EXHIBIT 11

In re: Appeal from Claims Administrator

Claimant: [redacted]
SID No.: [redacted]

Pursuant to Paragraph 8.05 of Annex A to the Settlement Facility Agreement ("SFA"), the undersigned, makes the following determination of the Appeal from the decision of the Claims Administrator:

Ms. [redacted] has, by letter, appealed from the decision of the Claims Administrator, and by such appeal seeks approval of her claim for additional benefits based upon rupture.

A review of the record evidence demonstrates that Ms. [redacted] had her Dow Corning implants removed on August 26, 1994. The Operative Report from that procedure states with regard to the left implant "The implant appeared to have been completely intact, but ruptured at the point of contact with the cautery during extraction. There was no gel spillage within the wound."

With regard to the right side, the Operative Report states "Again at extraction, the implant ruptured at the point of contact with the cautery. Again there was no gel spillage within the cavity or the wound, but there was some gel adherent to the superior most portion of the implant. There was probably a small leak at this point."

As can clearly be seen from the Operative Report, the implants were ruptured during removal and not prior thereto. Although the explanting surgeon hypothecated that there was a small leak at the superior most portion of the left implant, the doctor did not actually observe a tear or other opening in the implant as is required under the SF-DCT protocols.

Accordingly, the decision of the Claims Administrator will be affirmed, and Ms [redacted]s appeal is DENIED.

This the 22nd day of March 2006.

Frank Andrews, Appeals Judge

EXHIBIT 12

City of Ottawa
Province of Ontario, Canada
December 21, 2004

AFFIRMATION

RE: MDL 926 REVISED SETTLEMENT PROGRAM BREAST IMPLANT LITIGATION UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ALABAMA

Identification and Analysis of Implants by Direct Inspection
[redacted] (File No. [redacted])

I, Pierre Blais, Ph.D., affirm as follows:

1. I have extensively researched medical implants, including breast prostheses, and have studied manufacturing practices used in the fabrication of breast implants, as well as production records and catalogs from manufacturers. I have performed studies on the behavior of implants and their impact on surrounding structures. I have examined more than 8000 breast prostheses from many suppliers, including but not limited to Dow Corning, Dow Corning Wright, McGhan Medical, 3M, Medical Engineering Corporation, American Heyer-Schulte, Mentor Corporation and others. I have performed investigations and product identification pertaining to prostheses manufactured from about 1955 to the present.

2. I have been deposed many times as an expert witness in breast implant actions, providing formal court testimony in many such actions. I have been accepted as an expert on breast implant technology and failure analysis by Courts in Texas, California, Florida, Colorado, Nevada, Oregon, Ohio, Connecticut, Maryland, Louisiana, Washington, District of Columbia, New York, New Jersey as well as Alberta and British Columbia in Canada. I am known to defendants and many plaintiff attorneys active in the field.

3. I am acquainted with design, appearance, physical characteristics, performance and durability expectations of prosthetic devices in addition to the manufacturing and distribution practices of the industry engaged in breast implant commerce in the U.S. and abroad. I am aware of the many different products, their production periods, history and attributes. I am also familiar with singular attributes for nearly all commercially sold devices of this kind.

4. Over the past 25 years with reference to breast implants, I have developed techniques for identification, for establishing implant integrity and for determining implant condition in vivo on the basis of post-explantation examination. I have also developed methodologies for appraising the impact of failure, in particular rupture and extravasation of the filling media on surrounding tissue. I have published extensively on design, performance and failure analysis of medical implants and their impact on proximal tissue.

5. Amongst implants which I have examined, more than 3000 were made by Dow Corning. Surgical records for more than half of the users have been reviewed, including many with Product Identification labels. I have also reviewed archival material pertinent to mammary implants manufactured by Dow Corning including but not limited to corporate records, Lot Histories, regulatory documents, technical manuals, catalogs and advertisements.

