Responses, Replies and Supplemental Briefs

2:00-x-00005-DPH In Re: Settlement Facility v. **CASE CLOSED on 11/29/2000**

U.S. District Court

Eastern District of Michigan

Notice of Electronic Filing

The following transaction was received from Greenspan, Deborah entered on 2/7/2005 at 5:04 PM EST and filed on 2/7/2005

Case Name: In Re: Settlement Facility v.
Case Number: 2:00-x-5
Filer: Dow Corning Corporation
WARNING: CASE CLOSED on 11/29/2000
Document Number: 110

Docket Text:
RESPONSE to [90] MOTION *Response to Motion to Deem Pre-1971 Silicone Gel Breast Implants Dow* filed by Dow Corning Corporation. (Attachments: # (1) Exhibit A# (2) Exhibit B# (3) Exhibit C# (4) Exhibit D# (5) Exhibit E# (6) Exhibit F)(Greenspan, Deborah)

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1047317467 [Date=2/7/2005] [FileNumber=845221-0]
[9efd1f5fb3313438b5d433f8d74de2bcd82774d7b623986f0d8bc0790ce443552208e
3fa66342cc165e748e8c6b836913f84503f01cce5b3d358e2d4d821eb1a]]
Document description: Exhibit A
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1047317467 [Date=2/7/2005] [FileNumber=845221-1]
[31081edbe4d16ba431cb9492b580128d98a68d70a46e16093e1f636357373448404e5
6acb6c21dc708bac064f6235cd4ed616ff23f2f3c708664f54adc925498]]
Document description: Exhibit B
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1047317467 [Date=2/7/2005] [FileNumber=845221-2]
[92d2e9132f319a41be5d40052b4446b45fb16fe72fad6398cba4c069959a4e730182c
e806f18e0666d841abbacc27a504e553af1bdd755ad5f3fb10a80af468a]]
Document description: Exhibit C
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1047317467 [Date=2/7/2005] [FileNumber=845221-3]
[2649934951f9d5f98690c9037f813b0f72d06571c22d8917c02e2c480dae01a292412
5c03c849eed5bd887868021c317fb7784d453479775094c9f7c2dafac5b]]

Document description: Exhibit D
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1047317467 [Date=2/7/2005] [FileNumber=845221-4]
[a53322b125588bc6a9a50b121f469065338115a01d1954d11b7fd420fe047d1faa8ae
22437055697bf367f6abab995c4f404d9915c441b165d260a05aad4bbab]]
Document description: Exhibit E
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1047317467 [Date=2/7/2005] [FileNumber=845221-5]
[b54b6b07d16c7f069e6b8b572ff8afed9f8db74b90a59dd3ae628006d0c0be885d43c
ab347125d1b159f3805e607482b0d7495d04e99f73cbe17b626cceba945]]
Document description: Exhibit F
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1047317467 [Date=2/7/2005] [FileNumber=845221-6]
[06c50e73d09f65e92674a48879153744558e980a7c4345e4370dc983ab13922bb68c2
01a5af614ec2d8994a82f0935eef7796439d9cb292f7dd1a9771d495505]]

2:00-x-5 Notice will be electronically mailed to:

Leslie J. Bryan lbryan@dsckd.com,

Lamont E. Buffington lbuffington@garanlucow.com, swestphal@garanlucow.com

Michael L. Scheier mscheier@kmklaw.com,

2:00-x-5 Notice will be delivered by other means to:

Dawn M. Barrios
Barrios, Kingsdore,
701 Poydras Street
Suite 3650
New Oleans, LA 70139-3650

Stanley M. Chesley
Waite, Schneider,
1513 Central Trust Tower
Cincinnati, OH 45202

Frank J. D'Amico , Jr
622 Baronne Street
2nd Floor
New Orleans, LA 70113

David L. Ellerbe
Neligan, Tarpley,
1700 Pacific Aveue
Suite 2600
Dallas, TX 75201

Calvin C. Fayard
519 Florida Avenue SW
Denham Springs, LA 70726

Ernest H. Hornsby
Farmer, Price,
115 W. Adams Street
P.O. Drawer 2228
Dothan, AL 36302

Linda D. Houssiere
1990 Post Oak Blvd.
Suite 800
Houston, TX 77056-3812

Walter J. Leger , Jr
Leger & Mestayer
600 Carondelet Street
Ninth Floor
New Orleans, LA 70130

Matthew Lundy
Lundy and Davis
333 N. Sam Houston Parkway E
375
Houston, TX 77060

Dennis S. Meir
Kilpatrick Stockton
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309-4530

Dianna Pendleton-Dominguez
Blizzard, McCarthy, (Houston)
440 Louisiana Street
Suite 1710
Houston, TX 77002

John D. Peters
Charfoos & Christensen
5510 Woodward Avenue
Detroit, MI 48202

Harold V. Sullivan , II
3480 Torrance Boulevard
Suite 206
Torrance, CA 90503

Jeffrey S. Trachtman
Kramer, Levin,
919 Third Avenue
New York, NY 10022

Charles M. Wolfson
Wolfson Law Offices
Corner of Barrenjoey Rd. & Avalon Parade
MacMillan Court
Suite 8
Avalon, NSW,, 02107

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE:	§	
	§	**CASE NO. 00-CV-00005-DT**
DOW CORNING CORPORATION,	§	**(Settlement Facility Matters)**
	§	
REORGANIZED DEBTOR	§	**Hon. Denise Page Hood**
	§	

RESPONSE TO MOTION TO DEEM
PRE-1971 SILICONE GEL BREAST IMPLANTS DOW

Dow Corning Corporation ("Dow Corning") respectfully submits this *Response to Motion to Deem Pre-1971 Silicone Gel Breast Implants Dow* filed by Houssiere, Durant & Houssiere, LLP.[1]

The law firm of Houssiere, Durant & Houssiere, LLP ("Houssiere") claiming to represent "numerous claimants" filed the Motion to Deem Pre-1971 Silicone Gel Breast Implants Dow (the "Motion"). The Motion can only be characterized as an attempt to modify the confirmed and substantially consummated Amended Joint Plan of Reorganization (the "Plan").[2] Houssiere asserts in the Motion that Dow Corning was the only manufacturer of silicone gel breast implants prior to 1971 and that "neither the claims office nor Dow will accept responsibility for such implants." Motion at 2. Although not stated clearly in the Motion, it appears that Houssiere has submitted

[1] This Response is submitted in accordance with the Stipulation and Order Establishing Procedures for Resolution of Disputes Regarding Interpretation of the Amended Joint Plan, entered June 10, 2004.

[2] The motion uses the shorthand term "Dow" to refer to Dow Corning Corporation. This usage may engender confusion because The Dow Chemical Company, one of Dow Corning Corporation's shareholders, is frequently referred to as "Dow" and indeed its NYSE symbol is "DOW." It would therefore be more appropriate to refer to Dow Corning Corporation as "Dow Corning" or "DCC."

claims to the Settlement Facility-Dow Corning Trust (SF-DCT) for 7 individuals who received implants before 1971 and that those claimants have not provided the documentation of Proof of Manufacturer that is required by the Plan. Consequently, it appears, the claims have been found deficient by the claims office. *See* Motion at 2, 3, Exhibit G. Rather than pursuing the Individual Review Process (as permitted under the Plan) or awaiting the results of an appeal as specified by the Plan, Houssiere has filed this Motion asking this Court to, in effect, re-write the Plan.

The Motion must be denied. First, the Plan mandates a clear and specific procedure for the appeal of determinations of the claims office and that procedure does not authorize an appeal directly to this Court. Second, the Plan contains detailed guidelines defining acceptable Proof of Manufacturer: neither the SF-DCT nor the Court has authority to add to those guidelines as Houssiere requests. Finally, any objections to these Plan provisions should have been raised long ago in the context of the confirmation proceedings. It is improper and unfair for Houssiere to now ask the Court to circumvent the procedures, and alter the substantive guidelines, that were intensely negotiated between Dow Corning and counsel representing the interests of claimants, approved by an overwhelming majority of claimants, and confirmed by this Court.[3]

[3] Further, to the extent the Motion purports to seek relief applicable beyond Houssiere's own 7 claimants, it is overbroad and improper.

