

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE:

DOW CORNING CORPORATION,

REORGANIZED DEBTOR

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CASE NO. 00-CV-00005-DT
(Settlement Facility Matters)

Hon. Denise Page Hood

**RESPONSE TO PLAINTIFFS' MOTION FOR EXPEDITED CONSIDERATION
FOR 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**

Dow Corning Corporation ("Dow Corning") respectfully submits this response to the *Plaintiffs' Motion for Expedited Consideration for 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* (the "SKK Motion").

On May 31, 2006, Robert D. Steinhaus of the law firm of Siegel, Kelleher & Kahn filed a request on behalf of numerous, unnamed claimants seeking an extension of the June 1, 2006 rupture deadline under the Amended Joint Plan of Reorganization (the "Plan"), an extension for curing all past and present deficiencies, the disclosure of substantive criteria created, adopted and/or being applied by the Settlement Facility-Dow Corning Trust ("SF-DCT"), and the acceptance of proof of rupture regardless of whether the examination was contemporaneous or whether the report was prepared by a medical doctor. *See* SKK Motion at 1-2. The movant fundamentally misunderstands

the plain language, structure and intent of the Plan and essentially seeks an unauthorized modification of the negotiated requirements of the confirmed Plan.

With respect to the rupture deadline, the Plan provides that the Rupture Payment Option Form and supporting documentation must be submitted “on or before the second anniversary of the Effective Date” or June 1, 2006. Settlement Facility and Fund Distribution Agreement (“Settlement Facility Agreement”), Annex A at § 7.09(c)(i). The Plan carves out two limited exceptions to the rupture deadline: claimants explanted within the 90-day period preceding June 1, 2006¹ (*see* Settlement Facility Agreement, Annex A at § 7.09(c)(i)) and claimants in the Explant Assistance Program whose ruptured implants were not explanted by June 1, 2006 “solely because the surgeon failed to timely return documents and/or releases.” Settlement Facility Agreement, Annex A at §6.02(c)(iv). The movant has provided *no* evidence showing that *any* claimant on whose behalf the SKK Motion was filed falls within the scope of either of these narrow exceptions. Nevertheless, the movant requests a blanket extension of the firmly established rupture deadline. As set forth below, the request must be denied.

The movant’s reading of the proof of rupture requirements under the Plan is similarly misguided. The movant asks this Court to disregard the express language of

¹ Such claimants have until 30 days after the June 1, 2006 deadline to submit the Rupture Payment Option Form and supporting documentation. *See* Plan, Annex A at § 7.09(c)(i).

the Plan – which requires contemporaneous operative and/or pathology reports issued by a licensed physician – and instead compel the SF-DCT to adopt a more relaxed standard of proof without any justification whatsoever. Such a request constitutes an unauthorized and impermissible Plan modification and, for the reasons set forth below, must be denied.

Argument

The movant first alleges that many claimants either have limited access to qualified physicians to perform the explant surgery or limited financial means to pay for the surgery but provides no evidence to support these assertions. Instead, the movant relies on gross generalizations about the “economic picture” across the country, unsubstantiated financial hardships of claimants, and undocumented explantation surgeries scheduled after June 1, 2006 as bases to warrant a blanket extension of the firmly established rupture deadline. *See* SKK Motion at 2. Such an extension must be denied as an impermissible Plan modification.

The fact that the rupture deadline was extended for one particular claimant does not warrant the wholesale extension of the rupture deadline. In the case of Shirley Coyne, the parties investigated and Dow Corning learned that the claimant had indeed filed an explant assistance claim and therefore was eligible for one of the express exceptions to the filing deadline set forth in the Plan. By contrast, here the movant has provided *no* evidence demonstrating that *any* of the claimants on whose behalf the

motion was filed are covered by any Plan exception. Granting the blanket extension sought by the movant would violate the language and intent of the Plan and would open the floodgates for any claimant, regardless of her individualized circumstances, to ask this Court to amend the firmly established and carefully negotiated rupture deadline and therefore must be denied. The Plan quite clearly and specifically provides that the Settlement Facility Agreement's terms (which incorporate the Dow Corning Settlement Program and Claims Resolution Procedures and filing deadlines) can be amended only by written agreement of the parties and court approval where the proposed modification would – as here – increase the value of any payment to the claimant. *See* Settlement Facility Agreement § 10.06. The movant cannot seek such an amendment through a motion to this Court.

The movant also argues that certain claims are being “arbitrarily denied” by the SF-DCT based on the timing on the claimants’ explanation surgery. *See* SKK Motion at 5-7. Again, the movant totally misunderstands the plain language of the Plan. There is nothing “arbitrary” about the SF-DCT’s processing of such claims. To the contrary, the SF-DCT is simply applying the express distinctions for rupture proof set forth in the Plan. *See* Settlement Facility Agreement, Annex A § 6.02(e)(iii). In order to qualify for a rupture payment, a claimant must meet the following requirements, set forth in relevant part.

