

UNITED STATES BANKRUPTCY COURT  
EASTERN DISTRICT OF MICHIGAN  
NORTHERN DIVISION

In Re: § Case No. 00-CV-00005-DT  
DOW CORNING CORPORATION, § (Settlement Facility Matters)  
Debtor. § HON. DENISE PAGE HOOD

NOTICE OF ESTIMATE OF TIME, EXHIBITS AND WITNESSES  
WITH REGARD TO THE MOTION OF CLAIMANTS' ADVISORY  
COMMITTEE TO INTERPRET THE AMENDED JOINT PLAN SECTION 1.17  
REGARDING THE DEFINITION OF "BREAST IMPLANT"

The Claimants' Advisory Committee file this document consistent with the requirements of Section 2.01(d)(2) of the Stipulation And Order Establishing Procedures For Resolution Of Disputes Regarding Interpretation Of The Amended Joint Plan and the Fourth Amended Case Management and Administrative Order.


Estimate of time: 30 minutes

Witnesses: The Claimants' Advisory Committee does not see the need for Witnesses

Exhibits: The Claimants' Advisory Committee does not see the need for exhibits at a status conference on the motion.

Respectfully submitted this 19<sup>th</sup> day of July, 2004.

CLAIMANTS' ADVISORY COMMITTEE

  
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UNITED STATES BANKRUPTCY COURT  
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DOW CORNING CORPORATION,	§	(Settlement Facility Matters)
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Debtor.	§	HON. DENISE PAGE HOOD

**MOTION OF CLAIMANTS' ADVISORY COMMITTEE  
TO INTERPRET THE AMENDED JOINT PLAN  
SECTION 1.17 REGARDING THE DEFINITION OF "BREAST IMPLANT"**

The Claimants' Advisory Committee ("CAC") respectfully submits this motion pursuant to the Stipulation And Order Establishing Procedures For Resolution Of Disputes Regarding Interpretation Of The Amended Joint Plan dated June 10, 2004 ("the Stipulation"). For the reasons stated herein, we respectfully submit that the correct interpretation of the Amended Joint Plan language in Section 1.1.7 is that tissue expanders that were implanted in the breast meet the definition of "Breast Implants."

**Procedural History**

1. In 1999, the Claims Administrator (at that time, Katherine Kennedy) requested the parties to provide a Plan interpretation regarding the definition of "Breast Implants" as defined in Section 1.17 of the Amended Joint Plan. Section 1.17 provides that:

Breast Implant means all silicone gel and saline-filled breast implants with silicone elastomer envelopes manufactured and either sold or otherwise distributed by the Debtor.

2. On August 7, 2003, the Claims Administrator sent to the parties the Procedures for Resolution of Disputes under the Provisions of the Settlement Facility Agreement

Section 5.05 (“the Procedures”). Pursuant to these Procedures, the Tort Claimants’ Committee submitted its position statement to the Claims Administrator on September 19, 2003, and Dow Corning submitted its response on October 3, 2003.

3. Thereafter, the parties reached an agreement on procedures for resolution of disputes regarding interpretation of the Amended Joint Plan (“the Stipulation”). Pursuant to the terms of the Stipulation, a conference with the parties and the Claims Administrator was held on June 22, 2004. Thereafter, on June 28, 2004, pursuant to Section 2.01(c)(4) of the Stipulation, the Claims Administrator issued a statement informing the parties that she did not intend to issue a decision on the plan interpretation dispute regarding the definition of Breast Implant.

4. Therefore, pursuant to Section 2.01(d)(2) of the Stipulation, the parties have 15 business days from the date of the Claims Administrator’s June 28, 2004 statement to file cross motions with the District Court for a ruling on the plan interpretation dispute.

### **Standard of Review**

Although the Stipulation provides a standard of review in the event the Claims Administrator issues a decision (de novo), there is nothing in the Stipulation that specifies the standard of review when the Claims Administrator declines to issue a decision. The Claimants’ Advisory Committee believes, however, that the proper standard of review by the District Court is de novo.