Background

Under the Plan's settlement option a claimant is eligible for payment only if she or he meets several eligibility requirements and is able to submit appropriate medical documentation to support the requested payment option. These and other Plan terms were the subject of lengthy and contentious negotiations between Dow Corning and the Tort Claimants' Committee, which represented the interests of all claimants, including those with pre- and post-1971 implants. The Plan, including product identification guidelines agreed upon between Dow Corning and the Tort Claimants' Committee, was made available to all claimants – including the 7 claimants involved in the Motion as well as their counsel – during the solicitation and voting period and before the confirmation hearing. An overwhelming percentage of claimants then voted for these terms, and the Plan was approved by the Court. Neither these claimants nor Houssiere objected to any of these product identification provisions.

The Plan requires that Settling Personal Injury Claims shall be processed in accordance with the specified Claims Resolution Procedures and that "[o]nly those Claims that satisfy the eligibility criteria specified in the Claims Resolution Procedures as applicable are eligible to receive payment, except to the extent that the Reorganized Dow Corning accepts Claims through the individual Proof of Manufacturer Review...as specified at Schedule I, Part I.F. ...of the Claims Resolution Procedures." *Settlement Facility and Fund Distribution Agreement* (*Settlement Facility Agreement*) § 5.01(a). The Claims Resolution Procedures in turn define the threshold eligibility requirements for

all settling claimants: to be eligible for settlement payments, claimants must satisfy certain basic requirements including the submission of "acceptable Proof of Manufacturer, as set forth in Schedule I, Part I and/or II or III,... as applicable, of these Claims Resolution Procedures." *Claims Resolution Procedures* (*Annex A*) to the *Settlement Facility Agreement* § 5.01(f) at 7. The Proof of Manufacturer requirements for breast implant claimants are spelled out at Schedule I, Part I of Annex A. Section A specifies the brand and implant names that the SF-DCT is permitted to accept and the applicable time periods for each of those names. Section B lists 19 different forms of acceptable proof that a claimant may submit to demonstrate acceptable proof of a Dow Corning implant. Those forms of proof include hospital records, medical records, implant labels and affirmative statements from doctors and apply to all implants regardless of year of implantation.[4]

Section D lists Unique Product Identifiers – that specify 8 different identifying characteristics that can be used to demonstrate acceptable proof if the claimant submits a photograph of the explanted implant or the medical records of the surgeon who removed the implant. Thus, even if the claimant does not have specific implant records, she can rely on appropriately documented records related to the removal surgery. Notably, Schedule I contains particular Unique Product Identifiers for pre-1971

[4] Through these affirmative statements, claimants who cannot locate old medical records may substantiate product identification.

implants. *See* Annex A, Schedule I, Part I.D. 1-2, at 60-61. The SF-DCT has *no* authority to accept forms of proofs that do not meet these Plan requirements.

The Plan also contains a provision documenting Dow Corning's agreement to cooperate with the claims office in connection with the review of Proof of Manufacturer. In the event that the SF-DCT receives a Proof of Manufacturer submission that does not meet the requirements of the Plan, the SF-DCT has the authority to seek Dow Corning's review of such materials. Dow Corning has the discretion to accept or reject such documentation. The program under which Dow Corning reviews Proof of Manufacturer submissions is termed the "Individual Review Process" or "IRP." The IRP has been functioning since early to mid-2003 after the claim forms were mailed. As of January 25, 2005, the IRP had reviewed 1,983 submissions for breast implants provided by the claims office, including 190 with a known implant date before 1971, and had found acceptable Proof of Manufacturer in 79 of those submissions with a known implant date before 1971. *See* Affidavit of Kenneth L. Montague, attached hereto as Exhibit A (the "Montague Aff."), at ¶¶ 7-9. In addition, the Plan requires Dow Corning to provide to the SF-DCT sales records and lists of lot and serial numbers that will assist the SF-DCT in reviewing Proof of Manufacturer submissions. The Motion incorrectly alleges that Dow Corning has failed to provide the sales information to the SF-DCT. In fact, Dow Corning provided the sales data to the SF-DCT in electronic format in March 2003. Copies of the transmittal letters that accompanied the data are attached at Exhibit B.

The Motion indicates that 7 individuals represented by Houssiere have sought a determination from the SF-DCT that they have acceptable Proof of Manufacturer based on the mere "fact" that they received implants before 1971. The Motion does not explain or disclose the evidence submitted to the SF-DCT proving that these individuals actually received silicone gel breast implants. The Motion and its Exhibits appear to indicate that these individuals sought to appeal a determination by the SF-DCT that their Proof of Manufacturer submissions were deficient and that as of the date the Motion was filed, the claimants had not received a determination on re-review or appeal.

Although the Motion is directed at the processes employed by the SF-DCT, there is an assertion that Dow Corning has not accepted responsibility for implants it made "when the claimant could not meet the technicalities contained in the Plan... ." Motion at 3. None of the claims at issue, however, has been submitted to the IRP for review. *See* Montague Aff. at ¶¶ 10-12.

Argument

A. The Product Identification Requirements Are Specified By The Plan And Claimants Cannot Seek A Modification By The SF-DCT Or By This Court.

As the Court knows, the Plan was the result of lengthy and often contentious negotiations between the Tort Claimants' Committee and Dow Corning (the "Plan Proponents"). In the end, the Plan was overwhelmingly approved by claimants and approved by this Court. The Plan contains detailed guidelines – negotiated and agreed

to by the Plan Proponents – for the submission, review and allowance of claims in the settlement option. In particular, the Plan contains very specific requirements for the submission of Proof of Manufacturer. These provisions spell out clearly the type of documentation required for acceptable proof. The basic Proof of Manufacturer guidelines have been available to claimants since early 1999 when claimants were asked to vote on the Plan.[5] Shortly before the Effective Date, Dow Corning agreed to expand the forms of acceptable proof and, as a result, added Paragraphs 17 through 19 and expanded Paragraphs 5 and 13 of Schedule I, Part I, Section B.

The SF-DCT is authorized to accept only the forms of Proof of Manufacturer specified in Annex A to the Settlement Facility Agreement. Section 5.01 of Annex A states quite clearly that to be eligible to participate in the Settlement Program the claimant must submit acceptable Proof of Manufacturer as set forth in Schedule I to Annex A. Section 6.02(b)(ii) of Annex A states that "All Breast Implant Claimants must submit acceptable proof of a Dow Corning Breast Implant to receive benefits. The standards of acceptable proof of a Dow Corning Breast Implant are set forth at Schedule I, Part I to these Claims Resolution Procedures." The Proof of Manufacturer guidelines in the Plan have never contained a provision authorizing the SF-DCT to accept evidence that the claimant received the implant before 1971 as the sole and sufficient proof of

[5] In particular, these materials were available to Houssiere in early 1999 in connection with the confirmation hearing on the Plan. Houssiere did not object to the Plan's Proof of Manufacturer guidelines or appeal the Order confirming the Plan, which is now final, and has thereby waived the claims for relief now sought in the Motion. *In re Pardee*, 193 F.3d 1083, 1086-87 (9th Cir. 1999).

implantation of a Dow Corning implant. There is not, and has never been, a provision allowing for proof by inference or speculation. The negotiated and agreed-to product identification requirements in the Plan mandate an affirmative showing of proof of a Dow Corning implant. Further, claimants with pre-1971 implants who cannot meet these Proof of Manufacturer requirements applied by the SF-DCT are, in fact, receiving detailed scrutiny though the IRP, and those with legitimate claims are being approved for product identification in that process. *See* Montague Aff. Accordingly, the Plan in its current form provides adequate procedures and mechanisms to address claimants who had implant surgery before 1971. In addition, although Houssiere's selective excerpts in the Motion suggest that Dow Corning was the sole manufacturer of implants before 1971, this assertion is not only factually incorrect, but it is improperly raised by this Motion, which is procedurally deficient in seeking, in essence, a factual determination on product identification as to all pre-1971 claimants. [6]

