

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division**

In re:)	
SILICONE GEL)	Master File No. CV 92-P-10000-S
BREAST IMPLANT)	
PRODUCTS LIABILITY LITIGATION)	This Order Applies to All Cases
(MDL 926))	

Order 36
(Production and Exchange of Information Regarding Ongoing Studies)

The following procedures shall govern the production, designation, and handling of information produced by any party (“producing party”) pertaining to ongoing studies funded or conducted by the producing party, including, but not limited to, information produced in response to the “Plaintiffs’ Interrogatories Regarding Epidemiological Studies Underway” and “Plaintiffs’ Notice of Rule 30(b)(6) Deposition Re: Ongoing or Recently Completed Studies Combined With Request for Production of Documents.”

1. “Ongoing Research” means any toxicological, clinical, or epidemiological research pertaining to silicone products or silicone materials used internally in the human body or applied to the human body.

2. The producing party shall, with respect to ongoing research (i) being conducted by the producing party (or its employees, facilities, consultants, or attorneys), (ii) being funded by the producing party and being conducted in part or in whole through outside investigators, or (iii) about which the producing party is receiving reports from another source, including Dow Corning Corporation or a manufacturers’ trade association, provide a copy of any interim report received by the producing party to opposing counsel (the Plaintiffs’ Steering Committee or national coordinating counsel for Defendants), including any preliminary findings and conclusions regarding such ongoing research and any actual raw data contained in the interim report.

3. On a quarterly basis, beginning December 15, 1996, the defendants and the Plaintiffs’

Steering Committee shall provide each other and the Court with a written list of ongoing research that the producing party is (a) is conducting or has conducted with its own employees, facilities, or consultants; (b) is directly funding or has directly funded in whole or in part but is being performed or was performed through outside investigators; (c) is receiving or has received reports or data about from any other party or non-party, including Dow Corning and manufacturers' trade associations.

The information concerning such ongoing research shall, at a minimum, include the following:

- (1) the date of initiation of the study;
- (2) the expected total cost of the study;
- (3) the name of the principal investigator;
- (4) the anticipated date of completion of the study;
- (5) the purpose of the study;
- (6) a brief status report of the progress and findings made in the study to date; and
- (7) a description of the documents generated by the investigators while the study is ongoing.

At three month intervals for the duration of the multidistrict proceedings, the parties shall provide each other and the Court with an updated status report on all ongoing research, including in the updates a list of any ongoing research initiated since the date of the last report. In conjunction with each quarterly report, the parties shall provide each other (but not the Court) all unredacted documents concerning ongoing research that have been generated since the date of the last report.

4. This Order shall be binding upon the parties and all persons to whom an interim report is disclosed pursuant to paragraph 2, and shall remain in effect severally as to ongoing research identified by the producing party until such time as either (i) the ongoing research so identified has been completed and, if publication is intended, released to the public by the scientist responsible for the ongoing research, or (ii) the producing party, in good faith and with adequate notice to opposing counsel, indicates its intention to introduce at trial, either directly or as the basis of an expert witness's opinion, information pertaining to any ongoing research identified by the

producing party.

5. An interim report produced pursuant to paragraph 2 may be disclosed by members of the Plaintiffs' Steering Committee or national coordinating counsel for the Defendants, or by persons to whom such interim report is disclosed pursuant to the terms and conditions of this Order, only for purposes of this litigation and only to the individuals or entities as set forth herein, unless prior written consent for further disclosure has been obtained from the producing party or permission for such disclosure has been given by the Court. Disclosure of interim reports is limited to (i) attorneys in this breast implant litigation, and employees of such persons assigned to assist counsel in this litigation, (ii) outside experts retained for consultation or for testimony in this litigation, or (iii) a court, in accordance with paragraph 8 of this Order.

6. Prior to disclosure of an interim report produced pursuant to paragraph 2 to any person identified in paragraph 5, such person shall be provided with a copy of this Order and thereafter sign a Consent Agreement in the form annexed hereto as Exhibit A acknowledging that he or she has read this Order and agrees to be bound by its terms. The signed originals of all such Consent Agreements shall be retained by the attorneys divulging the interim report.

7. In the event a party wishes to disclose an interim report produced pursuant to paragraph 2 to any person or persons not specified in paragraph 5 of this Order, that party shall provide the producing party with notice of such intent and twenty (20) days in which to move the Court for an order preventing or limiting the disclosure. If the producing party does not file such a motion within said time, disclosure of the interim report may be made to the person or persons identified in the notice, provided that such person or persons read and sign a Consent Agreement in the form annexed hereto as Exhibit A.

8. An interim report produced pursuant to paragraph 2 subject to this Order may be included in whole or in part in pleadings, affidavits, motions, briefs, or other papers filed with the Court, provided any such papers shall be filed with the clerk of the Court in a sealed envelope prominently marked with the caption of this case and the notation: "Contains Confidential Information; To Be Opened Only as Directed by the Court."

9. Entry of this Order shall be without prejudice to any claim of privilege or motion for relief from the appropriate Court from any restriction hereof or any other further restriction on the production, exchange, or use of any document, testimony, or other information produced, given or exchanged in the course of pretrial discovery in these proceedings.

10. The following defendants are not subject to this Order: the Mentor Defendants (Mentor Corporation, Mentor Polymer Technologies, Inc.; Mentor O&O, Inc.; Mentor H/S, Inc.; Mentor Urology, Inc.; Mentor International, Inc.; and Teknar Corp.) and the McGhan Defendants (McGhan Medical; McGhan Medical Corp.). The court anticipates subsequent entry of an order defining the obligations of such defendants with respect to ongoing studies.

11. The Court reserves the power to amend any of the terms of this Order.
This the 27th day of November, 1996.

/s/ Sam C. Pointer, Jr.
Chief Judge Sam C. Pointer, Jr.

EXHIBIT A to Order 36

Consent Agreement

Pursuant to paragraph 6 of Order 36, the undersigned hereby acknowledges that he or she has read Order 36 and agrees to be bound by its terms before being provided with copies of any interim reports on ongoing studies funded or conducted by the producing party.

I, _____, am employed by _____ in the capacity of _____. I have read Order 36: Order For the Production and Exchange of Information Regarding Ongoing Studies. I agree to be bound by all of the terms and conditions of Order 36.

This the _____ day of _____, 19_____.

Signature

The attorneys divulging this interim report will retain this signed original Consent Agreement.