UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE:	§	
	§	**CASE NO. 00-CV-00005-DT**
DOW CORNING CORPORATION,	§	**(Settlement Facility Matters)**
	§	
REORGANIZED DEBTOR	§	**Hon. Denise Page Hood**

SUPPLEMENTAL RESPONSE REGARDING THE 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

Dow Corning Corporation ("Dow Corning") respectfully submits this Supplemental Response Regarding the Response of the Claimants' Advisory Committee to Plaintiffs' Motion (the "Supplemental Response").[1]

On May 31, 2006, Siegel, Kelleher & Kahn filed a motion (the "SKK Motion")[2] on behalf of unnamed claimants. Dow Corning filed its response to the SKK Motion on June 21, 2006, clarifying that the relief requested would constitute an unauthorized modification of the Plan. *See*

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[1] Dow Corning files this Supplemental Response in accordance with Local Rule 7.1(d)(2). On June 22, 2006, Dow Corning through its local counsel, Garan Lucow Miller PC, contacted the clerk of the Court seeking guidance regarding a supplemental response. Since the CAC Concurrence is a concurrence with the SKK Motion, the clerk confirmed that the Court would accept a supplemental response from Dow Corning pursuant to Local Rule 7.1(d)(2) which provides for a 14-day time period in which to submit a response. Because of a health problem experienced by a lawyer with principal responsibility for some of the issues raised by the CAC's Concurrence, Dow Corning requested from the CAC an extension of the July 11 deadline. Mr. Hornsby agreed to the extension, and on July 11 the Parties executed the *Agreed Order Extending the Deadline for Dow Corning Corporation to July 26, 2006 to File Supplemental Response Regarding the 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* (the "Agreed Order"), which extended the response deadline until July 26, 2006. This Supplemental Response is duly authorized by the local rules of this Court.

[2] The SKK Motion is entitled *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.*

Document No. 399 ("Dow Corning's Response").[3] That same day, the Claimants' Advisory Committee ("CAC") filed its Response to the SKK Motion, Document No. 412 (the "CAC Concurrence").[4] The CAC Concurrence supports the SKK Motion and requests the same relief. The CAC Concurrence blatantly disregards the letter and intent of the confirmed and substantially consummated Plan and seeks a unauthorized unilateral Plan amendment. The CAC Concurrence reads as if there were *no* confirmed Plan at all – as if there were *no* defined proof requirements that had been carefully negotiated, mutually agreed to, confirmed by the Bankruptcy Court and this Court and already applied to thousands of claims over the course of several years.

Argument

I. The CAC's Request That This Court Compel the SF-DCT to Accept Documents Not Authorized by the Plan as Proof of Rupture Constitutes an Impermissible Plan Amendment.

The CAC Concurrence is nothing more than a bald attempt to unravel the heavily negotiated Plan. During the nine-years of the Chapter 11 case, the Parties defined the key terms and provisions of the Plan. The Parties agreed to adopt the precise terms of the Revised Settlement Program ("RSP") with respect to the eligibility of rupture claims.[5]

The SKK motion and the CAC's concurrence seek to unilaterally amend the Plan through litigation. The Plan itself prohibits any amendment that would affect claim values absent agreement of both Dow Corning and the CAC. *See* Settlement Facility and Fund Distribution Agreement ("SFA") § 10.06. Neither the CAC nor any claimant or lawyer representing claimants can now seek

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[3] Dow Corning's Response is entitled *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.*

[4] The CAC Concurrence is entitled *Response of the Claimants' Advisory Committee 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.*

[5] There were some timing modifications to reflect the fact that the Dow Corning settlement occurred years after the RSP became effective and the Plan contains some additional procedures for proving a rupture claim that are not relevant here.

to impose through litigation over individual claims or group of claims any amendment to the Plan. This Plan was confirmed by the Bankruptcy Court nearly seven years ago and was substantially consummated two years ago. The fact that some claimants have been unable to present the documentation required by the Plan to qualify for benefits does not provide authority to create new criteria for qualification of claims. Indeed, these motions in effect seek to "appeal" the decision of the Claims Administrator and Appeals Judge in violation of the Plan. The CAC's Response constitutes an unauthorized, impermissible attempt to amend the Plan and therefore must be denied.

A. The Plan Requires A Claimant to Submit a Contemporaneous Operative Report and/or Pathology Report to Document a Rupture.

To prove a rupture claim, 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. *See* SFA, Annex A § 6.02(e)(iii). 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 the condition of the implant and can confirm the findings of the operative report. 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.

