Exhibit M

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**
	§	

AFFIDAVIT OF HAROLD J. BRANDON

I, Harold J. Brandon, D.Sc., P.E., declare and state as follows:

I. Background.

1. My training, education and experience are primarily in the areas of mechanical engineering and plastic surgery research. I hold degrees through the D.Sc. in Mechanical Engineering, and I am a Registered Professional Engineer in Missouri. I am currently an Assistant Research Professor of Plastic Surgery and an Affiliate Professor of Mechanical Engineering at Washington University, and a consulting engineer.

2. I have more than 35 years of industrial and academic experience. I have been a college professor since 1969, and have been involved in the analysis of silicone gel breast implants since 1992. I have published papers on breast implants in plastic surgery and biomaterials journals and have presented papers at national and international plastic surgery and biomaterials conferences. I have been awarded grants from the Plastic Surgery Educational Foundation, the National Endowment for Plastic Surgery, and the Aesthetic Surgery Education and Research Foundation for analysis of breast implants. I have also been awarded contracts and grants from breast implant manufacturers. I served as the Chairman of the Symposium on Biomaterials in Plastic and Reconstructive Surgery at the 6th World Biomaterials Congress in 2000, and at the 7th World Biomaterials Congress in 2004. My curriculum vitae is attached to this affidavit as Exhibit 1.

3. My background and experience qualifies me to assess how silicone gel breast implants should be evaluated to determine whether they are intact or ruptured.

4. This affidavit discloses the substance and opinions I have reached 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 affidavit is based on my background and experience and the supporting evidence presented herein.

II. Macroscopic Examination Is The Accepted Standard for Determining If A Breast Implant Is Ruptured.

5. Macroscopic examination of a breast implant is the accepted scientific standard for determining if the device is intact or ruptured. The FDA, Health Canada's Expert Advisory Panel on Breast Implants, and the IOM report have studied this issue and recommend this approach. In addition the two articles by Marotta, et al cited in the brief used macroscopic examination to determine implant rupture and evaluated a number of previously published studies that also used macroscopic examination to determine implant rupture.

6. Macroscopic examination of an implant at the time of explantation, by a surgeon and/or a pathologist, is sufficient to determine if the implant is ruptured. The macroscopic inspection consists of visual and physical examination of the implant. Microscopic analysis can give some insight into failure mechanisms, but it is not needed to determine if an implant is ruptured. Moreover, microscopic examination of an implant at a date after explantation raises issues regarding chain-of-custody, and increases the risk that the implant was damaged after explantation.

II.A. The FDA, The Expert Advisory Panel for Health Canada and the Institute of Medicine Find Macroscopic Examination To Be the Accepted Method For Determining Rupture.

7. The latest draft of the FDA guidance document for saline, silicone gel, and alternative breast implants ("Draft Guidance For Industry and FDA Staff, Saline, Silicone Gel

and Alternative Breast Implants") (Jan., 2004)) identifies the information that the FDA recommends be presented in a premarket approved (PMA) application. This guidance document updates a previous version published in February 2003. A new section "7. Modes and Causes of Rupture" was added to the guidance document. In this section the FDA recommends that modes and causes of rupture be addressed by a retrieval study involving examination and testing of breast implants that have been removed from patients. The FDA recommends the paper that I authored with my colleagues for the development of a retrieval study protocol. Our article gives the following protocol for determining whether an implant is intact or has an opening in its shell: "Document the integrity status of the explant (intact, pinhole defect, rupture/deflation) through macroscopic inspection." Brandon, HJ, et al., "Protocol for Retrieval and Analysis of Breast Implants," Journal of Long Term Effects of Medical Implants, 13(1): 49-61 (2003). Our paper also recommends microscopic analysis to document the surface morphology of areas of shell failure.

8. In September 2005, Health Canada formed an Expert Advisory Panel on Breast Implants to assist in reviewing and assessing license applications to sell silicone gel-filled breast implants in Canada. The panel was mandated to provide scientific, medical, and clinical advice on current and emerging issues related to the safety and effectiveness of breast implants. In January 2006 the Expert Advisory Panel submitted its report to Health Canada (Expert Advisory Panel on Breast Implants, "Record of Proceedings" (Sept. 29-30, 2005)). The report outlined the method recommended for determining if an implant is ruptured and the cause of failure. The following procedure is followed when evaluating an explanted device to determine the cause of failure:

- "visual inspection;"

- "slightly squeeze product to see if there is any opening through which gel extrudes;"
- "if a 'failed' region is detected, that region is examined under a microscope (optical or scanning electron microscope)."

