

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re: SILICONE GEL BREAST) Master File CV 92-P-10000-S
IMPLANT PRODUCTS LIABILITY)
LITIGATION (MDL-926)) (Applies to all cases)

FRANCESCA BUTLER, ALICE TAYLOR,)
GLENN E. POWELL, and BETTY)
DASHER, on Behalf of Themselves)
and All Other Similarly)
Situated,)
Plaintiffs;)

-vs.-

) Case No. 93-P-11433-S
)

MENTOR CORPORATION; MENTOR)
POLYMER TECHNOLOGIES, INC.;)
MENTOR O & O INC.; MENTOR H/S)
INC.; MENTOR INTERNATIONAL)
INC.; and TEKNAR CORP.;)
Defendants.)

ORDER No. 14

(ORDER APPROVING MENTOR SETTLEMENT
and CERTIFYING MENTOR SETTLEMENT CLASS;
FINAL JUDGMENT AS TO CLAIMS AGAINST MENTOR)

After due notice and following an evidentiary hearing on September 9, 1993, the application of the parties in Case No. 93-P-11433-S for certification of a plaintiff class and for approval of a class settlement has been submitted for decision. Upon consideration of the supporting documentation, declarations, and affidavits, the objections and comments filed or presented in open court, and the arguments presented at the hearing, the court concludes that the application should be approved with the clarifications made herein, which have been accepted by the parties, and ORDERS as follows:

1. The court finds that the plaintiff class and the "Mentor Defendants" have negotiated the proposed settlement non-collusively and in good faith, and that its terms -- with the

clarifications

contained in this order -- are fair, adequate, reasonable, and in the best interests of the members of the Mentor Settlement Class. Accordingly, subject to the provisions of this order, the proposed agreement is approved by the court under Fed. R. Civ. P. 23(e) and incorporated by reference as a part of this order. For ease of reference, the terms of the agreement may be modified to conform to the provisions of this order.

(a) The total amount that the Mentor Defendants shall pay for the benefit of the Mentor Settlement Class is increased, with the consent of the Mentor Defendants, from \$24,000,000 to \$25,800,000. The court reserves jurisdiction to determine when the additional \$1,800,000 is to be paid.

(b) The Mentor Defendants have also agreed that the total amount to be paid for the benefit of the Mentor Settlement Class will be further increased to include all additional funds subsequently recovered, through trial or settlement, by the Mentor Defendants under any insurance policies issued to Mentor Medical Systems, PTY, Ltd., or any other foreign Mentor affiliate, to the extent claims by class members potentially covered by such policies will be barred by this order. The court reserves jurisdiction to determine when any such additional funds are to be paid.

(c) Mentor Corporation will cause to be assigned to the representative plaintiffs, for the benefit of members of the Mentor Settlement Class, all assignable third-party claims which it or its subsidiaries may have relating to saline, silicone, or silicone gel products, including assignable claims that have been or may be asserted in Mentor Corp. v. Dow Corning Corp., 92-4248-CAL. This assignment shall not include, however, those claims described in paragraph 6 of this order, which bars all claims by or against Mentor Defendants (whether on the basis of contribution, indemnification, or other theories of action) seeking reimbursement for payments made to members of the Mentor Settlement Class or for expenses incurred in defending against claims and actions by members of the Mentor Settlement Class. Any claims by Mentor under paragraph 3(c) of the Settlement Agreement shall be limited to claims for reimbursement of expenses incurred by Mentor after April 14, 1993, in assisting in the prosecution of such third-party claims or in enforcing after this date the terms of this order.

2. Civil Action No. CV 93-P-11433-S is certified as a class action under Fed. R. Civ. P. 23(a) and 23(b)(1)(B).

(a) The action is declared as one maintained on behalf of a mandatory non-opt-out class of plaintiffs, known as the "Mentor Settlement Class," consisting of all persons and entities, wherever located, who have or may have any existing or future claim (including claims for injuries not yet known or manifest) under any federal or state law -- whether for damages, injunctive, declaratory, or other relief -- against any of the "Mentor Defendants" based upon or involving the breast implantation before June 1, 1993, of a product containing or consisting of saline, silicone, or silicone gel, or an elastomer made of silicone.