- ii) **Eligibility.** To be eligible under the Rupture Payment Option, Eligible Breast Implant Claimants must submit:

- a. acceptable proof of implantation with one or more Dow Corning silicone get Breast Implants in accordance with Schedule I, Part I and;
- b. documentation that a Dow Corning silicone get Breast Implant has been removed; and
- c. documentation, as specified at subparagraph (v) below, showing that the removed Dow Corning silicone get Breast Implant was ruptured as defined above.

(iii) **Rupture Proof.**

- a. Breast Implant Claimants explanted prior to January 1, 1992 must submit a contemporaneous operative or pathology report documenting the Rupture.
- b. Breast Implant Claimants explanted on or after January 1, 1992 and on or before the Effective Date must submit a contemporaneous operative report and, if available, a pathology report together with a statement as to whether the ruptured implants have been preserved and, if so, the name and address of the custodian.
- c.
 - 1. Breast Implant Claimants explanted after the Effective Date must submit a contemporaneous operative report and, if available, a contemporaneous pathology report. In addition, the Claimant must provide a statement from the explanting surgeon (or other appropriate professional approved by the Claims Officer) affirming that, in his or her opinion, the Rupture did not occur during or after the explantation procedure. This statement must describe the results of the inspection and provide a factual basis for the opinion (e.g., in light of silicone granuloma formation on the exterior of the biologic capsule, or findings concerning the nature of the destruction of the elastomer envelope). The Claimant shall use her best efforts to cause the removed implant to be preserved.
 - 2. If the explanting surgeon refuses to write the supplemental report giving his or her opinion of when the Rupture occurred, the Claimant may submit the

supplemental statement from another doctor who examined the removed implant. Claimants must also submit the contemporaneous operative report that documents the Rupture and, if available, a contemporaneous hospital report.

Settlement Facility Agreement, Annex A at § 6.02(e)(ii), (iii). The parties agreed to a more rigorous requirement requiring the submission of an operative and pathology report for those claimants explanted after the Effective Date since those claimants are on notice of the need for additional documentation (i.e., the Plan has become effective).

Additionally, the movant asserts that the disclosure of the substantive criteria applied by the SF-DCT and tolling of cure deadlines is warranted given the SF-DCT's inconsistent treatment of medical reports.² *See* SKK Motion at 7. The movant argues that to the extent that a claimant's operative report and pathology report are inconsistent, the SF-DCT has deferred to "whichever report supports a non-rupture." SKK Motion at 7. Dow Corning cannot respond to such a bald and unsupported assertion. The only "proof" of this alleged pattern cited by the movant is a single one-page letter from the SF-DCT denying an individual claimant's request for an Error Correction Review. *See* SKK Motion, Exhibit A. Without the underlying reports and related documents, it is impossible to determine the facts and circumstances of that particular claim. Moreover, the movant proffers no evidence to suggest that the SF-

² While the movant does not expressly limit his request for disclosure to those processing guidelines relating to rupture claims, Dow Corning assumes given the context of his request that such request is limited to rupture claims only.

DCT has intentionally and systematically accorded more weight to medical reports that fail to document a rupture. The movant's request to compel the broad disclosure of processing guidelines and the blanket extension of cure deadlines, based on unsubstantiated allegations of inconsistent treatment and irrespective of the individual claimant's circumstances must not be countenanced.

Furthermore, the movant's broad request for disclosure violates both the fundamental premise and structure of the Plan as well as prior Orders of this Court and must therefore be denied. The SF-DCT's judicial work product and privileged deliberative process are not subject to disclosure. As this Court's previous Order has already made clear, all actions taken by the Claims Administrator (or any of her employees or agents) in "implementing the Settlement Facility and in collecting, collating, processing, evaluating, and paying claims" constitute "judicial actions of this Court and shall be protected, to the maximum extent allowable by law, by the doctrine of judicial immunity." *See* Order Approving Elizabeth W. Trachte-Huber As Successor Claims Administrator Pursuant To The Settlement Facility and Fund Distribution Agreement (Nov. 29, 2000). The disclosure the movant requests would violate the confidentiality required to protect claimant confidences and to allow the SF-DCT to function as recognized by the Court.