9. In 1997, Congress asked the U.S. Department of Health and Human Services (DHHS) to sponsor a study of the safety of silicone breast implants by the Institute of Medicine (IOM) of the National Academy of Sciences (NAS). Upon the authority of the charter granted to it by Congress, the NAS has a mandate that requires it to advise the federal government on scientific and technical matters. The IOM acts under the responsibility given to the NAS by its congressional charter to be an advisor to the federal government on medical issues. The IOM study resulted in the publication of a report titled "Safety of Silicone Breast Implants". The IOM report (published in 2000, 540 pages in length) is a comprehensive review of the world's English language literature on silicone breast implants published through 1998. Some 1999 references are also included in the IOM report. In preparing the report, the IOM committee focused on evidence in the peer-reviewed, published scientific literature and information provided by manufacturers, breast implant patients, involved scientists, and others, in the form of industry technical reports, prepublications, medical histories, and private or personal submissions of various kinds. Almost 1,200 references are cited in the IOM report (about 80% are from the peer reviewed scientific literature). This report is precise in stating how the status of an implant should be determined. The IOM report states "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." Direct visual examination is conducted by both the explanting surgeon and the pathologist which is the standard for diagnosing whether an implant is intact or ruptured. Additional documentation over and above the operative and pathology reports are not needed. In particular, post-explant documentation that consists of a

microscopic examination of the implant is not needed to determine if the implant is ruptured. Microscopic examination can be used to determine the failure mechanism. Knowing the status of an implant, i.e., whether the implant is intact or ruptured, is not dependent on a knowledge of the failure mechanism.

II.B. Even The References Cited by the CAC Determined Rupture Using Macroscopic Examination.

10. The CAC brief cites the 1999 article by Marotta, et al on the analysis of 35 studies reporting an examination of more than 8,000 explants. Marotta, J, 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). The abstract of the article states that "Because examination of a prosthesis when explanted is the definitive method for determining shell integrity, the only studies that were used were ones for which shell rupture or failure ("not intact") was confirmed upon surgical removal." Marotta (1999)at 354. The database criteria is also stated in the methods section of the article: "To insure unequivocal failure data, only reports involving surgical removal and direct inspection of SGBIs were used in our analysis[58]." Marotta (1999)at 356. Reference 58 of this database is the paper by Brown, et al (Brown, SL, Silverman, BG, Berg, WA. "Rupture of silicone-gel breast implants: causes, sequalae, and diagnosis," Lancet 350:1531-1537 (1997)). The Brown, et al paper states "Examination at removal can reveal whether the implant is ruptured, but can give no information on the length of time since rupture." Hence, the 1999 Marotta, et. al article was based on studies which used macroscopic examination to determine whether the implants were intact or ruptured.

11. The CAC brief also cites a follow-up article published in 2002 by Marotta, et al that updated the 1999 study. Marotta, J, 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). The updated analysis encompassed 9,774 implants from 42 different studies by various authors. The article included the examination of 74 explants by Marotta, et al. The materials and methods section of the article gives the approach used by Marotta, et al to determine if the implants were intact or ruptured: "Visual and tactile characteristics, and the integrity of the prostheses were observed and photographed." Marotta (2002) at 229. In other words, Marotta, et al used macroscopic examination to determine whether the implants in their own study were ruptured.

12. After the implant status (intact or ruptured) had been determined from the visual and physical exanimation, Marotta, et al conducted a microscopic analysis on a few of the 74 implants to investigate the outer surfaces of urethane explants. Thus, Marotta, et al used the standard protocol for implant investigation, i.e., a macroscopic inspection to determine implant status (intact or ruptured) and a microscopic analysis to provide further details of the shell. Hence, the references cited in the brief demonstrate that microscopic examination is not needed to determine if the implant is ruptured.