---

[6] The Motion asserts through argument and recitation of excerpts from certain discovery collected in MDL 926 that Dow Corning was the only manufacturer of silicone gel breast implants before 1971. Aside from the improper attempt to create a factual record, the assertion is incorrect. The undisputed public record is replete with examples of non-Dow Corning implants pre-dating 1971, including off-brand experimental implants used by doctors well before 1970 and various other manufacturers' models sold in the mid- to late 1960s. *See, e.g.*, Peters, W., *The Evolution of Breast Implants*, 10 Can. J. of Plastic Surgery 5:223-236 (2002) (noting that polyurethane-coated (PU) silicone gel implants were introduced in 1968) (excerpts attached as Exhibit C); Middleton, Michael S. & McNamara, Michael P., *Breast Implant Imaging*, Ch. 7 at 3, 6 (2002) (inflatable silicone gel-filled Japanese implants reported to have been available from about 1966; the first polyurethane-coated silicone gel filled implant was introduced by Drs. Ashley and Pangman in about July 1968 in association with Polyplastics, and the implant was reported to have been in development since 1964) (excerpts attached as Exhibit D); *Dow Corning Center for Aid to Medical Research Bulletin*, Jan. 1971, vol. 13, no. 1, p. 3 (published literature in 1970 indicated that, out of 10,941 patients surveyed, 32.3% used "open-pore" implants) (excerpts attached as Exhibit E); Deposition of Rudolf R. Schulte, *In re Master Silicone Breast Implant Litig.*, No. 92-16550 (Dist. Ct Tex.) (12/17/92), tr. at 22, 31) (Richard Schulte, who had been President of Heyer-Schulte, testified that his company began selling a certain type of breast implant in 1965 and began to manufacture and sell gel-filled, smooth-walled

The SF-DCT has no authority to modify or deviate from the Plan requirements regarding Proof of Manufacture: the Settlement Facility Agreement provides that the "Claims Office shall process Settling Personal Injury Claims payable from the Settlement Fund in accordance with the Claims Resolution Procedures outlined in Annex A." *Settlement Facility Agreement* § 5.01(a). The SF-DCT does not have discretion to consider ANY other form of proof. Accordingly, if the SF-DCT receives a Proof of Manufacturer submission that does not contain one of the acceptable forms of proof, then the SF-DCT is required by the Plan to reject the submission as ineligible. Quite simply, the SF-DCT does not have discretion to consider the arguments or the attempt to create a factual basis for accepting implants inserted before 1971 that do not meet the standards for acceptable proof. Thus, if these 7 individuals submitted only an indication that they had a breast implant implanted before 1971 without any of the forms of acceptable proof, then the SF-DCT was required by the Plan to reject those submissions.

In the event that the SF-DCT finds the Proof of Manufacture submission ineligible, the SF-DCT has the authority to send the submission to Dow Corning for review under the IRP described above. In addition, the claimant may appeal the decision to the Claims Administrator and to the Appeals Judge. *See Annex A* §§ 8.04

---

silicone shell breast implants similar to Dow Corning's in 1969-1970) (excerpts attached as Exhibit F). Indeed, it is notable that while the Individual Review Process has been able to make good-faith positive product identification for dozens of cases, *in 111 of 190 submissions for pre-1971 implants alleged to have been Dow Corning implants reviewed in that process the review revealed that the evidence did not support a determination that Dow Corning was the manufacturer*. *See* Montague Aff. at ¶¶ 8-9.

and 8.05.[7] The Appeals Judge is required to apply the guidelines and protocols set forth in Annex A and is not permitted to modify any of the substantive eligibility criteria. Indeed, if the appeal involves an issue of new interpretation of any substantive eligibility criteria, the issue must be submitted to the Debtor's Representatives and the Claimants' Advisory Committee. *Annex A* § 8.05. Thus, the Appeals Judge does not have discretion to accept any Proof of Manufacturer submission that is not authorized in the Plan. The decision of the Appeals Judge is final and binding on the claimant. *Id.* There is no right to a subsequent appeal to the Court.

The Motion, therefore, improperly seeks to alter the Plan's product identification requirements. These requirements, negotiated and agreed upon and contained in the confirmed Plan, must be applied by the Claims Administrator and by the Appeals Judge; neither has discretion to alter the terms and requirements of the Plan, and individual claimants cannot appeal to this Court to seek a determination that would necessarily alter Plan requirements.

B. The Motion Is An Impermissible Attempt To Amend The Plan.

Without any showing that they have pursued – much less exhausted – the various procedures available under the Plan, Houssiere now asks this Court to re-write the Plan to create another form of "proof" of manufacturer that is not permitted under

---

[7] The Motion does not make clear whether they have filed an appeal: Exhibit G to the Motion states only that they have filed "re reviews (and various other forms of 'appeal')." Letters to Wendy Trachte-Huber and Frank Andrews dated November 29, 2004 at 3, contained in Exhibit G to Motion.

the Plan, which was negotiated by plaintiffs' lawyers, accepted by the vast majority of claimants, and approved by this Court. The Plan Documents do not authorize such unilateral relief from the Court. The Plan Documents themselves recite the requirements for any amendments. The Settlement Facility Agreement, of which Annex A is a part, provides that:

> [t]his Agreement may be amended to resolve ambiguities, make clarifications or interpretations or to correct manifest errors contained herein by an instrument signed by the Reorganized Dow Corning and the Claimants' Advisory Committee. All other amendments, supplements, and modifications shall require approval of the Court after notice to the Reorganized Dow Corning, the Shareholders, and the Claimants' Advisory Committee and such other notice and hearing as the Court may direct, provided that without the prior written consent of the Reorganized Dow Corning and the Claimants' Advisory Committee the Agreement shall not be amended, supplemented or modified if such amendment, supplement, or modification would, directly or indirectly: (i) increase the liquidation value or settlement value of any Claim, or the amount or value of any payment, award or other form of consideration payable to or for the benefit of a Claimant, including, without limitation, any cash payment or other benefits provided to a Claimant, (ii) affect the validity, requirement for or effectiveness of any release of the Released Parties, or any of them, (iii) increase the amount or change the due date of any payment to be made by the Debtor to the Settlement Facility pursuant to the Plan or the Funding Payment Agreement, (iv) affect the right of the Settlement Facility to receive payments pursuant to the Insurance Allocation Agreement, or (v) cause the Trust to no longer qualify as a Qualified Settlement Fund.

Settlement Facility Agreement § 10.06. Accordingly, any amendment that would result in making an ineligible claim eligible requires the prior written consent of Dow Corning and the Claimants' Advisory Committee since such amendment would have the effect of increasing the settlement value of the claim. Indeed, if the Court were authorized to amend the Plan upon the request of a claimant to allow new standards for settlement

eligibility, then Dow Corning would have the right to seek amendment of the Plan to disallow all settlement compensation for disease claims in light of scientific evidence that has become available since 1998 when the Plan terms were negotiated. The Plan, quite simply, is a negotiated contract: it can be modified to affect the requirements for payment of claims only by mutual consent of the parties to that contract (the Plan Proponents) or other parties specified in the contract (the Debtor's Representatives and the Claimants' Advisory Committee). Accordingly, the request to "deem" implants inserted before 1971 to be Dow Corning implants must be denied.

Conclusion

For the reasons stated herein, the Motion must be denied.

