	yes	yes	yes	yes

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan), ME

NATIONAL INSTITUTE OF HEALTH DATA SHEET
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AFTER IMPLANTATION

EXAMPLE

	1	2	3	4	5	6	7
IDENTIFIER /STATE	BI #71 IL 29	BI #72 IL 30	BI #73 IL 31	BI #74 IL 32	BI #75 IL 33	BI #76 IL 34	BI #77 IL 35
BI #1 TX							
1 3 YEAR OF BIRTH	1949	1943	1938	1953	1939	1948	1936
# OF IMPLANTS	1 set	8 sets	2 sets	2 sets	5 sets	1 set	1 set
SETS 1977 1979* YEAR(S) IMPLANTED	1974	1972 1972*	1976 1990	1990	1975 1976*	1984	1974
HS GEL MG DL* TYPE OF IMPLANTS	DO Gel	DO Gel 3M Gel*	DO Gel BR Gel	ME SA ME DL*	DO Gel BA Gel	MG Gel	DO Gel
1994 YEAR EXPLANTED	1996	still	still	1993	1983	still	still
12 # OF BREAST SURGERIES	2	8	2	3	6	1	1
NO PERIPHERAL NEUROPATHY	yes	no	yes	yes	yes	no	yes
NO DEMYELINATING NEUROPATHY	no	no	no	no	no	no	no
YES ATYPICAL NEUROLOGICAL	yes	yes	yes	yes	yes	no	no
YES ORGANIC BRAIN SYNDROME	yes	no	yes	yes	no	no	yes
NO LUPUS OR LUPUS LIKE	yes	yes	no	yes	no	no	no
NO FIBROMYALGIA	yes	yes	yes	no	yes	no	no
YES ATYPICAL CONNECT- IVE TISSUE	yes	yes	yes	yes	no	no	no
MIXED CONNECT- IVE TISSUE	yes	no	no	no	no	no	no
NO SCLERODERMA	no	no	no	no	no	no	no
NO ESOPHAGEAL REFLUX	yes	yes	yes	no	no	no	no
YES GASTRO-INTESTINAL DYSMOTILITY	yes	yes	yes	no	no	no	yes
NO CHRONIC FATIGUE	yes	yes	yes	yes	yes	no	yes
NO SJOJGREN'S SYNDROME	no	yes	no	no	yes	no	no
YES 1994* CANCER OR MGUS YEAR & TYPE	no	no	no	no	yes 1979*	no	no
1993 ME GEL No COMMENTS		1980 BA Gel 1982			Thyroid Cancer 1979 1980 1982		
NDOME- TRIAL CANCER NO ONLY	RUPTURE YES/NO	yes	yes	yes	5 ruptures	No	No

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

AB. VIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan) ME

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
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	1	2	3	4	5	6	7
IDENTIFIER	BI #78	BI #79	BI #80	BI #81	BI #82	BI #83	BI #84
/STATE	IL 36	ID 1	ID 2	FL9701	TX9701	TX9702	TX9703
1942 3 YEARS 1977 1979* HS GEL MG DL*	1942	1947	1938	1953	1944	1955	1946
# OF IMPLANTS	1 set	6 sets	2 sets	2 sets	2 sets	1 set	2 sets
YEAR(S) IMPLANTED	1976	1981 1982*	1979	1985	1973	1981	1976
TYPE OF IMPLANTS	BA	HS Gel HS Gel	DO GEL	DO Gel	DO Gel	Gel	DO Gel
1994 EXPLANTED	1996	1995	1993	1995	1994	1996	1992
# OF BREAST SURGERIES	2	7	5	2	2	2	3
12 PERIPHERAL NEUROPATHY	no	no	no	yes	yes	yes	yes
NO DEMYELINATING NEUROPATHY	no	no	no	yes	yes	yes	yes
YES ATYPICAL NEUROLOGICAL	no	no	no	yes	yes	yes	yes
YES ORGANIC BRAIN SYNDROME	yes	no	no	no	yes	no	yes
NO LUPUS OR LUPUS LIKE	no	yes	no	no	yes	yes	no
NO FIBROMYALGIA	yes	yes	yes	yes	yes	yes	yes
YES ATYPICAL CONNECT- IVE TISSUE	no	yes	no	yes	yes	yes	yes
NO MIXED CONNECT- IVE TISSUE	no	no	no	yes	yes	no	no
NO SCLERODERMA	no	no	no	no	no	no	yes
NO ESOPHAGEAL REFLUX	no	yes	no	yes	yes	no	yes
YES GASTRO-INTESTINAL DYSMOTILITY	no	yes	no	yes	no	no	no
NO CHRONIC FATIGUE	yes	yes	no	yes	yes	yes	yes
NO SJOJGREN'S SYNDROME	yes	no	no	no	no	yes	yes
YES 1994* CANCER OR MGUS YEAR & TYPE	no	no	no	no	no	no	no
1993 ME GEL No DOME- RIAL NCER NO ONLY		1988 HS Gel HS Gel ME DL ME DL					
RUPTURE YES/NO	yes	yes	no	yes	yes		yes

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS

ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan) ME

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

		1	2	3	4	5	6	7
BI #1	IDENTIFIER / STATE	BI #92 TX	BI #93 TX	BI #94 TX	BI #95 KY	BI #96 KY	BI #97 KY	BI #98 KY
1942	YEAR OF BIRTH	1948	1945	1930	1944	1949	1949	1955
3	# OF IMPLANTS	1 Set	1 Set	1 set	6 Sets	1 Set	2 Sets	1 Set
SETS	YEAR(S) IMPLANTED	1983	1968	1979	1972 1974*	1981	1984 1992	1979
1977	TYPE OF IMPLANTS	MeMe	DO		Gel		DO	
1979*		PU Gel	Dextran	DO Gel	PU*	HS DL	MG SA	DO Gel
HS GEL	YEAR EXPLANTED	1991	1995	1995	1994	1996	Still	Still
MG DL*	# OF BREAST SURGERIES	3	2	2	20plus	2	3	
	PERIPHERAL NEUROPATHY	No	Yes	Yes	Yes	Yes	Yes	Yes
	DEMYELINATING NEUROPATHY	No	Yes	No	No	No	No	No
	ATYPICAL NEUROLOGICAL	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	ORGANIC BRAIN SYNDROME	No	No	No	No	No	No	No
	LUPUS OR LUPUS LIKE	No	No	Yes	No	No	No	Yes
	FIBROMYALGIA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	ATYPICAL CONNECTIVE TISSUE	No	Yes	Yes	Yes	Yes	Yes	Yes
	MIXED CONNECTIVE TISSUE	No	Yes	Yes	No	No	No	No
	SCLERODERMA	No	No	Yes	No	No	No	No
	ESOPHAGEAL REFLUX	Yes	Yes	Yes	Yes	Yes	No	Yes
	GASTRO-INTESTINAL DISMOTILITY	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	CHRONIC FATIGUE	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	SJOGRENS SYNDROME	No	Yes	Yes	Yes	Yes	No	Yes
	CANCER OR MGUS YEAR & TYPE	Yes 1991*	No	Yes	No	No	Yes	No
	COMMENTS	Breast Cancer	Chemically induced Muscular Dystrophy		Been ill since 1976 *1975 1980/1 1984		Atypical MS	
	RUPTURE YES/NO	No	No		Yes		No	Yes

**PHOTOCOPY
PRESERVATION**

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS
ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan). ME (Mentor) DO(DOM) PU (polyurethane) GEL (silicone gel)

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
012. paper	Data sheet re: fax number (partial) (1 page)	03/31/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[012]

