UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

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

RESPONSE OF CLAIMANTS' ADVISORY COMMITTEE TO MOTION TO DEEM PRE-1971 SILICONE GEL BREAST IMPLANTS AS DOW

AND

MOTION OF CLAIMANTS' ADVISORY COMMITTEE TO AMEND ANNEX A TO THE SETTLEMENT FACILITY AND FUND DISTRIBUTION AGREEMENT TO ADOPT AN ADDITIONAL PROOF OF MANUFACTURER PROTOCOL

The Claimants' Advisory Committee ("CAC") submits this response in support of the *Motion To Deem Pre-1971 Silicone Gel Breast Implants as Dow* filed by Houssiere, Durant & Houssiere ("the Houssiere Motion"). The CAC also contemporaneously submits its own *Motion to Amend Annex A to the Settlement Facility and Fund Distribution Agreement to Adopt An Additional Proof of Manufacturer Protocol,* and respectfully requests that this Court enter an Order that medical records or other documentation that state that a claimant was implanted with a silicone breast implant (or some variation thereof, i.e., gel breast implant, breast implant) between 1963–1970 inclusive and do not contain any other identifying or contradictory information about the manufacturer of the implant(s) shall be deemed to be acceptable proof of a Dow Corning silicone gel breast implant pursuant to Schedule I, Part B of the Claims Resolution Procedures, Annex A to the Settlement Facility and Fund Distribution Agreement ("the Settlement Facility Agreement").

BRIEF IN SUPPORT

I. Proof of Manufacturer Protocols in the Revised Settlement Program

The Amended Joint Plan of Reorganization of Dow Corning Corporation ("the Plan") was negotiated in 1998 and was based on the existing criteria – including the product identification protocols – that were developed by the MDL 926 Claims Office and parties in the Revised Settlement Program ("RSP"). The original global settlement did not require a claimant to submit manufacturer identification to be eligible for benefits; it required only that the claimant document that she did in fact receive a breast implant. The RSP, however, did require a claimant to submit written documents that reliably establish which participating manufacturer made the implant(s). The protocols for acceptable proof were developed by reviewing the types of proof submitted in the original global settlement that reliably established the manufacturer of the implant. The protocols were included in the Notice for the Revised Settlement Program mailed in January 1996. That Notice package also included a Questions and Answers booklet approved by the MDL Court. See Order 27A in MDL-926, dated December 29, 1995 with attached Question and Answer Booklet, attached as Exhibit 1 hereto. The protocols were not rigid or absolute, but were designed to be flexible to allow for new types of proof to be added. Question 37 in the RSP Question and Answer Booklet, for example, states that claimants can:

> You may, however, send in proof -- even though not addressed by the existing rules -- that reliably establishes what kind of implant you received. The Claims Office will then advise you if new rules have been adopted to cover your situation or the participating companies have declined to accept your type of proof.

Id., Exhibit 1 attached hereto. Consistent with the answer to Question 37, the MDL 926 Claims Office did indeed add new protocols as claims were being processed. One such

protocol was developed after the MDL Claims Assistance Program (which was operated under the auspices of the Plaintiffs' Steering Committee and was external to the claims office itself) noticed a pattern of unmarked labels that they traced to a particular manufacturer, Heyer-Schulte. The proposed new protocol was submitted and accepted. Similarly, over time, additional "unique identifiers" for participating manufacturers were added to the existing array of acceptable proof of manufacturer. Thus, the experience from the RSP demonstrates that the proof of manufacturer criteria are not rigidly applied but are flexible and allow for new types of proof that reliably establish the implant manufacturer to be added.

II. Dow Corning Had Exclusive Market Share For Silicone Breast Implants Implanted In The U.S. During The 1960s

Dow Corning developed silicone gel breast implants in the early 1960s and was the sole manufacture of silicone gel breast implants in the U.S. from 1963-1970.[1] In approximately 1971, Heyer-Schulte (Baxter) began to sell primarily saline breast implants on a very small scale and limited geographically to the southern California area where they were located. See Exhibit 2 attached, memo dated March 30, 1973 from W.R. Pierie entitled "Heyer-Schulte – An Overview" (BAX 298157 – 298160). Heyer-Schulte's market share was so small in fact that they were described in the 1973 memo as a "Mom and Pop shop..." that operated out of trailers near the Santa Barbara airport. Id. Exhibit C to the Houssiere Motion contains interrogatory responses of Baxter, the company that purchased and assumed liability for implants made under the Heyer-Schulte brand. The interrogatory answers confirm that the earliest date that Heyer-

[1] In late 1969, polyurethane coated breast implants were manufactured in the United States on a limited basis.

Schulte sold silicone gel breasts implants was 1971. See Exhibit C to Houssiere Motion, Excerpts from Baxter Healthcare Corporation's Response to Interrogatories, Superior Court of the State of California, County of San Diego, Case No. JCCP-2754, at pp. 16-22, attached hereto as Exhibit 3 to this Motion. Similarly, Natural Y Surgical Specialties (Baxter and Bristol) was another company that entered the breast implant market in approximately late 1969 - 1970 but it marketed and sold only polyurethane-covered silicone gel breast implants, a type of implant that was never manufactured or sold by Dow Corning. Id., Exhibit 3 attached, at p. 20. Surgitek and Medical Engineering Corporation (Bristol) also acknowledged in their interrogatory responses that they first began to manufacture silicone gel breast implants in January 1971 (the Perras-Papillon Axillary Prolongation implant). See, Exhibit F to Houssiere Motion, Excerpts from Medical Engineering Corporation's Second Amended Answers To Plaintiffs' Interrogatories, Harris County, Texas, Cause No. 92-16550, at p. 13, attached hereto as Exhibit 4 to this Motion.

Other U.S. companies did not begin to manufacture and sell silicone gel breast implants until the mid-1970s. For example, Cox-Uphoff International (aka CUI) first sold silicone gel breast implants beginning in April 1976. See Exhibit B to the Houssiere Motion, Excerpts from Response of CUI Corporation to Plaintiffs' Master Interrogatories, Harris County, Texas, Master No. 92-16550, at p. 5, attached as Exhibit 5 to this Motion. Similarly, McGhan Medical first began to manufacture silicone gel breast implants in 1975. See Exhibit D to the Houssiere Motion, Excerpts from Responses of McGhan Medical Corporation, Inamed Corporation and Inamed Development Company To Plaintiffs' First Set Of Interrogatories, Superior Court of

California, County of San Diego, Case No. JCCP-2754, at p. 19, attached as Exhibit 6 hereto to this Motion. Thus, except for the very limited introduction of polyurethane-covered breast implants in late 1969, no other U.S. company made silicone gel breast implants in the United States during the 1960s except for Dow Corning.

The time frame that other companies manufactured silicone gel breast implants in the U.S. was documented in demonstratives prepared by Dow Corning employees. See Exhibit E to the Houssiere Motion, Excerpt from a "Product Reference Book, Silastic® Brand Mammary Implants Manufactured By Dow Corning Corporation 1964-1991," prepared by J.A. Ballender and C.J. Burda of Dow Corning, June 1992, and produced to the National Depository in the MDL 926 proceedings, attached hereto as Exhibit 7 to this Motion. The chart shows that other implant manufacturers first appeared in approximately 1971, a date which coincides with the interrogatory answers referenced above. Similarly, during the product identification training sessions presented by Dow Corning employees in 2002 and 2003 to Settlement Facility employees, Dow Corning provided a series of breast implant market share documents that are consistent with the June 1992 "Product Reference Book" prepared a decade earlier by Dow Corning. These documents – which Dow Corning has labeled as "confidential" -- demonstrate that 100% of the units (silicone gel breast implants) sold from 1963-1969 were made by Dow Corning. See Exhibit 8 attached hereto (the CAC believes that Dow Corning may contend that these documents are "confidential" – to which the CAC disagrees – but out of an abundance of caution, they are submitted under seal). Similarly, the chart also shows that Dow Corning's market share during this time frame was virtually 100%, with a very small percentage attributable to foreign-manufactured breast implants that were

primarily polyurethane or inflatable implants, not silicone gel breast implants like those made by Dow Corning. Id., Exhibit 8 attached hereto. In another chart – also provided to the Settlement Facility for purposes of training proof of manufacturer reviewers -- Dow Corning documents that from 1970-1972, Dow Corning by far had the overwhelming share of the market based on the number of units (implants sold). In 1970, for example, the chart suggests that over 95% of the units sold were made by Dow Corning. Id., Exhibit 8 attached hereto.

Dow Corning's own documentation of its exclusive market share and sales data is further supported by data obtained from the leading medical expert on manufacturer identification of breast implants, Michael Middleton, Ph.D., M.D. Dr. Middleton has published in peer reviewed literature, presented at scientific meetings on the subject of breast implants for the past 13 years, co-authored a book on breast implants containing a catalog of American implants with descriptions of more than 240 different styles, and has been invited to testify to the Committee on the Safety of Silicone Breast Implants at the National Academy of Sciences. See Declaration of Michael S. Middleton, Ph.D., M.D., attached hereto as Exhibit 9. He has also personally examined 5,691 breast implants for purposes of identifying the manufacturer. Id. His database on these implants reveals – consistent with the documents created by Dow Corning and other historical documents produced in the MDL 926 discovery phase – that, "For the years 1963-1967 I can state that in my opinion to a 99% degree of medical and scientific certainty that the manufacturer of a silicone gel breast implant implanted in the United States in those years would be Dow Corning." Id. For the years 1968-1969, he states that it is his "medical and scientific opinion to a virtual certainty" that smooth shell (non-polyurethane) silicone

gel breast implants implanted in the United States would have been manufactured by Dow Corning. Id. Further, he states that the "vast majority" of smooth shell silicone gel breast implants implanted in the United States during 1970-1971 would have been manufactured by Dow Corning as well.

The CAC submits that this information "reliably establishes" that medical records or other documentation of implantation in the U.S. from 1963-1970 inclusive can be accepted as proof of a silicone gel Dow Corning breast implant.[2]

III. The Court Has The Power To Amend The Settlement Facility Agreement To Adopt A New Protocol for Proof of Manufacturer

Section 10.06 of the Settlement Facility Agreement recognized that the Agreement could be amended either by joint agreement of the Debtor's Representatives and Claimants' Advisory Committee or by Court Order. Section 10.06 provides:

> This 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 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 ....

Similarly, Question 5-18 in the Claimant Information Guide recognized that new rules for proof of manufacturer could be added going forward. Question 5-18 provides:

> Q5-18. My proof of manufacturer documents are not covered by the rules above. Can I submit them?
>
> You may send in proof – even though it is of a type that is not addressed by the existing rules – if it reliably establishes what kind of implant you received. The Settlement Facility will then advise you if new rules have been adopted to cover

[2] Dow Corning did not manufacturer saline breast implants at anytime prior to 1970 so the implant could only be silicone gel.

your situation or if Dow Corning had decided to accept your type of proof through the confidential measures established by the Claims Assistance Program.

Exhibit 10 attached, excerpt from the Class 5 Claimant Information Guide at p. 18. [3]

As contemplated by Q5-18, claimants began to submit their Proof of Manufacturer claim form and documentation shortly after claim form packages were mailed in February 2003. Over the next 16 months, five additional protocols were developed and incorporated into both the executed Plan Documents and the SF-DCT Newsletter that accompanied the Effective Date package in June 2004. See Exhibit 11 attached, Excerpt from the SF-DCT Effective Date Newsletter, Spring 2004. Since the Effective Date, the CAC has proffered a number of suggested proof of manufacturer protocols to Dow Corning based on various types of records submitted to (and rejected by) the Settlement Facility under the existing agreed protocols. See Exhibit 12 attached hereto, letter dated September 20, 2004 from D. Pendleton-Dominguez to Deborah Greenspan, with attached chart to the letter. The CAC chart in Exhibit 12 included a number of new proof of manufacturer protocols including "Example 3" -- "All claimants implanted with a silicone gel breast implant prior to 1970." Dow Corning's responded by stating that the examples described by the CAC reflect how Dow Corning might respond to similar product identification examples submitted to it through the Individual Review Process – the process whereby claimants who do not have acceptable proof can seek review and acceptance of their documentation directly by Dow Corning. See Exhibit 13 attached, letter dated November 23, 2004 from D. Greenspan. Specifically, Dow Corning responded to "Example 3" – i.e., that pre-1970 implantations of silicone gel breast

[3] The CAC notes that the answer is virtually identical to the answer given to claimants in the RSP (see earlier discussion) that new proof of manufacturer protocols could be added if the records were determined to be "reliable."

implants would be deemed to be Dow Corning – that the Individual Review Process by Dow Corning would not accept these types of submissions. Id., Exhibit 13 attached hereto. The CAC therefore believes that it is appropriate to renew our requests to amend the Plan and allow for uniform treatment of claimants in a similar situation with regard to their product identification in the Settlement Option.