Respectfully submitted this 7th day of February 2005,

DICKSTEIN SHAPIRO MORIN & OSHINSKY, LLP

By: _____

Deborah E. Greenspan
2101 L Street, N.W.
Washington, DC 20037-1526
Tel.: 202-861-9100
Fax.: 202-887-0689
State Bar of Michigan Member Number P33632

DEBTOR'S REPRESENTATIVE AND
ATTORNEY FOR DOW CORNING CORPORATION

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE:	§	CASE NO. 00-CV-00005-DT
	§	(Settlement Facility Matters)
DOW CORNING CORPORATION,	§	
	§	HON. DENISE PAGE HOOD
REORGANIZED DEBTOR	§	

CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2005 a true and correct copy of the following pleading was served via electronic mail, telecopy, or overnight mail upon the parties listed below:

RESPONSE TO MOTION TO DEEM PRE-1971 SILICONE GEL BREAST IMPLANTS DOW.

DICKSTEIN SHAPIRO MORIN & OSHINSKY, LLP

By: _____
Deborah H. Greenspan
2101 L Street, N.W.
Washington, DC 20037-1526
Tel.: 202-861-9101; Fax.: 202-887-0689
GreenspanD@dsmo.com

DEBTOR'S REPRESENTATIVE AND
ATTORNEY FOR DOW CORNING CORPORATION

LOCAL COUNSEL:
Lamont E. Buffington
GARAN, LUCOW, MILLER, SEWARD, COOPER & BECKER
Woodbridge Place/1000 Woodbridge Street
Detroit, MI 48207-3192
Tel.: 313-446-1530; Fax: 313-259-0450
lbuffington@garanlucow.com

February 7, 2005 service parties:

CLAIMANTS' ADVISORY COMMITTEE

Dianna L. Pendleton-Dominguez
Blizzard, McCarthy & Nabers LLP
440 Louisiana Street
Suite 1710
Houston, TX 77002
Tel.: 713-844-3750
Fax.: 713-844-3755
dpendleton@blizzardlaw.com

Ernest H. Hornsby
Farmer, Price, Hornsby & Weatherford
100 Adris Place
Dothan, AL 36303
Tel.: 334-793-2424
Fax.: 334-793-6624
ehornsby@fphw-law.com

Sybil Niden Goldrich
256 South Linden Drive
Beverly Hills, CA 90212
Tel.: 310-556-1738
Fax.: 310-556-1858
sybilg58@aol.com

DEBTOR'S REPRESENTATIVES

Jeanne D. Dodd
Dow Corning Corporation
P.O. Box 994
Midland, MI 48686-0994
Tel.: 989-496-4980
Fax: 989-496-8543
j.d.dodd@dowcorning.com

Edward W. Rich
The Dow Chemical Company
2030 Dow Center
Midland, MI 48674
Tel.: 989-638-1700
Fax: 989-638-7133
ewrich@dow.com

Marcus Worsley
Dow Corning Corporation
Corporate Treasury CO 1116
P.O. Box 994
Midland, MI 48686-0994
Tel.: 989-496-1874
Fax: 989-496-8379
marcus.worsley@dowcorning.com

Jill K. Schultz
Nixon Peabody, LLP
P.O. Box 31051
Rochester, NY 14603-1051
Tel.: 585-263-1477
Fax: 866-947-1007
jschultz@nixonpeabody.com

DOW CORNING CORPORATION

Susan K. McDonnell
V.P., General Counsel and Secretary
Dow Corning Corporation
2200 W. Salzburg Road
Auburn, MI 48611
Tel: 989-496-5020
Fax: 989-496-8307
Sue.mcdonnell@dowcorning.com

HOUSSIERE, DURANT & HOUSSIERE, LLP

Linda D. Houssiere
Randal A. Kauffman
1990 Post Oak Blvd.
Suite 800
Houston, TX 77056-3812
Tel: 713-626-3700
Fax: 713-626-3709

SHAREHOLDER COUNSEL

Laurie Strauch Weiss
Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York NY 10103-0001
Tel.: 212-506-3749
Fax: 212-506-5151
lstrauchweiss@orrick.com

Richard F. Broude
Richard F. Broude, P.C.
400 East 84th Street
Suite 22A-
New York, NY 10028
Tel.: 917-301-3468
Fax: 212-628-1034
rfbroude@cs.com

FINANCE COMMITTEE

The Hon. Frank Andrews
P.O. Box 7829
4315 Lovers Lane
Dallas, TX 75209
Tel: 214-956-0050
Fax: 214-956-0053
fal@swbell.net

FINANCE COMMITTEE (cont'd)

Professor Francis E. McGovern
Duke University School of Law
P.O. Box 90360
Durham, NC 27708-0360
Tel: 202-744-6750
Fax: 919-613-7095
mcgovern@faculty.law.duke.edu

Elizabeth Wendy Trachte-Huber
Claims Administrator
Settlement Facility – Dow
Corning Trust
3100 Main Street, Suite 700
Houston, TX 77002
Tel: 713-874-6060
Fax: 713-874-6061
ewhuber@sfdct.com

Exhibit A

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

In Re:	§	
	§	Case No. 00-CV-00005-DT
Dow Corning Corporation,	§	(Settlement Facility Matters)
	§	
Reorganized Debtor	§	Hon. Denise Page Hood
	§	

AFFIDAVIT OF KENNETH L. MONTAGUE IN SUPPORT OF THE RESPONSE OF DOW CORNING CORPORATION TO THE MOTION TO DEEM PRE-1971 SILICONE GEL BREAST IMPLANTS DOW

STATE OF MICHIGAN	§
	§
COUNTY OF BAY	§
	§

Kenneth L. Montague, being duly sworn, deposes and says:

1. I am currently employed by Dow Corning Corporation ("DCC"), with the title of Senior Project Engineer. I make this affidavit in support of the Response of Dow Corning Corporation to the Motion to Deem Pre-1971 Silicone Gel Breast Implants Dow (the "Houssiere Motion to Deem").

2. I have personal knowledge of the matters set forth herein.

3. I have been designated by DCC to conduct the review and analysis necessary for the Individual Review Program ("IRP") for proof of manufacturer that has been established to comply with the requirements of Annex A to the Settlement Facility and Fund Distribution Agreement ("Settlement Facility Agreement"), Schedule I, Part F.

4. In that capacity, I have been involved in the set up of the procedure for the review of Proof of Manufacturer submissions and have participated in the review of such submissions.

5. Under the procedures agreed to with the Settlement Facility-Dow Corning Trust (the "SF-DCT"), the SF-DCT forwards Proof of Manufacturer submissions that it cannot accept to DCC for review. The submissions are sent to DCC in periodic batches.

6. Such submissions that did not otherwise qualify in the Settlement Facility may be found acceptable in the IRP.

7. As of January 25, 2005, DCC has reviewed 1,983 such submissions for breast implants through this IRP process.

8. This includes 190 submissions for breast implants with a known implant date prior to 1971 that have been reviewed through the IRP process as of January 25, 2005.

9. As of January 25, 2005, the IRP has agreed to accept 79 submissions for breast implants with a known implant date prior to 1971.

10. DCC maintains an electronic record of each submission and the result of the review are provided in electronic format to the SF-DCT.

11. The electronic record is dynamic and cannot be replicated and does not involve a process for ongoing audit.

12. I have personally reviewed this electronic record and have not found any submission for claimants Barbara Brewsaugh, Nan De Luca, JoAnn Gammage, Ruth Holzhauer, Esther Lefkowitz, Barbara Mitchum, and Vonda Smith (*see* Exhibit G to the Houssiere Motion to Deem).

13. Had these claims been forwarded to the IRP, the IRP would have reviewed them within 10 days.

14. I declare under penalty of perjury, under the laws of the State of Michigan, that the foregoing is true and correct.

FURTHER AFFIANT SAYETH NOT.

Executed this 27 day of [Jan] 2005.

Kenneth L. Montague

Kenneth L. Montague

Subscribed and sworn to before
me this 27 day of [Jan.] 2005.