EXAMPLE

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

BI #85 BI2 #86 BI #87 BI #88 BI #89 BI #90 BI #91

BI #1 TX	IDENTIFIER /STATE	Mo.1-KJ	Ill. S.M.	Okla. R.W.	MO.2 M.H.	MO.3 M.M.	MO.4 S.P.	MO.5 P.S.
1942	YEAR OF BIRTH	1951	1958	1949	1930	1953	1925	1946
3	# OF IMPLANTS	1	2	1	1	1	XXXX 1	2
SETS 1977 1979*	YEAR(S) IMPLANTED	1984	1977	1977	1982	1978	1987	1977
HS GEL MG DL*	TYPE OF IMPLANTS	H/S-gel	Dow-gel Mentor	H/S-gel	Dow/gel	Dow-gel	Dow-gel	Dow-gel
1994	YEAR EXPLANTED	1994	1992-gel SA.-still	1995	still	still	1994	1996
12	# OF BREAST SURGERIES	3	3	2	1	1	2	2
NO	PERIPHERAL NEUROPATHY	yes	yes	yes	no	yes	no	no
NO	DEMYELINATING NEUROPATHY	no	no	no	no	no	no	no
YES	ATYPICAL NEUROLOGICAL	yes	yes	yes	no	no	no	no
YES	ORGANIC BRAIN SYNDROME	no	no	no	no	no	no	no
NO	LUPUS OR LUPUS LIKE	yes	yes	yes	no	yes	no	yes
NO	FIBROMYALGIA	yes	yes	yes	no	yes	no	no
YES	ATYPICAL CONNECTIVE TISSUE	yes	yes	yes	no	yes	no	no
NO	MIXED CONNECTIVE TISSUE	no	no	no	no	no	no	no
NO	SCLERODERMA	no	no	no	no	no	yes	no
NO	ESOPHAGEAL REFLUX	yes	no	no	no	no	no	no
YES	GASTRO-INTESTINAL DYSMOTILITY	no	yes	yes	no	no	no	no
NO	CHRONIC FATIGUE	yes	yes	yes	yes	yes	yes	yes
NO	SJOGRENS SYNDROME	yes	no	no	no	no	no	no
YES 1994*	CANCER OR MCGUS YEAR & TYPE	no	no	no	no	yes	yes	no
1993 ME GEL NO	COMMENTS	silicone found in blood/spinal fluid.		silicone in lymph nodes.	implants leaking.	cervical ca-1980	br.ca 1987	
ENDOMETRIAL CANCER	RUPTURE Yes/no	yes	yes	yes	yes	no	yes	yes

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS
ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU (polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan), ME (Mentor), DO(DOW), 3M, CX(Cox-Upkopf)

NATIONAL INSTITUTE OF HEALTH DATA SHEET
TO ANSWER YES TO ANY DISEASE CATEGORY, DIAGNOSIS MUST BE
AFTER IMPLANTATION

EXAMPLE		1	2	3	4	5	6	TOTALS
BI #1 TX	IDENTIFIER /STATE	BI #99 KY	BI #100 KY					
2	YEAR OF BIRTH	1954	1961					Ave. Age 51 y
SETS 1977	# OF IMPLANTS	1 Set	1 Set					Ave. 1.73Set
1979*	YEAR(S) IMPLANTED	1989	1986					
HS GEL MG DL*	TYPE OF IMPLANTS	BR Gel	DO Gel					
1994	YEAR EXPLANTED	1996	1996					
12	# OF BREAST SURGERIES	2	2					Ave. 3.35
NO	PERIPHERAL NEUROPATHY	Yes	Yes					68%
NO	DEMYELINATING NEUROPATHY	?	No					36%
YES	ATYPICAL NEUROLOGICAL	Yes	Yes					70%
YES	ORGANIC BRAIN SYNDROME	No	No					42%
NO	LUPUS OR LUPUS LIKE	No	No					52%
NO	FIBROMYALGIA	Yes	Yes					87%
YES	ATYPICAL CONNECT- IVE TISSUE	Yes	Yes					78%
NO	MIXED CONNECT- IVE TISSUE	No	No					39%
NO	SCLERODERMA	No	No					12%
NO	ESOPHAGEAL REFLUX	Yes	Yes					55%
YES	GASTRO-INTESTINAL DYSMOTILITY	Yes	Yes					63%
NO	CHRONIC FATIGUE	Yes	Yes					95%
NO	SJOGRENS SYNDROME	Yes	No					47%
YES 1994*	CANCER OR MGUS YEAR & TYPE	Yes	No					9%
1993 ME GEL No	COMMENTS							
ENDOME- TRIAL CANCER NO 1 ONLY	RUPTURE YES/NO	No	No					53%

* IF YOU RUN OUT OF ROOM ADD ADDITIONAL INFORMATION IN COMMENTS
ABBREVIATION CODES: GEL(silicone gel), DL (double lumen), SA(saline), PU
(polyurethane); HS(Hyer-Schulte), BA(Baxter), BR(Bristol), MG(McGhan). ME
(Mentor), DO(DOW), 3M, CX(Cox-Upkopf)

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
013. letter	Marlene Keeling et al. to Vivian Pinn re: phone number, fax number, and address (partial) (2 pages)	08/26/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of
personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed
of gift.

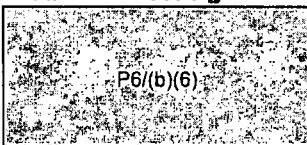
PRM. Personal record misfile defined in accordance with 44 U.S.C.
2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of
an agency [(b)(2) of the FOIA]
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financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information
concerning wells [(b)(9) of the FOIA]

Murlene Keeling



Pamela Stott-Kendall

P. O. Box 030153
Fort Lauderdale, Florida 33303
Telephone: (954) 563-1715
Fax: (954) 467-3882

Diane Griffith

6490 Silver Ridge Circle
Alexandria, Virginia 22315
Telephone: (703) 922-5260

August 20, 1997

Dr. Vivian Pinn
Associate Director for Research on Women's Health
Office of Research on Women's Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Pinn,

Your letter of July 18, in response to concerns expressed with regard to NCI-supported research on breast implants, is appreciated. We are all in agreement that scientifically sound research relating to implant study is direly needed. The point made on the relevance of lifestyle, as one study aspect, is well noted.

However, such study published in *JAMA* on May 28 presents conflict of scientific goals. "Misinterpreted," indeed, a report on merely 20 study subjects, in some instances, with breast implants is hardly deemed worthy of publication. Further, though Dr. Brinton claims unawareness of existing industry involvement on the part of joint researchers, a suggestion might be that NCI-associated researchers, like Dr. Brinton, have a responsibility, when entering into joint publication, to be fully informed of bias circumstances in ultimate discredit of the Institute. The implications of NCI research cooperation under elements of bias are quite serious.

We do realize that the study's supposed purpose, to investigate factors influencing breast cancer development, might have been well intended. It is true that oral contraceptives, due to synthetic estrogen dose, play an important role in cancer development. Estrogen—delivered in inappropriate amounts at inappropriate intervals—can lead to cancer as well as fetal development abnormalities through protracted hormonal stimulation with cell division. Therefore, the fact that silicone has been found to act as "an orally active estrogen," as reported by Dow Corning and Dow Chemical joint testing conducted in Sweden during the mid-seventies, raises sufficient alarm. Apparently, these companies also recognized the risks for cancer increase in women exposed to silicone compounds; Corning and Chemical held these findings secret for twenty years. (A copy of this 147-page study is available for your review upon request.) It is also known that silicone attracts and stores the female hormones as readily as it does the body's lipids. Perhaps now is a good time, after several decades of unsupervised silicone experimentation, to pursue related study investigation at NCI. In prior study of breast implant/cancer connection (for example, the plastic surgeons' Deapen study), the twenty to thirty-year latency factor associated with chemical exposure/cancer occurrence has been conveniently ignored.