Without contemporaneous proof, complex evidentiary issues and chain of custody questions arise, making it difficult if not impossible determine whether there was a qualifying rupture of an implant. The Settlement Facility-Dow Corning Trust ("SF-DCT") does not, cannot and should not accept a non-contemporaneous report in lieu of the operative or pathology report. Allowing rupture to be assessed at later times and at potentially distant locations introduces the risk that the implant

may be damaged at some time after explantation or that the chain-of-custody may be disrupted.[6] Given that the explanting surgeon and/or pathologist already conduct the macroscopic examination (i.e., visually inspecting and manually squeezing the implant) that is the accepted scientific standard for diagnosing rupture, a later microscopic analysis of an implant that may have been damaged in the interim is both unnecessary and scientifically unsupportable. *See infra*, Section II(B). That aside, the Plan clearly and expressly prohibits the use of non-contemporaneous statements to document rupture. *See* SFA, Annex A § 6.02(e)(vii)a. and (vii)f.

The Plan also makes unmistakably clear that these documentation requirements cannot be modified absent written consent of the Parties and court approval where the proposed modification would, as here, alter the funding obligations of Dow Corning. *See* SFA §§ 5.05, 10.06; SFA, Annex A § 8.05. The Parties spent years negotiating the terms of the Plan, including the appropriate standard for documenting a rupture. The agreed-upon criteria, set forth in unambiguous terms, provides clear-cut standards that can be applied in an administrative claims processing system. The Plan structure does not contemplate and does not allow the Claims Administrator to adopt a case-by-case "expert" evaluation to attempt to determine rupture. Such a mechanism would be tantamount to a litigation type of evaluation for each claim. The Parties clearly rejected such an approach. The suggestion by the CAC that the requirements are minimum requirements is ludicrous. The Plan does and was intended to spell out the exact documents required, and the only documents permitted, to prove a rupture claim. The Plan does not permit the use of other types of documents to prove a compensable rupture claim.

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[6] The practical reality is that after explantation, breast implants often pass through a number of hands over the course of several years, often being shipped great distances. A patient may request to receive the implant from the hospital, which she may then store in unknown conditions, before later passing the implant to her attorneys, who may also store it in unknown conditions, ultimately shipping the implant to one or more experts for examination and testing. During this journey, the implant may be improperly handled, improperly stored, improperly sterilized or improperly tested. It may be subject to accidental damage. The chain-of-custody may be disrupted or unknown. Each of these steps introduces a substantial risk that the implant may be damaged, mishandled or misidentified.

Methods of determining rupture that are not authorized by the Plan are irrelevant.[7] If the CAC believed that certain forms of proof, i.e., the examination of implants by "experts," represented the "gold standard" for determining rupture, they should have attempted to negotiate to include such forms of proof in the Plan. Clearly, they did not. The CAC does not have license, years after the terms were negotiated and the Plan became effective, to rewrite the settlement to accommodate ineligible claimants. The Claims Administrator can consider information in addition to the contemporaneous report of the explanting surgeon (and pathology report if there is one) *only if* the claimant is explanted after the Effective Date and *only if* the surgeon refuses to provide a supplemental report detailing when the rupture occurred. *See* SFA, Annex A § 6.02(e)(iii)(c)(2). The requirement of a contemporaneous statement from the explanting surgeon was put in place so the record would be clear as to whether or not the implant was ruptured before removal. Where the explanting surgeon refuses to provide that statement – and only in that case – is the claimant allowed to prove rupture by submitting a statement from another doctor who subsequently examined the implant. In all other respects, the Parties agreed that the determination of rupture would be based on the contemporaneous records of the explanting surgeon (and pathology report if available).

The arguments advanced in the SKK Motion and the CAC Concurrence, seeking to engraft new and different terms onto Section 6.02 so as to permit, or even require, the Claims Administrator to accept statements from non-physicians years after the implant was removed violates basic canons of contract construction. These include the principle that if the Parties recognize certain exceptions – but not others – to a rule, the contract will be read to exclude the other exceptions under the cannon "expressio unius est exclusio alterius" (or the "expression of one thing is the exclusion of

[7] It is Dow Corning's understanding that the SF-DCT may accept documents other than pathology reports and/or operative reports to *clarify* the findings in such reports, but not to prove a rupture.

the other"). *See In re Dow Corning Corp.*, 113 F.3d 565, 569 (6th Cir. 1997) (on petition for writ of mandamus); *National Fire Ins. Co. v. Roofmaster Const., Inc.* 2005 WL 1030326 at *10 (E.D. Mich. 2005). This venerable contract rule is based in simple logic, namely that the parties would have included the other exceptions had they intended them to be part of the agreement. Here, the agreement contemplates a supplemental statement in only one narrow circumstance, and that limited exception to the rule requiring a contemporaneous statement of the explanting physician logically excludes other exceptions to that rule, including the broad introduction of supplementary statements and materials advocated by SKK and the CAC.