Ann M. Draves

Notary Public in the State of Michigan

My commission expires:

Ann M. Draves
Notary Public, Saginaw County, Michigan
My Commission Expires August 28, 2007
Acting In Saginaw County

Exhibit B

DOW CORNING

Law Department
Legal Fax (989) 496-5349
Patent Fax (989) 496-6354
Litigation Fax (989) 496-8543

March 13, 2003

Elizabeth W. Trachte-Huber
3100 Main Street
Suite 700
Houston, TX 77002

Re: Dow Corning Breast Implant Sales Information

Dear Wendy:

Pursuant to the Settlement Facility Agreement, Annex A, Schedule I, Part F, enclosed is a disc containing a Microsoft Access database listing Dow Corning breast implant sales by customer, date, quantity and implant type.

Please be advised that this is the best information currently available to Dow Corning and compiled in a usable format. Dow Corning makes no representation that this information is complete and is aware that there are several significant gaps described below. It is also likely that copies of sales records produced to the MDL Document Depository in the early 1990s document some sales not recorded in this database.

The database includes sales both by Dow Corning Corporation and by Dow Corning Wright (DCW), its subsidiary through which most final sales of breast implants were handled beginning in late 1977 or 1978. DCW sales information is missing for the months of January and May 1981 and June and October 1984.

DCW sales records for 1978 through 1980 were not contemporaneously recorded in electronic form. This data was compiled from hard copy shipping records in the early 1990s and collected in a separate database which we expect to ship to you this Friday. Given the passage of time and the data entry by contractors, there may be significant gaps and errors in this data.

Electronic recording of sales outside the United States began at different times in Dow Corning's history. Sales in the Pacific region were recorded beginning in 1985 and in the European region beginning in 1983. Sales in the Inter-Americas region (including all of the western hemisphere outside the United States) began in 1981. However, sales data for the Inter-Americas is missing for 1986 and the data for the years 1981 through 1990 lack customer names.

Dow Corning Corporation
Midland, Michigan 48686-0994
Phone: (989) 496-4000
www.dowcorning.com

Finally, it must be remembered that this database represents a consolidation of a number of disparate electronic data files and formats, with the resultant inconsistency of data and overall database design inefficiencies necessarily inherent to such a consolidation.

Sincerely,

Douglas B. Schoettinger
Associate General Counsel and
Manager, DCC Litigation Facility, Inc.

DOW CORNING

Law Department
Legal Fax (989) 496-5849
Patent Fax (989) 496-6354
Litigation Fax (989) 496-8543

March 28, 2003

Elizabeth W. Trachte-Huber
3100 Main Street
Suite 700
Houston, TX 77002

Re: Dow Corning Breast Implant Sales Information – Part II

Dear Wendy:

Enclosed is a disc containing additional Dow Corning breast implant sales data. This is the additional data for the years 1978-80 to which we referred in our letter of March 13, 2003. This sales data is being provided pursuant to the Settlement Facility Agreement, Annex A, Schedule I, Part F.

The data is provided in a Microsoft Access database listing Dow Corning breast implant sales citing customer, date, quantity and implant type.

Please be advised that this is the best information currently available to Dow Corning in a usable format. Dow Corning makes no representation that this information is complete and is aware that there are errors in this data.

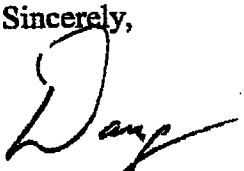
The sales data forwarded to you earlier was from Dow Corning Corporation's electronic sales system. Beginning sometime in 1978, breast implant sales were handled through Dow Corning's newly acquired subsidiary, Dow Corning Wright (DCW). DCW's sales were not recorded in the Dow Corning Corporation electronic sales system until sometime in 1980. Accordingly, the sales data on the enclosed disc was not electronically recorded when these sales were made. Rather, this data was compiled in the early 1990s from original shipping papers and entered into an electronic system by a contractor.

We know that there are numerous errors in this data but cannot identify all of them. We know that some sales dates are wrong because they reflect years after Dow Corning ceased all sales of breast implants. To avoid confusion, we have deleted those sales dates. You will note that there are other sales dates outside the time period (1978-80) missing from the Dow Corning electronic sales system. We suspect that those dates are the results of data-entry errors or are duplicative of sales listed on the earlier disc covering sales in those years. Thus, we urge caution in using this data.

Dow Corning Corporation
Midland, Michigan 48686-0994
Phone: (989) 496-4000
www.dowcorning.com

Finally, it must be remembered that this database represents an extensive manual entry effort by an outside contractor having no understanding of Dow Corning products or product naming conventions. This lack of understanding, combined with overall database design inefficiencies, the absence of data-input standardization requirements and keying errors due to human error exacerbated by multiple data-entry personnel, and the resultant inconsistency of data, are all factors that need to be taken into consideration as you weigh the value of this data against your informational requirements.

Sincerely,



Douglas B. Schoettinger
Associate General Counsel and
Manager, DCC Litigation Facility, Inc.

Exhibit C

Register
Subscribe
Log-in
forgot your password?

THE CANADIAN JOURNAL OF
PLASTIC SURGERY
JOURNAL CANADIEN DE CHIRURGIE PLASTIQUE
Official Journal of: Canadian Society of Plastic Surgeons

Top of Page
Pulsus Home
Instructions to Authors
Plastic Surgery Links
Advertising Info
Permissions
Calendar of Events
email
Reprints

HISTORICAL REVIEW

November/December 2002, Volume 10, Number 5: 223-236

The evolution of breast implants

W Peters

The present review traces the evolution of breast implants over the past 50 years. During the early years (from 1951 to 1962), a number of different sponges were used for breast augmentation. The first of these was Ivalon, a polyvinyl alcohol sponge. Other sponges were introduced subsequently, including Etheron (a polyether sponge popularized by Dr Paule Regnault in Montreal) and Polystan (fabric tapes that were wound into a ball). Subsequently, polyethylene strips enclosed in a fabric or polyethylene casing were also used for breast augmentation. All of these materials had similar outcomes. Although the initial results were encouraging, within one year of augmentation, breasts became very firm and lost over 25% of their volume. This was due to capsular contracture, a process that would lead to the collapse of the sponge and would continue to plague plastic surgeons and their patients for the next 50 years. In 1963, Cronin and Gerow introduced the silicone gel 'natural feel' implant, which revolutionized breast augmentation surgery. Approximately 10 companies have manufactured many types of silicone gel breast implants over the years. They obtained their raw materials for gels and shells from a similar number of other companies that entered and left the market at intervals. Many of the suppliers and manufactures changed their names and ownership over the years, and most of the companies no longer exist. No formal process of United States Food and Drug Administration premarket testing was in effect until 1988. There have been three generations of gel implants and a number of other lesser variations. First-generation implants (1963 to 1972) had a thick gel and a thick wall. They have generally remained intact over the years. Second-generation implants (1973 to the mid-1980s) had a thin gel and a thin wall. They have tended to disrupt over time. Third-generation implants (mid-1980s to 1992) had a thick wall and a thick gel. Except for those made by Surgitek, these implants remain intact. The breast implant business was competitive and companies introduced changes such as softer gels; barrier low-bleed shells; greater or lesser shell thickness; surface texturing; different sizes, contours and shapes; and multiple lumens in search of better aesthetics. Ultimately, more than 240 styles and 8300 models of silicone gel breast implants were manufactured in the United States alone. Inflatable breast implants were introduced in Toulons, France in 1965 (the Simaplast implant). There have been three main eras of inflatable implants: seamed, high-temperature vulcanized and room temperature vulcanized implants. In 1973, spontaneous deflation rates of 76% to 88% over three years were reported for many types of inflatable implants. Because of this, most

Journal Ho
Past Issue
Table of Cont

plastic surgeons abandoned their use. From 1963 until the moratorium on gel implants (January 6, 1992), about 95% of all breast implants inserted were silicone gel filled. Only 5% were saline filled. Since the moratorium, this ratio has been reversed and 95% of all implants have been saline-filled, with only 5% being gel filled. Polyurethane-coated (PU) silicone gel implants were introduced in 1968. Over the next 20 years, they were shown to reduce the prevalence of capsular contracture to 2% to 3%. Other forms of surface texturing (Biocell, Siltex, multistructured implant) also appear to reduce capsular contracture with gel implants, but the reduction has been much less dramatic than that seen with PU implants. Contoured (anatomical) shaping appears to have advantages in some patients with gel implants. No such advantage has been seen for texturing or shaping with saline-filled implants. The story of gel implants has culminated in the largest class action lawsuit in medical history, with US$4.2 billion being awarded to women with silicone gel implants. During the past decade, there has been a tremendous amount of research on the reaction of a woman's body to gel implants. A plethora of studies have demonstrated that silicone gel implants are not associated with the development of any medical diseases. Silicone gel-filled implants have therefore been approved for use under Health Canada's Special Access Program. Silicone gel-filled implants may now be used in certain patients in whom they would provide advantages over saline implants. Silicone gel implants have not been approved for unrestricted general use. The evolution of breast implants occupies the past half century. It has been a stormy course, with many exciting advances and many bitter disappointments. The universe of breast implants is large and the variation among the implants is substantial. The purpose of the present review is to trace the evolution of breast implants over the past 50 years.