With regard to epidemiological study, "likely to contribute" to an assessment of implant risks, the problem is that those conducted to date (industry funded) have not contributed significantly. In fact, world-renown epidemiologist Dr. Sandar Greenland stated before the July 22-24 National Science Panel, convened by Judge Samuel Pointer (MDL) in Birmingham, Alabama, that these examples of research are a "misuse of data." We are all aware of the scientific criticism that the findings have evoked for faulty design, means and methods of study. Seemingly, the industry-supported epidemiological study has been designed not to report the atypical illness as it occurs in breast implant patients.

On the subject of NCI's breast implant study conducted by Dr. Louise Brinton, some clarification is necessary. Your July 18 correspondence had suggested that our understanding of NCI's original time-schedule for study release was incorrect. Yet Anne Bavior, herself, had approved the text of our written, submitted summary of an April 4 NIH Office of Research on Women's Health meeting. With Ms. Bavior's initialed approval, this summary noted that "The NCI study is undergoing scientific review at the moment." (Federal Acquisition rules prohibited discussion of the project while in review.) "The research findings will, hopefully, be released later this year, and Mrs. Bavior said she would keep us up-to-date."

We find it interesting that Dr. Brinton was able to analyze data from four, NCI-supported projects, including the one project supported by NICHD on the unsavory lifestyles of women with breast implants, but apparently had not found time to analyze other data on implant rupture rates, gel bleed, local complications and related, disease occurrence. In questioning delay of scrutiny of data collected with distinct bearing on causation issues, we trust that special-interest, liability considerations, on the side of industry embroiled as well in liability issues, were not a contributing factor. Certainly, we were distressed to learn, upon review of documents turned over to HHS Secretary Shalala and the House Committee on Government Oversight, that the same industry (including implant manufacturers and a prominent plastic surgeons' society) had been involved, from day one, in Dr. Louise Brinton's NCI Women's Health Study. Since Dr. Brinton has assured you that she will be "open" with all interested parties, we would request an opportunity to discuss these compromising documents with Dr. Brinton.

Another question pertains to submitted, proposed protocols for NIH study that have long gone without follow-up, "sitting" at NIH, according to testimony presented before the July 22-24 National Science Panel. Utilizing Dr. Brinton's cohort, this suggested study would appropriately entail physical examinations with the collection of serum and cells in breast implanted subjects. Curious about its status, it would be helpful to obtain information on this proposed study.

We should mention that, when speaking with Judge Pointer upon conclusion of the MDL-sponsored National Science Panel, he was most interested in our Washington activities. Earlier, during our April 4 meeting with your office in February, we had discussed the possibility of NIH study of currently-ill, implanted women. What better way could there be to properly define the syndrome, with disease-criteria established, than to conduct study of those women suffering the harmful effects of extensive toxic assault? Judge Pointer had subsequently conveyed interest in NIH discussion. Later, after having passed-on Judge Pointer's interest and upon meeting and conversing with you in Louisiana, it seemed that our purpose in promoting the

study of currently-ill, implanted women (through MDI approval of NIH's use of claimants' records totaling in excess of 400,000) had been misunderstood. It was, and still remains, our purpose to secure study of the association between occurrences of illness and implant rupture/gel leakage and complications rates based upon review of medical documentation contributed from implant patients with confirmed, disease diagnoses.

We have also received news, from Dr. Blumenthal, of an IOM study called for by congressional directive. Of course, one concern coming to mind is the possibility that the Institute of Medicine might be an AMA stronghold, heavily supported by plastic surgeons. In 1992, the ban of gel-fill devices, used in the second most-frequently performed cosmetic surgery, had deprived surgeons of, literally, half their incomes. Bias on the part of plastic surgeons is to be considered as unacceptable as that of manufacturers. And bias of any kind has no place in the formation of scientific conclusions.

Due to our valid concerns, we would like to schedule a meeting with you in the near future to discuss some of these issues in greater detail. We believe that you might be able to offer assurances of NIH's commitment to scientific integrity. We are further encouraged to learn that both you and current Deputy Director Joyce Rudick look forward to working productively with our group, as one committed to research study of health effects of silicone breast implantation in women. We hope that the NIH Office of Research on Women's Health will make will this concern a prime priority for the 21st century.

Your truly,

Patricia S. W. " "
Marlene Keeling
Diane Griffith

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
014. letter	Marlene Keeling to Vivian Pinn re: phone number, fax number, and address (partial) (3 pages)	06/03/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
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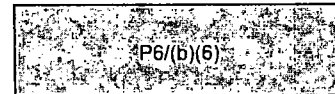
C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



June 3, 1997

Dr. Vivian Pinn, Director
Office of Research on Women's Health
National Institutes of Health
9000 Rockville Pike
Bethesda, Md. 20892

Dear Dr. Pinn,

Thank you for meeting with our group on April 4, 1997 regarding our concerns about silicone gel breast implants. We were sorry to learn that Anne Bavier is no longer with your office. Has your office appointed a replacement to serve as Deputy Director? If so, I would appreciate notification at your earliest convenience.

In update, Pamela Stott-Kendall and Diane Griffith attended, upon FDA invitation, the April 17 Atypical Rheumatic Disease and Silicone Breast Implant Workshop. They noticed that you were unable to attend, but were pleased to note the consensus of the expert panel who concluded that there is reason to believe a possible association may exist between atypical Connective Tissue Disease and silicone breast implants. NIH researcher Dr. Potter had stated that the data and information presented "calls for unbiased study" of a type that NIH would be able to conduct.

I hope that you have had time to review the data submitted on 100 breast-implanted women that we brought with us to the April 4th meeting. Unfortunately, we left off one important category - Multiple Sclerosis or MS-like. We would like to expand this data collection to 100,000 women and welcome your suggestions before continuing. We had further discussed the possibility of using already available, medical records of approved documentation submitted to the MDL Claims Office. Judge Pointer's phone number was provided after obtaining his interest and permission. I wonder whether or not you have had an opportunity to call him.

During our meeting, we also inquired about the status of Dr. Louise Brinton's Women's Health Study and were told that Federal Acquisition Rules prohibited NIH and others from discussing the project while it is still under review.

Therefore, we were quite surprised to find that Louise A. Brinton, Environmental Epidemiology Branch, National Cancer Institute, Bethesda, Md. was listed as one of the researchers on the recently published JAMA article titled "Characteristics of Women With and Without Augmentation". This research article was reported on NBC national news, CBS, CNN, The Wall Street Journal, USA Today, and many newspapers across the country. In our opinion this was a thinly-disguised attempt by industry public relation firms,

to use character assassination of all breast-implemented women to influence the general public (jury pool). To infer a study of 80 breast-implemented women (or 21 in the case of the Core Studies) in any way reflects the lifestyle of more than 1 million women with implants is ludicrous. It is my opinion, and that of many qualified researchers, that a JAMA publication of such research is questionable.