The fact that post-explant documentation of rupture by microscopic examination is not listed as an unacceptable form of proof (*see* CAC Concurrence at 3) means nothing. Section 6.02(e)(iii) of Annex A to the SFA is a mandatory provision: it identifies the specific documentation *required* to support a rupture claim. By contrast, Section 6.02(e)(vii) is an illustrative provision: it identifies a non-exhaustive list of *examples* of proof that the SF-DCT would deem unacceptable. Nowhere does that provision indicate that forms of proof not included on the list would or should be considered acceptable by the SF-DCT, as the CAC erroneously suggests.

B. Bankruptcy Law and the Plan Expressly Prohibit Modification of the Confirmed Plan.

The Plan was confirmed by the Bankruptcy Court nearly seven years ago and was substantially consummated over two years ago. It is a well-established principle of bankruptcy jurisprudence that after confirmation, a plan of reorganization may be modified only in limited circumstances. Section 1127(b) of the Bankruptcy Code provides, in relevant part, that the

> proponent of a plan or the reorganized debtor may modify such plan at any time after confirmation of such plan and before substantial consummation of such plan.... Such plan as modified under this subsection becomes the plan only if circumstances warrant such modification and the court, after notice and a hearing, confirms such plan as modified, under section 1129 of this title.

11 U.S.C.A. 1127(b). The statute thus allows modification of a confirmed plan only if "substantial consummation" has not occurred. *See In re American Home Patient, Inc.*, 420 F.3d 559, 563 (6th Cir. 2005) *citing Unofficial Comm. of Co-Defendants v. Eagle-Picher Indus., Inc.* (*In re Eagle Picher Indus., Inc.*), 1998 WL 939869, at *4 (6th Cir. Dec.21, 1998) (unpublished) (citation and quotation marks omitted); *LLP Mortg., Ltd. v. Park Bowl, Inc.*, 2003 WL 22995011 at *5 (E.D. Mich. 2003); *In re Hayball Trucking, Inc.*, 67 B.R. 681, 682 (Bankr.E.D.Mich.1986). "Substantial consummation" is defined in the Bankruptcy Code as the "(A) transfer of all or substantially all of the property proposed by the plan to be transferred; (B) assumption by the debtor or by the successor to the debtor under the plan of the business or of the management of all or substantially all of the property dealt with by the plan; and (C) commencement of distribution under the plan." *See* 11 U.S.C. § 1101(2). Clearly, all three prongs of this test are met here. Dow Corning has transferred to the SF-DCT assets far in excess of the amounts due under the Funding Payment Agreement at this time. Indeed, the Plan requires additional payments only if necessary to pay claims. The responsibility for resolution of claims and distribution of property to claimants was turned over to the SF-DCT and Litigation Facility over two years ago and the Reorganized Dow Corning assumed responsibility for management of its property on the Effective Date. Plan § 8.2. Of course, distribution of assets to tort claimants and other creditors commenced over two years ago and, indeed, as of May 31, 2006, over $614 million has been distributed to tort claimants and over $1 billion has been distributed to commercial creditors.[8] There can be no argument that the Dow Corning Plan is not substantially consummated, and because the Plan *is* substantially consummated, Section 1127(b) prohibits its amendment.

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[8] To confirm substantial consummation, courts consider the practicality and legality of restoring the pre-Plan status quo. *See LLP Mortg.* At *4. Obviously, it is impossible to restore the status quo here. Tens of thousands of creditors have been paid over $1.5 billion.

Moreover, the Plan prohibits the modification suggested by the CAC. The CAC's amendment would increase Dow Corning's financial obligations under the Plan, potentially affect the payments to other claimants and would, of course, increase the value of the currently ineligible rupture claims. The Plan expressly prohibits any post-Effective Date modifications of the SFA and Annex A that would increase the value of a claim absent agreement of both Parties. *See* SFA § 10.06. *See also Eagle Picher,* 1998 WL 939869 *(modification of a Plan that would affect the rights of parties not before the Court is impossible and impermissible).*

C. Claimants Have No Right to Litigate the Merits of Their Claims.

It is the function of the Claims Administrator to evaluate claims on an individual basis and determine whether the documentation provided by the claimant satisfies the relevant Plan requirements. In the event of a dispute, the Plan establishes detailed error correction and appeal procedures that specifically address how such disputes must be resolved. *See* SFA, Annex A §§ 8.01-8.06. The Plan expressly provides that the "decision of the Appeals Judge will be final and binding" on the claimant. *See* SFA, Annex A § 8.05. Thus, the Plan expressly prohibits litigation over the proper evaluation of each individual claim in the settlement program. *See* SFA §§ 4.02(a), 4.03(a), 5.05; SFA, Annex A § 8.05. This attempt by the CAC and other plaintiffs to bypass the agreed-upon administrative process and seek (in effect) impermissible reviews of their individual claims through motion practice must be rejected.

II. Plaintiffs' Litigation Experts Are Biased and Provide Scientifically Unreliable Opinions That Cannot Support A Rupture Claim Under the Plan.