The class consists of (1) all persons who have received such implants (whether or not the implant was later removed); and (2) all other persons or entities -- including, but not limited to, executors, administrators, personal representatives, spouses, relatives, and "significant others" -- that, because of some relationship to the recipients of a breast implant, may have an independent or derivative claim based on such implants.

(b) The class claims are limited to those against any of the following "Mentor Defendants": Mentor Corporation; Mentor Polymer Technologies Company; Mentor O&O, Inc.; Mentor H/S, Inc.; Mentor Urology, Inc.; Mentor International Sales Corp.; Mentor Medical Systems, UK; Mentor Deutschland, GMBH; Mentor Medical Systems, PTY, Ltd.; Teknar Corporation; and their respective predecessors, successors, parent and subsidiary companies and divisions, and current and former attorneys, officers, directors, agents, distributors, sales agents, and employees.

Claims by or on behalf of the class members against any other manufacturer, distributor, or supplier of implant products or component parts of such products -- or against physicians, hospitals, or other health-care providers -- are not certified for class action treatment.

(c) The class claims are further limited to those

claims that are based upon or involve the breast implantation before June 1, 1993, of a product containing or consisting of saline, silicone, silicone gel, or an elastomer made of silicone.

(d) Francesca Butler, Alice Taylor, Glenna E. Powell, and Betty Dasher are designated as representative plaintiffs for the class, and the members of the Plaintiffs' Steering Committee, as previously appointed and as may be hereafter modified by the court, are designated as counsel for the class. The court reserves the power to define appropriate subclasses, including the designation of representatives and counsel for such subclasses, should conflicts arise within the class in the course of supplemental and ancillary proceedings involving implementation of the settlement agreement, including the distribution or use of funds recovered on behalf of the class.

3. The Mentor Settlement Class is certified as a mandatory, non-opt out class based upon the court's finding that the assets (including insurance benefits) of the defendants in this action constitute a limited fund and that, within the meaning of Fed. R. Civ. P. 23(b)(1)(B), the prosecution of separate actions by individual class members against the Mentor Defendants would create a risk that adjudications with respect to such class members would substantially impair or impede the ability of other class members to protect their interests.

4. As to all claims and all parties, Civil Action No. 93-P-11433-S is hereby dismissed with prejudice, but preserving the rights and benefits accorded to members of the Mentor Settlement Class under the terms of the Settlement Agreement. All class claims, as defined in paragraphs 2(b) and (c) of this order, by members of the Mentor Settlement Class against any of the Mentor Defendants in any other actions pending in this court are similarly hereby dismissed with prejudice, but preserving the rights and benefits accorded to members of the Mentor Settlement Class under the terms of the Settlement Agreement. Under Fed. R. Civ. P. 54(b), the court expressly determines that there is no just reason for delay and expressly directs that this judgment shall, upon filing in Master File No. CV 92-P-10000-S, be deemed entered as a final judgment with respect to all class claims by members of the Mentor Settlement Class against the Mentor Defendants in all cases that are pending in this court, and shall be deemed entered as a final judgment with respect to such claims in all cases subsequently filed in, transferred to,

or removed to this court immediately upon such cases being so filed, transferred, or removed.

5. Subject to performance by the Mentor Defendants of their obligations under the Settlement Agreement:

(a) the Mentor Defendants are forever released from any and all class claims, as defined in paragraph 2(b) and 2(c), which any member of the Settlement Class had, has, or may have in the future against any Mentor Defendant; and

(b) each member of the Mentor Settlement Class is barred and permanently enjoined from instituting, asserting, or prosecuting against any of the Mentor Defendants in any pending or future action in any federal or state court any and all class claims that the member had, has, or may have in the future.