Of utmost concern is the similarity of the information sighted and singled out in this study and the information requested in the Women's Health Study. For instance:

WOMEN'S HEALTH STUDY	JAMA, MAY 28, 1997
Drinking history of Alcohol	Drinking history of Alcohol
Age at first time birth	Pregnant at an early age
How many abortions, etc.	Numbers of pregnancies ended
Use of Oral Contraceptives	Use of Oral Contraceptives
History of Smoking	History of Smoking

I see that the JAMA study was supported in part by grants and contacts R01-CA-41416, R35-CA-39779, K07-CA-01364 and N01-CP-95671 from the National Cancer Institute, Bethesda, Md. and N01-HD-62914 from the National Institute of Child Health and Human Development, Bethesda, Md. Furthermore, researcher Dr. Weiss and Dr. Daling served as expert witnesses or consultants to the manufacturers in breast implant litigation. I feel that it is inappropriate for the NIH and Louise Brinton, PhD to participate in such research designed to reveal the most unsavory lifestyles of a few breast-implemented women.

As we discussed with you in the April 4th meeting, we desperately need research on good methods for the detection and measurement of amounts of silicone in the body and resulting damage as well as the detection of consequent antibody production. We have also requested a study of the toxic effects of silicone and the "new" non-traditional, atypical illness, with unique characteristics, that it produces. Additional research projects requested for the future were those pertaining to second generation harm done to either the fetus, during a critical period of human development, or infants exposed to silicone and implant toxins through breast-feeding.

I must ask when might we expect the results of the Women's Health Study as to rupture rates, gel bleed or leakage, skin necrosis, delayed wound healing, breast feeding problems, enlarged lymph nodes, rashes, hardening or tight capsule, changes in nipple sensation, Scleroderma, Lupus, Sjogren's Syndrome, Raynaud's Syndrome, Fibrositis (Fibromyalgia Syndrome), Vasculitis, Human Adjuvant Disease, Chronic Fatigue Syndrome, and other Connective Tissue Disorders. We anxiously await the results of unbiased science which will ultimately resolve this issue.

We hope the scientific community will focus foremost on

trying to reach a better understanding of this illness. Thank you for your consideration of these valid concerns. I look forward to seeing you in New Orleans on June 11th where I will be giving public testimony on Women's Health Needs for the 21st Century. In advance of meetings with Health and Human Services, I am forwarding this correspondence to Dr. Susan Blumenthal and the Honorable Donna Shalala.

Respectfully,

Mrs. Marlene Keeling

P6(b)(6)

CC: Dr. Susan Blumenthal
The Honorable Donna Shalala

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
015. letter	Vivian Pinn to Marlene Keeling re: address and fax number (partial) (3 pages)	07/18/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20474

FOLDER TITLE:

[Silicone Breast Implants] [Binder] [1]

2012-0463-S

rc823

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

July 18, 1997

Mrs. Marlene Keeling

P6(b)(6)

[018]

Dear Mrs. Keeling:

Thank you for your letter of June 3, 1997, in which you raise a number of concerns related to the National Institutes of Health's (NIH) support of research on the possible effects on health of silicone breast implants. I also appreciate the testimony that you presented in New Orleans on June 11th at the "Beyond Hunt Valley" meeting convened by the Office of Research on Women's Health (ORWH). We were pleased that you were able to participate throughout the scientific workshop.

I agree that we need scientifically sound research on the effects of silicone breast implants on health. The analysis published in the May 28th issue of JAMA represents one such effort, in which the authors analyzed data derived from several studies. Among them were four projects supported by the National Cancer Institute (NCI) and one supported by a contract between the National Institute of Child Health and Human Development (NICHD) and the University of Washington for a study of the use of oral contraceptives and rheumatoid arthritis.

Unfortunately, the analysis published in the JAMA article has been widely misinterpreted, both by the media and the public. The intent of the analysis and the article was to address the many factors that must be taken into account to understand the relationship of breast implants to subsequent disease processes. In order to assess the effect of implants on health, other lifestyle factors which can influence health and disease must be taken into account. Thus, the article attempted to clarify what these factors might be by comparing several characteristics of women with and without implants, using collected data on control subjects who had participated in several previous case-control studies.

Dr. Louise A. Brinton of the National Cancer Institute contributed data from a case-control study of breast cancer in 2,649 younger women subjects selected through random digit dialing in three areas of the country (Atlanta, Seattle, and Trenton, New Jersey). The information obtained in this study consisted of data on educational status, reproductive behavior, smoking, and alcohol consumption, but did not contain any data on use of hair dye or sexual behavior. Thus, the results inferred concerning these latter variables and published in the JAMA article were derived, not from the NCI-supported study, but from data obtained in other studies used in the analysis. No information from Dr. Brinton's ongoing follow-up study, the Women's Health Study, was provided for the analysis published in JAMA, although Dr. Brinton is collecting similar information in order to assess fully the relationship of breast implants to a variety of diseases.

Page 2 - Mrs. Marlene Keeling

Until the JAMA article was published, Dr. Brinton had not been aware that two of the authors of the paper had served as expert witnesses or consultants to the manufacturers of silicone breast implants. She knew only the authors' reputations as established epidemiologists interested in ensuring that research on the effects of breast implants is conducted in a methodologically correct manner.

Since the impetus for the Women's Health Study is to assess breast implants in relation to cancer risk — in particular, breast cancer — it is important to collect information on factors that have been shown to be associated with breast cancer, including age at first birth, abortion, and use of oral contraceptives. The collection of such information is an attempt to assess scientifically several factors for cancer risk, not an attempt to disparage or impugn women participating in the study.

I think we both could agree with the statement in the JAMA article that "No inferences can be drawn concerning the roles of these [lifestyle] characteristics in the decision to have breast augmentation." In fact, on the same page, the authors make an important point: "Our results highlights the importance of careful consideration and evaluation of confounding variables when investigating the impact of breast augmentation on the risk of subsequent disease."

Consideration of correlated disease predictors — in this case, the lifestyle factors you cite in your letter — is an essential element in assessing the effects of a particular exposure on health in an epidemiological study. This is in order to ensure that effects are not incorrectly implicated, but also to ensure that true effects are not dismissed. For example, since oral contraceptives appear to reduce the risk of rheumatoid arthritis, it is important to consider study subjects' use of oral contraceptives in assessing the possible effects of silicone implants on this disease. As the article states on page 1616: "If indeed oral contraceptive use decreases the risk for rheumatoid arthritis, failure to adjust for oral contraceptive use could mask an elevation in the risk of rheumatoid arthritis associated with having breast implants." Clearly, this type of confounding factor needs to be considered for the benefit of women with implants, because not to do so might underplay any health-related effects of the implants. Since women with implants report higher use of oral contraceptives, failure to adjust for this exposure in analysis of the relationship of implants to subsequent risk of the disease could lead to an erroneous conclusion that there is no association. Thus, it is of paramount importance to consider all predictors of disease risk if we are to obtain scientifically valid data on how implants may affect a variety of diseases.

Epidemiologic studies are likely to contribute substantially to assessing the benefits and risks of silicon implants. For these studies, identification of epidemiologic confounders is essential.

Page 3 - Mrs. Marlene Keeling

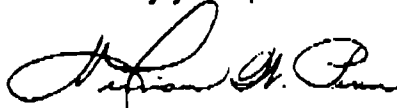
Data collection for the Women's Health Study will be ending within the next few months, and Dr. Brinton expects to begin data analysis in the fall. Because it has been such a large and complex study, it may take some time to complete all the necessary analyses. Results of the study should begin to be available sometime during 1998. Dr. Brinton has assured me that she has and will continue to be open with all interested parties during the course of this investigation.

I also think there may have been some miscommunication in your previous discussion with this office. I would assume that the study to which Ms. Bavier was referring when she spoke of a project under review was not the Women's Health Study per se, but the then to be funded FDA/NIH study of rupture rates.

