UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE:	)	**Case No. 00-CV-00005-DT**
	)	**(Settlement Facility Matters)**
DOW CORNING CORPORATION,	)	
	)	**Hon. DENISE PAGE HOOD**
REORGANIZED DEBTOR.	)	

RESPONSE OF CLAIMANTS' ADVISORY COMMITTEE TO PLAINTIFFS' MOTION FOR EXPEDITED CONSIDERATION OF TOLLING OF RUPTURE DEADLINE; REQUEST FOR SIX MONTH EXTENSION FOR CURING PAST AND FUTURE DEFICIENCIES; AND TO COMPEL THE ACCEPTANCE OF EXPERT AFFIDAVITS IN REGARDS TO PROOF OF RUPTURE CLAIMS

A number of plaintiffs, by and through their counsel, filed a Motion seeking to toll the rupture deadline of June 1, 2006 based on problems experienced by their clients in undergoing explantation, on their own and through the SF-DCT's Explant Assistance Program. (Docket Number 399, hereinafter "the Motion") The Motion also challenged the SF-DCT's apparent policy on giving priority to language in a pathology report over that in the operative report when evaluating rupture claims, and requested that the Court order the SF-DCT to review and consider reports by experts who examine and opine on the mechanism of implant failure to pinpoint the source of the "tear or other opening" in the elastomer shell as required by the Plan. For the following reasons, the Claimants' Advisory Committee ("CAC") supports the Motion and urges the Court to enter an Order providing the relief sought.

1. **Tolling The Rupture Deadline of June 1, 2006**

The CAC recently filed a motion seeking similar relief from the June 1, 2006 deadline for various groups of claimants, including 1) those who have encountered great difficulty finding

surgeons locally who are willing to perform the explant surgery through the Explant Assistance Program ("EAP"), 2) those who have encountered difficulty finding a surgeon whose surgical and other related charges are not greater than the$5,000 Explant Payment (a significant number of surgeons have routinely quoted amounts in excess of $5,000), and 3) those who have encountered surgeons who will perform the surgery only if they are paid in advance (which the Explant Assistance Program does not do). As noted in the Motion, health insurance policies routinely exclude coverage for explant surgery – even though it is deemed medically necessary to remove ruptured implants – when the reason for the implant surgery was for cosmetic reasons. As a result, a significant number of women have been unable to afford explant surgery.

The SF-DCT has, in the past 6-8 months, devoted resources to the problems in the Explant Assistance Program, and it has been responsive to the concerns voiced by claimants and the CAC on this issue. Claimants, however, have not had adequate time to locate a willing surgeon in the EAP and schedule surgery before the June 1, 2006 deadline. The CAC believes it is appropriate to extend the June 1, 2006 deadline for this group of claimants by one year, or until June 1, 2007.

2. Processing Problems with Rupture Claims

As noted in Section 3 below, pathology reports are not the best evidence to determine if an implant is ruptured. Pathologists are simply not trained to determine whether a medical device has failed, nor is failure analysis part of their job. As noted in virtually all pathology reports on removed implants, pathologists perform only a gross or visual examination. It is therefore improper for the SF-DCT to give priority to gross observations by the pathologists regarding the integrity of the implant. We support the plaintiffs' Motion on this issue.

3. Expert Proof Establishing That The Implant(s) Is Ruptured

Section 6.02(e)(iii) of the Claims Resolution Procedures (C.R.P.) provides that the SF-DCT should review the Operative and, in some instances, the Pathology Reports for language concerning whether the implant is ruptured. This standard provides the **minimum documentation** that a claimant must submit to qualify for a rupture payment. The C.R.P. does not preclude a claimant from producing **additional documentation** over and above the operative and pathology reports that demonstrates or is supportive that a rupture occurred. This includes post-explant reports, letters and other clarifying medical documentation from the explanting surgeon or an expert who has examined the implant microscopically and documents that the implants have a tear or other opening in them, consistent with the Plan's definition of rupture. In support of our position, we note that Section 6.02(e)(vii) of the C.R.P. lists six types of rupture proof that are unacceptable and that the SF-DCT is directed not to consider.[1] Interestingly, post-explant documentation of rupture by microscopic examination performed by an expert is not on the list of unacceptable proof. This was by design. Post-explant documentation that consists of a microscopic examination of the implant is a highly reliable and accurate way of determining if the implant is ruptured.