The opinions of plaintiffs' litigation experts (such as Dr. Blais) were purposely excluded from the list of acceptable proof to demonstrate rupture under the Plan and for good reason. *First*, many of the plaintiffs' experts in breast implant litigation, including especially Dr. Blais, revealed themselves to be biased to the point that their opinions could not be deemed scientifically reliable. *See*, *infra*, Section II(A). Those opinions cannot now form the basis for reliable evidence of rupture

before the SF-DCT. *Second*, the use of a third party to microscopically examine an implant is not the scientifically accepted method for determining rupture. *See*, *infra*, Section II(B). *Third*, as set forth above, relying on a third party who is removed both in time and location from the explantation surgery presents an unacceptable risk of damage to the implant, as well as chain-of-custody concerns, after it is removed from the patient's body. *See*, *infra*, Section I(A).

A. Plaintiffs' Litigation Experts Cannot Provide Scientifically Reliable Evidence of Rupture.

In drafting and negotiating the Plan, the Debtor was well aware of plaintiffs' partisan expert witnesses such as Dr. Blais, and purposely excluded the opinions of such witnesses as acceptable proof of rupture. While the litigation history of every potential plaintiffs' biomaterials witness is beyond the scope of this memorandum, Dr. Blais' history alone demonstrates why the claims of such experts cannot be deemed reliable evidence of rupture. As set forth in Dow Corning's Response to the SKK Motion, Dr. Blais' opinions lack scientific credibility and Dr. Blais has consistently shown himself to be irretrievably biased on the subject of breast implants. *See* Dow Corning Response at pp. 10-12. The story of Dr. Blais' involvement with implants reveals an ongoing intellectual and scientific bias and lack of integrity that, at the very least, disqualifies his assertions from providing adequate support for any scientific assertions with respect to breast implants.

Dr. Blais is a Canadian chemist with a Ph.D. in physical chemistry. He claims expertise regarding silicone breast implants based on fourteen years of employment as a research scientist in the Bureau of Radiation and Medical Devices of the Canadian Department of National Health and Welfare. (Ex. A, Merlin Dep. 27:16-28:20.) In 1989, Dr. Blais was fired from the Canadian Government for "several serious infractions which place[d] into question both [his] scientific integrity and the element of trust and confidence [essential to his position]," including the

"unauthorized release of scientifically unsubstantiated material" criticizing the Meme silicone gel breast implant. (Ex. B at 1, 2 (emphasis in original).)[9]

Dr. Blais then founded Innoval, a company he runs out of a storage room adjacent to his home in Ottawa, Canada.[10] Innoval's primary business has been operated in cooperation with breast implant plaintiffs' attorneys for the purpose of supporting Dr. Blais' litigation activities in breast implant cases. *Id.* at 1243 ("In fact, the vast majority of Innoval's business comes from plaintiffs involved in breast implant litigation.") In 1996, Dr. Blais spent 90% of his time consulting and testifying in breast implant cases. (Ex. C, *Spitzfaden* Tr. 2110-16.) Blais has been so discredited in Canada that he ceased testifying there after he was rebuked in 1990 by the British Columbia Supreme Court for "setting aside the mantle of the scientist and replac[ing] it with that of the zealot." (Ex. D, *Wilson v. Guichon*, Nos. C863922 and C865281, B.C.J. No. 1812, at 34 (B.C. Supr. Ct. Aug. 7, 1990), *appeal dismissed*, 76 B.C.L.R. (2d) 191.[11] Following this rejection in his home market, Dr. Blais shifted his focus to the United States where plaintiffs' attorneys named Dr. Blais as an expert in hundreds of cases. As U.S. courts began to examine Dr. Blais' methods and opinions, however, those courts also began to exclude Dr. Blais from testifying. Numerous courts

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[9] Blais appealed his dismissal, and his discharge was upheld. Ultimately the matter was settled, and Blais left the government. (*Spitzfaden* Tr. at 2137).

[10] "Innoval is a 'barebones implant and materials retrieval system.' . . . Dr. Blais has testified that Innoval is a corporation and/or trade name under with Dr. Blais does business. . . . Blais is the only chemist on staff. Innoval has never had any [medical] doctors on staff. . . . Innoval's facilities consist solely of Blais' house in Ottawa." *In re Breast Implant Litigation*, 11 F.Supp.2d 1217, 1241 (D. Colo. 1998).

[11] In the words of that Court:

> [Blais'] 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. His crusade and his methods used in attempting to discredit the Meme appear to have cost him his job. They have also colored his evidence such that I do not believe that it would be safe to accept it unless it is corroborated by other evidence. . . . He was not responsive, he was not forthright, he exaggerated and was evasive.

Id. at 34-35. *See also In re Breast Implant Litigation*, 11 F.Supp.2d at 1244.

have now rejected Dr. Blais' opinions, in whole or in part, finding them tainted by his own personal bias and scientifically unsound.