6. Information derived from the analysis of pathological material and review of documents has been classified and portions have been incorporated into a database which provides criteria of identification and durability characteristics for all types of mammary implants as well as their impact on surrounding tissue. The database contains information on more than 300 Dow Corning implants which would be contemporaneous to Ms. [redacted] implants and share the same physical characteristics. These implants would be substantially equivalent inasmuch as they incorporate a thick shell of contour shape fitted with discrete coin-size fixation patches on the posterior side and filled with a thick cohesive silicone-based gel.

7. Ms. [redacted] implant history, as reflected by the provided records, is as follows:

01/16/73 - (Aultman Hospital, Canton, OH) - ptosis - augmentation mammoplasty with silicone gel-filled prostheses (Dow Corning 500 Series, Cat. No. 532, Lot No. HH 1296 - from Product Identification label)
xx/xx/xx - mammographic study - consistent with implant rupture on right (from Dr. Stroup's report of 04/30/93)
circa 1992 - trauma to chest, right side followed by development of capsular contracture and pain
04/30/93 - (Dr. R. Stroup, University Hospitals of Cleveland, Cleveland, OH) - ruptured implant on right, capsular contracture on left (Grade II-III) - removal of implants via extracapsular capsulectomy with implants enclosed within capsules (*implants unseen by surgeon*); replacement with "250 cc Mentor Siltex ... gel-filled implants ... catalog number 354-2504 ... lot number - 64365"
05/13/93 - (Dr. J.M. Anderson) - pathology - implants submitted within dense fibrous capsules showing focal dystrophic calcification and gel bleed; two fixation patches noted on each implant

8. Ms. [redacted] implants, inserted in January 1973 and removed in April 1993, were received at Innoval on December 10, 2004. The specimens were provided under pathology code "9306873". The containers bore mechanographic clinical labels which included the patient's name. The side of origin was shown only as "I" and "II" but could be correlated with the side of origin from the provided pathology report. The clinical labels are shown in Attachment A. The implants were identified by direct inspection as Dow Corning "Cronin Technique" silicone gel-filled mammary prostheses of Sub-Series 530, contour style with a nominal size of 225 cc. They were of the later variants as evidenced by the array of five round tissue fixation patches visible on the posterior side. Shell dimensions and gravimetric measurements confirmed products derived from mandrel type "S", a mandrel colloquially termed "Small" in Dow Corning documentation. The implants had all fixation patches of the same size with the two lowermost bridged together to constitute a 'dumbbell'-like object. Both implants had nearly identical attributes and fabrication peculiarities indicating contemporaneous products originating from the same batch, consistent with items sold as a pair as was then the custom. The identity of the implants as derived from direct inspection is definitive and is consistent with the medical records which include a Product Identification label showing that the implants were purchased as a pair under Catalog Number 532 bearing Lot Number HH 1296 (Attachment B).

9. Ms. [redacted] implants comply fully with the expected MDL 926 Unique Identifiers for Dow Corning products of this era as per Section 5 - Proof of Manufacturer, Q5-8, paragraph 1: **"For implantations or implants manufactured between 1969 and 1973 a high profile contour 'ski slope' design implant with Dacron® fixation patches on the posterior with the upper portion of the implant being concave and the bottom portion convex".**

The second Unique Identifier is Q5-8, paragraph 2.: **"An implant with fixation patches where white Dacron® knit mesh loops were either sewn or bonded to the elastomer patch surface with the fixation patches in turn bonded to the envelope posterior. Products with the following configurations of fixation patches are acceptable:**

(iii) For implants implanted or manufactured between 1968 and 1982, two (2) to five (5) circular Dacron® mesh fixation patches on the posterior implant shell of the embedded/ pleated design, consisting of a clear elastomer disc about 22-25 mm diameter, with a pattern of embedded Dacron® mesh in a pleated pattern, with the actual Dacron® mesh present or absent.