13. Many if not all of the 42 studies referenced in the Marotta, et al article also used macroscopic examination to determine if the explants were intact or ruptured. I conducted a review of a sampling of those studies -- 18 of the 42 studies -- to confirm the approach taken to determine implant status (intact or ruptured). The 18 studies listed in Figure 12 of the Marotta, et al article included: (1) Robinson, (2) Berg, (3) de Camara, (4) Rolland, (5) Guidoin, (6) Phillips, (7) Peters (1994), (8) Forsberg, (9) Young, (10) Wolf, (11) Peters (1986), (12) Gabriel,

(20) Cohen, (21) Beekman, (30) Duffy, (35) Feng, (39) Rohrich, (41) Lockwood. My review confirmed that macroscopic examination was the technique used to determine if the implants were intact or ruptured in all of the 18 studies. While I did not have the opportunity to review all of the studies, I have no reason to believe that macroscopic examination was not likewise used in all of the remaining studies to determine implant integrity.

III. The Marotta And Goldberg Studies are Flawed And Draw Conclusions That Are Not Supported By Published Data.

14. The CAC brief also includes a discussion of the flawed analyses and conclusions concerning implant degradation that Marotta and Goldberg derive in their two papers. Hence, a critique of those analyses and conclusions is appropriate. My colleagues and I have published such a critique, which was published in two articles. The first article (Brandon HJ, et al., "Discussion of 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*, Vol. 49, No. 3, pp. 16-21, 2002) appears immediately after the Marotta, et al second paper. The second article (Brandon HJ, et al., "Letter of Reply to the Discussion of 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*, Vol. 51, No. 3, pp. 334-336, 2003) appears in a reply to comments by Goldberg, et al. Our critique demonstrates the selectivity, omission, and misinterpretation of data by Marotta, et al. A few of the highlights of the critique are presented in the following paragraphs.

15. **Shell Degradation**. The CAC brief states that it was only through post-explantation examination that Marotta, et al were able to document one cause for implant rupture, i.e., shell degradation over time. Marotta, et al reached the conclusion of shell

degradation by comparing the strength of explanted breast implants with control implants, i.e., implants that were never implanted. Marotta, et al claim that the strength of all explants was less than the strength of unimplanted control implants -- hypothesizing that breast implants lose strength when implanted in the body.

16. This conclusion is incorrect according to the literature and data on Dow Corning gel implants. One of our studies summarized the published mechanical property data for Dow Corning Silastic 0 and Silastic I implants and showed that the tensile strength data for explants from six separate studies all fell within the data range for control implants. Brandon HJ et al., "Ultimate Strength Properties of Control and Explanted Silastic I and Silastic 0 Silicone Gel-filled Breast Implant Shells," Aesthetic Surg. J. 1999; 19:381. In fact, the tensile strength data in the article by Marotta, et al also fall within the published control range, as do their elongation data. This means that silicone elastomer from Dow Corning Silastic 0 and Silastic I implants does not decrease substantially in strength when implanted. Similarly, Marotta's data for Silastic II explants also agree with the explant and control data from our investigation and six other studies. Brandon (2002) at 243.

17. **Shell Swelling.** The phenomenon known as "swelling" describes movement of non-crosslinked silicones from the gel into the shell of the implant, thereby "swelling" the shell. Marotta, et al contend that swelling causes a marked degradation of shell mechanical properties, beginning when the implant is filled with gel, and continuing whether the implant is sitting on the shelf or is implanted in the patient.

18. Our research has refuted the claim that swelling adversely affects the mechanical properties of silicone breast implants over time. While swelling does initially affect the

mechanical properties of the shell, this effect is completely reversible, demonstrating that the process does not degrade the polymer network. Moreover, the process of shell swelling reaches equilibrium following implantation, after which the strength of the implant remains substantially stable. And although the amount of swelling in many explanted implants can be significant, as high as 20%-40%, our experiments found that, in general, the observed mechanical properties of swollen implants were still higher than the minimum acceptable ASTM values. *See* Brandon (2002) at 244. Our research has described various types of silicone gel breast implants that have remained intact with a large degree of shell swelling (20-40%) for implantation times ranging from 13 to 32 years. *Id.* As a comparison, Marotta, et al found that Dow Corning shells were swollen with an average of 20% which is on the lower end of the range of our extraction experiments.