The ORWH and the NIH are committed to ensuring and supporting research of the highest possible quality to elucidate the health effects of silicone breast implants. In addition to the studies described above, the National Institute of Allergy and Infectious Diseases (NIAID) is supporting several studies related to autoimmunity and autoantibodies in women with silicone breast implants.

Thank you again for your letter and your participation in the ORWH's meeting in New Orleans. Along with the Acting Deputy Director of the ORWH, Ms. Joyce Rudick, I look forward to working productively with you and with others concerned about the effects of silicone breast implants on women's health.

Sincerely yours,



Vivian W. Pinn, M.D.
Associate Director for Research
on Women's Health

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[016]

Characteristics of Women With and Without Breast Augmentation

Linda S. Cook, PhD; Janet R. Daling, PhD; Lynda F. Voigt, PhD; M. Patricia deHart, ScD;
Kathleen E. Malone, PhD; Janet L. Stanford, PhD; Noel S. Weiss, MD, DrPH; Louise A. Brinton, PhD;
Marilie D. Gammon, PhD; Donna Brogan, PhD

Objective.—To compare selected characteristics of women with and without augmentation mammoplasty to identify differences between these 2 groups of women.

Design and Study Participants.—While women identified as controls in previously conducted population-based, case-control studies formed the study population for the present cross-sectional analysis (N=3570).

Main Outcome Measure.—Interview information on selected characteristics was compared between women who had received augmentation mammoplasty (n=80) and other women (n=3490) using the prevalence odds ratio (pOR) as the measure of association.

Results.—Women with breast implants were more likely to drink a greater average number of alcoholic drinks per week (for ≥ 7 drinks vs 0 drinks: pOR=2.9, 95% confidence interval [CI]=1.5-5.5), be younger at first pregnancy (for age <20 years vs age 20-29 years: pOR=1.6, 95% CI=1.0-2.7), be younger at first birth (for age <20 years vs age 20-29 years: pOR=1.9, 95% CI=1.1-3.3), have a history of terminated pregnancies (for ≥ 1 termination vs 0 terminations: pOR=2.0, 95% CI=1.2-3.4), have ever used oral contraceptives (pOR=2.2, 95% CI=1.0-4.7), have ever used hair dyes (pOR=4.5, 95% CI=1.3-15.4), and have had a greater lifetime number of sexual partners (for ≥ 14 partners vs ≤ 4 partners: pOR=8.9, 95% CI=3.1-25.5) than other women. A history of smoking, lactation, high blood pressure, or thyroid disorders, as well as the number of pregnancies, full-term births, or miscarriages, differed little between women with and without implants. Women with breast augmentation were much less likely to be heavy than other women (for ≥ 74 kg vs <56 kg: pOR=0.1, 95% CI=0.03-0.3).

Conclusion.—The differences we found between women with and without breast implants suggest that consideration and evaluation of confounding factors in future studies will help to clarify some of the long-term health consequences of having breast implants.

JAMA 1997;277:1612-1617

BREAST IMPLANTS, particularly silicone gel-filled implants, have been hypothesized to predispose women to several types of illness, including connective tissue disease, rheumatic complaints, and cancer.^{1,4} To date, the majority of epidemiologic studies have found little, if any, adverse health effect of implants.⁵⁻¹¹ However, since an estimated 1 million to 2 million women in the United States have received breast implants,¹²⁻¹⁴ it is likely that research in this area will continue. Confounding is an issue that deserves attention in both past and future investigations. Women who have breast implants for the purpose of augmentation

For editorial comment see p 1643.

may have, on average, different demographic, lifestyle, reproductive, or medical characteristics than other women—differences that potentially make these women more or less likely to develop certain diseases. We compared a range of characteristics between women with and without breast implants to identify any differences between these 2 groups.

METHODS

Two groups of women identified as controls in previously conducted case-control studies formed the study population for this analysis. Each of the case-control studies was reviewed and approved by an appropriate human subjects review board. One group participated in the Women's Interview Study of Health (WISH), a multicenter study that included geographic areas in Georgia (Atlanta), central New Jersey, and

From the Division of Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, Wash (Drs Cook, Daling, Voigt, deHart, Malone, and Weiss); Department of Epidemiology, University of Washington, Seattle (Drs Daling, Voigt, Malone, and Weiss); Department of Oncological Sciences, Huntsman Cancer Institute, University of Utah, Salt Lake City (Dr Stanford); Environmental Epidemiology Branch, National Cancer Institute, Bethesda, Md (Dr Brinton); Division of Epidemiology, Columbia University, New York,

NY (Dr Gammon), and Department of Biostatistics, Emory University, Atlanta, Ga (Dr Brogan).

Dr Daling once served as an expert witness in epidemiologic methods in litigation relating to breast implants. Dr Weiss has been a consultant to several law firms that were representing defendants in litigation relating to breast implants.

Corresponding author: Linda S. Cook, PhD, Fred Hutchinson Cancer Research Center, 1110 Fairview Ave N, PO Box 19024, Seattle, WA 98109-1024.

Table 1.—Description of Study Population of Women

Characteristic	With Breast Implants, No. (%) (N=80)	Without Breast Implants, No. (%) (N=3490)
Age at reference date, y*		
<35	9 (11.3)	631 (18.1)
35-39	18 (20.0)	785 (22.5)
40-44	21 (26.3)	919 (26.3)
45-49	15 (18.8)	438 (12.5)
50-54	18 (18.8)	471 (13.5)
55-59	4 (5.0)	247 (7.1)
Study participant		
Core†	21 (26.3)	1599 (45.8)
WISH‡	59 (73.8)	1891 (54.2)
Age at implant placement, y§		
<25	8 (7.5)	...
25-34	38 (45.0)	...
35-44	27 (33.8)	...
45-49	11 (13.8)	...
Time between implant placement and reference date, y		
<5.0	24 (30.0)	...
5.0-9.9	18 (22.5)	...
≥10.0	38 (47.5)	...

*See "Methods."

†Women from western Washington State who participated in case-control studies of breast cancer, endometrial cancer, and rheumatoid arthritis.

‡Women from Atlanta, Ga, central New Jersey, and western Washington State who participated in the Women's Interview Study of Health (WISH).

§Ellipses indicate data not applicable.

western Washington State.^{15,16} In WISH, control women within each geographic area were frequency matched to the expected age distribution of women diagnosed with breast cancer between May 1, 1990, and December 31, 1992. WISH controls were identified in 13 waves that occurred over the same time period of ascertainment as breast cancer cases.¹⁶ Each woman was assigned a reference date that corresponded to the first telephone screening date. Over three quarters of the WISH controls were identified through random digit dialing (RDD) at each study site by Westat Inc (Rockville, Md); the RDD method and response are explained in detail elsewhere.¹⁶⁻¹⁷ Briefly, screening for eligible household members was successful in 90.5% of all residential telephone numbers called. After an age-stratified random sample was selected from all women who had been screened (n=2710), 139 were found to be ineligible due to communication problems (n=35), incorrectly recorded age (n=59), residence outside of study area (n=11), and other screening errors (n=34). Of the remaining 2571 women, 2009 (78.1%) were interviewed. The overall response (RDD screening proportion multiplied by the interview response) was 70.7%. The remaining WISH controls from Atlanta were identified by sampling households in the same areas as case households. Screening was

Table 2.—Demographic Characteristics and Body Size Among Women With and Without Breast Implants