Pursuant to Section 10.06 of the Settlement Facility Agreement, the CAC submits this Motion requesting the Court to amend the proof of manufacturer protocols set forth in Paragraph B, Schedule I of Annex A, the Claims Resolution Procedures to deem as acceptable proof of a Dow Corning silicone gel breast implant medical records or other documentation that state that a claimant was implanted with a silicone breast implant (or some variation thereof, i.e., gel breast implant, breast implant) between 1963 – 1970 inclusive and do not contain any other identifying or contradictory information about the manufacturer of the implant(s).

IV. The Burden of Proof for Settling Claimants Is One of Reliability; It Should Not Be A Higher And More Difficult Burden Than That For Claimants in Litigation

The Settlement Option in the Amended Joint Plan was designed and intended to allow claimants to qualify for benefits without the need to prove causation. It was also intended that the Settlement Option would be faster, claimant-friendly, and provide more certainty about qualifying for compensation than the Litigation Option. See, e.g., Exhibit 14 attached, a letter from the Tort Claimants' Committee that was included in the Effective Date mailing packages.

As noted above, the answer agreed to by Dow Corning and the Tort Claimants' Committee in the Claimant Information Guide states that new protocols would be developed if the documentation "reliably establishes" the type of implant that was used. We believe that this is the appropriate standard in which to evaluate the CAC's request for additional proof of manufacturer protocols. In contrast, claimants who proceed with litigation of their implant claim would need to establish product identification and causation by a preponderance of the evidence. If the Settlement Option were intended to be more simple and less burdensome to qualify for compensation than through litigation as the CAC believes it was, then it stands to reason that the burden of demonstrating that the proof of manufacturer is "reliable" would be less onerous than the litigation burden of preponderance of the evidence.

Using the standard of whether the proposed proof of manufacturer protocol is "reliable" or "reliably establishes" the manufacturer of the implant, the CAC submits the burden has been met in the present instance. Indeed, we believe that claimants would prevail under even more rigorous burdens of proof required in litigation. As noted in Dr. Middleton's statement, he states "beyond a degree of medical certainty" that "silicone gel-filled breast implants placed in the United States in or before 1968 were very likely manufactured by Dow Corning." See Exhibit 9 attached. Further, "in excess of about 80% of silicone gel-filled breast implants placed in the United States during the years 1969, 1970, and 1971 were manufactured by Dow Corning, to a degree of medical certainty."

Unfortunately, records during the 1960s did not affirmatively record the name of the implant manufacturer or other identifying information. Medical records during this

time note only that the claimant was implanted with silicone breast implants or, more generically, breast implants. Since Dow Corning was the only manufacturer in the United States during this time frame, this is hardly surprising. There was no need for doctors or surgical nurses to record the obvious name of the manufacturer in the operative report, nor were there implant stickers with the manufacturer's name on them as there were in subsequent years when multiple manufacturers were manufacturing breast implants.

When the product identification protocols were adopted in the Amended Joint Plan, they were adopted wholesale with just a few minor variations. The issue of pre-1971 implant proof was not raised or discussed, so it is fair to state to the Court that the issue was not rejected outright by Dow Corning when the Plan was drafted. Indeed, it just was not considered. Now that the Settlement Facility has two years of processing experience – with the primary focus on proof of manufacturer – it is reasonable to expect claimants to submit types of proof that are not covered by the existing protocols. Indeed, as noted above, new types of protocols and brand names were added frequently in the RSP during the first year of the program as that settlement also was presented with types of proof that are credible and reliable.

The Plan and the underlying criteria for proof of manufacturer was never contemplated to be rigid and inflexible. Indeed, the parties wrote into it the ability to modify and amend the Settlement Facility Agreement, and adopted the same Question and Answer used in the RSP regarding adding new proof of manufacturer protocols. Based on the foregoing, the CAC submits that it has "reliably established" that

implantations performed in the U.S. from 1963-1970 inclusive were for Dow Corning silicone gel breast implants.

V. Relief Requested

For the reasons stated herein and in the attached exhibits, the CAC respectfully requests that this Court enter an Order that medical records or other documentation that state that a claimant was implanted with a silicone breast implant (or some variation thereof, i.e., gel breast implant, breast implant) between 1963 – 1970 inclusive and do not contain any other identifying or contradictory information about the manufacturer of the implant(s) shall be deemed to be acceptable proof of a Dow Corning silicone gel breast implant.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and accurate copy of the foregoing Response to the Houssiere Motion and the Motion of Claimants' Advisory Committee to Amend Annex A to the Settlement Facility Agreement To Adopt An Additional Proof of Manufacturer Protocol and attached exhibits were served by me this 7th day of February 2005 by electronic mail on the Debtor's Representatives and Houssiere, Durant & Houssiere.

Dianna Pendleton-Dominguez

Dianna Pendleton-Dominguez

Exhibit 1	MDL 926 Order 27A, dated December 29, 1995, with Excerpt from attached Question and Answer Booklet
Exhibit 2	Memo dated March 30, 1973 from W.R. Pierie entitled "Heyer-Schulte – An Overview" (BAX 298157 – 298160)
Exhibit 3	Excerpts from Baxter Healthcare Corporation Response to Interrogatories, Superior Court of the State of California, County of San Diego, dated December 6, 1993
Exhibit 4	Excerpts from Medical Engineering Corporation's Second Amended Answers To Plaintiffs' Interrogatories, Harris County, Texas, Cause No. 92-16550, dated December 4, 1995.
Exhibit 5	Excerpts from Responses of CUI Corporation To Plaintiffs' Master Interrogatories, Harris County, Texas, Master No. 92-16550, dated September 26, 1992
Exhibit 6	Excerpts from Responses of Defendants McGhan Medical Corporation, Inamed Corporation and Inamed Development Company To Plaintiffs' First Set of Interrogatories, Superior Court of California, County of San Diego, dated December 10, 1993.
Exhibit 7	Excerpt from Product Reference Book, Silastic® Brand Mammary Implants Manufactured By Dow Corning Corporation 1964-1002, by J.A. Vallender and C.J. Burda, June 1992
Exhibit 8	Excerpt from Tab 2 to the Dow Corning Product Identification Training Manual (filed under seal)
Exhibit 9	Statement of Michael Middleton, Ph.D., M.D.
Exhibit 10	Excerpt from Class 5 Claimant Information Guide
Exhibit 11	Excerpt from SF-DCT Effective Date Newsletter
Exhibit 12	Letter dated September 20, 2004 from D. Pendleton-Dominguez with attached chart
Exhibit 13	Letter dated November 23, 2004 from D. Greenspan
Exhibit 14	Tort Claimants' Committee letter included in the Effective Date mailing package

EXHIBIT 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re: SILICONE GEL BREAST IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 926)	)	Master File No. CV 92-P-10000-S
HEIDI LINDSEY, et al., Plaintiffs; -vs.- DOW CORNING CORPORATION, et al., Defendants.	)	Civil Action No. CV 94-P-11558-S

ORDER No. 27A
(Approval of Exhibit G and Question and Answer Booklet under Revised Settlement Program)

It is hereby ORDERED as follows:

1. Attached to this order are "Exhibit G" and a "Question and Answer Booklet", which are approved for distribution as part of the new Notice package relating to the Bristol, Baxter, 3M, McGhan & Union Carbide Revised Settlement Program.

2. In the effort not to delay distribution of the Notice package, the Question and Answer Booklet has not been subjected to the same degree of intensive scrutiny as the revised Notice itself. In the event of conflict in terms between the revised Notice and the Question and Answer Booklet, the former governs; and the Court, acting through the Claims Office, reserves the right to make changes in, or additions to, the Question and Answer Booklet, as well as to make typographical, grammatical, and other non-substantive changes in the Booklet during the printing process.

This the 29th day of December, 1995.

/s/ Sam C. Pointer, Jr.
Chief Judge

QUESTION AND ANSWER BOOKLET

ANSWERS TO COMMON QUESTIONS

ABOUT THE REVISED BREAST IMPLANT SETTLEMENT PROGRAM

CLAIMS OFFICE
P.O. BOX 56666
HOUSTON, TEXAS 77256

DECEMBER 27, 1995

Telephone Numbers:

Claims Office	800/600-0311 or 713/951-9106
Information Line	800/887-6828 or 713/752-2515
Computer Bulletin Board	713/951-9420
Fax	713/951-9427

Q36. I want to participate in the new program, but I have no idea who made my implants. How much time do I have to research this? What is the deadline to get this information to the Claims Office?

A. There is currently no deadline set for filing this proof (other than it must be filed by the expiration of the 15-year life of the program). If, however, you are a current claimant, you must file this proof and form by December 16, 1996, or you will be reclassified as an "other registrant."

Q37. I remember being told when I had my surgery in 1981 that my implants were McGhan, but I don't have the records yet to prove that fact. Can I send in the Proof of Manufacturer form now, and try to find the proof later?

A. You should not send in that form with clearly unacceptable proof or no proof at all. You may, however, send in proof -- even though not addressed by the existing rules - that reliably establishes what kind of implant you received. The Claims Office will then advise you if new rules have been adopted to cover your situation or the participating companies have declined to accept your type of proof.

Q38. I had my McGhan implants implanted in late August, 1984. It seems logical to me that they were manufactured before August 3, 1984. How can I prove that I am eligible for the 3M benefits, and not just for the post 8/84 McGhan benefits?

A. If you submit a certified copy of your medical records containing the package label from your implants, and the label has "3M" on it, you are eligible for the 3M benefits. If you cannot prove it was a 3M implant by providing the package label, 3M and McGhan have agreed to provide an identification packet that should help you determine and prove when your implants were manufactured. Please call the Claims Office and request that packet. We will mail it to you as soon as it is available. Unless you send us acceptable proof that the implants you received were indeed manufactured by 3M, your claim will be processed with those implants treated as post 8/84 McGhans.

Q39. The Proof of Manufacturer form has a place for me to explain why I can't identify who made my implants. Can't I fill out that portion of the form instead of filing proof of my covered implant, and still participate in this program?

A. No. To be eligible for benefits, you must submit the required proof of having a covered implant. The portion on the Proof of Manufacturer form for describing your unsuccessful efforts to identify an implant is only for other implants in your history.

Q40. I included my implant history with my registration form back in 1994. Since you already have this information, do I have to complete the implant history portion of the Proof of Manufacturer form?

A. Yes. You must complete the entire form if you want to participate in this revised settlement program.

Q41. I have some information about my implants, but I only have some numbers. I can't tell from this exactly who made them or what the brand name was. Can you help me?

A. The settling defendants have provided lists of lot and serial numbers used for their implants. If you have one of these lot or serial numbers, but no brand name or manufacturer information, call the Claims Office, and we will send you those lists. If you need additional assistance, please call the Claims Assistance Office at 513/651-9770.