(iv) For implants implanted or manufactured between 1968 and 1976, a dumbbell-shaped Dacron® mesh-reinforced fixation patch on the posterior implant shell, together with one (1), three (3) or four (4) additional round fixation patches on the implant shell. Internal to the dumbbell-shaped fixation patch are either two (2) round shell holes (one larger than the other) separated by a slit in the shell, or a single round shell hole".

Ms. [redacted] implants comply with all of the Unique Identifiers cited above. They have the characteristic shell shape with a prominent apex and 'ski slope'-like anterior surface. These characteristics are retained in spite of the ruptured condition because of the thick, cohesive gel filling substance. The tissue fixation patch configuration includes the five patch style with the dumbbell-shaped lowermost patches. The configuration of the shell obturating system (internal shell patches) is as described and reflects a late production series for this style of prosthesis. The implants also comply with unpublished criteria of identification, specifically shell assembly peculiarities, position and dimensions of individual fixation patches and internal components employed to reinforce the posterior side. Such items are reproduced in illustrations from Dow Corning documents of the early seventies, specifically Bulletin Number 51-024A, dated September 1971 (Attachment C).

10. A radiographic study performed prior to explantation is referenced in the explanting surgeon's operative report. This study was consistent with a ruptured right implant. The explantation was performed by Dr. R. Stroup via extracapsular capsulectomy, a procedure which retained the implants entrapped within their capsules. Thus, the implants and capsules were submitted to pathology as composite entities, the implants unseen by the explanting surgeon. The pathology study performed at the explantation facility by Dr. J.M. Anderson documented receipt of the composite implants but only small fragments of tissue were detached from the outer part of the enclosing capsules. The implants were again unseen by the pathologist who evidently noted only two of the five patches on each implant. Focal calcification was also observed. Thus, the pathology study consisted only of gross findings for implants fully enclosed by their capsules.

11. My direct inspection of Ms. [redacted] pathological material comprised both implants and their associated capsules. Both implants showed a multiplicity of small ruptures proximal to the fixation patches nearest to the equator. Additionally, each implant showed larger ruptures on the equator in the upper quadrant, a notoriously rupture-prone site for this style of prosthesis. The largest ruptures were on the right implant, the implant noted as 'ruptured' according to the pre-explantation radiologic findings. Direct examination of both implants under transillumination and under magnification showed bilateral damages consistent with natural time-dependent ruptures. These damages ranged from 0.1 to 30.0 mm and were coincident with pleats. There was focal crazing, fragmentation of the shell material and erosion of the rupture edges, creating a rounded rupture line in some parts. The damages are consistent with ruptures that predated removal by many years inasmuch as the rupture sites showed post-rupture in vivo erosion. Additionally, major pleats were observed on the anterior of each implant and there was severe erosion and gouging from protracted dwell time within a mineralized, abrasive capsular environment. Some gouge sites showed complete penetration through the shell, creating additional perforating damages equivalent to ruptures with dimensions in the 0.1-0.5 mm range. For each implant, the gel was turbid with solid debris. There was dispersed calcific and tissue deeply intercalated within the gel indicating a prolonged contact between calcified capsular tissue and uncontained gel. Supplemental iatrogenic damages such as featureless cuts and evidence of shell severance with a shearing instrument were also noted, more so on the right implant shell. These damages were unrelated to the clinical performance of the implants.

12. The foregoing observations are consistent with multiple independent shell ruptures initiated mostly on the equator in the upper quadrant. The damages coincide with areas of extensive morphologic changes typical of wear and deterioration processes that take many years to develop. Magnified views of these areas reveal changes such as deeply inset pleats with focal craze zones, fragmentation, erosion and rounding of the failure edges, characteristics which are encountered only when ruptures occur many months before implant removal. This is because implants residing in abrasive capsular environments continue to suffer abrasion and excoriation which further worsen the rupture sites in characteristic ways which cannot be duplicated ex vivo. Post-rupture shell erosion at rupture sites and fragmentation of the elastomeric parts are definitive criteria for spontaneous use-related ruptures. User movement results in cyclic displacement of implants against the capsule wall. Such movements become imprinted in the fine structure of the implants, taking the form of gouge lines and surface excoriation which appear even on portions of the shell which do not suffer rupture. The original rupture site morphology is drastically altered by the process and the severity of the alterations reflects the time elapsed between formation of the rupture and removal of the implant debris.