	With Breast Implants, No. (%) (N=80)	Without Breast Implants, No. (%) (N=3490)	Prevalence, OR (95% CI)*
Annual household income, \$			
Core study†			
<30 000	5 (23.8)	658 (41.8)	1.0 (Referent)
30 000-45 000	6 (28.6)	415 (26.0)	1.9 (0.6-6.4)
>45 000	10 (47.6)	498 (31.1)	2.7 (0.9-8.3)
Unknown/refused	0 (0)	18 (1.1)	...
WISH study†			
<25 000	6 (10.2)	267 (14.1)	1.0 (Referent)
25 000-49 999	20 (33.9)	616 (32.6)	1.4 (0.8-3.6)
≥50 000	32 (54.2)	960 (50.8)	1.4 (0.6-3.4)
Unknown/refused	1 (1.7)	48 (2.5)	...
Education, y			
≤12	17 (21.3)	1060 (30.1)	1.0 (Referent)
13-16	57 (71.3)	1984 (56.8)	1.6 (1.0-3.2)
>16	6 (7.5)	456 (13.1)	0.8 (0.3-2.0)
Marital status			
Single	7 (8.8)	322 (9.2)	1.0 (Referent)
Married	50 (62.5)	2535 (72.6)	0.7 (0.3-1.7)
Separated/divorced/widowed	23 (28.8)	833 (23.8)	1.3 (0.5-3.2)
Height, cm‡			
<161	20 (25.0)	1022 (29.3)	1.0 (Referent)
161-164	15 (18.8)	662 (19.5)	1.1 (0.6-2.2)
165-169	21 (26.3)	950 (27.2)	1.1 (0.6-2.1)
≥170	23 (28.8)	811 (23.2)	1.5 (0.8-2.8)
Unknown	1 (1.3)	26 (0.7)	...
Weight, kg§			
<66	34 (42.5)	757 (21.7)	1.0 (Referent)
66-84	21 (26.3)	938 (26.8)	0.5 (0.3-0.8)
85-73	21 (26.3)	883 (25.3)	0.6 (0.3-0.9)
≥74	4 (5.0)	906 (25.9)	0.11 (0.03-0.3)
Unknown	0 (0)	9 (0.3)	...
Body mass index, kg/m²			
<20.5	36 (45.0)	721 (20.7)	1.0 (Referent)
20.5-23.4	22 (27.5)	859 (24.6)	0.5 (0.3-0.8)
23.5-27.4	16 (20.0)	614 (17.6)	0.3 (0.2-0.6)
≥27.5	5 (6.3)	1052 (30.4)	0.18 (0.03-0.2)
Unknown	1 (1.3)	34 (1.0)	...

*Adjusted for age in years (<35, 35-39, 40-44, 45-49, 50-54, 55-59). OR indicates odds ratio; and CI, confidence interval.

†Data from core study (21 women with implants, 1599 without implants). From WISH study (59 women with implants, 1891 without implants). Ellipses indicate data not applicable. Core and WISH are defined in the second and third footnotes to Table 1.

‡1 cm=0.3937 in.

§1 kg=2.2046 lb

¶P for trend <.001.

successful at 8150 (94.9%) of the eligible households contacted. Of the 794 eligible women randomly selected to participate, 640 (80.6%) were interviewed. The overall response (household screening proportion multiplied by the interview response) was 76.5%.¹⁸ Thus, there were 2649 WISH controls (2009 RDD controls and 640 area controls) available for the present analysis.

The second group of population-based controls participated in one of several case-control studies that included 3 counties (King, Pierce, Snohomish) in western Washington State.¹⁹⁻²¹ Henceforth, this group will be referred to as "core" control women. These women were frequency county matched and age matched with women diagnosed with breast cancer, endometrial cancer, and rheuma-

toid arthritis between 1976 and 1991. Each woman was assigned a reference date that corresponded to the distribution of diagnosis dates in the frequency age-matched cases. These control women were identified using RDD.¹⁷ Of the total 52 046 random-generated telephone numbers, 23 528 (45.2%) were residential numbers, 26 405 (50.7%) were non-residential numbers, and 2113 (4.1%) could not be evaluated as to residential status. Screening for eligible household members was successful at 96.3% (22 651) of residential numbers called. Of the 3493 eligible women identified, 2781 (79.6%) were interviewed. The overall response (RDD screening proportion multiplied by the interview response) was 76.7%. Women with reference dates prior to 1983 (n=9) or

Table 3.—Smoking and Alcohol History in Women With and Without Breast Implants

	With Breast Implants, No. (%) (N=80)	Without Breast Implants, No. (%) (N=3490)	Prevalence, OR (95% CI)*
Smoking history			
Smoked ≥ 8 mo			
No	33 (41.3)	1749 (50.1)	1.0 (Referent)
Yes	47 (58.8)	1738 (49.8)	1.4 (0.9-2.2)
Former smoker	24 (30.0)	871 (25.0)	1.4 (0.8-2.4)
Current smoker	23 (28.8)	867 (24.8)	1.4 (0.8-2.4)
Pack-years smoked, No			
<5.0	14 (17.5)	456 (13.1)	1.7 (0.9-3.2)
5-14	9 (11.3)	491 (14.1)	1.0 (0.5-2.1)
15-24	10 (12.5)	370 (10.8)	1.4 (0.7-2.8)
≥ 25	14 (17.5)	421 (12.1)	1.6 (0.8-3.0)
Unknown	0 (0)	3 (0.1)	
Alcohol history			
Ever drank ≥ 4 drinks/y			
No	15 (18.8)	863 (24.7)	1.0 (Referent)
Yes	65 (81.2)	2616 (74.9)	1.5 (0.9-2.7)
Lifetime average No. drinks/wk			
<1.0	6 (7.5)	596 (17.1)	0.6 (0.2-1.8)
1.0-2.9	19 (23.8)	782 (22.4)	1.5 (0.8-3.0)
3.0-5.9	15 (18.8)	708 (20.3)	1.3 (0.6-2.7)
≥ 7.0	25 (31.3)	829 (23.8)	2.9 (1.5-5.5)
Unknown	0 (0)	12 (0.3)	

*Adjusted for age in years (<35, 35-39, 40-44, 45-49, 50-54, 55-59). OR indicates odds ratio; CI, confidence interval; and ellipses, data not applicable.

screened for hysterectomy status prior to interview ($n=494$), which included all women with reference dates in 1991, were excluded. Thus, there were 2278 core women with reference dates from 1983 to 1990 available for the present analysis. None of these women were screened for a prior diagnosis of cancer or rheumatoid arthritis. Women with a history of breast cancer, endometrial cancer, or rheumatoid arthritis were excluded in the analysis phase of each respective core case-control study.

From the total 4927 (2649 WISH and 2278 core participants) women with available interview data, the following women were excluded from the analysis: 523 women who were 60 years of age or older at reference date; 794 women whose self-reported ethnicity was other than white; 34 women with a prior history of breast cancer; and 6 women who had had 1 or both breasts surgically removed. The present analysis was based on the remaining 3570 white women. Eighty women (2.2%) (1.3% of core women and 3.0% of WISH women) reported having breast implants for the purpose of breast augmentation. These percentages do not reflect the overall prevalence of breast augmentation in the general population since the age distribution of the women included in this sample differs from that of women in the general population.

Among the women excluded from the present analysis, only 1 (0.2%) of the 523 women aged 60 years or older reported having breast implants. Of the 794 wom-

en younger than 60 years whose self-reported ethnicity was other than white, 583 were African American, 14 were Native American, 131 were Asian American, 35 were Hispanic, 29 were of "other" ethnicity, and 2 declined to provide ethnic information. Only 2 of the Asian-American women (1.5%) and 1 Hispanic woman (2.9%) had breast implants for the purpose of breast augmentation; no African-American women, Native American women, or women with "other" or unknown ethnicity reported having breast implants.