The movant also asks this Court to direct the Claims Administrator to consider proof of rupture "regardless of whether the experts' examination was contemporaneous

with the explantation or whether the expert is a medical doctor.” SKK Motion at 1-2, 7-8. The movant acknowledges that many claimants have operative and/or pathology reports that “do not address or inconsistently address whether a rupture is present”, but essentially argues that the absence or inconsistency of such language is simply a matter of semantics – that is, that the surgeons’ failure to use the term “rupture” should not be determinative of whether a rupture in fact occurred. *Id.* at 7. The movant’s suggestion that certain medical reports failed to address a rupture because either the definition did not exist at the time of explantation or was not provided to the surgeons is completely without merit. *See id.* The Plan is simple and eminently clear: it requires affirmative and contemporaneous proof of rupture. The Plan also expressly states that medical reports need not use the word “rupture.” The definition of “rupture” in the Plan³ is not so technical or uncommon that a qualified surgeon performing explantation surgery or a qualified pathologist who examines the implant immediately thereafter would be unable to recognize the existence of a “rupture” – by that name or other comparable description - and document it accordingly.

The movant’s assertion that the SF-DCT should be compelled to accept medical reports as proof of rupture even if such reports are not contemporaneous and even if the expert is not a medical doctor is likewise completely untenable. *See* SKK Motion at

³ The Plan defines a rupture as “the failure of the elastomer envelope(s) surrounding a silicone-gel Breast Implant to contain the gel (resulting in contact of the gel with the body), not solely the result of “gel bleed”, but due to a tear or other opening in the envelope after implantation and prior to the explantation procedure.” Plan, Annex A at § 6.02(e)(i).

1-2, 7-8. Again, the movant fundamentally misunderstands the explicit language, intent and structure of the Plan. In order to qualify for a rupture payment under the Plan, a claimant must submit an operative report and/or a pathology report showing that the implant was ruptured, and such report(s) must be contemporaneous. These explicit documentation requirements have a distinct and important purpose: the explanting physician (at the time of explant) is in the best position to determine whether there is a tear or breach in the elastomer envelope and whether that tear or breach occurred *before* the removal surgery. The pathologist who examines the removed implant immediately thereafter is able to determine upon close examination whether there is a tear or breach. The first-hand observations of those physicians as to the condition of the implants upon explantation are eminently reliable due to the immediate and hands-on nature of the physicians' involvement. In the absence of contemporaneous proof, complex evidentiary issues and chain of custody questions arise, making it difficult if not impossible to find a factual basis on which to conclude that there was a qualifying rupture of an implant. The SF-DCT does not and cannot under the Plan accept a non-contemporaneous report in lieu of the operative or pathology report. For example, the implant may have ruptured during the explantation surgery rather than prior thereto or during handling, shipping or storage when the implant is removed from the lab or operating room and taken into possession by the claimant, her counsel or other third

parties. The Plan expressly prohibits compensation under these circumstances. *See* Settlement Facility Agreement § 6.02(e)(i).

The movant's assertion that it is "arbitrary" for the SF-DCT to dismiss the reports of Pierre Blais, Ph.D. "based solely on the timing of the inspection" is also misguided. SKK Motion at 8. The extensively negotiated substantive proof requirements of the Plan can hardly be described as "arbitrary." These requirements are grounded in sound medical and practical judgments and they cannot be waived or modified. *See* Settlement Facility Agreement § 5.05; Annex A § 8.05. Moreover, the movant suggests that the burden is on the *SF-DCT* to demonstrate that there is a "material change in the product between the time of explantation and inspection." SKK Motion at 8. This suggestion is directly contradicted by the express language of the Plan. As the Plan makes clear, it is incumbent on the *claimant* to timely submit any additional documentation to support her claim. It is wholly inappropriate for the movant to appeal to this Court, making bald assertions that are fundamentally misguided and in direct contravention of the Plan's plain language.

Furthermore, the fact that Blais does not have a medical license is entirely relevant to the determination of a rupture. Blais is neither trained nor qualified as a pathologist or explanting surgeon. As set forth above, the Plan expressly requires that a claimant submit documentation of a rupture from a surgeon explanting the implants or a pathologist who examines the removed implant immediately thereafter. Also, it bears