### **Relevant Facts**

1. In Dow Corning’s product brochure on tissue expanders, it states that:

The SILASTIC® Percutaneous Tissue Expander is an inflatable envelope made of high performance medical grade silicone elastomer. It is designed for temporary subcutaneous implantation. After wound healing,

the implant is slowly inflated by a series of percutaneous injections of sterile, isotonic saline.

(Exhibit 1 hereto)

2. It is undisputed that tissue expanders were manufactured and sold by Dow Corning. Some tissue expanders were specifically designed and marketed for implantation in the breast, as shown by the brochure attached as Exhibit 1 and the product label attached as Exhibit 2 (“breast design”). According to Dow Corning’s product literature, Dow Corning made breast design tissue expanders in three shapes and a variety of sizes and also marketed their ability to make “custom” tissue expanders.

### **Argument**

#### **Dow Corning Made And Sold Tissue Expanders That Contained A Silicone Elastomer And Were Filled With Saline; They Therefore Qualify Under The Plan’s Definition Of “Breast Implant”**

To meet the definition of a “Breast Implant” as that term is defined in the Amended Joint Plan, the implant must meet all four criteria listed below:

- 1) It contains silicone or saline. As established by Dow Corning’s product literature, the breast design tissue expander is filled with saline;
  - 2) It is implanted in the breast. Once again, there is no dispute that breast design tissue expanders were intended to and were in fact implanted in the breast;
  - 3) It must have a silicone elastomer envelope. Dow Corning’s product literature confirms that tissue expanders do indeed have a silicone elastomer envelope; and
  - 4) It is manufactured and either sold or otherwise distributed by the Debtor.
- Again, this criteria is not in question given the product literature attached as Exhibits 1 and 2.

The Plan does not impose any other criteria other than the four outlined above. Dow Corning concedes that these four criteria are present with breast design tissue expanders. They have, thus far, refused to allow these implants to be included in the Amended Joint Plan claiming that because they were marketed for short-term use and were intended to be removed, that this somehow exempts tissue expanders from the agreed definition of Breast Implant. Yet nowhere in the Plan is there any requirement that any implant be implanted for any specific period of time. Dow Corning would concede that a silicone gel-filled breast implant that was implanted one week before removal would qualify without regard to the short length of implantation. Yet they seek to use the issue of length of implantation in an attempt to exclude claimants from qualifying based on their Dow Corning breast design tissue expander.

Secondly, Dow Corning claims that tissue expanders did not contain silicone or saline at the time they were sold but again, this is not a criteria in the definition of Breast Implant. The fact that they were filled with saline – and were indeed intended to be filled with saline – at the time of implantation in no way should disqualify them as Breast Implants. If this were the criteria, then virtually no saline implants would qualify because these were also filled at the time of the implantation.

#### **The RSP Treated Tissue Expanders Implanted In The Breast As Breast Implants**

The Settlement Facility and Fund Distribution Agreement (SFA) at Section 4.03(a) states that:

The Claims Office shall operate using the claims-processing procedures and quality control process of the MDL 926 Claims Office. It is expressly intended that the Settling Breast Implant Claims shall be processed in substantially the same manner in which claims filed with the MDL 926 Claims Office under the Revised Settlement Program are processed except

to the extent criteria or processing guidelines are modified by this Settlement Facility Agreement or the Claims Resolution Procedures ....

According to correspondence received from Veronika Willard, who was at that time the Claims Operation Manager for the Settlement Facility, tissue expanders were treated like breast implants for the purposes of disease claims. (See Exhibit 3 attached). Wendy Trachte-Huber, the Claims Administrator, further clarified this at the June 22, 2004 conference by confirming that the RSP treated tissue expanders the same as breast implants. (See Exhibit 4 attached, excerpt of Transcript of June 22, 2004 Conference at pp. 48-49).<sup>1</sup>

Dow Corning has suggested that it would be inequitable to pay tissue expander claims in the Amended Joint Plan because a claimant's combined recovery from the Joint Plan and the RSP may exceed 100% of the Base Amount available to Dow Corning Breast Implant Claimants. This argument is simply not relevant. The Amended Joint Plan does not prohibit the recovery of more than 100% of the Base Payment from the combined awards of the RSP and Amended Joint Plan. To the contrary, there are certain categories of claimants who were intended to recover more than 100% and others who will receive less than 100%. This fact is simply not a relevant consideration in interpreting Section 1.17's definition of "Breast Implant."