---

[1] Section 6.02(e)(vii) provides that, "Unacceptable Proof. The following types of proof are examples of unacceptable proof of rupture:

a. Non-contemporaneous statements from medical personnel recalling that a Claimant's Breast Implant was ruptured upon explantation, or a similar statement from the Claimant (or a Claimant's relative or friend).
b. Proof that fails to show that the ruptured Breast Implant has been surgically removed.
c. Proof that affirmatively reveals that the Breast Implant was intact before the explant surgery, but was ruptured during the explant surgery.
d. Proof that reveals that no Rupture as defined (including proof that shows only gel bleed).
e. Proof that shows that only the saline portion of a double-lumen Breast Implant ruptured, leaving the gel portion intact.
f. For explantations after 1/1/92, a pathology report alone, with no contemporaneous operative report.

In a February 1999 peer-reviewed article by Marotta, et al., the authors state that, "examination of a prosthesis when explanted is the **definitive** method for determining shell integrity ...." See Exhibit 1 attached hereto, "Silicone Gel Breast Implant Failure and Frequency of Additional Surgeries: Analysis of 35 Studies Reporting Examination of More Than 8000 Explants," James S. Marotta, et al, J. *Biomed. Mater. Res (Appl Biomater)*, 48: 354-364 (1999). The authors – including the lead author, Eugene P. Goldberg of the Biomaterials Center at the Department of Materials Science and Engineering at the University of Florida, report on data from 35 different studies totaling 8,000 removed breast implants and found that degradation of the implant's elastomer shell envelope occurred as a result of swelling of the silicone of the shell by the silicone fluid. Id. at p. 355. This causes a significant decrease in the shell tensile strength and tear strength, weakening the implant over time. Id. It was only through post-explantation examination that the authors were able to document one cause for implant rupture, i.e., shell degradation over time.

In a follow-up article in 2002 by Dr. Goldberg and others, they again reported on their investigation of the shell and gel properties from explanted silicone gel breast implants. See Exhibit 2 attached, "Silicone Gel Breast Implant Failure: Evaluation of Properties of Shells and Gels for Explanted Prostheses and Meta-analysis of Literature Rupture Data," by James S. Marotta, et al., *Annals of Plastic Surgery*, Vol. 49, No. 3, 227-242 (2002). The authors examined the explanted implant shells from intact implants and ruptured implants to test their tensile and tear strength. They reported finding "a remarkable loss in the strength and toughness of the shells" over time in all implants, including those that weren't implanted but had simply sat on a shelf. Id. Further:

> This adverse change in properties has made these prostheses vulnerable to the forces exerted on them during implantation and the cyclic stresses incurred during use. We

> regard this deterioration in strength as a major factor in the high rupture/failure rate observed in the current study and previously. These data support the view that a primary mechanism for rupture must be the progressive cyclic mechanical stress-induced creation and enlargement of tears in weakened silicone fluid-swollen silicone elastomer shells. These tears are most likely to be initiated at sides of folds and/or defects, where stresses are concentrated.

Id. Their findings again documented the importance of post-explantation examination of implant shells.

Notwithstanding the foregoing, claimants who chose to remain in the Settlement Option are not required to submit a biomaterials or expert examination of their removed implant. To do so would have placed a higher burden of rupture proof on Settling Claimants than that placed on claimants who elected litigation. Instead, the parties deliberately elected and included in the Plan Documents a lower burden of rupture proof, *i.e.*, the only documents claimants are required to submit are the operative and pathology reports where a gross examination of the implants is done. Clearly, claimants can elect to submit additional proof that is "definitive" proof of rupture, *i.e.*, microscopic examination of the implant shell by an expert, and this should be reviewed and considered by the SF-DCT. In many instances, explanting surgeons deliberately do not opine on whether there is a rupture because it is not possible to determine from this based on a gross observation. Thus, an expert review is needed. Similarly, a pathologist is not trained to nor do they conduct a microscopic examination of the implant. Their job is to examine tissue for signs of disease, and thus the only observation noted on removed breast implants in virtually all pathology reports is that it is a gross observation only.

In some instances, plaintiffs' rupture claims in the SF-DCT have been denied because they did not provide documentation of the exact source of the tear or other opening in the shell. See, e.g., Exhibit 11 attached, redacted decision of the Appeals Judge dated March 23, 2006 denying a claim because the claimant did not demonstrate that there was "a tear or other opening

in the implant as required under the SF-DCT protocols." If the doctor is not able to visually see the tear or other opening as it appears the situation was in the appeal in Exhibit 11, then the only way a claimant can meet her burden of proof is to rely on an expert's examination and evaluation to locate the "tear or other opening" in the implant shell. The SF-DCT should not be permitted to both deny a claim because an expert report was not submitted documenting the source of the rupture, and yet reject expert reports that do just that.