Q42. My answers on my Proof of Manufacturer form are going to be different from what I stated earlier on my registration form. I earlier answered that I had Dow Corning implants but now discover from using the brand name list (or from getting my medical records) that they weren't

EXHIBIT 2

Interoffice Correspondence

American Hospital Supply Corporation

Executive Offices

DATE: March 30, 1973
FROM: W.R. PIERIE
LTR OF SUBJ: Heyer-Schulte -- An Overview

TO: TOM COWLEY - XO ✓
BILL REGAN - 2020

cc: B. Hoesman - XO
H. Bernthal - XO
J. Crotty - XO

On March 12, 1973, Jim Rudy and I made a site visit to Heyer-Schulte in Santa Barbara, California. This brief summary of our visit represents a simple overview of Heyer-Schulte's operations, primarily from an engineering and manufacturing standpoint.

1. General - The company currently occupies a two-story structure and four trailers near the airport at Santa Barbara. The facility is divided into many, many small rooms much like the original facility on Dyer Road for Edwards Laboratories. Each room accommodates perhaps two to no more than six employees where manufacturing operations of various sorts are performed. More on this later.

The best way to describe Heyer-Schulte's business is perhaps to simply state that the business is of the "Mom and Pop shop" type which simply recognized a void in the marketplace and managed to fill the void by manufacturing a variety of products almost on custom-made bases to neurosurgeons and, more recently, plastic surgeons by simply making a wide variety of very low-volume, special silicone elastomer products. Their catalog is evidence of this philosophy in that the number of products manufactured are numerous and the catalog is filled with data sheets, each of which states the name of a specific medical user of the product. Via this means, they have established for themselves a very clean and excellent reputation in the fields of neurosurgery and plastic surgery with numerous very happy customers who respect them for their responsiveness to the needs of the medical profession. In fact, they have a custom shop where they will make special Silastic substrate prostheses for facial implants, etc. The doctors seem to love them for this; and as a result, they will buy the rest of the Heyer-Schulte product line. Although they have tried to expand

PLAINTIFF'S EXHIBIT 2

BAX 29815

TO COWLEY
REGAN

DATE: March 30, 1973
FROM W. R. PIERIE
LTR. OF
SUBJ Heyer-Schulte

1. (continued)

internationally, their success to date has been primarily in the domestic marketplace and especially in localized regions such as California and the Southeast.

2. Heyer-Schulte's Products - It is safe to say, and probably accurate to say, as well, that none of Heyer-Schulte's products are engineered. One possible exception would be a new experimental product called a cystometer used in the field of urology. Quite frankly, this is a piece of capital equipment, and Rudy Schulte is rather disenchanted with pursuing this product even if it turns out to be successful, because he is not interested in caring for all the problems related to servicing of capital goods. All of the remainder of his products are disposables consisting of silicone rubber implant prostheses or special drain tubes, catheters, etc. The silicone rubber products are not manufactured to close tolerances. They are combinations of purchased silicone rubber extrusions or calendared sheets combined with small, compression-molded silicone rubber parts or dipped silicone rubber subassemblies, all bonded together by the use of RTV or other adhesives. Until a little more than a year ago, their entire drawing system consisted essentially of hand-sketches. Rudy Schulte indicates that now, all products are defined by drawings although we did not personally see his drawing system. The patent situation will be pursued in depth by Bill Regan with help from Jack Lungmus as required; but it is doubtful that any patents of real significance exist.

Heyer-Schulte has one engineer in its staff. The only man with an engineering degree is Don McGann, who is a former Dow Corning employee and works as the Vice President of Marketing. To my knowledge, with the exception of the cystometer, none of their future products are planned to be much different than their present products; that is, essentially they will continue following the path of silicone rubber technology for plastic surgery and neurosurgery.

TO COWLEY
REGAN

DATE March 30, 1973
FROM W. R. PIERIE
LTR. OF.
SUBJ Heyer-Schulte

3. Manufacturing - Their products consist of assemblies of small parts in simple shapes. They are not critical in dimension or general processing demands. All products are now shipped non-sterile. Their manufacturing costs can be minimized. As a result, they have been able to produce a return of 18% NEAT as a percentage of sales. If they continue to grow and follow this path, present manufacturing techniques can probably be expanded consistent with growth and a high gross profit margin can be expected to continue. Capital investment will be required, however, to increase the rate of production. Now everything is done by hand, and they are very crowded. They plan to move this summer to a 30,000 square foot facility which should be considerably better than what they have, but it might be austere if pending medical devices legislation comes to pass in the immediate future.

4. Sterility, Toxicity, etc. - They do not routinely control batches of material or manufacturing processes, and this is an area where we would certainly have to make some improvements to protect ourselves from product liability and regulatory problems. For example, they sell a silica gel-filled mammary prosthesis which the implanting surgeon is to autoclave sterilize. Since the gel is nonsterile and autoclave will only sterilize the surface, if the mammary were to leak, it could lead to massive infection. Their answer to this, however, is that they have not known one to leak, except possibly during implantation; therefore, it is not a problem. A solution, of course, would be to insist that all gel-filled mammary prostheses be radiation sterilized. No problems were apparent that were beyond solution to make manufacturing processes suitable to American Hospital Supply Corporation, but one must recognize that each additional step increases manufacturing cost and will thus have at least a minor adverse effect on earnings.

5. Synergism with Medical Specialties Group - There is no question at all that Heyer-Schulte's product line and their silicone rubber manufacturing know-how would be synergistic with the Medical Specialties Group. Discussions with Bill Bartlett revealed that Dow Corning is developing its own marketing organization and

TO COWLEY
REGAN

DATE: March 30, 1973
FROM: W. R. PIERIE
LTR OF SUBJ: Heyer-Schulte

5. (continued)

that he envisions that within two years Dow Corning will probably discontinue using V. Mueller as a distributor, just as Howmedica did recently. V. Mueller expects to sell $3 million in Dow Corning mammary prostheses in the year 1973. It is obvious, then, that Heyer-Schulte, with its manufacturing capability, good line of products, and respected image in their marketplace, in combination with V. Mueller's sales force could represent a winner, assuming that the company could be acquired at a reasonable price. It should be recognized that every product that Heyer-Schulte manufactures could be manufactured by American Hospital Supply Corporation but nothing comes without investment. Essentially, considerable dollars would have to be invested to develop the technology and team to compete against Heyer-Schulte, and it might take a long time to earn a reputation such as theirs in the medical/professional marketplace.

All in all, although there are some rough spots and, most certainly, American Hospital Supply Corporation could do a great deal to help them prepare to beat the regulatory compliance threats of the future, Heyer-Schulte is a company of interest to us and would fit well into the Medical Specialties Group, assuming the price is right.

WRP/mm

EXHIBIT 3

Debra E. Pole (State Bar No. 97316)
Kathryn C. Gregman (State Bar No. 123117)
Karen S. Bril (State Bar No. 119633)
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BAXTER HEALTHCARE CORPORATION

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN DIEGO

IN RE COORDINATED BREAST IMPLANT LITIGATION	CASE NO. JCCP-2754
	RESPONSES TO INTERROGATORIES
GENERIC FILING	

PROPOUNDING PARTIES: ALL PLAINTIFFS IN THE CALIFORNIA COORDINATED PROCEEDINGS

RESPONDING PARTIES: BAXTER HEALTHCARE CORPORATION

SET NUMBER: ONE (1)

PRELIMINARY STATEMENT AND GENERAL OBJECTIONS

Baxter Healthcare Corporation ("Baxter") has never designed, manufactured or marketed breast implants. Therefore, Baxter was not in the business of designing, manufacturing or marketing breast implants on the dates that plaintiffs allegedly received their breast implants. Baxter's involvement in this litigation is solely limited to and is a result of its merger with American Hospital Supply Corporation, an Illinois Corporation.

Heyer-Schulte Corporation, a California corporation (H-S) manufactured and sold breast implants. On August 20, 1974, American Hospital Supply Corporation (AHSC

Baxter
Heyer-Schulte

PRODUCT DESIGN/SPECIFICATION DEVELOPMENT

INTERROGATORY NO. 12:

Please IDENTIFY every style, type, or model of BREAST IMPLANT that YOU manufactured, sold, and/or distributed and, for each, provide the following information:

(a) The name, number or other identifier by which such implant was sold;

(b) The model name, number or other identifier associated with each such impl

(c) The IDENTITY of the designer of each such implant;

(d) The sizes in which each such implant was offered;

(e) A description of the distinguishing features of each style, or type, and mod including without limitation the type of shell, filler and any valve used;

(f) The date each style, or type, model and size of implant was first manufactu

(g) The date each style, or type, model and size of implant was last manufactu

(h) The dates during which each style, or type, model and size of implant was marketed;

(i) IDENTIFY the PERSON most knowledgeable regarding the decision to mar each style, or type, and model of implant;

(j) State the reason(s) for the decision to market each style, or type, and model implant;

(k) IDENTIFY the PERSON most knowledgeable regarding the decision to discontinue marketing each style, or type, and model of implant; and

(l) State the reason(s) for the decision to discontinue marketing each style, or t and model of implant.

RESPONSE TO INTERROGATORY NO. 12:

Baxter objects to this interrogatory on the following grounds:

Heyer-Schulte manufactured several different types of breast implants over the cour of many years. To provide information for each of the subsections for every style, type or model of breast implant is unduly burdensome and oppressive.

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However without waiving the above objections, Baxter responds as follows

(2-h) Between August 20, 1974, the date American Hospital Supply Corporation acquired Heyer-Schulte, and March 30, 1984, the date American Hospital Supply Corporation divested its mammary prostheses product lines to Mentor Corporation the following breast implants were manufactured and distributed by Heyer-Schulte. This response does not include information regarding special and custom mammary prostheses manufactured by Heyer-Schulte as Baxter is not in possession of such information

Name:	Heyer-Schulte Gel-Filled mammary prosthesis
Type of Implant:	Silicone elastomer gel-filled mammary prosthesis with optional fixation patch or optional orientation tab; was available in various sizes
Designer:	Style 2000, a modified tear drop shape, was originally designed by John E. Williams, M.D., 2080 Century Park East, Los Angeles, CA 90067; Style 2100, a round shaped mammary prosthesis, was originally designed by Kurt Wagner, M.D., 9400 Brighton Way, Beverly Hills, CA 90210; Style 2200, a low profile shape, was originally designed by H.E. Sterling, M.D., 301 Bastanchury Road, Fullerton, CA 92632
Mfg. and Market Dates:	Approximately 1971 through March 30, 1984

Catalog Numbers:			
	350-2012	350-2013	350-2014
	350-2015	350-2016	350-2017
	350-2020	350-2021	350-2030
	350-2031	350-2060	350-2061
	350-2090	350-2091	350-2092
	350-2093	350-2094	350-2095
	350-2110	350-2111	350-2114
	350-2115	350-2116	350-2117
	350-2120	350-2121	350-2124

350-2125	350-2130	350-2131
350-2132	50-2133	350-2214
350-2215	350-2218	350-2219
350-2222	350-2223	350-2224
350-2225	350-2226	350-2227
350-2230	350-2231	350-6125
350-6150	350-6175	350-6200
350-6225	350-6250	350-6275
350-6300	350-6350	350-6400
350-6450	351-6125	351-6150
351-6175	351-6200	351-6225
351-6250	351-6275	351-6300
351-6350	351-6400	351-6452
350-7100	350-7125	350-7150
350-7175	350-7200	350-7225
350-7250	350-7275	350-7300
350-7325	350-7350	350-7400
350-7450	351-7100	351-7125
351-7150	351-7175	351-7200
351-7225	351-7250	351-7275
351-7300	351-7325	351-7350
351-7400	351-7450	350-8150
350-8175	350-8225	350-8250
350-8275	350-8325	350-8375
351-8150	351-8175	351-8225
351-8250	351-8275	351-8325
351-8375		

Name:	Heyer-Schulte Hanley Combination Gel-Inflatable mammary prosthesis
Type of Implant:	Combination gel-inflatable, silicone gel-filled prosthesis enclosed within a larger silicone elastomer inflatable prosthesis which features a retention valve; was available in various sizes
Designer:	John Hanley, M.D., 1938 Peachtree Road, N.W., Suite A, Atlanta, Georgia 30309
Mfg. and Market Dates:	Approximately 1975 through March 30, 1984

Catalog Numbers:

350-3012	350-3013	350-3014
350-3015	350-3016	350-3017
350-3020	350-3021	350-3030
350-3031	350-3060	350-3061
350-3110	350-3111	350-3112
350-3113	350-3114	350-3115
350-3116	350-3117	350-3118
350-3119	350-3120	350-3121
350-3130	350-3131	
350-3214	350-3215	350-3218
350-3219	350-3222	350-3223
350-3224	350-3225	350-3226
350-2230	350-2231	350-6125
350-3227		
360-7150	360-7175	360-7275
360-7175	360-7325	360-7425
360-6175	360-6200	360-6625
360-6300	360-6350	360-6450
360-5175	360-5200	360-5225

	350-1920	350-1930	350-1940
	350-1950		

Name: Natural Y mammary prosthesis

Type of Implant: Silicone gel-filled mammary prosthesis with a "Y" shaped divider inside and a polyurethane outer covering; was available in various sizes

Designer: William John Pangman, II, M.D. (deceased)
Franklin Ashley (deceased)

Mfg. and Market Dates: Approximately 1969 through April 20, 1978

Catalog Numbers:

350-1570	350-1572	350-1574
350-1576	350-1578	350-1580
350-1582	350-1571	350-1573
350-1575	350-1577	350-1579
350-1581	350-1583	350-1569
MM-570	MM-571	MM-572
MM-573	MM-574	MM-575
MM-576	MM-577	MM-578
MM-579	MM-580	MM-581
MM-582	MM-583	

Name: Gel-Saline Reconstructive mammary prosthesis

Type of Implant: An adjustable volume, gel-filled, polyurethane foam covered mammary prosthesis which allowed for staged normal saline injections at later intervals; was available in various sizes

Designer: Richard Jobe, M.D., 762 Los Altos Oaks Drive, Los Altos, California 94022

Mfg. and Market Dates:	Approximately 197[illegible]		
Catalog Numbers:	350-2714	350-2715	350-2718
	350-2722	350-2723	350-2724
	350-2725	350-2726	350-2727
	350-2730	350-2731	

Name:	Polyplastic Adjustable Volume mammary prosthesis
Type of Implant:	Inflatable mammary prosthesis with a contoured inner polyurethane sponge encapsulated within a silicone rubber envelope
Designer:	William John Pangman, II. M.D. (deceased)
Mfg. and Market Dates:	Approximately 1971
Sizes:	1-6

Name:	New Polyplastic - Silicone Compound Prosthesis for Breast Augmentation (Pangman Technique)
Type of Implant:	A polyurethane core, encapsulated in silicone rubber, encapsulated in very thin sheath of polyurethane
Designer:	William John Pangman, II. M.D. (deceased)
Mfg. and Market Dates:	Unknown
Sizes:	1-5

Name:	Tabari Inflatable mammary prosthesis
Type of Implant:	A seamless silicone rubber inflatable mammary prosthesis with an integral pocket on the posterior surface for the insertion of the fill to
Designer:	Kuros Tabari, M.D., F.A.C.S., 25 North 14th Street, Suite 104[illegible] San Jose, California 95112

Mfg. and Market Dates:	Unknown
Sizes:	A, B, C
Name:	Inflatable Mammary Prosthesis as used by Diran M. Seropian, M.D.
Type of Implant:	A seamless silicone elastomer inflatable mammary prosthesis with a one-way retention valve and a positive secondary plug
Designer:	Diran M. Seropian, M.D. 1930 N.E. 47th Street, Suite 308, Fort Lauderdale, Florida 33308
Mfg. and Market Dates:	Unknown
Sizes:	Small, Medium, Large, X-large

(i-l) Based on Baxter's review of available Heyer-Schulte documents, Baxter is unable to identify the person most knowledgeable regarding the decision to market each breast implant, and is unable to state the reason for the decision to market each breast implant. The person most knowledgeable regarding the decision to discontinue the manufacture of the Natural Y product line was James Rudy, former President of Heyer-Schulte. Other than the Natural Y product lines, the Heyer-Schulte mammary prostheses product lines were not discontinued. The product lines were divested by AHSC to Mentor Corporation on March 30, 1984. The documents relating to the divestiture are identified as BAX 74782-75700; 276489-276622.

INTERROGATORY NO. 13:

For each style, or type, and model of BREAST IMPLANT that YOU manufactured, sold, and/or distributed, please describe the following:

(a) Any distinctive feature incorporated into the design of such BREAST IMPLANT that allows YOU to IDENTIFY the implant, upon physical examination, as manufactured by YOU or allows YOU to IDENTIFY the specific style, type or model; and

(b) Any test or analysis that can be applied to an explanted implant that can provide a basis to determine the manufacturer, model, type and/or style of such implant.

VERIFICATION

I, J. Patrick Fitzsimmons, state that I am Assistant Secretary for Baxter Healthcare Corporation and as such am authorized to and do make this verification on its behalf. I have read the foregoing and verify that the information contained herein was supplied by others within the Company and is true and correct to the best of my knowledge, information and belief.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this verification was executed on December 6, 1993, at Deerfield, Illinois.

J. Patrick Fitzsimmons
Assistant Secretary

DATE: December 6, 1993

STATE OF ILLINOIS)
) SS.
COUNTY OF LAKE)

Subscribed and sworn to before me on the 6th day of December, 1993.

Notary Public

"OFFICIAL SEAL"
ANN BERWALD
Notary Public, State of Illinois
My Commission Expires 5/30/97

EXHIBIT 4

CAUSE NO. 92-16550

IN RE:	§	IN THE DISTRICT COURT OF
	§	
SILICONE BREAST	§	HARRIS COUNTY, T E X A S
IMPLANT LITIGATION	§	
	§	157TH JUDICIAL DISTRICT

MEDICAL ENGINEERING CORPORATION'S
SECOND AMENDED ANSWERS TO PLAINTIFFS' INTERROGATORIES

PRELIMINARY STATEMENT

Medical Engineering Corporation states that in the preparation of its responses to plaintiffs' interrogatories, Medical Engineering Corporation has made, and continues to make, a concerted good faith effort to collect all of the requested information or documents.

Medical Engineering Corporation will not produce any documents generated by its counsel directed to other counsel or to their officers, directors or employees regarding legal matters, and will not produce any documents generated by the officers, directors or employees of Medical Engineering Corporation to its counsel regarding legal matters. Medical Engineering Corporation will not produce any documents which are work-product drafted by attorneys employed by Medical Engineering Corporation. As for its responses to interrogatories, Medical Engineering Corporation states that when the requested information is readily available from documents, the documents will be produced or have been made available as noted in individual interrogatory responses. In response to requests for documents and interrogatories, Medical Engineering Corporation will produce information relevant to breast implants.

Medical Engineering Corporation reserves the right to change its responses if it appears from additional research that omissions or errors have been made herein or that further or more accurate information should be provided. Furthermore, Medical Engineering Corporation has not completed discovery in this action. Because the responses contained herein are based only

V E R I F I C A T I O N

STATE OF NEW YORK)
: ss.:
COUNTY OF NEW YORK)

STEPHEN CHESNOFF, being first duly sworn, deposes and says that he is the Assistant Secretary of Medical Engineering Corporation, the defendant herein; that he has read the foregoing Medical Engineering Corporation's answers to plaintiffs' Interrogatories by him subscribed and knows the contents thereof; that said answers were prepared with the assistance and advice he has relied; that the answers set forth herein, subject to inadvertent and undiscovered errors, are based on and therefore necessarily limited by the records and information still in existence, presently recollected and thus far discovered in the course of the preparation of these answers; that he and Medical Engineering Corporation consequently reserve the right to make any changes in the answers if it appears at any time that omissions or errors have been made therein or that more accurate information is available; that subject to the limitations set forth herein the said answers are true to the best of his knowledge, information and belief.

STEPHEN CHESNOFF
Assistant Secretary

Sworn to before me this 4
day of December, 1995.

Claire Mansfield
Notary Public

CLAIRE MANSFIELD
Notary Public, State of New York
No. 4918491
Qualified in Nassau County
Commission Expires February 1, 1996

MESB:S44265.1

INTERROGATORY NO. 12:

Please list separately by brand name and type each style of breast implants manufactured and/or marketed by Defendant. Please include the following information concerning each style of breast implant listed: (a) the date manufacturing commenced and the date manufacturing ceased; (b) the date marketing commenced and the date marketing ceased; (c) the name of each person who had responsibility in the decision to cease manufacturing or marketing; (d) the name of each person who had responsibility for the design or modification of the design of each style breast implant; (e) the reason the particular style of implant was discontinued; (f) any patent or licensing agreement that pertains to the breast implant or its component parts; (g) the type and kind of substance used to fill the envelope(s) of each implant; (h) the chemical composition of each component part or ingredient used to manufacture the implant.

ANSWER:

1) Perras-Papillon Axillary Prolongation
   (a) 1/71 - 11/79;
   (b) 1/71 - 11/79;
   (c) Management decision;
   (d) Drs. Perras and Papillon;
   (e) Lack of market demand;
   (f) Patent will be produced;
   (g) Silicone gel;
   (h) Silicone gel, silicone elastomer.

2) Modified Teardrop Gel
   (a) 10/72 - 7/91;
   (b) 10/72 - 7/91;
   (c) Management decision;
   (d) Dr. Gilbert Snyder;
   (e) Medical Engineering Corporation's decision not to file a Premarket Approval Application for this model;
   (f) Royalty agreement will be produced;
   (g) Silicone gel;
   (h) Silicone gel, silicone elastomer.

3) Contour Georgiade
   (a) 10/73 - 3/88;
   (b) 10/73 - 3/88;
   (c) Management decision;
   (d) Dr. Nicholas Georgiade;
   (e) Lack of market demand;

(f) Royalty agreement will be produced;
(g) Silicone gel;
(h) Silicone gel, silicone elastomer.

4) Oval Gel
(a) 10/73 - 7/91;
(b) 10/73 - 7/91;
(c) Management decision;
(d) "Me too" product;
(e) Medical Engineering Corporation's decision not to file a Premarket Approval Application for this model;
(f) None;
(g) Silicone gel;
(h) Silicone gel, silicone elastomer.

5) Round Gel
(a) 10/73 - 7/91;
(b) 10/73 - 7/91;
(c) Management decision;
(d) "Me too" product;
(e) Medical Engineering Corporation's decision not to file a Premarket Approval Application for this model;
(f) None;
(g) Silicone gel;
(h) Silicone gel, silicone elastomer.

6) Inflatable
(a) 11/74 - 6/79;
(b) 11/74 - 6/79;
(c) Management decision;
(d) "Me too" product;
(e) Economics of production and associated QC procedures in conjunction with deflation concerns;
(f) Patent on SSI Valve will be produced;
(g) Saline;
(h) Saline, silicone elastomer.

7) Gel/Saline s/SSI Valve
(a) 9/76 - 3/88;
(b) 9/76 - 3/88;
(c) Management Decision;
(d) Dr. Robert Wood;
(e) Lack of market demand;
(f) Royalty agreement will be produced;

(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

8) Bi-Lumen w/SSSI Valve
(a) 1/77 - 11/79;
(b) 1/77 - 11/79;
(c) Management Decision;
(d) Dr. John Munna;
(e) Economics of production and associated QC procedures in conjunction with deflation concerns;
(f) Consulting agreement will be produced;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

9) Contour Georgiade Bi-Lumen w/SSSI Valve
(a) 12/77 - 8/81;
(b) 12/77 - 8/81;
(c) Management Decision;
(d) Dr. Nicholas Georgiade;
(e) Economics of production and associated QC procedures in conjunction with deflation concerns;
(f) Royalty agreement will be produced;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

10) Low Volume Bi-Lumen w/SSSI Valve
(a) 11/79 - 3/88;
(b) 11/79 - 3/88;
(c) Management Decision;
(d) Dr. John Munna;
(e) Lack of market demand;
(f) Consulting agreement will be produced;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

11) High Volume Bilumen w/SSSI Valve
(a) 11/79 - 1/81;
(b) 11/79 - 1/81;
(c) Management decision;
(d) No one;
(e) Economics of production and associated QC procedures in conjunction with deflation concerns;
(f) None;
(g) Saline, silicone gel;

(h) Saline, silicone gel and silicone elastomer.