19. Our critique has also refuted the Marotta, et al contention that degradation begins once the implant is filled with gel, and continues whether the implant is sitting on the shelf or implanted in a patient. "We have investigated the effect of aging on stored control implants. Specifically, in 1997 we tested Dow Corning control implants from the same manufacturing lots as those tested by Battelle in 1986. The Table compares the tensile strength and elongation for the controls tested at Battelle and at Washington University. The mechanical property values measured by both groups are very similar for both types of implants after an additional 11 years of storage. We attribute the differences between our data and the Battelle data ranges primarily to variability within a lot and the effects of different testing techniques. Regardless, there is no evidence that these stored implants continued to weaken over time. This comparison supports the idea that once an implant shell achieves equilibrium swelling, the properties remain relatively constant thereafter." Brandon (2002) at 244-45.

20. **Selectivity, Omission And Misrepresentation of Data.** The conclusions of Marotta and colleagues are flawed for additional reasons. In particular, Marotta and Goldberg draw unwarranted conclusions from very selected data, and by omitting and/or misrepresenting data that does not support their hypotheses. As we stated in our published critique: "The authors are consistently selective when citing published studies on the variability of mechanical properties of control implant shells." Brandon (2002) at 242. Among other lapses, Marotta, et al ignored our data for Dow Corning control and explanted implant shells and chose instead to reference studies of explants that did not characterize the devices according to manufacturer, specific type, or manufacturing lot, and did not compare explants with proper controls. It was only by selective use of these improper "controls" that Marotta, et al were able to support their assertions regarding loss of implant strength.

21. An example of misinterpretation of data is the use of the Wolf reference (number 10) in Figure 12 of the second Marotta, et al article. My colleagues and I conducted this study which included an analysis of gel viscosity of five silicone gel explants. Five explants with different viscosity characteristics were chosen from our inventory. Four of the five explants happened to be ruptured. Our study had nothing to do with the percent of failed explants in our inventory. Yet, Marotta, et al used our study in their prediction of silicone gel breast implant failure as a function of implantation time. This misinterpretation of data is discussed in our critique: "They use that reference as the basis for plotting a data point of 80% implant failure at 16 years when, in reality, that particular investigation examined gel viscosity, had nothing to do with implant failure, and involved only five explants, four of which happened to be ruptured. Five intact explants could just as easily have been studied, but implant integrity was not our

purpose. The use of these five explants as a data point for predicting failure versus implant duration is absurd." Brandon (2003) at 335.

22. Our critique presents examples of how Marotta, et al selectively used published literature that supported their theories and ignored portions of the literature that did not. One such example is presented here. "They cite van Rappard and colleagues, who investigated the pressure resistance of 50 explanted Dow Corning silicone gel breast implants. All 50 explants were intact at the time of removal and had an average implantation duration of four years (range=0.1 to 8.0 years). This data point of 0% failure at four years does not appear in Marotta's meta-analysis (Figure 12), which predicts about 25% failure at four years. While the van Rappard study is ignored in the meta-analysis, it is included as support for the proposition that explant strength is low compared to new, non-implanted controls (and they do not acknowledge the control range tested by van Rappard was limited)." Brandon (2002) at 243 (footnote omitted).

23. Marotta, et al draw further unwarranted conclusions in predicting the percent of failed implants versus the duration of implantation. They contend that their analysis is representative of the implant aging properties and rupture characteristics of the general population of breast implants that remain implanted.

24. Our critique discusses that this assertion is insupportable, as it again relies on biased samples and selective use of data: "The analysis does not address failure in relation to critical questions such as different manufacturers, models, or generations of breast implants. Furthermore, all the studies incorporated in the meta-analysis are comprised of biased samples, usually involving women who were concerned about their implant status or ruptured explants

retrieved for study purposes. Thus, the meta-analysis is not representative of all breast implants or all implanted women. Grouping many biased studies together to generate a plot of percent failure versus implantation time does nothing to eliminate or even reduce the underlying bias. We have previously discussed the kind of cohort study needed to accurately determine the prevalence and incidence rate of breast implant rupture. Although Marotta and colleagues say their failure analysis is based on a 'large cohort,' their data do not represent a true cohort study but a compilation of many cross-sectional studies of a highly selected group of implants." Brandon (2002) at 245.