1. Bias. Numerous federal and state courts have echoed the findings of the Canadian courts regarding the extent of Dr. Blais' bias. These courts have found Dr. Blais to be a "troubling witness" who is so biased that he is incapable of providing reliable, honest scientific opinions.[12] His lack of objectivity and biased "evidence" have been described as so extreme as to preclude his opinions from being presented to a jury. After being shut down by courts across North America, Dr. Blais should not now be permitted to shift his focus again by providing his tainted speculations to the SF-DCT in the guise of post hoc rupture assessments.

2. Lack of Scientific Reliability. Courts have also excluded Dr. Blais' opinions because they are scientifically unsound and therefore unreliable. *See, e.g., Johnson v. Baxter,* Second Judicial District, Cty of Bernalillo, No. CV-92-07501 at 4 (1990), Ex. E,. From a scientific standpoint, the problems with Blais' methods are legion. To date courts have found:

(a) Blais is unqualified to testify on the subjects in which he purports to be an expert. Blais is not a medical doctor or a pathologist, yet he has continually attempted to render opinions that bear on those subjects.[13] It is hoped that Blais will not be seeking to render medical opinions here, but his repeated attempts to do so in the past are symptomatic of the scope of his unsupportable opinions. *See In re Breast Implant Litigation*, 11 F.Supp.2d at 1241 ("Although

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[12] *See, e.g., In re Breast Implant Litigation,* 11 F.Supp.2d at 1243 ("Dr. Blais' opinions are also challenged because they were developed for litigation purposes and demonstrate extraordinary bias and disregard of scientific methods. . . . Whether or not testimony is biased and unreliable because it was developed solely for litigation purposes is an important factor in determining the admissibility of evidence. . . . This factor provides an additional reason for excluding Dr. Blais' testimony here."); *See also Pozefsky v. Baxter Healthcare Corp.*, 2001 WL 967608 at *7 (N.D.N.Y. 2001) ("It is important to note that Dr. Blais' theories have been created solely for the purpose of litigation.").

[13] At least two courts have stated that Dr. Blais is unqualified to render an opinion on medical issues. *See In re Breast Implant Litigation*, 11 F.Supp.2d at 1242 ("Dr. Blais is not qualified by knowledge, skill, experience, training, or education to testify about medical issues such as the presence of disease, the mechanism of disease, the causes of disease, or what occurs in the human body in response to the presence of a breast implant.");*Giddings v. Bristol-Myers Squibb Co.*, 192 F.Supp.2d 421, 426 (D. Md. 2002).

Plaintiffs represent that Dr. Blais will not testify about medical issues, his reports are rife with conclusions about medical issues.").

Dr. Blais has also been judged unqualified to render opinions on product defects in connection with breast implant litigation. The U.S. District Court for the District of Maryland ruled that "the Court finds Dr. Blais to be unqualified to state an opinion on product defects." *Giddings*, 192 F.Supp.2d at 425. Likewise, the court in *Johnson* ruled that "[Dr. Blais] will not be allowed to give general opinions on the manufacture or design of implants, . . . nor the issues of implant failure." *Johnson* at 5. The District Court for the District of Colorado agreed: "As to his opinions concerning implant design, manufacturing, marketing and labeling, Dr. Blais is a chemist with no experience in the design, manufacturing, marketing, or labeling of silicone breast implants and lacks qualifications to opine about these subjects." *In re Breast Implant Litigation*, 11 F.Supp.2d at 1243. Dr. Blais' attempts to assess rupture here are no more within his area of expertise as a chemist than they were when he attempted to opine on breast implant failure and product defects in earlier litigation.

(b) Dr. Blais' opinions are not generally accepted in the scientific community.

Numerous courts have found Blais' opinions to be unsupported by the scientific community.[14] While these judicial opinions often relate to Blais' attempts to opine on medical or toxicological issues, the criticisms of Blais' methods and conclusions are equally applicable to his rupture assessments. As discussed further below, Blais' use of microscopic examination is not the scientifically accepted way of determining whether an implant was ruptured at the time it was removed from a patient's body.

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[14] *See, e.g., In re Breast Implant Litigation*, 11 F.Supp.2d at 1243 ("Plaintiffs have not demonstrated that Dr. Blais' methodology or opinions are generally accepted in the scientific community. . . The theories offered by Dr. Blais are not supported by generally accepted scientific data."); *Johnson* at 4 ("His opinions are peculiarly his own without any general acceptance in the scientific community and without any ability of testing or peer review.").