12) Low Volume Bilumen w/Quin-Seal Valve
(a) 4/81 - 10/88;
(b) 4/81 - 10/88;
(c) Management decision;
(d) Dr. John Munna;
(e) Lack of market demand;
(f) Consulting agreement will be produced;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

13) Gel/Saline w/Quin-Seal Valve
(a) 7/81 - 10/88;
(b) 7/81 - 10/88;
(c) Management decision;
(d) No one;
(e) Lack of market demand;
(f) None;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

14) Teardrop Gel/Saline w/Quin-Seal Valve
(a) 7/81 - 10/88;
(b) 7/81 - 10/88;
(c) Management decision;
(d) No one;
(e) Lack of market demand;
(f) None;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

15) Contour Georgiade Bi-Lumen w/Quin-Seal Valve
(a) 8/81 - 3/88;
(b) 8/81 - 3/88;
(c) Management decision;
(d) Dr. Nicholas Georgiade;
(e) Lack of market demand;
(f) Royalty agreement will be produced;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

16) Contour Georgiade (Hi-Profile) Bi-Lumen w/Quin-Seal Valve
(a) 5/82 - 9/88;

(b) 5/82 - 9/88;
(c) Management decision;
(d) Dr. Nicholas Georgiade;
(e) Lack of market demand;
(f) Royalty agreement will be produced;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

17) High Profile Round Gel
(a) 7/82 - 7/91;
(b) 7/82 - 7/91;
(c) Management decision;
(d) No one;
(e) Medical Engineering Corporation's decision not to file a Premarket Approval Application for this model;
(f) None;
(g) Silicone gel;
(h) Silicone gel and silicone elastomer.

18) Adjustable Reconstructive-Teardrop
(a) 10/83 - 10/88;
(b) 10/83 - 10/88;
(c) Management decision;
(d) Rita Taylor and Lance LaForest;
(e) Lack of market demand;
(f) Patent will be produced;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

19) Round Adjustable Reconstructive
(a) 1/84 - 10/88;
(b) 1/84 - 10/88;
(c) Management decision;
(d) Rita Taylor and Lance LaForest;
(e) Lack of market demand;
(f) Patent will be produced;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

20) SCL Round Gel
(a) 11/86 - 3/88;
(b) 11/86 - 3/88;
(c) Bristol-Myers Squibb Company's decision;
(d) No one;

(e) The FDA's decision not to proceed with a full scale review of Medical Engineering Corporation's Pre-market Approval Application;
(f) None;
(g) Silicone gel;
(h) Silicone gel and silicone elastomer.

21) SCL Hi-Pro Round Gel
(a) 3/88 - 9/91;
(b) 3/88 - 9/91;
(c) Bristol-Myers Squibb Company's decision;
(d) No one;
(e) The FDA's decision not to proceed with a full scale review of Medical Engineering Corporation's Pre-market Approval Application;
(f) None;
(g) Silicone gel;
(h) Silicone gel and silicone elastomer.

22) SCL Teardrop Gel
(a) 3/88 - 9/91;
(b) 3/88 - 9/91;
(c) Bristol-Myers Squibb Company's decision;
(d) No one;
(e) The FDA's decision not to proceed with a full scale review of Medical Engineering Corporation's Pre-market Approval Application;
(f) None;
(g) Silicone gel;
(h) Silicone gel and silicone elastomer.

23) SCL Broad Base Round Gel
(a) 3/88 - 9/91;
(b) 3/88 - 9/91;
(c) Bristol-Myers Squibb Company's decision;
(d) No one;
(e) The FDA's decision not to proceed with a full scale review of Medical Engineering Corporation's Pre-market Approval Application;
(f) None;
(g) Silicone gel;
(h) Silicone gel and silicone elastomer.

24) SCL Gel/Saline w/Quin-Seal Valve
(a) 10/88 - 9/91;
(b) 10/88 - 9-91;
(c) Bristol-Myers Squibb Company's decision;
(d) No one;

(e) The FDA's decision not to proceed with a full scale review of Medical Engineering Corporation's Pre-market Approval Application;
(f) None;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

25) SCL Adjustable Reconstructive
(a) 10/88 - 9/91;
(b) 10/88 - 9/91;
(c) Bristol-Myers Squibb Company's decision;
(d) No one;
(e) The FDA's decision not to proceed with a full scale review of Medical Engineering Corporation's Pre-market Approval Application;
(f) None;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

26) SCL Bi-Lumen w/Quin-Seal Valve
(a) 10/88 - 9/91;
(b) 10/88 - 9/91;
(c) Bristol-Myers Squibb Company's decision;
(d) No one;
(e) The FDA's decision not to proceed with a full scale review of Medical Engineering Corporation's Pre-market Approval Application;
(f) None;
(g) Saline, silicone gel;
(h) Saline, silicone gel and silicone elastomer.

27) Dahl Inflatable Implant
(a) circa 1974
(b) circa 1974
(c) Management decision
(d) Wilfred Lynch and Dr. Carl Dahl
(e) Lack of market demand
(f) See 5/20/75 patent at the following range in the MDL Depository:
MED 21468-21473
(g) Silicone gel
(h) Silicone gel

In addition, Medical Engineering Corporation states that it occassionally manufactured custom breast implants pursuant to a request from a particular plastic surgeon.

EXHIBIT 5

Master No. 92-16550

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

RESPONSES OF CUI CORPORATION TO
PLAINTIFFS' MASTER INTERROGATORIES

Defendant CUI Corporation (CUI) responds to Plaintiffs' Master Interrogatories as follows:

PRELIMINARY STATEMENT

Cox-Uphoff Corporation was incorporated in California on or about September 18, 1975, and at or about that time began making breast implants. On or about May 25, 1989, INAMED Corporation acquired Cox-Uphoff Corporation and its name was changed to CUI Corporation. Since May 25, 1989, CUI has operated as a wholly-owned subsidiary of INAMED Corporation. From January 1990 to June 1991, CUI was in Chapter 11 bankruptcy. Since emerging from bankruptcy, CUI has had little or no involvement in the manufacture and sale of silicone gel-filled breast implants. Most of the persons knowledgeable about the history of the Cox-Uphoff silicone gel-filled breast implant product line have left the company, making it difficult to answer these interrogatories.

The following four companies were subsidiaries of Cox-Uphoff Corporation. On May 25, 1989 Cox-Uphoff Corporation was acquired by INAMED Corporation, at which time its name was changed to CUI Corporation. Also on May 25, 1989, the Cox-Uphoff subsidiaries became subsidiaries of INAMED Corporation.

1. Cox-Uphoff International, Inc. - incorporated in Nevada.

2. Cox-Uphoff International, Inc. - incorporated in the Northern Mariana Islands in January 1985.

3. Cox-Uphoff Netherlands, B.V. - incorporated in the Netherlands, and dissolved in 1992.

4. Silicone Engineering, Inc. - incorporated in California.

c.-e. The following is a list of silicone gel-filled breast implants that have been manufactured by CUI Corporation and its predecessors, including the dates of beginning and ending manufacture:

STYLE	DESCRIPTION
TRL	TRI-LUMEN MAMMARY PROSTHESIS (July 1983-November 1988)
EHP	ENHANCED HIGH PROFILE MAMMARY PROSTHESIS (December 1985-July 1991)
RDL	REVERSE DOUBLE LUMEN MAMMARY PROSTHESIS (May 1982-January 1990)
SLP	SINGLE LUMEN SALINE ADJUSTABLE MAMMARY P (August 1987-July 1991)
RHD	DRIE ROUND HIGH PROFILE MAMMARY PROS. (August 1987-July 1991)
DRI	DRIE II ROUND LOW PROFILE MAMMARY PROS. (November 1987-July 1991)
RDD	DRIE REVERSE DOUBLE LUMEN MAMMARY PROS. (July 1984-July 1991)

RLP	ROUND LOW PROFILE MAMMARY PROSTHESIS (April 1976-July 1991)
OHP	OVAL HIGH PROFILE MAMMARY PROSTHESIS (April 1976-July 1991)
RCP	ROUND CONICAL PROFILE MAMMARY PROS. (April 1976-January 1990)
OLP	OVAL LOW PROFILE MAMMARY PROSTHESIS (April 1976-July 1991)
SGR	SALINE GEL ROUND MAMMARY PROSTHESIS (June 1977-July 1991)
SGO	SALINE GEL OVAL MAMMARY PROSTHESIS (June 1977-March 1990)
RHP	ROUND HIGH PROFILE MAMMARY PROSTHESIS (January 1983-July 1991)
RLD	DRIE ROUND LOW PROFILE MAMMARY PROS. (March 1986-July 1991)
RDX	RDL-XPAND MAMMARY EXPANDER/PROSTHESIS (July 1986-January 1990)

f.-g. CUI has never sold or acquired any silicone gel-filled breast implant product lines from any other entities.

INTERROGATORY NO. 5:

List and describe the history and transfer from Cox-Uphoff to Inamed Corporation, including but not limited to the following:

a. the type of transfer and manner in which the transfer was accomplished;

b. the date and all facts relating to the acquisition by Inamed Corporation of Cox-Uphoff Corporation;

c. the investment banking firms or banks involved in the acquisition;

d. the stock brokerage firm that handled the transfer;

e. who performed the "due diligence" on the transfer; and

ANSWER:

See response to Interrogatory No. 14 which is incorporated herein by reference.

Respectfully submitted,

HOLTZMAN & URQUHART

By: James B. Warren

JAMES B. WARREN
TBA No. 20886500
900 Two Houston Center
909 Fannin Street
Houston, Texas 77010
(713) 739-0000
FAX (713) 739-8432

ATTORNEYS FOR DEFENDANT
MINNESOTA MINING AND
MANUFACTURING COMPANY

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document has been forwarded to designated counsel of record on this 21st day of September, 1992.

James B. Warren
JAMES B. WARREN

[illegible]

EXHIBIT 6

PALMIERI, TYLER, WIENER, WILHELM & WALDRON
Frank C. Rothrock, Bar No. 54452
John R. Lister, Bar No. 105979
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PREUSS, WALKER & SHANAGHER
Charles F. Preuss, Bar No. 45783
Cynthia C. Roenisch, Bar No. 151908
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San Francisco, California 94105

Attorneys for Defendants
McGhan Medical Corporation, CUI Corporation, INAMED Corporation, INAMED Development Company, Minnesota Mining and Manufacturing Company and Donald McGhan

SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN DIEGO

IN RE COORDINATED BREAST IMPLANT LITIGATION	Case No. JCCP-2754
GENERIC FILING	RESPONSE OF DEFENDANTS McGHAN MEDICAL CORPORATION, INAMED CORPORATION AND INAMED DEVELOPMENT COMPANY TO PLAINTIFFS' FIRST SET OF INTERROGATORIES

RESPONDING PARTIES: McGHAN MEDICAL CORPORATION, INAMED CORPORATION AND INAMED DEVELOPMENT COMPANY

SET NUMBER: ONE

PROPOUNDING PARTIES: ALL PLAINTIFFS IN THE CALIFORNIA COORDINATED PROCEEDINGS

Defendants McGhan Medical Corporation ("McGhan"), INAMED Corporation ("INAMED") and INAMED Development Company ("INAMED Development") (hereinafter referred to jointly as "Defendants")

(c) The IDENTITY of the designer of each such implant;

(d) The sizes in which h such implant was offered;

(e) A description of the distinguishing features of each style, or type, and model, including without limitation the type of shell, filler and any valve used;

(f) The date each style, or type, model and size of implant was first manufactured;

(g) The date each style, or type, model and size of implant was last manufactured;

(h) The dates during which each style, or type, model and size of implant was marketed;

(i) IDENTIFY the PERSON most knowledgeable regarding the decision to market each style, or type, and model of implant;

(j) State the reason(s) for the decision to market each style, or type, and model of implant;

(k) IDENTIFY the PERSON most knowledgeable regarding the decision to discontinue marketing each style, or type, and model of implant; and

(l) State the reason(s) for the decision to discontinue marketing each style, or type, and model of implant.