After obtaining written informed consent, study information was collected through structured interviews for both WISH and core women. Calendars that recorded major life events and photographs of oral contraceptive and hormone preparations were used to enhance recall of past exposures. All interviews were conducted in person except those for 23 core women (1.4%) who completed the same interview over the telephone after receiving the same calendars and photographic displays. Relevant study information was recorded only for exposures that occurred prior to the reference date. The questionnaire in the WISH study was different than the questionnaire in the core studies; however, basic information on reproductive, medical, and lifestyle characteristics was collected in a completely analogous manner. Thus, it was possible to recode the raw data from the WISH study and the core studies to produce the same summary variables. The categories of house-

hold income used in the WISH study could not be combined with the categories of income used in the core studies to produce an informative summary variable; thus, annual household income was reported separately for WISH and core women. Information on lifetime number of sexual partners and hair dye use was available for western Washington State core women only. All information used in the present analysis is from the original interviews of the WISH and core studies.

Control women in the present study population (from the above described case-control studies) were frequency age-matched to case women with disease. Thus, the age distribution shown in Table 1 does not reflect that of the general population, and all comparisons in Tables 2 to 6 were adjusted for age (<35 years, 35-39 years, 40-44 years, 45-49 years, 50-54 years, 55-59 years). While women from Atlanta were more likely than women from the other study sites to have breast implants, further adjustment for area of residence (western Washington State, central New Jersey, or Atlanta) did not alter the estimated odds ratios. The following characteristics were compared between women with breast implants ($n=80$) and those without breast implants ($n=3490$): income, education (number of years of schooling completed), marital status, height (meters), weight (kilograms; self-reported weight for core women, measured weight for WISH women), body mass index (BMI, weight in kilograms divided by the square of height in meters), smoking and alcohol consumption history, reproductive history, and medical history. For the core women only, lifetime number of sexual partners and hair dye use was compared between women with breast implants ($n=21$) and those without breast implants ($n=1599$). The data used in the present analysis is cross-sectional in nature, and the prevalence odds ratio (pOR) was used as the measure of association comparing characteristics of women with breast implants with those of women without breast implants. Logistic regression²⁴ was used to calculate age-adjusted pORs and 95% confidence intervals (95% CIs). Trends were evaluated with the likelihood ratio statistic.²⁴

RESULTS

The mean age at breast augmentation was 34 years (range, 17-49 years); for most women, implant placement occurred between the ages of 25 and 44 years (Table 1). Women with breast implants were more likely than those without implants to have had more than a high school education and tended to have a higher

shold income (Table 2). Marital status differed little between the 2 groups. While women with breast augmentation were somewhat taller, they were much less likely to be heavy than those who did not have implants (for ≥ 74 kg vs < 56 kg: $pOR=0.1$, 95% CI=0.03-0.3; and for ≥ 27.5 kg/m² vs < 20.5 kg/m²: $pOR=0.1$, 95% CI=0.03-0.2).

A history of smoking, both former and current, was slightly more common among the women with breast augmentation than their nonimplant counterparts, but the differences were small and did not increase with increasing intensity of smoking (Table 3). Consumption of alcoholic beverages (any combination of beer, wine, or liquor) was also more common among women with breast implants, although only notably so for women who drank an average of 7 or more drinks per week ($pOR=2.9$, 95% CI=1.5-5.5).

Lactation history, as well as the total number of pregnancies, full-term births, or miscarriages, differed little between women with and without implants (Table 4). A younger age at first pregnancy (for age < 20 years vs age 20-29 years: $pOR=1.6$, 95% CI=1.0-2.7), a younger age at first full-term birth (for age < 20 vs age 20-29 years: $pOR=1.9$, 95% CI=1.1-3.3), and a history of terminated pregnancies (for ≥ 1 pregnancy vs 0 pregnancies: $pOR=2.0$, 95% CI=1.2-3.4) was more common among women with breast augmentation than those without implants. Ever use of oral contraceptives was also relatively more common among women with breast implants ($pOR=2.2$, 95% CI=1.0-4.7), especially the longest durations of use (for ≥ 8 years' use vs none: $pOR=2.9$, 95% CI=1.3-6.7).

Women with breast augmentation were somewhat more likely to report a history of breast cancer in a first-degree relative (although the observed association was well within the limits of chance given no true association), whereas a history of high blood pressure and a thyroid disorder was similar to that reported by women without breast implants (Table 5). None of the women with breast augmentation reported a history of diabetes, but fewer than 2 cases would have been expected based on the prevalence of diabetes among women without implants.²⁶ Surgical removal of the uterus, ovaries, or both was more common among women with breast implants than those without ($pOR=2.7$, 95% CI=1.6-4.5).

Among the women who participated in the core studies, women with breast augmentation were more likely than those without augmentation to have had a greater lifetime number of sexual partners (for ≥ 14 partners vs ≤ 4 part-

Table 4.—Reproductive History, Breast-feeding, and Oral Contraceptive Use Among Women With and Without Breast Implants

	With Breast Implants, No. (%) (N=80)	Without Breast Implants, No. (%) (N=3490)	Prevalence, OR (95% CI)*
No. of pregnancies			
0	8 (10.0)	508 (14.6)	1.0 (Referent)
1	8 (10.0)	437 (12.5)	1.1 (0.4-2.9)
2	24 (30.0)	940 (26.9)	1.4 (0.6-3.2)
3	20 (25.0)	708 (20.3)	1.6 (0.7-3.6)
≥ 4	20 (25.0)	897 (25.7)	1.2 (0.5-2.8)
Age at first pregnancy, y†			
< 20	25 (31.3)	744 (21.3)	1.6 (1.0-2.7)
20-29	41 (51.3)	1932 (55.4)	1.0 (Referent)
≥ 30	5 (6.3)	301 (8.6)	0.8 (0.3-2.0)
Unknown	1 (1.3)	5 (0.1)	
No. of spontaneous abortions			
0	63 (78.8)	2635 (75.5)	1.0 (Referent)
≥ 1	17 (21.3)	855 (24.5)	0.8 (0.4-1.3)
No. of induced abortions			
0	58 (72.5)	2884 (82.8)‡	1.0 (Referent)
≥ 1	22 (27.5)	606 (17.4)	2.0 (1.2-3.4)
No. of full-term births			
0	16 (20.0)	733 (21.0)	1.0 (Referent)
1	11 (13.8)	568 (16.3)	0.8 (0.4-1.8)
≥ 2	53 (66.3)	2189 (62.7)	0.9 (0.5-1.7)
Age at first full-term birth, y‡			
< 20	21 (26.3)	553 (15.8)	1.9 (1.1-3.3)
20-29	36 (45.0)	1842 (52.8)	1.0 (Referent)
≥ 30	7 (8.8)	362 (10.4)	1.1 (0.5-2.4)
Breast-fed infant ≥ 2 wk§			
No	28 (35.0)	1045 (29.9)	1.0 (Referent)
Yes	36 (45.0)	1712 (49.1)	0.8 (0.5-1.4)
Duration of breast-feeding, mo			
≤ 6	9 (11.3)	653 (18.7)	0.5 (0.3-1.2)
7-18	17 (21.3)	565 (16.2)	1.2 (0.6-2.3)
> 18	10 (12.5)	469 (13.4)	0.9 (0.4-1.8)
Unknown	0 (0)	25 (0.7)	
Use of oral contraceptives			
No	8 (10.0)	854 (24.3)	1.0 (Referent)
Yes	72 (90.0)	2636 (75.7)	2.2 (1.0-4.7)
Duration of oral contraceptive use, mo			
≤ 12	15 (18.8)	593 (17.0)	2.1 (0.9-5.1)
13-48	11 (13.8)	889 (25.5)	1.1 (0.4-2.8)
49-96	24 (30.0)	717 (20.5)	2.8 (1.3-6.5)
≥ 97	22 (27.5)	637 (18.3)	2.9 (1.3-6.7)

*Adjusted for age in years (< 35 , 35-39, 40-44, 45-49, 50-54, 55-59). OR indicates odds ratio; CI, confidence interval; and ellipses, data not applicable.