emphasizing that numerous courts have found that Blais is unqualified to render opinions on a variety of subjects. *See, e.g., Giddings v. Bristol-Myers Squibb Co.*, 192 F.Supp.2d 421, 425-26 (D. Md. 2002) (precluding Blais' proffered opinion entirely, reasoning that Blais "lacks the basic skills, education and training of a medical doctor, toxicologist or pathologist to opine that the gel is harmful to the human body"); *Pozefsky v. Baxter Healthcare Corp.*, No. 92-0314, 2001 WL 967608, at *5-6 (N.D.N.Y. Aug. 16, 2001) (stressing that a number of federal and state courts in the U.S., as well as Canadian courts, have excluded or strictly limited Blais' testimony); *Grant v. Bristol-Myers Squibb*, 97 F.Supp.2d 986, 991 (D. Ariz. 2000) ("Blais may not testify as to any opinion he may have as to defects of breast implants or any other topic that is beyond his qualifications as a chemist."); *In re Breast Implant Litig.*, 11 F.Supp.2d 1217, 1243 (D. Colo. 1998) (explicitly denouncing Blais' opinions as "nothing more than subjective opinions"); *Wilson v. Guichon*, 22 A.C.W.S.3d 374 (B.C.S.C. Aug. 17, 1990), available at 1990 A.C.W.S.J. LEXIS 54549, appeal dismissed 76 B.C.L.R.2d 191 (B.C.Ct. App. 1993) ("I can give little weight to Dr. Blais unsubstantiated assertions. I frankly consider them to be a form of scare tactic adopted by Dr. Blais in his almost desperate attempt to stop the use of the Meme implant. ... In advancing his cause against the Meme implant ... Dr. Blais set aside the mantle of the scientist and replaced it with that of a zealot.... In many respects his evidence was not the objective and unbiased evidence which the Court expects of, and requires from, a scientist, an expert. It was instead so obviously biased

that in most respects it is of little value to the Court.... He was not responsive, not forthright, he exaggerated and was evasive.”). *See also Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1423 (9th Cir. 1998) (affirming district court’s exclusion of Blais’ testimony in action against a brain shunt manufacturer because he was “relying on underground knowledge, untested and unknown to the scientific community”). Moreover, the fact that Blais’s reports allegedly have been accepted by the SF-DCT as proof of product identification is without consequence. The Plan requirements for product identification are completely different from the requirements for proof of rupture and acceptance of a report for one purpose does not presume, much less necessitate, acceptance for another purpose. *Compare* Settlement Facility Agreement, Annex A § 6.02(e)(iii) (rupture proof); Schedule I, Part I(D).

Finally, the movant’s request for a six-month extension for curing all past and present deficiencies is moot since the Court has already extended all cure deadlines to enable the Claims Administrator to complete certain quality control and audit reviews. The Debtor’s Representative and the CAC recently submitted an agreed order resetting all cure deadlines that will expire by January 16, 2007 to January 17, 2007. *See Proposed Agreed Order Resetting Cure Deadlines to January 17, 2007* (“Agreed Order”) The Proposed Agreed Order specifically provides that “[t]he Court will not, during this Temporary Period of Suspension, hear argument on any additional motions for relief from cure deadlines.” *See Agreed Order Temporarily Suspending All Cure Deadlines* at 2

(filed August 5, 2005), as modified by the Proposed Agreed Order. It is unclear from the SKK Motion which, if any, of the claimants have cure deadlines that expire before the January 16 deadline since the movants have provided absolutely no evidence for these individual claims. Even if some of the claimants have cure deadlines after January 16, 2007 and therefore do not technically fall within the scope of the Agreed Order, their request should nevertheless be denied given that such claimants have more than ample opportunity – indeed more than the six months requested – to schedule any necessary procedure and that the express purpose of the Agreed Order was to allow the Claims Administrator additional time to review and address precisely the kinds of issues raised by the movants. Accordingly, the six-month extension of all cure deadlines should be denied in its entirety.

Conclusion

Implicit in the request of the SKK Motion is the assumption that this Court can abolish the carefully negotiated Plan deadlines and direct the SF-DCT to adjust the June 1, 2006 rupture deadlines on a wholesale basis. Such relief would constitute an unauthorized modification of the Plan and must not be countenanced. Furthermore, the movant's request for an extension of all cure deadlines should be denied in its entirety. Should the Court determine that the request is not moot in light of the Agreed Order, Dow Corning adopts its arguments regarding the extension or tolling of cure deadlines stated in various responses to similar motions previously filed with the

Court. Moreover, the movant's request for disclosure of substantive criteria applied by the SF-DCT – whether or not limited to rupture claims – violates the fundamental premise and structure of the Plan and Orders of this Court, is impractical and would invite endless litigation as to the meaning and validity of every factual interpretation applied by the SF-DCT and therefore must be denied. Finally, the movant essentially asks this Court to re-write the language of the Plan to compel the SF-DCT to accept proof of rupture regardless of whether the examination was contemporaneous or whether the report was prepared by a medical doctor. Such a request violates the Plan's language, structure and intent and reveals the movant's total misinterpretation of the Plan documents and must also be denied.

Respectfully submitted this 21st day of June 2006.

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§ (Settlement Facility Matters)
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§ HON. DENISE PAGE HOOD
REORGANIZED DEBTOR §

CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2006 a true and correct copy of the following pleading was served via electronic mail, telecopy, or overnight mail upon the parties listed below:

**RESPONSE TO PLAINTIFFS' MOTION FOR EXPEDITED CONSIDERATION
FOR TOLLING OF RUPTURE DEADLINE; REQUEST FOR SIX MONTH EXTENSION FOR CURING
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