RESPONSE TO INTERROGATORY NO. 12:

Defendants object to Interrogatory No. 12 on the grounds that it is overly broad, unduly burdensome and oppressive. Subject to and without waiver of the foregoing objections, defendants respond as follows:

The following are the types of breast implants manufacture by McGhan and its predecessors, the year introduced and/or discontinued and a brief description of each:

STYLE	DATE INTRODUCED/ DISCONTINUED	DESCRIPTION
80,81,82	1975-1991	•Single Lumen Gel •Standard shell

90,91,92,93, 95	1975-1979	•Single Lumen Saline Inflatable •Standard Shell
70,71,72	1975-1977	•Double Lumen Gel/Saline •Large volume saline ratio •Standard shell
76,77,78	1976-1991	•Double Lumen Gel/Saline •Smaller ratio saline volume •Available in smaller size increments
85	1978-1991	•Single Lumen High Profile Round Gel •Standard shell
20	1979-1983	•Single Lumen Gel •Silica Free Outer Layer of Standard Shell
40	1979-1/1992	•Single Lumen Round Gel •Intrashiel® shell
56,57	1981-1991	•Triple Lumen, Gel/ Saline Reconstructive Implants with inner gel-filled envelope •Standard shell material
60,62,64,66,68	1986-Present	•Single Lumen Saline Inflatable •RTV Shell
50,51	1987-1991	•Reversed Double Lumen Round and Oval Gel/Saline Mammary Expanders with integral injection site •Intrashiel® shell
52,54	1987-1989	•Reversed Double Lumen Round and Oval Gel/Saline Mammary Expanders with removable auto seal remote injection site •Intrashiel® shell

48(246)	1988-1/1992	•Single Lumen Round Gel Filled •U.H.P. shell
46	1989-1/1992	•Double Lumen Gel/Saline •Intrashiel® shell
100	1987-1990	•Single Lumen Round Gel/Saline BIOCELL® textured shell •Intrashiel® shell
110,120	1988-1/1992	•Single Lumen Round Gel •BIOCELL® textured shell •Intrashiel® shell
168	1990-Present	•Single Lumen Saline-Filled Inflatable •BIOCELL® textured shell •RTV shell
278,256	1990-1/1992	•Double and Triple Lumen Reconstructive Implants •U.H.P. shell
148,178,156	1990-1/1992	•Single Lumen and Double and Triple Lumen Gel/Saline •BIOCELL® textured shell •U.H.P. shell
153	1991-1/1992	•BIOCELL® Textured Gel Filled •Anatomically Shaped Reconstructive Implant with inner filled gel envelope •Intrashiel® shell

For additional information concerning these breast implants, see the catalog sheets and package inserts described in the Index attached hereto as Exhibit A, pages 253 and 254.

The major components of all McGhan silicone gel-filled implants are the shell or envelope and the gel. The purpose of

RESPONSE TO INTERROGATORY NO. 90:

Deposition of Donald K. McGhan, In Re Silicone Breast Implant Litigation, Harris County, Texas (10/29/92, 10/30/92, 3/16/93, 3/17/93, 5/3/93, and 5/4/93).

Dated: December 10, 1993

PALMIERI, TYLER, WIENER, WILHELM & WALDRON

By _____
John R. Lister

Attorneys for Defendants McGhan Medical Corporation, CUI Corporation, INAMED Corporation, INAMED Development Company, Minnesota Mining and Manufacturing Company and Donald McGhan

F:\PRODUCT\8520\INTERROG.142
12/09/93

EXHIBIT 7

PRODUCT REFERENCE BOOK

SILASTIC® BRAND MAMMARY IMPLANTS

MANUFACTURED BY DOW CORNING CORPORATION

1964 - 1992

Assembled by

J. A. Vallender and C. J. Burda

June 1992

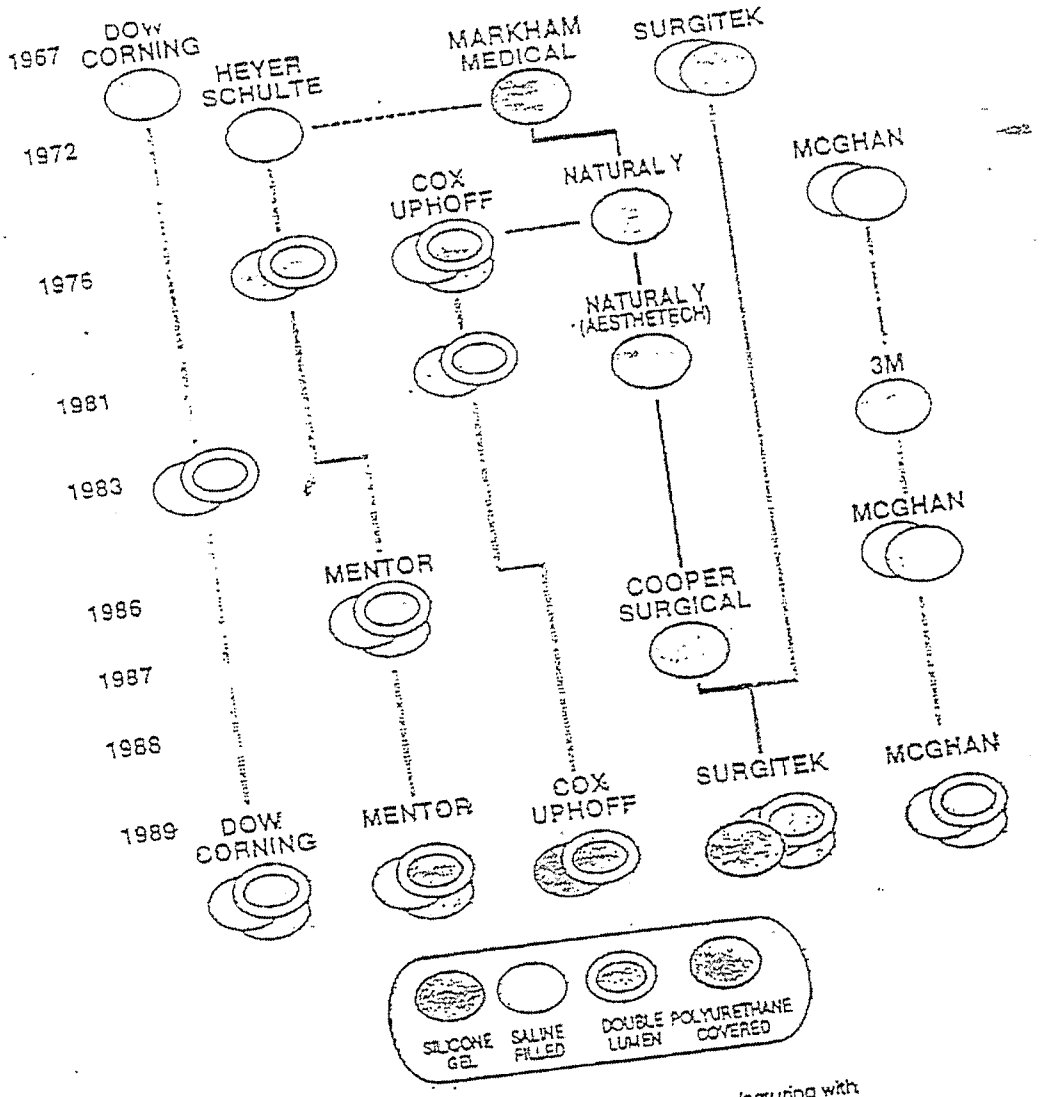

Fig. 6 Highlights of silicone breast implant manufacturing with emphasis on the polyurethane covered implants. This is an incomplete chart with only the major manufacturers who sell in Canada included. The dotted line or name in brackets indicates the plant actually manufacturing the PU implants. This chart does not include information on the newest addition to the market, the textured silicone implant.

DCCK MM 53:

EXHIBIT 10

CLAIMANT
INFORMATION GUIDE

DOW CORNING BREAST IMPLANT CLAIMANTS
(CLASS 5)

Q5-13. What is a "certified copy" of my medical records?

A certified copy is a copy of records with a certificate attached, usually signed by the custodian of records for that office or facility, affirming that the attached pages are true and accurate copies of records in a particular patient's file.

Q5-14. What is an implant package label? How can I recognize it?

An implant package label is a label made by the manufacturer with pre-printed information about the breast implant. The label will almost always have the name of the manufacturer, the type of breast implant (saline, for example), the catalog number, and the lot number. Doctors frequently placed these implant labels in a patient's medical files following the implant surgery.

Q5-15. What does "Cronin" refer to? Is that the name of a breast implant?

"Cronin" is not the name of a breast implant, but of a plastic surgeon — Dr. Thomas Cronin — from Houston, Texas who developed silicone gel breast implants in conjunction with Dow Corning. As a result, breast implants were frequently referred to as "Cronin implants" in medical records prior to 1972. Dow Corning has agreed only for purposes of the Settlement Option to accept the name "Cronin" as acceptable proof of a Dow Corning breast implant if it was used during or between 1963 and 1971.

Q5-16. I remember my doctor telling me (or my relative or a friend) that I had Dow Corning breast implants. Can I rely on that as acceptable proof?

No.

Q5-17. What if I can't get my medical records (for example, the doctor has since died, the records were destroyed or lost, or the doctor won't give them to me)? What can I do?

If you cannot find your implanting physician or his/her office no longer has a copy of your records, you can ask for the name of an appropriate responsible person at that office (such as a nurse, a person in charge of the files or records, or another doctor) who can write a letter stating under oath that you were implanted with a Dow Corning breast implant and stating the basis for this conclusion.

If you cannot locate anyone qualified to write this letter, there may be other ways to show who made your breast implants. For assistance, call the Claims Assistance Program at Toll Free 1-866-874-6099 or e-mail your question to the Settlement Facility at info@sfdct.com.

Q5-18. My proof of manufacturer documents are not covered by the rules above. Can I still submit them?

You may send in proof — even though it is of a type that is not addressed by the existing rules — if it reliably establishes what kind of implant you received. The Settlement Facility will then advise you if new rules have been adopted to cover your situation or if Dow Corning has decided to accept your type of proof through the confidential measures established by the Claims Assistance Program.

EXHIBIT 11

Settlement Facility News

VOLUME III

"A NEWSLETTER FOR BREAST AND OTHER IMPLANT CLAIMS (INCLUDING LARGE AND SMALL JOINT ORTHOPEDIC IMPLANTS, TMJ, CHIN, FACIAL AND PENILE) AND SILICONE MATERIALS"

SFDCT

SETTLEMENT FACILITY

DOW CORNING TRUST

HOUSTON OFFICE (US)
P.O. BOX 52429
HOUSTON, TEXAS 77052-2429
USA
PHONE NUMBER:
(713) 874-6099
TOLL FREE NUMBER: 1 866 874-6099 (WITHIN THE U.S.)
INTERNATIONAL TOLL FREE NUMBER: AT&T DIRECT ACCESS NUMBER + 866 + 874-6099 (OUTSIDE THE U.S.)
EMAIL: INFO@SFDCT.COM

AMSTERDAM OFFICE
P.O. BOX 94355
1090 GJ AMSTERDAM

SPECIAL POINTS OF INTEREST:

- Message From the Claims Administrator
- Effective Date Notice
- Frequently Asked Questions

FOR ADDITIONAL INFORMATION

U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN

WWW.MIED.USCOURTS.GOV/_DOW/DOWDEFAULT.HTM

TORT CLAIMANTS' COMMITTEE
WWW.TORTCOMM.ORG

DOW CORNING
WWW.IMPLANTCLAIMS.COM

A MESSAGE FROM THE CLAIMS ADMINISTRATOR

DEAR CLAIMANT:

The time has finally arrived. We have an Effective Date! I know that is welcome news to all of you who have waited so patiently to settle your claims. Now that we have an Effective Date there are many things that you need to know. This packet contains your Effective Date notice that details the Effective Date, along with the dates and deadlines associated with it. It also contains the Participation Form, the form you will use to elect to settle, reject the settlement option or withdraw your claim from the Dow Corning Bankruptcy. In addition, the Settlement Facility has provided you with Volume 3 of Settlement Facility News, the latest edition of the newsletter that focuses mainly on the latest questions asked by claimants regarding the Settlement Program.