In the underlying litigation that preceded the filing of Dow Corning's bankruptcy, plaintiffs routinely employed experts to examine removed implants to determine whether the implant was ruptured and if so, the mechanism that caused the elastomer shell to tear or develop an opening.[2] Likewise, defendants retained experts on the mechanism of rupture and relied on in-house microscopic analysis and testing of removed implants to determine why the implant failed.[3] One expert, Pierre Blais of Innoval Failure Analysis in Canada, is a research specialist in materials and medical devices, and in this capacity, he has examined over 8,000 breast implants from many manufacturers over the past 25 years. He is a recognized expert in analyzing the mechanism of implant failure. His C.V. is attached as Exhibit 3. In addition, Dr. Blais is intimately familiar with the manufacturers' documents produced in this litigation and with the history of implants that have been marketed as well, providing a well-rounded basis for his opinion on how and whether implants have failed. Dr. Blais' examination and vast experience with breast implants enables him to identify and differentiate implant shell ruptures caused by

[2] For example, when explanted implants were returned to Dow Corning via surgeons and Dow Corning sales representatives, Dow Corning established a complaint file for each incidence, and then relied on in-house staff to examine the implant and issue a report on the status of the implant. This analysis included microscopic analysis and sometimes, destructive testing on the implant's tensile strength and physical properties. Indeed, Dow Corning's Removal Assistance Program's certification form included a box that claimants were urged to check that allowed the removed implants to be returned to Dow Corning for physical and chemical testing. See Exhibit 10 attached, Dow Corning Breast Implant Removal Assistance Program's Patient Certification, DCC 050230579. The Removal Assistance Program also had an "Explant Return Checklist" that Dow Corning personnel completed when the testing was performed. See Exhibit 10 attached.

poor adherence of the fixation patch to the elastomer, stress and wear spots on the shell, elastomer shell degradation, manufacturing defects such as pinholes in the elastomer shell, crease and tear fold failures, and impact or trauma fractures, among other mechanisms. Most of these defects are not visible on gross examination and can only be documented through sophisticated MRI scans pre-explant and microscopic examination post-explant, thus necessitating the use of expert opinion with regard to rupture.

Specifically, Dr. Blais generally reviews all medical documentation about a claimant that is made available to him, and then examines the implants and their associated tissue capsules. See, e.g., Exhibit 12 attached, redacted example of a report from Dr. Blais, Innoval Failure Analysis. He conducts a direct examination of the implant under transillumination and magnification to detect time-dependent ruptures, i.e., tears or other openings in the implant caused as a result of the implant's degradation over time. Id. at page 5. Dr. Blais is able to detect focal crazing, fragmentation of the shell material and erosion of the rupture edges, major pleats in the shell material and erosion and gouging over time from protracted implantation times within a mineralized, abrasive capsular environment. Id. His reports are very detailed and note specific measurements of various defects in the shell and the source of the tear or other opening in the envelope. Id.

Over the years that it made silicone gel breast implants, Dow Corning was aware that its elastomer implant shells weakened over time and failed. Numerous internal Dow Corning documents detail the many problems experienced by Dow Corning in making the thin elastomer shell, the thinness of which has been likened to Saran Wrap by one implant company. See Exhibit 4 attached, MEC 9178 - 9180 (Wilf Lynch and Bill Stith, MEC, memo to the Field Force regarding Dow Corning's new shell material for their inflatable implant. "Regrettably one of the

characteristics of silicone rubber is that it has a very low tear strength. Even if Dow Corning has made a shell with twice the tear strength of what they presently have, the new value will still be low compared to other materials, such as **Saran Wrap**.") For example, in a 1971 internal DCC memo, an employee noted that the implant degraded over time, stating, "The terms, friable, disintegration and degradation are being used frequently in some areas to describe the condition of the envelope of removed SILASTIC ® mammary prostheses." See Exhibit 5 attached, M 570119. In addition to elastomer shells which weaken and degrade over time, Dow Corning was aware of numerous manufacturing problems and design flaws with the elastomer envelopes on its breast implants. Numerous other internal documents evidence the ongoing problems Dow Corning experienced with the elastomer shells of implants. See, e.g., Exhibit 6 attached, F 534 (Dow Corning employee T. Talcott expressed dismay in a 1976 memo that at Dow Corning the consensus was that the envelope was 'good enough' despite finding "gross thin spots and flaws in the form of significant bubbles… The allowable flaws are written into our current specifications…. When will we learn at Dow Corning that making a product 'just good enough' almost always leads to products that are 'not quite good enough'?"); and Exhibit 7 attached, KMM 219982 – 219984 (Dow Corning report from 1976 entitled, "Mammary Envelope Producing Problems To Date – 1976" in which numerous manufacturing problems were noted, such as air bubbles in the implant shells, brown spots on the envelopes caused by chemical drying spots, and weak areas and bulges on the elastomer. In addition, the "rotten" envelope syndrome was encountered. The author of the report noted that "some of the critical sizes are being produced at a very, very high reject level with no relief in sight."),