The Mentor Defendants are entitled to dismissal, with prejudice and without costs, of all such claims in all actions and proceedings in all state and federal courts, tribunals, and agencies.

6. Subject to performance by the Mentor Defendants of their obligations under the Settlement Agreement, all current or future claims by or against any of the Mentor Defendants -- whether based on contribution, indemnity, or other theories of action -- seeking reimbursement for payments made to members of the Mentor Settlement Class or for expenses incurred in defending against claims and actions by members of the Mentor Settlement Class are barred.

7. The Mentor Defendants are permanently enjoined from:

(a) participation in any formal or informal discovery proceedings in any case or cause of action involving silicone gel or saline breast implant products except:

(1) with this Court's express consent;

(2) in proceedings conducted, requested, and coordinated with representative plaintiffs on behalf of the Settlement Class which are necessary and appropriate to implement and effectuate the terms of the Settlement Agreement, this order, or the assignment of claims under paragraph 1(c); or

(3) in state court actions, when permitted by the state court in response to discovery initiated by persons not parties to any action that is a part of CV 92-P-10000-S.

(b) further manufacture or sale of silicone gel breast implant products:

(1) for breast augmentation purposes (subject to the exception that, if representatives of members of the plaintiff class or their designated counsel enter into a settlement agreement the terms of which directly or indirectly authorize any other entity to remain in the business of manufacturing silicone gel breast implants for sale or distribution, this injunction shall be deemed vacated and of no effect), or

(2) for breast reconstruction/adjunct study patients as authorized by the United States Food and Drug Administration ("FDA") after the earlier of (A) an FDA approved gel-substitute or (B) eighteen (18) months from the Closing as defined by the Settlement Agreement, subject to the exception described in paragraph 7(b)(1); and

(c) from studying or otherwise funding research concerning the safety and efficacy of silicone gel, including silicone gel breast implants, for use in augmentation or reconstruction, except as to (1) prior binding contracts with third parties, (2) tests mandated or required pursuant to FDA rulings, and (3) tests consistent with FDA requirements for post-mastectomy and other reconstruction/adjunct studies.

8. Claims by or on behalf of any class members against any other manufacturer, distributor, or supplier of implant products or component parts of such products, or against physicians, hospitals, or other health-care providers, are not released and shall not be barred, precluded, limited, or reduced as a consequence of the class settlement, this order and judgment, or the subsequent award and distribution of funds to such class member from the settlement fund, except if and to the extent required under federal, state, or foreign law applicable under choice-of-law doctrines in the forum in which any such claims may be instituted or pursued.

Because individual members of this mandatory class are not

afforded any option to exclude themselves from the class, and because the settlement fund is a "limited fund" that will not be sufficient to pay in full the claims of class members against the Mentor Defendants, each member of the class shall be afforded at an appropriate time the option -- if and to extent permitted under such laws -- to waive any participation in the distribution of settlement funds, to agree to a non-suit, to execute an agreement that any award of settlement funds shall reduce claims against other persons on only a pro tanto basis, or to take advantage of any other procedures available under such laws as will preserve to the maximum extent possible their remaining claims against such other parties. If the applicable law requires that, in order to treat amounts received as constituting only a pro tanto release, such an agreement must be made at the time of dismissal, then such an agreement is deemed to have been made as of this date by such class member and the Mentor Defendants.

9. Without deferring or delaying the finality of this order and judgment, this Court retains exclusive and continuing jurisdiction as needed or appropriate in order to:

(a) implement, interpret, or enforce the Settlement Agreement;

(b) conserve, allocate, or distribute the settlement fund after appropriate notice; and

(c) rule on any applications for attorneys' fees, costs or expenses incurred in implementing this order and the Settlement Agreement. The court will not, however, entertain any applications for fees made by class counsel premised upon negotiating and securing this settlement.

DATED: September 10, 1993

/s/ Sam C. Pointer, Jr.
Sam C. Pointer, Jr.
United States District Court