†Among women with 1 or more pregnancies.

‡Among women with 1 or more full-term births.

§Among women who breast-fed.

||Among women who used oral contraceptives.

ners: $pOR=8.9$, 95% CI=3.1-25.5) and to have used semipermanent or permanent hair dyes ($pOR=4.5$, 95% CI=1.3-15.4) (Table 6).

COMMENT

There are several limitations of this analysis that should be considered in the interpretation of our results. We had limited power to detect modest differences between women with and without breast implants because of the relatively small number of women (80) with breast implants in these population samples.

The level of response among women eligible for the studies included in this

analysis varied between 70.7% and 76.7%. If substantial differences existed in the demographic, lifestyle, reproductive, or medical characteristics between participating and nonparticipating women, especially among the women with breast augmentation, our results may overestimate or underestimate associations with breast augmentation. In particular, publicity about breast implants may have influenced a selective group of women with breast implants to participate in research studies and another selective group not to participate. While this potential bias cannot be dismissed, it is unlikely that it had a substantial impact on our study results, since the

Table 5. Medical History Among Women With and Without Breast Implants

	With Breast Implants, No. (%) (N=80)	Without Breast Implants, No. (%) (N=3480)	Prevalence, OR (95% CI)*
History of breast cancer in first-degree relative			
No	71 (88.8)	3217 (92.2)	1.0 (Referent)
Yes	9 (11.3)	254 (7.3)	1.6 (0.8-3.2)
Unknown	0 (0)	19 (0.5)	
History of diabetes†			
No	60 (100)	3419 (98.0)	
Yes	0 (0)	71 (2.0)	
History of high blood pressure‡			
No	68 (82.5)	2998 (85.9)	1.0 (Referent)
Yes	14 (17.5)	487 (14.0)	1.2 (0.7-2.2)
Unknown	0 (0)	4 (0.1)	
History of thyroid disorder			
No	72 (90.0)	3020 (86.8)	1.0 (Referent)
Yes	7 (8.8)	457 (13.1)	0.8 (0.3-1.3)
Unknown	1 (1.3)	4 (0.1)	
Surgical removal of reproductive organs†			
None	55 (68.8)	3028 (86.8)	1.0 (Referent)
Uterus and/or ovaries	24 (28.8)	456 (13.1)	2.7 (1.6-4.5)
Unknown	1 (1.3)	4 (0.1)	

*Adjusted for age in years (<35, 35-39, 40-44, 45-49, 50-54, 55-59). OR indicates odds ratio; CI, confidence interval; and ellipses, data not applicable.

†Self-reported disease or surgery.

‡The prevalence of diabetes among women with implants is consistent with a 95% CI of 0% to 3.6%. * This range includes the prevalence of 2.0% seen in the nonimplant group.

Table 6. Lifetime Number of Sexual Partners and Hair Dye Use Among Women Who Participated in the Core Studies

	Women With Breast Implants, No. (%) (N=21)	Women Without Breast Implants, No. (%) (N=1998)	Prevalence, OR (95% CI)*
Lifetime number of sexual partners			
1-4	8 (38.0)	1033 (64.5)	1.0 (Referent)
5-13	4 (19.0)	389 (24.4)	1.8 (0.5-5.5)
>14	8 (38.1)	151 (8.5)	8.9† (3.1-25.5)
Unknown	1 (4.8)	26 (1.8)	
Use of hair dyes‡			
No	3 (14.3)	677 (42.3)	1.0 (Referent)
Yes	18 (85.7)	922 (57.7)	4.5 (1.3-15.4)
Age at first hair dye use, y§			
<30	14 (66.7)	669 (35.5)	6.2 (1.8-22.1)
≥30	4 (19.0)	950 (22.1)	2.1 (0.4-9.7)
Unknown	0 (0)	3 (0.1)	

*Adjusted for age in years (<35, 35-39, 40-44, 45-49, 50-54, 55-59). OR indicates odds ratio; CI, confidence interval; and ellipses, data not applicable. The Core study is defined in the second footnote to Table 1.

†P for trend = .001.

‡Permanent or semipermanent dyes.

§Among women who used hair dyes.

majority of women (94% of core women and 76% of WISH women) were interviewed prior to the restrictions initiated by the Food and Drug Administration in 1992 on the use of silicone gel implants and the ensuing heightened publicity and controversy.¹²

This is a cross-sectional study, and information on the women reflects their status at their assigned reference date, not at the time of breast implant placement for women with breast augmentation (eg, total number of pregnancies at reference date, not at the time of implant placement). Therefore, these data are best viewed as a comparison of selected characteristics of women who already have breast implants with those

who do not have breast implants; no inferences can be drawn concerning the role of these characteristics in the decision to have breast augmentation. Additionally, we restricted our analysis to white women, since the small number (3) of women with breast implants in the other ethnic groups precluded any meaningful comparison.

We found that some demographic, lifestyle, reproductive, and medical characteristics of women with breast augmentation were notably different than those among women in general in our sample population. Other characteristics (eg, diet, occupation, family history of disease other than breast cancer) that were not evaluated in the present analy-

sis may also differ between women with and without breast implants. These differences between women with implants and those without are important insofar as they influence the risk of a given disease. For example, some studies, but not all,²¹ suggest that the use of hair dyes²² or hair straighteners²³ may increase the risk of systemic lupus erythematosus or systemic scleroderma. Our results suggest that women with breast augmentation are more likely to use semipermanent or permanent hair dyes than other women. If it is true that hair dye use is associated with some connective tissue diseases, failure to adjust for hair dye use when evaluating the risk of connective tissue disease associated with breast augmentation could possibly result in a spurious elevation in risk. Alternatively, the results of some studies,²⁴⁻²⁶ but not all,²⁴ suggest that oral contraceptive use may decrease the risk for rheumatoid arthritis, particularly in young women. Our results suggest that women with breast augmentation are more likely to have used oral contraceptives, and to have used them for longer periods of time, than other women. If indeed oral contraceptive use decreases the risk for rheumatoid arthritis, failure to adjust for oral contraceptive use could mask an elevation in the risk of rheumatoid arthritis associated with having breast implants. There are numerous other examples of potentially confounding characteristics that could influence the association between having breast implants and disease; these particular examples are used merely for illustrative purposes. We emphasize that the potential for a large degree of confounding exists when evaluating the association between implants and any weight-related diseases, due to the substantial differences in weight and body mass index between women with augmentation and other women.

Our results highlight the importance of careful consideration and evaluation of potential confounding variables when investigating the impact of breast augmentation on the risk of subsequent disease. Furthermore, based on the results of a similar comparison among breast cancer patients (P. deH., unpublished data, June 1996), it is likely that the characteristics of women with breast implants for augmentation purposes are quite different than those of women with breast implants for reconstructive purposes following surgical treatment for breast cancer. Separate evaluation of women with breast implants for augmentation purposes and women with breast implants for reconstructive purposes, with adequate consideration of confounding characteristics, may help

to study some of the long-term health impacts of having breast implants in future studies.

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