For the foregoing reasons, the Claimants' Advisory Committee respectfully requests that this Court interpret "Breast Implants" to include tissue expanders implanted in the breast.

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<sup>1</sup> The June 22, 2004 transcript provides that, "Claims Administrator Huber: And I'd be happy to give you all copies an [sic] email from Ann Cochran indicating: Bristol, Baxter and 3M tissue expanders were considered breast implants for purposes of qualifying to participate in the RSP. They could be the basis of explant benefits since from my understanding they were all saline filled. They could not be the basis of a ruptured [sic] claim since there would be no escape of a silicone gel involved."

Respectfully submitted this 19<sup>th</sup> day of July, 2004.

CLAIMANTS' ADVISORY COMMITTEE

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**CERTIFICATE OF SERVICE**

The undersigned represents that (s)he caused a copy of the foregoing Motion to be sent by electronic mail, to each member of the Debtor's Representatives and to the Claims Administrator on July 19, 2004.

Dianna Pendleton-Dominguez  
Dianna Pendleton-Dominguez

The SILASTIC® Percutaneous Tissue Expander is an inflatable envelope made of high performance medical grade silicone elastomer. It is designed for temporary subcutaneous implantation. After wound healing, the implant is slowly inflated by a series of percutaneous injections of sterile, isotonic saline. When a suitable skin pocket has been developed, the tissue expander is surgically removed and can be replaced with a SILASTIC® brand prosthesis.

This product is available with either a self-contained, permanently attached, self-sealing valve on the anterior of the prosthesis, or with a remote valve permanently attached to the prosthesis through the use of a connecting tube.

The self-contained valve includes an elevated rim to aid palpation. This allows targeting the injection port after implantation. The remote valve consists of a self-sealing dome which aids in palpation. An important safety feature in both valves is the inclusion of a stainless steel needle stop in the valve which helps to prevent inadvertent needle perforation of the silicone envelope through the valve. Suture tabs, made of polyester-reinforced silicone sheeting are attached to the base of the envelope. These tabs can be used to secure the envelope to the underlying tissue and may be trimmed or removed, as desired.

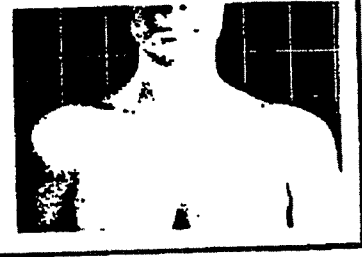
The SILASTIC® Percutaneous Tissue Expander is provided in three shapes and is available in a variety of sizes.

### SPECIFIC ADVANTAGES

- Palpation ring acts as a guide to target injection site.
- Metal-backed needle stop provides tactile feedback for unambiguous position within valve.
- Surgical stainless steel needle stop prevents inadvertent puncture of prosthesis.
- Convenient valve collar reduces prosthesis foldover at low fill level and gives suture option.
- Available in three shapes and a variety of sizes, with remote or self-contained valves.
- Fabricated of high performance, medical-grade silicone elastomer to provide greater resistance to tear propagation than ordinary silicone elastomer.
- Body tissue is non-reactive to implant if sterile and uncontaminated.
- Convenient sterile packaging.
- Rigorous quality control through all phases of manufacturing process.

Note: Custom Tissue Expanders are also available from Dow Corning Wright. See catalog or contact your Dow Corning Wright representative for ordering details.