The complaints regarding poor quality of implant shells continued throughout the 1980s as well. See Exhibit 8 attached, DCC KKA 119771 – 119774 (Memo from R. Dumas to G.

Jakubczak and others within Dow Corning, dated August 14, 1984, entitled "Project Report – Complaint Analysis, Plastic Surgery"). Dumas notes that Dow Corning has established a program to collect and analyze the complaint files on the returned breast implants, and is working to address the backlog of complaints. Id. at DCC KKA 119771. He notes the purchase of a Polaroid system for taking photomicrographs of the removed implants for implant failure analysis. Id. at DCC KKA 119772. With regard to the implant analyses that are complete, Dumas reported that there was a "pattern of complaints of small pin hole tears" in the implant shells. Id. Upon investigation, it was confirmed that the pin holes were caused by burs on the wire screen. Id. Dumas notes that the pin holes caused a greasy surface to the implant on the unopened units causing him to "sympathize with one surgeon stating that he believed we were soaking the units on [in] Mazola oil before shipping." The ease of tear propagations in implant shells were found to be the cause of Silastic II and Standard Gel ruptured implants, as well as a susceptibility to rupture upon insertion of the implant. Id. at DCC KKA 119773. Dumas further noted that "non-uniformity of the envelope was noted along most tears examined, suggesting thickness variation to be a contributing factor to the rupture." Id. He concludes by recommending that they increase stress resistance in the elastomer envelope of the Silastic II implant, suggesting a "new formulation to increase the elongation modulus."

Internal documents from other manufacturers that were produced in the litigation also note significant problems with crease and fold failures in the shells of silicone gel breast implants, wrinkling and degradation of the shell over time that leads to implant rupture, and the presence of pinhole defects in the implant shells that eventually lead to the implant's failure. See, e.g., Exhibit 9 attached, MEC 20791 – 20798 (MEC Medical Device Report No. S0163R, dated December 15, 1986, that found a crease hole in the implant shell documented by the Q.A.

lab and "R&D." MEC notes that "**The occurrence of crease holes in mammary implants is a state-of-the-art concern.** A statement in our package insert warns, 'Implant may rupture and/or deflate due to material fatigue (i.e. crease fold phenomenon)." (emphasis added)). Numerous other internal documents exist in the National Depository and in published, peer-reviewed literature that confirm the various mechanisms of implant failure that are not observable by gross examination, but can be detected through by trained and experienced biomaterials experts and other qualified persons.

Summary

The CAC submits that an expert report that discusses the results of a microscopic examination of removed implants to document the mechanism of how the implant failed or ruptured are definitive and reliable. Qualified experts such as Dr. Pierre Blais can differentiate the mechanism of implant failure to confirm that the rupture was caused by shell degradation, crease fold failures in the shell, pinhole defects, tear propagations, difference in shell thickness throughout the implant shell, etc. as distinguished from a nick in the implant shell by the surgeon. The Plan does not classify expert examinations as "unacceptable." Since examination of removed implants are the "gold standard" and are "definitive" of the mechanism of implant failure, claimants should be permitted to submit this type of documentation and have it considered by the SF-DCT.

The CAC supports the relief requested in the Motion.

Respectfully submitted,

FOR THE CLAIMANTS' ADVISORY COMMITTEE

/s/
Dianna Pendleton-Dominguez, Esq.
Law Office of Dianna Pendleton

401 North Main Street
St. Marys, OH 45885
Tel: 419-394-0717
Fax: 410-394-1748

Ernest Hornsby, Esq.
Farmer, Price, Hornsby & Weatherford
100 Adris Place
Dothan, AL 36303
Tel: 334-793-2424
Fax: 334-793-6624

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing Response of the CAC was electronically filed with the District Court this 21st day of June 2006, and by also sent via e-mail to the Debtor's Representatives, counsel for Plaintiffs in the Motion (Siegel Kelleher and Kahn) and to the Claims Administrator this 21st day of June 2006.

/s/
Dianna Pendleton-Dominguez