(c) Dr. Blais' theories are unscientific, untested and unpublished. Courts excluding Dr. Blais' opinions routinely cite his failure to meet even the most fundamental scientific requirements, including (a) following an accepted methodology, (b) testing theories, and (c) publishing results for review and comment by the scientific community. As the District Court for the District of Colorado explained when excluding Blais' testimony: "Dr. Blais has not applied any definable scientific methodology, much less a generally accepted methodology, to reach his opinions. . . . Dr. Blais has no measured or quantitative data to support his opinions. Dr. Blais' opinions amount to nothing more than subjective opinions." *In re Breast Implant Litigation*, 11 F.Supp.2d at 1243. "No publication of Dr. Blais' hypotheses, methodology or opinions exists in the peer review[ed] literature. Dr. Blais concedes that he does not publish." *Id.*

These comments have been mirrored by a number of other courts:

- "He publishes nothing [and] keeps no set of systematic records of his tests or observations." *Johnson* at 4.
- "By Blais's own characterization, he is relying on underground knowledge, untested and unknown to the scientific community. An opinion based on such unsubstantiated and undocumented information is the antithesis of the scientifically reliable expert opinion admissible under *Daubert* and Rule 702." *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1423 (9th Cir. 1998) (excluding Dr. Blais from testifying in a silicone catheter case).
- "To be sure, Dr. Blais' testimony lacks reliability and relevance. Dr. Blais has not published any related research or opinions in peer review literature." *Giddings*, 192 F.Supp.2d at 425.
- "Many other courts have excluded Blais' opinion on the alleged defect of implants finding it unreliable and not accepted in the general scientific community as to systemic injury caused by silicone breast implants. This Court agrees that Blais is not a medical doctor and has not supported his theories with testing. Further Blais did not develop his opinions independent of litigation." *Grant v. Bristol-Myers Squibb,* 97 F.Supp.2d 986, 991 (D. Ariz. 2000).

Dr. Blais has proven himself incapable of using accepted scientific methods to attain any sort of reliable scientific conclusion. Instead, in his decades-long crusade against breast implants, he has looked only to his own biased and subjective beliefs – beliefs which have been resoundingly rejected by those courts that have undertaken a detailed examination of his methods and opinions.

Those "totally unscientific and therefore unreliable" opinions cannot now be revived as acceptable proof of rupture before the SF-DCT.

B. Macroscopic Examination At The Time Of Explantation Is The Scientific Standard For Determining The Existence Of Rupture.

Plaintiffs' claim that examination using a microscope is needed to determine if an implant was ruptured once again disregards accepted science. Independent scientists *have* developed unbiased and reliable scientific protocols for assessing whether an implant was ruptured at the time it was in a patient's body. These published protocols for implant retrieval and analysis define the information that should be collected at different stages of the explantation and examination process, including information on whether an implant was ruptured.

The U.S. Food and Drug Administration recommends a single publication that addresses the sequence of steps for reliably collecting information on explanted breast implants. Ex. G, FDA, *Draft Guidance for Industry and FDA Staff, Saline, Silicone Gel, and Alternative Breast Implants* (Jan. 13, 2004). The article – H. Brandon, et al., "Protocol for Retrieval and Analysis of Breast Implants," *Journal of Long Term Effects of Medical Implants*, 13(1): 49-61 (2003), co-authored by Dr. Harold Brandon[15] and other researchers at Washington University – specifies (as does the Plan) that whether an implant is ruptured should be determined by the *explanting physician.* Specifically, the protocol states that the explanting surgeon should assess and record the "integrity status of the explant (intact, pinhole defect, rupture, deflation)" as well as "suspected mode of explant failure, if known and applicable." Brandon (2003) at 51. As Dr. Brandon notes in his declaration that is attached as Ex. F, the explanting surgeon and associated pathologist are readily able to assess

[15] As an eminent researcher in his field, Dr. Brandon has received research funding for his work on the mechanical properties of breast implants from Dow Corning and other breast implant manufacturers, in addition to well-respected research foundations including the Plastic Surgery Educational Foundation, the National Endowment for Plastic Surgery, and the Aesthetic Surgery Education and Research Foundation. He has also been named as an expert witness in breast implant litigation on behalf of implant manufacturers, but has not testified in litigation.

rupture through this *macro*scopic inspection; that is, visually inspecting and manually squeezing the implant. Moreover, the physician and/or pathologist are in the best position to determine whether an implant was ruptured before or at the time it was removed from the patient. (Ex.M, Brandon Aff. at 2-5.)

Thus, at the time of the explantation surgery, the surgeon determines *whether* an implant was ruptured through a straightforward visual and manual examination of the implant. Typically, only *if* an implant is determined to be ruptured is it then subjected to further examination to determine *why* the implant may have ruptured. It is at this later stage that microscopic examination may be employed to look, for instance, for evidence that the implant may have been damaged by surgical instruments or through other means.

The scientists at Washington University are not the only researchers to set out a reliable scientific methodology for rupture analysis. Health Canada (the Canadian equivalent of the FDA) convened an expert scientific panel which was asked to review certain issues relating to breast implant rupture. The Record of Proceedings from September 2005, states:

> The following procedure is followed when evaluating an explanted device to determine the cause of failure: (1) *visual inspection*; (2) *slightly squeeze product* to see if there are any openings through which gel extrudes.