## SILASTIC<sup>®</sup> TISSUE EXPANDER H.P.



PRODUCED BY DCC & DCW

M-010045

**DOW CORNING**

WRIGHT

Exhibit  
2





Subj: **Tissue Expanders**  
Date: 1/25/2002 1:47:09 PM Central Standard Time  
From: [wwillard@sfdct.com](mailto:wwillard@sfdct.com)  
To: [Deborah@thefeinberggroup.com](mailto:Deborah@thefeinberggroup.com), [dpend440@aol.com](mailto:dpend440@aol.com)  
CC: [EWHuber@sfdct.com](mailto:EWHuber@sfdct.com)  
*Sent from the Internet (Details)*

I now have more information on how tissue expanders were treated at RSP. Tissue expanders were treated like implants for purposes of disease claims. However, tissue expanders made by Dow Corning did not trigger the 50% reduction in benefits that the breast implants did. I thought this might be useful in helping to phrase something for the Q&A.

Exhibit  
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UNITED STATES BANKRUPTCY COURT  
EASTERN DISTRICT OF MICHIGAN  
NORTHERN DIVISION

IN RE:  
DOW CORNING CORPORATION,]           CASE NO. 0005  
                                  DEBTOR.]           Settlement Facilities Matter  
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AMENDED JOINT PLAN OF REORGANIZATION  
Detroit, Michigan - Tuesday, June 22, 2004

Appearances:

Claims Administrator:  
ELIZABETH W. TRACHTE-HUBER, ESQ.  
Settlement Facility Dow Corning Trust  
Claims Administrator, C.E.O  
3100 Main Street  
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Houston, Texas 77002  
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Foreign Liaison to Claimant's Advisory Committee:

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Kroefteler Strasse 5  
Glashuetten, Germany 61479  
(011) 425-6202

(Appearances continuing)

Exhibit  
4

7 CLAIMS ADMINISTRATOR HUBER: And this  
8 doesn't -- the indication that it leaves a reverse  
9 double lumens memory prosthesis in place. It looks  
10 like it's convertible in this Givney?

11 MR. HORNSBY: Right. And I think that  
12 this was just a particular type product that they  
13 had that many of these were convertible, that part  
14 of it could be removed and part of it left behind  
15 as a breast implant. But in many cases the entire  
16 device would be removed as well.

17 CLAIMS ADMINISTRATOR HUBER: And where  
18 does the Dow Corning literature indicate that it  
19 can be left in?

20 MR. HORNSBY: Well, we don't have all of  
21 their literature so we don't have that. We just  
22 have what we submitted to you both as the  
23 attachment in September and what we have today.

24 MS. PENDLETON-DOMINGUEZ: Again, to follow  
25 up, there is no requirement for the time duration

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48  
1 for implantation for any product in this plan.

2 CLAIMS ADMINISTRATOR HUBER: And where  
3 does the product information say "breast"?

4 MR. HORNSBY: I'm sorry. In the one, the  
5 Attachment 1 this one does not although it has a

6 picture of a woman's breast in the upper right-hand  
7 corner. The one that I've submitted to you, which  
8 is the actual product label that comes with the  
9 device, shows you that it is a breast design  
10 product. It has the word "breast design" on the  
11 label itself. The one I just gave you.

12 CLAIMS ADMINISTRATOR HUBER: The label --

13 MR. HORNSBY: Yes.

14 CLAIMS ADMINISTRATOR HUBER: Yeah.

15 MR. HORNSBY: And the distinction here is  
16 irrelevant in the RSP because, as Diana pointed  
17 out, this didn't matter. It didn't matter one way  
18 or the other.

19 CLAIMS ADMINISTRATOR HUBER: And I'd be  
20 happy to give you all copies an e-mail from Ann  
21 Cochran indicating:

22 Bristol, Baxter and 3M tissue expanders  
23 were considered breast implants for purposes  
24 of qualifying to participate in the RSP. They  
25 could be the basis of explant benefits since

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49

1 from my understanding they were all saline  
2 filled. They could not by the definition be  
3 the basis of a ruptured claim since there