Key Words: *Breast implants; Evolution*

L'évolution des prothèses mammaires

RÉSUMÉ : Le présent article retrace les grands faits qui ont marqué l'évolution des prothèses mammaires au cours des 50 dernières années. Au début (de 1951 à 1962), on a eu recours à différents types d'éponge pour l'augmentation mammaire. Le premier modèle a été commercialisé sous le nom d'Ivalon, éponge en poly(alcool de vinyle). D'autres types d'éponge ont été mis en marché plus tard, dont Etheron (éponge de polyéther, promotionnée par la Dre Paule Regnault, à Montréal) et Polystan (galons en croisé enroulés sous forme de balle). Ont suivi les bandes de polyéthylène contenues dans des enveloppes de tissu ou de polyéthylène. Toutefois, ces matériaux connaissaient tous le même sort : après des débuts encou-rageants, les seins commençaient, au cours de la première année postopératoire, à devenir très fermes et à perdre 25 % de leur volume. La déformation était due à une rétraction capsulaire, processus qui menait à l'affaissement des éponges et qui allait hanter

Exhibit D

breast implant integrity, will illustrations of abnormal examples of the various implant types. The history of breast augmentation in general was covered in *Chapter 1* and the history of sponge implants in particular in *CDROM 4*, and so historical detail will be only be referenced here if it has not been covered elsewhere.

Our information about the various implant types is derived mainly from patients and implants seen at UCSD where this information either was elicited from the patient, obtained from medical records, or determined on the basis of an actual examination of implants[3]. To supplement our understanding, we also reviewed parts of the objective data and database as produced by breast implant manufacturers and others (such as the FDA) as part of the MDL 926 Breast Implant Litigation (~170 CDROMs, ~270,000 documents).

1. Single lumen silicone gel-filled

A. Non-polyurethane-coated

Just over three-fourths of breast implants evaluated at UCSD have been *single-lumen silicone gel-filled.* About 87% had a smooth silicone elastomer shell surface, and the rest were textured. The normal appearance on MR imaging varies from no evident folds to simple folds, to complex folds (see **Figures 4.01** to **4.12**, and **4.19** to **4.24**).

The first silicone gel-filled implants were placed experimentally in 1962, and were first marketed in late 1963 by Dow Corning. Inflatable silicone gel-filled Japanese implants are reported to have been available from about 1966 **[8]**

---

3 Medical records from over 4250 patients, MR imaging examinations of over 1200 patients with implants, and direct examination of over 5300 breast implants.

The history of the use of polyurethane in breast implants is quite complex (see *CDROM 1 and 4*), and so only a brief overview will be given here. The first polyurethane-coated silicone gel-filled implant, generally referred to as the *Ashley* implant, was introduced by Drs Ashley and Pangman in about July 1968 **[9]** in association with Polyplastics. That implant was reported to have been in development since 1964[5]. Heyer-Schulte took over production in 1971. Some implants from that period were only partially covered with polyurethane, such as the Capozzi and Pennisi implants from Heyer-Schulte **[10]**. The Capozzi implant was coated with polyurethane foam everywhere except on the anterior superior surface of the implant. This design sought to eliminate the problem of anterior vertical furrowing in the breast contour after placement **[11]**. The polyurethane coating was observed partially to fragment and detach from the implant over time **[11, 12]**. Increased foreign body reaction also is associated with polyurethane foam covered implants **[11]**. Cox-Uphoff also produced the *Natural-Y* implant in or about 1978-79. Aesthetech took over the Pangman patent covering the *Natural-Y* implant in about 1981, and expanded and developed the product line to include the *Optimam*, *Vogue* and *Même* ME implants. Later the *Même* MP and *Replicon* implants were added. Surgitek assumed production of the *Même* MP and *Replicon* implants in 1988, and ceased production in 1992. Polyurethane coated implants also may have been available from Unimed in connection with

---

5 "Augmentation mammaplasty" by Robert H. Pudenz M.D., Heyer-Schulte Corporation, dated July 1978 (MB 104861)

Exhibit E

The BULLETIN

of the DOW CORNING CENTER FOR AID TO MEDICAL RESEARCH

VOLUME 13 NUMBER 1 MIDLAND, MICHIGAN JANUARY, 1971

Some filler effects on diffusion in silicone rubber

C. F. Most, Jr., J App Poly Sci 14:1019-1024, 1970

Relatively high diffusivities and minimal tissue response of polydimethyl siloxane rubber has led to a number of studies of its use as an implantable slow-release carrier for medicaments. This study determines the relationship between observed transmission rates and diffusivity through silicone rubber membrane containing varying amounts of a high surface area fumed silica filler using a new technique for assaying multiple samples.

Ethyl p-aminobenzoate was chosen as the model for this work because of solubility in both aqueous and nonaqueous systems, ease of identification in the desorption medium, and its small molecule which exhibits high diffusivity.

A special permeation cell assembly was developed consisting of a tube containing the permeant, sealed on one end with the membrane, suspended inside a 2 oz. french square bottle containing the desorbing solution. The cell was rotated at an angle of 35° in a constant temperature bath.

Values for transmission rates and apparent diffusivities for membranes of different thickness were in good agreement indicating initial absorption and desorption are not rate limiting. Time lag values for membranes containing fillers indicate a disparity reflected in a large decrease in calculated diffusivities compared to moderate decrease in transmission rates as filler loading is increased, such results are attributed to absorption of the permeant on the filler. Distribution coefficients were measured and were found to give additional evidence of the filler absorption phenomenon.

In view of these results it is suggested that for polar and unsaturated chemicals in general, the unmodified time lag technique used by Daynes[1] and Barrer[2] will not be valid for determining diffusivities in silicone rubbers since these usually contain silica fillers.

[1] Daynes, H., Proc Roy Soc Ser A 97, 286 (1920)
[2] Barrer, R. M., Diffusion in and through solids. Cambridge University Press, London, 1941.
From Dow Corning Corporation, Midland, Michigan.

Replacement of the aortic valve with molded autogenous grafts grown in response to implanted Silastic

A. S. Geha, T. Salaymeh, G. L. Davis and A. E. Bave. J Thor and Cardiovas Surg 60:5, 661-671, Nov, 1970

The fibrocollagenous tissue developed in response to implanted molds shaped like aortic cusps was used as a substitute for the aortic valve in dogs. Aortic and pulmonary valve cusp-shaped solid molds were made by first filling the aortic and pulmonary roots, or models of the roots, from sacrificed dogs, with Silastic® elastomer. Each root mold was divided into three cusp molds which were implanted under the paniculus carnosus of the abdominal wall of mongrel dogs and the tissue response allowed to reach maturity previously determined to be about three months. The mold with the membrane attached was then excised and a single semi-lunar valve cusp replaced in each of 25 adult mongrel dogs. A group of 10 dogs received a right coronary or noncoronary aortic cusp grown in the dog itself, a second group of 10 dogs received a right coronary or noncoronary aortic cusp of tissue grown in dogs of the first group. Two additional dogs received a left semilunar pulmonary valvular autograft and a fourth group received left pulmonary grafts of tissue grown in dogs in the third group. All cusp replacements were carried out with cardiopulmonary bypass and with body temperature at 30°C.