Now that the Effective Date is in place, it is of the utmost importance that you stay in contact with the Settlement Facility. Pay attention to the correspondence that you receive from the Facility and check our website, www.dcsettlement.com for the latest information. There you will find the latest Frequently Asked Questions, and, in the near future, we hope to unveil our "interactive website" which will allow you to access your claim information in a secure and confidential manner. You may also obtain the final versions of all Plan documents through the Downloads section on our website. In looking at the Participation Form, you should consult your Claimant Information Guides, particularly Sections 2 and 3 that outline the Settlement Options (which vary by class) and the Litigation Option.

Should you have any questions, please contact a Claims Assistance Representative, either by a toll-free telephone call (1-866-874-6099), or through electronic mail (info@sfdct.com). This is an exciting time and we look forward to assisting each of you in the process of settling your claims.

Important Notices:

(1) If you have already signed and returned an unconditional "Waiver of Opt-Out Right" form, then your claim is deemed to be permanently in the Settlement Facility and you cannot opt-out now. Do not complete the Participation Form. A valid Waiver will override a different election on the Participation Form.
(2) Check the Settlement Facility website regularly for new Q&A's. The final, signed version of the Plan Documents will be posted there as well.

New Proof of Manufacturer Protocols and Clarifications—Assistance on Your Proof of Manufacturer

We have worked closely with the Plan Proponents on Plan clarifications, particularly on the Proof of Manufacturer protocols. We are happy to report that since the claim form packages were mailed last year, there are now additional ways to meet the "acceptable" proof standard for your implant. In addition, Claims Assistance has developed a helpful checklist of places to look for your medical records or other identifying information for your proof of manufacturer. This checklist is available at the Settlement Facility website. Below is a summary of the new Plan clarifications or protocols for proof of manufacturer:

1. Rubin
   There may have been references in medical records to "Rubin" implants or labels that state, "Silastic Mammary Implant Rubin Design High Profile Contour, Q7-2573." This implant was commercially available during 1984 through 1986. Credible, contemporaneous documents identifying the claimant's breast implants as "Rubin" implants, "Rubin Design" implants or "Q7-2573" implants would be deemed "acceptable" proof of manufacturer for implants implanted between 1984 and 1986. Any claim outside these years containing the terms "Rubin", "Rubin Design" or "Q7-2573" could be reviewed by Dow Corning on a case-by-case basis at the claimant's request.

2. Ben Gregory
   Approximately 50 breast implant patients were implanted by Dr. Ben Gregory of Florida as part of a Dow Corning-sponsored clinical study. Dow Corning has supplied the names of the study participants to the Settlement Facility and advised that these 50 persons will have acceptable proof of manufacturer of a Dow Corning breast implant for that implantation. If you were implanted by Dr. Ben Gregory or believe that you were a participant in the Ben Gregory clinical study, call the Claims Assistance Program toll free within the U.S. and Canada at 1-866-874-6099 for more information.

3. Internal Affirmative Dow Corning Statements
   A determination made by Dow Corning and documented in internal memoranda that particular implants were in fact made by Dow Corning constitutes "acceptable" proof. To be acceptable, it must be clear that Dow Corning made an independent determination and was not simply reporting on statements made by others.

4. Implants in Dow Corning's Possession
   Dow Corning has a number of implants in its possession that were sent to it by physicians and claimants over the last 20 years. Dow Corning has reviewed some – but not all – of these implants and has sent a letter to the Settlement Facility identifying claimants whose implants were determined to be made by Dow Corning. Contact Claims Assistance to determine if your name is on this list or if your implants are currently in the possession of Dow Corning.

Claims Assistance has developed a helpful checklist of places to look for your medical records or other identifying information for your proof of manufacturer.

5. Affirmative Statements by Implanting Doctors
   The Settlement Facility will accept affirmative statements or affidavits from a physician (or a responsible person at the treating facility where the implantation took place) that otherwise meet the criteria listed in Schedule I of Annex A but were written for a different claimant if the affidavit or statement affirmatively identifies the doctor's use of only certain brands of implants during a specific time period and the claimant provides properly authenticated documents showing that she had implantation surgery by that doctor during the time frame listed in the affirmative statement or affidavit.

EXHIBIT 12

BLIZZARD MCCARTHY & NABERS LLP
440 Louisiana Street, Suite 1710
Houston, TX 77002
Phone: 713-844-3750
Fax: 713-844-3755

Dianna Pendleton-Dominguez
Direct Number: 281-703-0998
or 281-997-9148
Direct Fax: 281-997-9148
Email: dpendleton@blizzardlaw.com

Via E-Mail to DGreenspan@thefeinbergroup.com
September 20, 2004

Deborah Greenspan, Esq.
The Feinberg Group
Suite 740 South
1120 20th Street NW
Washington DC 20036-3437

Re: Examples of Product ID Deemed "Unacceptable" in the Settlement Option

Dear Debby,

As we discussed, I am enclosing the following documents for our meeting this week and for consideration by Dow Corning to include the types of examples as acceptable proof in the Settlement Option:

1. Chart summarizing 15 examples of unacceptable product ID examples and proposals for modifying the Plan to include additional product ID protocols; and

2) Scanned documents that provide actual claimant submissions for the 15 examples summarized in the chart. We are sending these to you with the understanding that Dow Corning will maintain the confidentiality of claimant names and information contained in the submissions.

In addition to the product ID issues, we would like to formally request that Dow Corning make available to the Settlement Facility, Claimants' Advisory Committee, and Office of Plaintiffs' Liaison Counsel *either* the database that correlates to the redacted medical records that Dow Corning submitted to the National Depository in MDL 926 *or* a complete set of the unredacted medical records. We have discussed this issue previously and believe that the medical records in the National Depository may constitute the only available medical records claimants can access to document their product ID, explant and/or rupture claims, so access to these records by claimants is urgent and vital.

Sincerely,

Dianna Pendleton-Dominguez

Dianna Pendleton-Dominguez
On behalf of the Claimants' Advisory Committee

cc: Doug Schoettinger, via email
Professor Francis McGovern, via email
E. Wendy Trachte-Huber, via email
Ernest Hornsby, via email
Sybil Goldrich, via email

Example Number / Proposal	SF Review Status	Represented? Y/N	Description
File: POM Example 1 **Proposal:** Sworn affidavits that meet the legal burden of proof (reasonable degree of medical certainty) should be acceptable. Also an implanting physician's personal knowledge and clear recollection of a claimant's implantation should be acceptable.	NOS – Minor Deficiency Did not submit waiver or go through IRP	Y	Sworn affidavit of implanting doctor stating "to a reasonable degree of medical certainty" that Dow Corning implants were used. Other language – "Using Dow Corning breast implants was my normal standard practice in 1975" and the affidavit states that the doctor is personally acquainted with this claimant's case and has "clear recollection" that she received Dow Corning implants
File: POM Example 2 **Proposal:** same as above	NOS – Unacceptable Submitted Conditional Waiver Form to request IRP review	Y	Sworn affidavit of implanting doctor stating "to the best of my recollection and to a reasonable degree of medical probability" he used Dow Corning implants in 1979 for patients such as this claimant. Other language – "to the best of my recollection and to a reasonable degree of medical certainty ..." and "It is my knowledge to a medical degree of certainty that I used Dow Corning breast implants in the year 1979 for breast reconstruction and augmentation. Using Dow Corning breast implants was my normal standard of practice in 1979." The doctor also handwrote a note stating "Mr. Fagie was the agent for (Dow) and I personally remember this case."
File: POM Example 3 **Proposal:** All claimants implanted with a silicone gel breast implant prior to 1970 should be deemed	NOS – Unacceptable	Y	Signed letter dated 10/31/95 from the Office Coordinator for Dr. Raymond Brauer of the Cronin & Brauer Plastic Surgery Center stating that the records are lost, but she did find this patient's name on a breast implant study list

Example Number / Proposal	SF Review Status	Represented? Y/N	Description
to have acceptable proof of a Dow Corning implant b/c Dow Corning was the only manufacturer of SGBI in the 1960s. **Proposal:** Claimants implanted at Cronin and Brauer clinic prior to 1970 should be deemed to have acceptable proof of a Dow Corning breast implant b/c Cronin used Dow Corning breast implants exclusively. **Proposal:** Study records that clearly document implantation with a Dow Corning implant should be acceptable.	accepted by SF per email		in 1967. She states, "Her surgery was done on February 1, 1967, at St. Joseph Hospital, by Dr. Raymond O. Brauer, and a petite size implant (which his a model name at that time for Dow Corning implants) with a dacron backing." Attached is a printout of the breast implant study record listing all of the information set forth in the letter.
File: POM Example 4 **Proposal:** Contemporaneously created medical records that document usage of a Dow Corning breast implant and are accompanied by a sworn statement from the implanting doctor and/or a responsible person at the doctor's office should be acceptable.	NOS – Minor deficiency Upon re-review, the SF reversed its prior decision and stated that the claimant had acceptable POM.	Y	Sworn affidavit from the Medical Records Custodian for the implanting doctor who confirms that the medical records were destroyed except for a one-page medical record dated in 1992. The medical record reflects that the claimant called asking for information about her implantation. The affiant personally made a telephone call to the medical records department at the hospital where the surgery took place and was informed that the implants were "DC Lot HH2166 Catalog 542-S." The affiant recorded this information in the claimant's medical records in 1992.
File: POM Example 5 **Proposal:** Statements	NOS – Unacceptable IRP – DC denied	Y	Signed letter from the implanting doctor stating that he implanted the claimant in June 1975, that the original

Example Number / Proposal	SF Review Status	Represented? Y/N	Description
from implanting doctors that detail their personal knowledge and recollection of Dow Corning implant usage should be acceptable.	POM accepted by SF		records are no longer available, but he knows "from my personal knowledge and recollection that in 1975, I used Dow Corning implants exclusively." This was also supported by a letter on the implanting doctor's stationary stating that, "In June of 1975 we were utilizing Dow Corning implants ...."
File: POM Example 6 **Proposal:** Add a Unique Identifier for the 900 Series.	NOS – Unacceptable IRP – DC denied	Y	Pierre Blais identified the implants as Series 500 or 900. Other examples submitted to the CAC are from Michael Middleton in which he also states that a Unique Identifier for Cronin Technique Series 530/540 and Weiner 590/570, Cronin Technique Early 900 needs to be developed. Parties trying to draft Unique Identifier for Series 900 implants.
File: POM Example 7 **Proposal:** Contemporaneous records identifying the implant brand – even if not signed by the doctor – should be acceptable if the record was kept in the ordinary course of business as part of the claimant's medical file.	NOS – Minor deficiency Not submitted through IRP DC needs to cover ltr that records are true & accurate copy of file	Y	Contemporaneous medical record from implantation in 1976 with handwritten notation of "Dow Corning Prosthesis, Cat # 965, Lot N. H3149." POM was found deficient b/c implanting surgeon did not sign the report.
File: POM Example 8 **Proposal:** How to deal with inconsistent processing results from SF to give claimants and attys predictability in submitting POM?	NOS – Unacceptable	Y	Two affirmative statements from O. Gordon Robinson stating that implants implanted in claimants in 1973 and 1976 were made by DC. The basis for this statement is that "We were using Dow Corning implants during this time." This identical statement (a form used by the same law firm)

Example Number / Proposal	SF Review Status	Represented? Y/N	Description
			was used for another client implanted by O. Gordon Robinson in 1971 with the identical language but this one was approved and the 1973 and 1976 statements were not approved.
File: POM Example 9 **Proposal:** Statements from implanting doctor that provide the basis for their knowledge of why the implant was identified as a Dow Corning implant should be acceptable.	NOS – Unacceptable	Y	Affirmative statement from the implanting doctor stating that he implanted the claimant with a Dow Corning breast implant and the basis for this is "When I replaced this 1980 implant (recorded as an inflatable implant) I stated that this implant was a Dow Corning implant because there were identifying markings on the implant that would definitely indicate the manufacture as Dow Corning."
File: POM Example 10 **Proposal:** Statements of implanting surgeon that positively identify the implants as Dow Corning and state the basis for the identification should be acceptable even if the letter is not contemporaneous with the implantation.	NOS – Unacceptable	Y	Implanting doctor wrote a letter in 2003 stating that "REDACTED" was implanted with Dow Corning (a.k.a. Cronin) breast implants on 5-16-73. These implants were purchased through our office from a Dow Corning representative. Information is no longer available to us on Dow Corning or their representatives."
File: POM Example 11 **Proposal:** Sworn statement of implanting doctor (deposition, interrogatory or court testimony) stating unequivocally that claimant was implanted with a Dow Corning breast implant should be	NOS – Unacceptable IRP – DC denied	Y	Attached deposition testimony of implanting doctor in which he admits he implanted claimant with 235 cc silicone gel breast implants from Dow Corning, and also did replacement implants years later using Dow Corning breast implants.