The panel further concluded that it was only "*if* a 'failed' region [is] detected, that [the] region is examined under a microscope."[16] (Ex. H, Health Canada, Expert Advisory Panel on Breast Implants, Record of Proceedings Sept. 29-30 (2005).)

After an extensive examination of scientific literature, the independent and authoritative Institute of Medicine (a part of the National Academy of Sciences) came to the same

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[16] The surgeon may also "evaluate damage occurring from surgical incidences (primary cause of failure; suture needle or scalpel) identified by matching striations on implants to scalpel blade grind lines, and imprints due to needle tips." *Id.*

recommendation in 2000.[17] The IOM's 2000 report, comprehensively reviewing the world's literature on breast implants, addressed the question of how an implant should be examined for rupture. It concluded, "Careful explantation and direct visual examination are the standard for diagnosis of silicone-gel filled implant rupture, both unsuspected or silent, and for confirmation of rupture." (Ex. I, IOM Report at 131.) Thus, the scientists who have developed protocols for implant examination agreed that *macro*scopic inspection (visual inspection and squeezing) is the accepted method for determining whether an implant was ruptured at the time it was explanted. *Micro*scopic inspection is needed *only if* a failure is already detected by the macroscopic examination, to determine the cause of the failure such as possible surgical damage.

C. The Goldberg and Marotta Studies Support Macroscopic Examination at Explantation, Not a Later Microscopic Examination.

The articles by Drs. Goldberg and Marotta[18] cited by the CAC do not, as the CAC suggests, recommend the use of microscopic examination to determine whether an implant was ruptured. Goldberg and Marotta conducted what they describe as a meta-analysis, looking at a number of rupture studies. But in many, if not all, of the studies that Goldberg and Marotta collected, the existence of a rupture was determined by the explanting surgeon using *macro*scopic examination, rather than a later microscopic examination by a third party. Examples include the studies by Dr. Brandon and colleagues, in which the explanting physician, using the protocol developed at Washington University, determined the implant was ruptured.[19] Thus, the Marotta and Goldberg studies provide no support for the use of after-the-fact microscopic examination to determine rupture. Even assuming that the studies did support an alternative form of rupture proof, such proof

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[17] The Institute of Medicine was established in 1970 under the charter of the National Academy of Sciences, to provide "independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public." Institute of Medicine Website, http://www.iom.edu/.

cannot be engrafted onto the confirmed and substantially consummated Plan. Both the express Plan language and well-settled law prohibit such modifications.

Moreover, the CAC's argument that Dr. Marotta could only document one *cause* of rupture by post-explant examination misses the point. CAC Br. at 4. As the published scientific protocols explain, macroscopic examination by the explanting surgeon and/or pathologist is the key to determining *whether* an implant was ruptured *in vivo*, that is, in the patient's body – which is the only relevant inquiry before the SF-DCT. Later examination to determine the *cause* of the particular rupture is not relevant to the question the SF-DCT must answer with respect to a particular implant.

D. Implant Strength Remains Stable Over Time.

The CAC's claims that breast implants deteriorate and lose strength over time are untrue and unavailing. The CAC again relies on papers by Drs. Goldberg and Marotta to support these claims. Dr. Goldberg, however, is another paid litigation witness for plaintiffs' attorneys and suffers from the same bias demonstrated by Dr. Blais. Indeed, Dr. Goldberg and his colleagues have received direct funding for their research from breast implant plaintiffs' attorneys. (Ex. J, Goldberg Trial Testimony in *Spitzfaden* at 2762.)[20] Following his receipt of this, Dr. Goldberg began his career as

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[18] J. Marotta et al., "Silicone Gel Breast Implant Failure: Evaluation of Properties of Shells and Gels for Explanted Prostheses and Meta-analysis of Literature Rupture Data," Annals of Plastic Surgery 49(3): 227-42 (Sept. 2002); J. Marotta et al., "Silicone Gel Breast Implant Failure and Frequency of Additional Surgeries: Analysis of 35 Studies Reporting Examination of More than 8000 Explants," J. Biomed. Mater. Res. (Appl. Biomater.) 48: 354-64 (1999).

[19] The CAC further cites Goldberg and Marotta for the proposition that "examination of a prosthesis when explanted is the definitive method for determining shell integrity." CAC Concurrence at 4 (quoting Marotta (1999) at 355). Marotta and colleagues were not, however, arguing in favor of microscopic examination to determine rupture. Rather, they were simply arguing for the importance of examining only implants that have been removed from the patient, rather than attempting to assess the rupture of an implant while it remains in the patient's body (which some studies attempt to do using MRI or other techniques). *See* Marotta (1999) at 355 (criticizing study result that "was based upon the use of the total patient cohort [of explanted and non-explanted patients]. . . . In our view, only the explanted patient population should have been used in the calculation to give a scientifically valid result.").