I declare under penalty of perjury that the above information is true and correct. Executed this 25th day of July, 2006, at St. Louis, Missouri.

Harold J. Brandon

Harold J. Brandon

Exhibit 1

CURRICULUM VITAE

Harold J. Brandon, D.Sc.

Date of Birth: February 13, 1942

Place of Birth: St. Louis, MO

Citizenship: United States

Address and Telephone:
5143 Olde Silver Pl.
St. Louis, Missouri 63128
W: (314) 935-8480
H: (314) 849-0033
Fax: (314) 935-4014
e-mail: hjb@me.wustl.edu

Present Position:
Affiliate Professor, Mechanical Engineering
Research Assistant Professor, Plastic and Reconstructive Surgery
Washington University Schools of Engineering and Medicine, St. Louis, MO

Education
1963 B.S. Aeronautical Engineering, St. Louis University, St. Louis, MO
1965 M.S. Engineering Science, St. Louis University, St. Louis, MO
1969 D.Sc. Mechanical Engineering, Washington University, St. Louis, MO

Professional Registration
Registered Professional Engineer, Missouri

Academic Positions/Employment:
Industry Experience
1963-1965 McDonnell Aircraft, Test Engineer
1968-1971 Allison Division of General Motors, Senior Research Engineer
1972-1978 McDonnell Douglas, Technical Specialist/Program Manager
1978-1984 Barry-Wehmiller Company
1978-1979 Chief Engineer
1979-1984 Director of Research & Development
1984-present Brandon Research Inc., Owner

Academic Experience

1969	Purdue University, Instructor	
1972-1979	University of Missouri-Rolla Graduate Engineering Center	
	1973-1978	Lecturer (Mechanical Engineering)
	1978-1979	Affiliate Associate Professor (Mechanical Engineering)
1979-present	Washington University	
	1979-present	Affiliate Professor (Mechanical Engineering)
	1984-1985	Visiting Professor (Mechanical Engineering)
	1994-1998	Research Instructor (Department of Surgery)
	1998-present	Research Assistant Professor (Department of Surgery)

Honors and Awards:

1965-1966	Olin Grant, Washington University
1966-1968	NDEA Fellowship, Washington University
1974	"A Recirculating Combustion Apparatus Incorporating a Jet Pump," U. S. Patent
1982	"Filler Tube with Check Valve for Container Filling Devices," U. S. Patent
1982	Presidential Award from the Master Brewers Association of the Americas
1983	Presidential Award from the Master Brewers Association of the Americas
1984	Best Paper Award from the Society of Soft Drink Technologists

Committee Appointments:

1980-1986	Chairman, Environment and Energy Management Committee of the Society of Soft Drink Technologists
1983-1986	Member, Board of Directors, Society of Soft Drink Technologists

Symposium Appointments:

2000	Chairman, Biomaterials in Plastic and Reconstructive Surgery Symposium, 6th World Biomaterials Congress
2004	Chairman, Biomaterials in Plastic and Reconstructive Surgery Symposium, 7th World Biomaterials Congress

Panel Appointments:

2005	Panel Member, Health Canada's Expert Advisory Panel on Breast Implants

Editorial Board Appointments:

2005 - present	Board Member, Journal of Long-Term Effects of Medical Implants

Professional Societies:
American Institute of Aeronautics and Astronautics, 1965-1978
American Society of Heating, Refrigeration, and Air-Conditioning Engineers, 1978-1984
Society of Soft Drink Technologists, 1978-1986
Master Brewers Association of the Americas, 1978-1988
American Society of Mechanical Engineers, 1978-Present
Society for Biomaterials, 1996-Present
American Society for Testing and Materials, 2000-Present
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19. Brandon HJ, Renaud J, Staack G, and Puskarz S. "Assessment of Energy Conservation/New Energy Systems in the Brewing Industry," MBAA Technical Quarterly, Vol. 17, No. 1, 1980.

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