Example Number / Proposal	SF Review Status	Represented? Y/N	Description
acceptable.			
File: POM Example 12 **Proposal:** Letters from implanting surgeons that are signed and written for purposes of the original global settlement that identify the type of implant used for a particular claimant should be acceptable proof.	NOS – Unacceptable	Y	Doctor wrote a handwritten letter and a typed letter in 1994 for the global settlement stating that "In July, 1978, I performed an augmentation mammoplasty on [claimant] utilizing Dow Corning prostheses." In the global, this was acceptable proof but the Settlement Plan now requires doctors to state the basis for how they remember that they used Dow Corning implants. The doctor is deceased though and unable to provide the additional statement. In the Dow Corning RAP, this type of proof was acceptable for Dow Corning to pay explantation costs.
File: POM Example 13 **Proposal:** Same as above.	NOS – Unacceptable	Y	Variation of # 12 above where implanting doctor writes a letter for the original global settlement and states that, "In 1973, I was using Dow Corning gel-filled implants." He does not state that he was using only Dow Corning breast implants. He executed an affidavit several years later using the legal language noted in Example #1 above ("to a medical degree of certainty [ ] I used exclusively Dow Corning breast implants in the year 1973 for reconstruction and augmentation because only Dow Corning breast implants were used in breast reconstruction and augmentations in my office in 1973. Using Dow Corning silicone breast implants was my normal and only standard of practice in 1973."

Example Number / Proposal	SF Review Status	Represented? Y/N	Description
File: POM Example 14 **Proposal:** Affirmative statement from a close associate who worked with the implanting doctor should be acceptable.	NOS – Unacceptable	Y	Claimant's medical records refer to the implantation of a soft gel silicone gel breast implant. The implanting surgeon is deceased but a doctor who practiced with the implanting surgeon "as his close associate" wrote a letter stating that he "has personal knowledge of the facts herein" and has reviewed other patient's records from the implanting surgeon. He states, "From my own personal knowledge and experience with Doctor Masters he used only Dow-Corning implants which he referred to as soft gel to describe Dow Corning silicone gel implants. This was true for the records from years 1976-1983. During my entire eight year experience with Doctor Masters I never knew him to use any other type of implant than Dow-Corning, which he referred to as soft gel."
File: POM Example 15 **Proposal:** Contemporaneous medical records created pre-operatively that document the doctor's intended usage of Dow Corning implants and are consistent with information in the operative report should be acceptable.	NOS – Unacceptable	Y	Pre-op examination on 9/16/75 documents the doctor's intent to do "Augmentation mammoplasty with 235 cubic centimeters Dow Corning round implant." In the subsequent surgery on 9/24/75, the operative report does not identify the implants as Dow Corning but does refer to "augmentation mammoplasty under local anaesthesia 235 cc."

EXHIBIT 13

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PRIVILEGED AND CONFIDENTIAL
Prepared Solely in the context of Settlement Discussions

November 23, 2004

VIA ELECTRONIC MAIL

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100 Adris Place
Dothan, AL 36303

Sybil Niden Goldrich
256 South Linden Drive
Beverly Hills, CA 90212

RE: Comments On Product Identification Examples

Dear Dianna, Ernie, and Sybil:

Following are the Debtor's Representatives' comments regarding the product identification examples you forwarded to us in late September and that we discussed in various meetings.

We understand that you requested our views on how these product identification submissions might be treated if they were to be submitted to Dow Corning under the Individual

Review Process (IRP) set up under the Plan. The comments set forth below contain observations about each submission. These comments are based solely on the precise information submitted. In other words, if there were other materials submitted with the claim that expanded upon or, perhaps, contradicted the information in these submission, the outcome could be different. In addition, we make no comment as to whether the Settlement Facility would forward these submissions to Dow Corning. Finally, these comments in no way can be used or construed as admissions of Dow Corning or any agent of Dow Corning.

1. **Example 1** — REDACTED **Affidavit:** Taking the affidavit in its entirety, and assuming no contrary or inconsistent information, the submission would be accepted under the IRP. Dow Corning considers the credibility of the statement as a whole, whether the statement is consistent with any other information in any medical records, and will give weight to a statement that the doctor personally recalls the specific surgery.

2. **Example 2** — REDACTED : Taking the affidavit in its entirety and assuming no other conflicting or inconsistent information, the affidavit would be accepted under the IRP. *See* comments in Example 1 above.

3. **Example 3** — REDACTED : The IRP would not accept this submission.

4. **Example 4** — REDACTED : We understand that the Settlement Facility has accepted this submission, and we therefore make no comment.

5. **Example 5** — REDACTED : We understand that the Settlement Facility has accepted this submission, and we therefore make no comment.

6. **Example 6** — REDACTED : The IRP would not accept this submission.

7. **Example 7** — REDACTED : The IRP would not accept this submission without verification that the handwritten notes on the medical record appear on the original record. As it stands, it is impossible to determine whether that language was on the original or was added later. If the record was verified, then the IRP would accept it.

8. **Examples 8 and 9:** In these cases the issue appears to be inconsistent statements from the same doctor. The IRP cannot address that issue and would not have information about these inconsistent submissions.

9. **Example 10** — REDACTED We assume this was denied for lack of basis but it is unclear from the Settlement Facility e-mail.

10. Example 11 — REDACTED; The IRP would accept uncontradicted, sworn deposition or trial testimony of the implanting physician provided that (1) the testimony establishes that the person testifying was a the person who performed the implant surgery, (2) there is no contrary testimony or record, and (3) the statements are made either on personal recollection or after reference to a physician's own records or files. To consider sworn testimony the IRP would need the entire record relating to implant identification and not just an excerpt from the deposition or trial testimony.

11. Example 12 — REDACTED The IRP would not accept this submission.

12. Example 13 — REDACTED The IRP would accept the affidavit if there were sufficient information that this doctor performed the surgery.

13. Example 14 — REDACTED The IRP would accept this submission.

14. Example 15 — REDACTED The IRP would accept this submission under the specific circumstances presented. Acceptance is based on the specific facts in these records, including proximity in time of the preoperative report and date of implantation surgery as well as consistency of description of implants used in surgery.

Let me know if you would like to discuss any of the above.

Sincerely,

Deborah E. Greenspan

DEG:dlb
cc: Doug Schoettinger
Bridget Snow-Swantek

EXHIBIT 14

AN IMPORTANT MESSAGE TO LAWYERS FOR TORT CLAIMANTS FROM THE TORT CLAIMANTS' COMMITTEE

We are writing you as representatives of the Tort Claimants' Committee. We were appointed to represent the interests of the personal injury claimants in the Dow Corning bankruptcy case. Our purpose in including this letter in this package is to give you information to assist you in helping your clients to decide how they want to proceed with their claims.

The Amended Joint Plan of Reorganization was the result of lengthy negotiations between the Tort Claimants' Committee and Dow Corning. The Plan gives your clients two ways to resolve their claims. The first is to resolve their claims in the Settlement Option, as described below. The second option is to file a lawsuit in court against DCC Litigation Facility, a corporation that has been created to defend the lawsuits brought by claimants who reject the Settlement Option. It is our view that, for the vast majority of claimants who have acceptable proof of an eligible implant, the Settlement Option provides the most certain means of obtaining compensation in a timely manner. We believe that for most breast implant claimants with acceptable proof of an eligible implant the Settlement Option offers payments that are better than those available from other settlements, such as the Revised Settlement Program (offered by Bristol, Baxter and 3M) and, generally, provides claimants with greater certainty than does the Litigation Facility.

In the Settlement Option, eligible Dow Corning breast implant claimants may receive a $20,000 Rupture Payment without filing a claim for disease. Dow Corning breast implant claimants, whether they are sick now or become sick in the future, may also file a disease claim using either the criteria from the original (1994) global settlement or using more stringent criteria developed as part of the Revised Settlement Program (1996) for the other manufacturers. If they choose the original disease criteria, then they do not have to resubmit the same documents and can rely on that prior submission (they still must however submit a Disease Claim Form). The Settlement Facility will have access to all of their records from the previous settlements. Both the Rupture and Disease Payment(s) may be enhanced in the future with the possible addition of "Premium Payments." The Explant Payment has been increased to $5,000 to pay for the removal of your clients' Dow Corning breast implants after 1990.

The Settlement Option claims process is intended to be confidential, user-friendly, and provide for prompt payment if your clients' claims are approved. Most importantly, you do not have to prove that your client's implant caused her problems. A Claims Assistance Program is available so that you can obtain answers to your questions and accurate information about your client's claim. You can call Claims Assistance toll-free at the number listed in the enclosed materials.

Before recommending that your clients elect the Settlement Option, however, it is important for you to determine that your clients are, in fact, eligible to participate

in the Settlement Options. For certain categories of claimants, there are no settlement benefits available and claimants falling in those categories must affirmatively opt-out within the 6 month deadline to assert their claims through the Litigation Facility. These categories include, for example, claimants who received silicone injections, claimants with custom Dow Corning implants, and, possibly, claimants with tissue expanders.[1] If you have any concerns about whether your clients are eligible for the Settlement Option, please contact www.tortcomm.org for additional information.

If any of your clients reject the Settlement Option by opting out, then the Plan requires that you file a lawsuit in the United States District Court in the Eastern District of Michigan within specific time frames. Your clients' rights will be governed by the Case Management Order(s) entered by the presiding judge, United States District Judge Denise Page Hood. Read the Case Management Order Outline carefully to understand what will be required of you and your clients, including submitting written interrogatory responses, undergoing a deposition, and possibly being examined by a physician selected by Dow Corning. If you file a lawsuit, you will be required to prove that your clients' implants caused their problems. While the complete litigation procedures are not yet in place, we believe that the Litigation Facility will be vigorous in its defense of claims, especially those that assert a claimant is suffering from a disease. There will be a litigation committee, comprised of lawyers experienced in representing breast implant recipients that will coordinate the litigation for the Plaintiffs. We do believe that the decision to pursue a lawsuit is a serious one and one that you and your client should make after careful consideration and consultation.

We recognize that this may be a difficult and frustrating decision for many of your clients. They have waited years to resolve their claim against Dow Corning. The Plan provides that, after the Effective Date, a Claimants' Advisory Committee will be appointed to represent the interests of you and your clients. That committee will continue to monitor the process as it moves forward. Whether your clients choose to accept the settlement payments or opt out to file a lawsuit in court, we urge you to carefully review your clients' options and discuss them fully. For more information about opting out to litigate a case, you may contact the Office of Plaintiffs' Liaison Counsel at 205-252-6784.

[1]The eligibility of claimants with tissue expanders to receive benefits through the Settlement Facility is under discussion. Please check the Settlement Facility website (www.dcsettlement.com) for updated information prior to completing the Participation Form.