The implanted tissue reflected the size and shape of the Silastic® mold and in gross appearance closely resembled that of a normal cusp, with a thickness of 0.3 mm.

Animals in groups 1 and 2 died within 24 hours of complications which the authors judged to be unrelated to valve function. The hemodynamic status and valve function were satisfactory.

There were no operative deaths in dogs with pulmonary valvular replacements and good valve function was evident for more than 5 weeks. Homograft cusps in dogs in this group sacrificed at 3 or 4 weeks were rigid and thickened because of fibrin and platelet thrombus. It was not determined if this was a rejection phenomenom.

The early postoperative results with autogenous pulmonary grafts of this tissue showed satisfactory function.

® Silastic 382 Medical Grade Elastomer

From the Depts of Surgery and Pathology, The Jewish Hospital of St. Louis, and Washington University School of Medicine, St. Louis, Mo.

Studies on the revascularization of tendons grafted by the silicone rod technique

H. Conway, J. W. White and M. P. Elliot. Plas and Recon Surg 46:6, 582-587, Dec, 1970

This work was undertaken to demonstrate use of a tendon prosthesis to reduce the number of adhesions and increase the range of gliding when the prosthesis is removed and replaced with a tendon graft.

A tendon and surrounding connective tissue was excised from the forelimb of six dogs and replaced with a silicone tendon prosthesis®. After 10 weeks the prosthesis was removed and the anterior tibial tendon transplanted into the sheath formed around the prosthesis.

At the time of sacrifice, eight weeks after transplantation of the tendon, there appeared to be no adhesions between the prosthesis and the sheath except at points of tendon suture, where adhesions were extensive. The tendon grafts appeared to be well vascularized but the orientation of the blood supply was observed to be on the superficial surface of the tendon rather than entering the deep surfaces as observed in normal tendons. The blood vessels appeared to originate from blood vessels along the inner surfaces of the surrounding sheath. The vascular connections were delicate and friable and had a pleated configuration which allowed them to stretch with the free-gliding function of the tendon graft.

® Hunter Tendon, manufactured by Hoiter Co., Philadelphia, Pa.

From the Dept. of Plast Surgery of the New York Hospital-Cornell Medical Center.

Notice: The only purpose of this Bulletin is to disseminate scientific information involving the uses of silicones in various medical practices. We do not advocate use of these materials as "drugs", nor warrant their safety or efficacy. If they are to be employed, it is the responsibility of the user to determine and comply with all FDA regulations.

Augmentation mammaplasty: survey of complications in 10,941 patients by 265 surgeons.

T. deChalain. J Plast and Reconstr Surg 45:6, 573-577, June, 1970.

This world-wide survey covers over 10,000 operations and indicates a use of 3% autogenous materials, 32.3% "open pore" implants, 63.3% smooth surface prostheses and 1.3% silicone fluid injection for mammary augmentation, with follow-ups to 18 years. The age of patients reported on ranged from 16 to over 40 years, with 80% falling into the 16-30 year category.

Infections were observed in 2.5% of all operations, most immediately post-operative, with a few late infections. Post-operative fluid accumulation was observed in some of the cases using the smooth surface implants, perhaps as a result of using antibiotics for irrigation. The most widely used implant was the Cronin prosthesis with 58% of the total cases.

A 16.4% incidence of skin perforations occurred with augmentation after subcutaneous mastectomies compared to 2% following simple augmentation.

Problems of shrinkage and hardening were reported with the "open-pore" implant and substantial numbers were replaced by smooth-surface type prostheses. Transplants of gluteal fat and similar materials were generally subject to absorption and hardening. Some degree of firmness occurred with smooth surface implants but these were reported to give generally more satisfactory performance.

With the Cronin-type prosthesis edges and ripples which could be palpated through the skin were reported as a minor complication.

Breasts with implants were apt to be heavier and more congested than normal during pregnancy but seemed to be softer and have better contour after childbirth. Cases are reported where patients nursed babies adequately. In one case an Etheron prosthesis developed marked shrinkage after pregnancy.

The author reported no personal experience with breast cancer in connection with mammary prostheses. Follow-up examinations reported in the survey revealed only 0.22% benign and 0.007% malignant tumors. The latter is far below the incidence encountered in the general population. This may be related to the generally young age of the patients. These malignancies could probably be assumed to have been present at time of operation. Follow-up surveys of a large number of implants over a long period are needed to be certain of the lack of tumor formation.

Cysts were frequently reported with silicone fluid injection but no cases of carcinoma were revealed. This procedure is illegal in the United States.

From the Dept. of Plastic and Reconstructive Surgery, Greenwich Hospital, Greenwich, Conn.

Our experiences with the Silastic gel breast prosthesis.

J. D. Cronin and R. L. Greenberg. Plast and Reconstr Surg 46:1-7, July, 1970

A study of 183 cases of augmentation with a new version of the Silastic breast prosthesis* is reported.

Criteria for choosing size of implant and surgical procedure are outlined. Possible complications include fluid accumulation, hematoma, firmness, infection, palpable edges, failure of fixation to the chest wall, and exposure. Treatments for these conditions are described.

Evaluation of the results based on degree of palpability of the implant, contour and softness of the breast on six month to one year follow-up indicated 85% of the patients had excellent or good results, 12% were judged fair and 3% poor.

* Dow Corning Corp., Midland, Michigan.

A new type of breast prosthesis: preliminary report.

F. L. Ashley. Plast and Reconstr Surg 45:5, 421-424, May, 1970

A new type of breast prosthesis made of silicone, silicone gel and urethane is described*. The prosthesis is a breast-shaped silicone sheath, filled with a low viscosity silicone gel and covered entirely with a 1 mm thick fine-cell urethane sponge. A Y-shaped septum is built into the prosthesis to eliminate sag and maintain a natural shape.

The prosthesis has been implanted in animals, and histological studies up to one year after implantation show inertness. More than 60 patients receiving these implants have been evaluated for as long as one and one-half years. Results are reported to be extremely satisfactory for cosmetic augmentation or after subcutaneous mastectomy.

* Edward Weck, Long Island City, N. Y.

From the Dept. of Plastic Surgery of the UCLA School of Medicine.

Augmentation of the small ptotic breast.

M. Spira, F. Gerow and S. B. Hardy. Plast and Recon Surg 46:2, 201-203, Aug., 1970.

Late results of breast augmentation on patients with hypoplastic and ptotic breasts have an appearance of excessive fullness in the upper half of the breast, a nipple which points downward and the prosthesis may be easily palpable.

To improve these results in patients with small breasts and mild to moderate ptosis, the authors position the Silastic gel prosthesis 3 to 4 cm lower than the usual placement site. This appears unnatural at first but results in an improved contour especially when patient is in a standing position.

From Cora and Webb Mading Dr of Surgery (Plastic) of the Baylor College o Texas.

Silicone fluid research: a follow-up summary.

T. D. Rees, D. L. Ballantyne, Jr. and G. Hawthorne. Plas and Reconst Surg 46:1, 50-55, July, 1970.

This report covers results observed in studies conducted on the injection of dimethylpolysiloxane fluid* in more than 1000 animals including mice, rats, guinea pigs, rabbits, dogs, monkeys, apes and baboons.

It was observed that all animal species showed similar lack of response to the cutaneous injection of 350 cs. silicone fluid. Differences in the gross or microscopic appearances depend on the site, volume and procedure of injection.

Gross observation of subcutaneous sites showed multiple cysts of varying sizes, which were presumed to contain silicone fluid. Massive doses became encapsulated in thin-walled spherical or ellipsoid spaces with moderate fibrosis and an occasional giant cell appearing after six months.

When large subcutaneous doses or intraperitoneal injections were given, atrophy of omental and mesenteric fat was often observed. Droplets or vacuoles assumed to be injected fluid were found in the reticuloendothelial system of rodents and baboons. The authors also observed what they believe is fluid in blood cells but their findings are inconsistent and have not been reproduced by other investigators.