[20] In 1991 and 1992, Dr. Goldberg wrote to Dow Corning on several occasions seeking $2.5 million in research funding, and offering to create a Dow Corning Wright research center at the University of Florida. (Ex. J, Spitzfaden Tr. at 2763-2778.) In one letter, Dr. Goldberg explained that "DCW clearly appears to have emerged as a leader in sophisticated biomaterials and

a plaintiffs' expert in breast implant litigation, testifying for the very same attorneys who funded his work.[21] (Ex. J, Spitzfaden Tr. at 2763-2778.)

One unwarranted conclusion reached by Goldberg and Marotta is their assertion that implants degrade and experience a significant loss of strength over time, including those implants that were never implanted but simply sat on a shelf. See CAC Br. at 4. This conclusion is refuted by controlled studies in the scientific literature, and is not even supported by Goldberg and Marotta's own data. Research by Dr. Brandon and colleagues on Dow Corning breast implants demonstrates that implant strength remains essentially stable over time, whether the implant is in a patient's body or is left unimplanted. Dr. Brandon's group tested Dow Corning implants that had been implanted for as long as 32 years, comparing them to "control" implants (implants of the same model and era that had never been implanted). Their research analyzed implants with the entire range of implantation times available to date, including the oldest known first, second and third generation silicone gel explants, and the largest known inventory of explants with lot-matched controls. They "demonstrated that the strength and elongation properties of these tested explants did not vary markedly with implantation time." (Brandon (2002) at 244.) In other words, implants did not degrade over time in the body.

Drs. Goldberg and Marotta also seize on the existence of "swell" to claim that implant strength decreases with time, even for implants that just sit on a shelf. Swell occurs when there is

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device technology and we would certainly be interested in establishing a mutually beneficial relationship with you." (Ex. L, August 1991 Goldberg Letter.) After Dow Corning declined Dr. Goldberg's request for millions of dollars of research funding, he turned to plaintiffs' attorneys for funding and became a paid expert witness for plaintiffs – and thus has a profound bias.

[21] The extent of Dr. Goldberg's bias is evident in his published work on breast implants. His research has been criticized as being "consistently selective when citing published literature;" that is, Goldberg and Marotta select certain studies that support their opinions for inclusion while ignoring the data that refutes their conclusions. Ex. K, H. Brandon et al., "Invited Discussion," Ann. Pl. Surg. 49(3): 242-47, at 242 (2002). "Along with selectively citing references, Marotta and colleagues refer only to those portions of publications with which they agree, even when that means misrepresenting other findings from the same study." *Id.* at 243. Goldberg and colleagues have been further criticized for drawing unsupportable assertions from their own data and the data of other researchers. *Id.* at 246.

movement of some of the non-crosslinked silicone from the gel into the shell of the implant. As this swell occurs, the strength of the elastomer decreases somewhat. But, the phenomenon of swell occurs only for a limited time following manufacture, after which the elastomer shell reaches equilibrium and the strength remains stable. *See* Brandon (2002) at 245 ("There is no evidence that these stored implants continue to weaken over time. This comparison supports the idea that once an implant shell achieves equilibrium swelling, the properties remain relatively constant thereafter.").

Importantly, Dow Corning breast implants were designed to have sufficient strength for human implantation even after the occurrence of swell. This has been borne out by controlled studies. Additional research by the scientists at Washington University showed that, even after an implant has undergone swell, the mechanical properties are still sufficient to meet acceptable standards. Brandon (2002) at 244 ("[T]he observed mechanical properties of swollen implants were still higher than the minimum acceptable ASTM standards."). Moreover, swell did not degrade the elastomer shell: "Our extraction studies found that the elastomeric shells of Dow Corning explants are not degraded chemically by the swelling process." Brandon (2002) at 244.

Conclusion

Debates about the scientific reliability of microscopic examinations and the long-term strength properties of implants are completely irrelevant to the determination that must be made under the Plan. The Plan specifies the only forms of proof acceptable to document a compensable rupture claim. The CAC Concurrence is a thinly-veiled attempt to rewrite the Plan so that claimants can qualify for benefits even though they clearly fall short of the long-established requirements of the confirmed Plan. Black letter law and the terms of the Plan prohibit this attempt to unilaterally amend the Plan and this Court must rule accordingly.

Moreover, not only does the Plan prohibit the use of "opinions" by so-called "experts" to support a rupture claim, but the argument that Dr. Blais is an "expert" is clearly misguided. Dr.

Blais is neither trained nor qualified to render an opinion regarding the rupture of implants and numerous courts have questioned his credibility and the scientific reliability of his findings on a variety of subjects. The SKK Motion and the CAC Concurrence seek an unlawful modification of the Plan and must be denied.

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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	§	

CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2006 a true and correct copy of the following pleading was served via electronic mail, telecopy, or overnight mail upon the parties listed below:

SUPPLEMENTAL RESPONSE REGARDING THE 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

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