13. Ms. [redacted] capsular tissue was provided for study, consisting of more than 80% of the theoretical capsules and their mineralized inclusions. All parts of the capsules were represented in the submitted material. Notwithstanding severe calcification of the tissue secondary to necrotic processes which reflect many years of chronic inflammation from aggressive prosthetic effluents, the capsular tissue also showed focal granulomata. Large zones of granulomatous tissue were observed in the upper quadrant on the equator of each implant pocket. These granulomata were agglomerates of fibrous tissue with encapsulated gel and oil within cystic pockets of variable size. Such granulomata were consistent with protracted exposure of capsular tissue to uncontained oily filling material extravasated from each implant. Further, the position of the granulomata was proximal to the primary ruptures observed on each implant. Additional granulomatous sites were also noted but were overshadowed by the ones on the upper quadrant. Large quantities of fragmented elastomeric material were also dispersed within tissue and intermingled with other prosthetic constituents indicating comprehensive failure and disaggregation of the prosthetic system and major adverse impact on surrounding tissue. Such tissue damages, in particular granulomata, are possible only in situations where ruptured implants are retained in situ for many years.

14. Ms. [redacted] explantation records mention a traumatic event affecting the right side of the chest. This event was followed by the onset of firmness and discomfort. Implicit in the introduction of the patient's condition is the traumatic etiology of the rupture. Damages resulting from traumatic impact and compression of augmented breasts take place but, with the exception of penetrating trauma, do not habitually affect an implant. Instead, capsules undergo damages which frequently result in dispersal of the filling material far beyond the original implant pocket.

15. The ruptures observed by me on Ms. [redacted] right implant are not consistent with impact or trauma as such events create large featureless ruptures. This is in contrast to Ms. [redacted] rupture pattern which consists of multiple small primary ruptures in fatigue-prone implant areas such as the upper quadrant. Of special note, is that Ms. [redacted] implants had an uninterrupted dwell time of approximately 20 years, far in excess of the service life of such implants. Furthermore, shell failure does not occur as a single instantaneous event under normal conditions. Repeated flexing and cold working of the shell material along pleat lines causes deterioration in the quality of the elastomer culminating in multiple small crevices, as seen on both of Ms. [redacted] implants. With time, the crevices merge together creating networks of interconnected microscopic channels which present as 'craze' areas with spallation and fragmentation. Such processes, in combination with erosion, cannot be duplicated through any process other than what takes place in vivo. Material fatigue thus constitutes the primary limit on service life and causes natural failure of breast implants. Material fatigue is consistent with the morphologic observations of the primary rupture sites on both of Ms. [redacted] implants, some visible to the eye unaided.

In summary, Ms. [redacted] was implanted with Dow Corning implants made circa 1971. Both were ruptured and the ruptures predate surgical removal by many years. The capsules were extensively calcified with large incisive plaques which, by themselves, would have sufficed to induce multiple independent ruptures through penetration and attrition of the shell incidental to the user's movements. Additionally, pleating and material fatigue led to multiple independent ruptures which worsened progressively, exacerbating capsular contracture. The combination of all factors doomed the prostheses to early rupture and extravasation. Failures of this kind are consistent with the service life expectation of Dow Corning "Cronin Technique" mammary augmentation products of the early seventies. The Innoval database confirms that the near totality of implants of the kind received by Ms. [redacted] fail and rupture within about ten years and that large quantities of prosthetic material become incorporated in the surrounding tissue.

Dated at: City of Ottawa, Province of Ontario, Canada this 21st day of December, 2004

PIERRE BLAIS, Ph.D., F.C.I.C.