An evaluation of the effects of the silicone fluid on full thickness skin autographs in rats showed no adverse reactions on the vascularization or viability of the grafted skin. No tumor or granuloma occurred in this short term study. Successful autographs were done following storage in silicone at 4°C for four days. Preliminary findings, however, showed that silicone fluid does not protect excised skin from freezing injury.

Over a period of 5 years the authors have tried to induce neoplasms in several animal species using varying amounts of silicone in several sites but have not demonstrated a relationship between 350 cs. dimethylpolysiloxane injection and carcinogenesis or sarcogenesis.

* Dow Corning 360 Medical Fluid

From the Institute of Reconstructive Plastic Surgery, New York University Medical Center, New York.

The status of injectable silicone fluid for soft tissue augmentation.

S. Bruley. Plas & Recon Surg 47:4, 343-344, April, 1971

It is emphasized that injection of silicone fluid for soft tissue augmentation is still under an Investigative New Drug application to investigate safety and efficacy. Only eight investigators are authorized. It is not available to the medical profession for general clinical use.

From the Dow Corning Center for Aid to Medical Research.

Exhibit F

NO. 92-16550

IN RE:	*	IN THE DISTRICT COURT OF
	*	
MASTER SILICONE BREAST IMPLANT LITIGATION	*	HARRIS COUNTY, TEXAS
	*	
	*	270TH JUDICIAL DISTRICT

VIDEOTAPED DEPOSITION OF

RUDOLF R. SCHULTE

On December 17, 1992, the videotaped deposition of the Witness in the above-styled cause was taken at the instance of the Plaintiffs at the Biltmore Four Seasons Hotel, 1260 Channel Drive; Santa Barbara, California, pursuant to Stipulations of Counsel contained herein.

A That's correct.
Q How long did you work in manufacture of medical valves as a sole proprietorship?
A Until 1963.
Q During those two years you had the same arrangement with Mr. Heyer - that is, you would manufacture the product, he would send it off to the company and receive a percentage of the sales?
A Pretty much, yes.
Q First let me ask you, what happened in 1963 that changed?
A We formed a corporation.
Q Being what?
A Heyer-Schulte Corporation.
Q That was formed in 1963?
A I am pretty sure.
Q Other than you and Mr. Heyer, was there anyone else involved in the incorporation of the company Heyer-Schulte?
MR. FREED: Meaning were there any other officers?
Do you understand the question?
THE WITNESS: Yes, I was trying to think if there was.
A I don't think at the beginning. It was

just Ted Heyer and myself.

Q What did you form the business to do?

A To manufacture and sell these valves.

Q Okay. Was there a reason that you wanted to have a corporation? What was the reason that you wanted a corporation instead of continuing with the way that you had been doing business in the previous two years?

A Probably was advice by my attorney.

Q In our discussion you say that you were making the valves. Did you mean to convey to me that you personally were the person that actually manufactured and did the hands-on work?

A That's correct.

Q Did anybody help you with that over those first two years, or was it just a one-man operation?

A No, one-man operation.

Q At the time that you established Heyer-Schulte with Mr. Heyer, were there any products that you were involved in initially at Heyer-Schulte other than these valves?

A There might have been some other small products, yes.

Q Like what?

A Different catheters.

Q These, too, would be sold to the company that you were selling the valves to?

A That's right.

Q Tell me that name again, please, sir.

A Codman and Shurtleff, today known under -- Codman, yes, which is now a subsidiary of Johnson and Johnson.

Q Did the business of Heyer-Schulte expand after 1963 into areas other than catheters and valves?

A You mean immediately?

Q No, sir. At some time after 1963 did the business ---

A (Interrupting) Yes.

Q What was the next product line that you-all became involved in from the manufacturing standpoint?

A Plastic surgery, and urology.

Q Well, who, to your understanding, was using BP shunts? Wouldn't those have been neurologists?

MR. FREED: He said urology.

Q Urology?

A Urology, yes.

Q So, the new products that you became involved in after catheters and valves involved plastic surgery products and urology products?

A Correct.

Q Do you remember approximately when it was that you and your company became involved in that product line?

A Probably around 1965.

Q How many people were working at your company in 1965?

A Maybe ten.

Q What were the plastic surgery products that you became involved in in 1965?

A Breast implants.

Q What were the urology products that you became involved with in 1965?

A It might have been a little bit later than '65, but that would be penile implants and other prosthetic devices.

Q In what way was Heyer-Schulte initially involved with the manufacture of breast implants?

A Through a person, his name was Hal Markham.

Q Explain to me how Heyer-Schulte became involved in breast implants through Mr. Markham.

A He was a friend of a Dr. Pangman in Beverly Hills who was very active in implanting breast implants.

Q Well, how did Heyer-Schulte get involved is

what I am trying to figure out. I know it is through Mr. Markham. Did he approach you? Did you approach them? Did he have a product in mind that he wanted you to make? Was he asking to you design something? I mean, there is a whole variety of ways that one could be involved. I am trying to get to how it was that Heyer-Schulte became involved in the initial manufacture of breast implants.

A We were asked to make some prototypes for Dr. Pangman.

Q Were you asked to design the prototypes, as well; or did the design come to you?

A The design pretty much came to us.

Q Who brought that to you?

A Hal Markham.

Q Okay. Was the design something where there were written specifications, or was it more of an idea that he wanted to see if it could be developed commercially?

A More of an idea.

Q What was the general idea that he had that he wanted you-all to work on?

A The core would be a polyurethane sponge material with the silicone coating, and then the top was a silicone coating - would be another

Q Okay. Was that the reason that you-all went to a new type of implant?
A Yes, with other doctors.
Q Other doctors other than Dr. Pangman?
A Yes.
Q Did it also still include Dr. Pangman?
A I don't think so.
Q Why was the Pangman implant that was manufactured by Heyer-Schulte between '65 and '67 discontinued?
A I believe that a lot of them were failures. It became very hard.
Q Product problems in use?
A Yes.

MS. TERK: To the extent that response may be speculative, I am going to object.

Q Well, what position did you have with Heyer-Schulte in 1967?
A I was president.
Q Was Mr. Heyer actively involved in the day-to-day business operations of the company?
A Not in '67, no.
Q You were the man with Heyer-Schulte that was at the top of the hierarchy there and the one who

was involved in day-to-day business decisions and the business of the company?

A Mostly in the research area, yes.

Q How long after the discontinuation of the Pangman implant due to product problems was it before this second type of implant began to be manufactured and sold by Heyer-Schulte?

A Probably in '69, '70, before we really started selling the product.

Q So, in '67 the original Pangman implant is discontinued for product problems. There is a hiatus of a year or two, maybe three, before Heyer-Schulte reenters the silicone breast implant business?

A Right.

Q Who was it that was primarily involved in the design of the second type of Heyer-Schulte implant?

A Myself.

Q It was your idea to use silicone gel in the center?

A Yes.

Q Was it your idea to use a smooth-walled silicone shell without holes in it?

A Yes, but you have to remember that Dow Corning already was manufacturing a similar product.

So, it was basically a "me, too" product.

MR. WEST: Objection.

Nonresponsive.

Q What you are telling me is that, yes, you were the one that decided to use the silicone elastomer shell without perforations on the Heyer-Schulte product; and one of the reasons that you made that decision was because Dow Corning had a product on the market that had that feature?

A Yes.

Q You said that it was basically a "me, too" product. What did you mean by that?

A Just a silicone gel material with a silicone shell around it.

Q In this silicone-gel-filled implant - the first one that we are now talking about at Heyer-Schulte - had you abandoned the use of the polyurethane both on the interior and the exterior of the implant?

A Not totally.

Q Tell me how you still used polyurethane in this Heyer-Schulte implant that followed the Pangman?

A I believe there were still doctors that believed that an outer polyurethane coating was necessary for tissue ingrowth.