UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ALABAMA Southern Division

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

STIPULATION BETWEEN PLAINTIFFS AND THE SIGNATORY DEFENDANTS REGARDING DOCUMENTS PRODUCED BY DEFENDANTS

The Plaintiffs' Steering Committee ("PSC") and the undersigned Defendants enter into the following stipulation respecting certain possible objections to the admissibility of documents produced by such Defendants (or copies made therefrom). These stipulations are intended to apply to, be binding on, and be for the benefit of all parties in all pending and future "breast-implant" cases in the United States District Courts and, to the extent permitted by applicable law, also in state courts.

- 1. <u>Nature of Stipulation</u>. This stipulation, with its various appendices, exhibits, and indices (collectively referred to as "appendices") identifying and indicating the status of documents produced by the signatory Defendants (or in some instances by their current or former affiliates), also serves as such Defendants' responses to questions contained in depositions served on them under Fed. R. Civ. P. 31 as a basis for determining admissibility of the identified documents. With its various appendices, this stipulation supersedes and replaces any prior responses by such Defendants to those questions, and such superseded responses shall not be used by or against such Defendants.
- 2. Reservations and Scope. All parties reserve the right to object to the admissibilty of such documents (or copies made therefrom) in a particular case on grounds not covered by this stipulation, including (but not limited to) grounds of relevance, materiality, prejudicial effect, or double (or multiple or included) hearsay, or other grounds available under the law applicable in the particular jurisdiction. A stipulation that an exhibit is what it is claimed to be ("authenticity") or that a copy may be used in lieu of the original ("contents of writings, recordings, and photographs") or that a document satisfies the "business records" exception to the hearsay rule simply addresses certain potential objections to admissibility; it does not constitute a stipulation that the exhibit should be admitted or—if admissible—when, during a trial, it should be so admitted.
 - (a) This stipulation respecting potential objections to admissibility is based on standards contained in the Federal Rules of Evidence ("FRE") and in part on the Federal Rules of Civil Procedure ("Fed. R. Civ. P."). The parties reserve the right to make special objections in state courts to the admissibility of the identified documents to the extent applicable state rules vary from federal standards, such as with respect to "records maintained in the course of regularly conducted business activities" and "business records." Moreover, some objections that might be valid under the FRE may not be valid under applicable state evidentiary rules.

^{1 .} Should a court conclude that, under applicable law, some party in a case before it is not bound by these stipulations, then the court may consider whether, in fairness, it should relieve other parties, including signatories to this stipulation, from some or all of their obligations under this stipulation.

- (b) The parties recognize that federal and state trial courts may, in pretrial orders or by general or local rules, impose additional requirements affecting the admissibility of evidence or the preservation of objections. This stipulation is not intended to limit or extend any such judicial authority, nor to limit the authority of parties in a case to enter into additional stipulations regarding admissibility of documents.
- (c) The appendices may list some documents that, based on a claim of privilege, have not been produced to the Depository or that were produced pursuant to the terms of a Protective Order. The listing of such a document in an appendix does not waive any claim of privilege or the terms of any applicable Protective Order.
- 3. <u>Copies</u>. Each Signatory Defendant asserts as an answer to a deposition question (and the PSC and such Defendant hereby stipulate) that—to the extent indicated by the letter "Y" or "X" (or the word "Yes") in column 3 of the appendices provided by that Defendant (or by listing in a special appendix of such documents provided by that Defendant)—the copy of the document in the MDL Document Depository or imaged on a CD-ROM disk made by the PSC is an accurate copy of the document that was produced to the Depository—and hence that an accurate copy of such document or image is admissible under FRE 1003 to the same extent as would be the document that was then in the custody of the producing company. With respect to such documents, however, this stipulation is subject to the following conditions and exceptions:
 - (a) The parties recognize the possibility that some documents, after being produced to the Depository, may have been inadvertently altered in some way, as by adding highlights or annotations—perhaps even before the document was imaged on a CD-ROM disk or more likely while the document was available for inspection and copying at the Depository or after a copy was made from the document in the Depository or from its image on a CD-ROM disk.
 - (1) A party asserting that a document on file at the Depository or imaged on a CD-ROM disk is not an accurate copy of the document produced from a company's records may, as provided in paragraph 8 of this stipulation, seek a ruling from the MDL-926 Transferee Judge relieving it from this stipulation with respect to such document. The party seeking that relief must demonstrate the basis for its claim of alteration and must have available, for substitution, what it contends is an unaltered copy of that document.
 - (2) A party is not precluded from objecting in a case that an exhibit being offered as a copy of a document on file at the Depository or imaged on a CD-ROM disk is not an accurate copy of that document or image. The objecting party has the obligation to demonstrate to the trial court the basis for its claim of alteration and ordinarily should have available, for substitution, what it contends is an unaltered copy of that document or image.
 - (b) The CD-ROM disks contain some images that are "blotchy", cutoff, or of poor legibility. A party is not precluded from objecting in a case that an exhibit being offered, although accurately reproducing the image on a CD-ROM disk, nevertheless does not, because of problems with the image on the disk, fairly and accurately portray the document from which the image was made. The objecting party ordinarily should have available, for substitution, what it contends is an accurate copy of that document.
- 4. <u>Marginalia and Annotations</u>. Some documents in the Depository or imaged on CD-ROM disks contain marginalia and annotations—which may include highlighting or redactions—that were on the document when it was produced to the Depository.

- (a) Each Signatory Defendant asserts as an answer to a deposition question (and the PSC and such Defendant hereby stipulate) that such marginalia and annotations are authentic in the sense that they were present on the document in the custody of the producing company at the time it was produced to the Depository. (Any assertion that marginalia and annotations were placed on the document after production is subject to the provisions of paragraph 3(a) above.)
- (b) The PSC and the producing Defendant further agree that, with respect to a document drafted or created by that Defendant (or its then affiliate), there is a <u>rebuttable presumption</u> that marginalia and annotations on the copy of the document when produced were placed on the document by someone employed by or associated with that Defendant (or affiliate). There is no stipulation or presumption as to such person's identity or authority.
- (c) Except to the extent indicated in 4(a) and 4(b) above, there is no stipulation and no presumption that such marginalia and annotations were placed on a document at any particular time (other than prior to production) or by any particular person, entity, or source. If such questions affect admissibility or weight, the judge and jury may under FRE 104 and 901 (or to the extent permitted under applicable state evidentiary rules) consider, in addition to any relevant direct evidence, such matters as appearance, contents, distinctive characteristics, and other identifying information and circumstantial evidence.
- 5. Business Records Exception to Hearsay Rule. Each Signatory Defendant asserts as an answer to a deposition question (and the PSC and such Defendant hereby stipulate) that—to the extent indicated by the letter "Y" or "X" (or the word "Yes") in column 4 of the appendices provided by that Defendant (or by listing on a special appendix of such documents provided by that Defendant)—the listed document satisfies the standards of FRE 803(6) as a business record of that Defendant (or its affiliate). For many documents, "Y", "X", or "Yes" is shown in column 4a to reflect an assertion and stipulation that the document satisfies all of the standards of FRE 803(6); for other documents, "Y", "X", or "Yes" may be shown in particular columns of column 4 to reflect an assertion and stipulation that the document satisfies those particular standards of FRE 803(6).
 - (a) Some errors have likely occurred in classifying, in these appendices, documents as satisfying or not satisfying the standards of FRE 803(6). As the purpose of this stipulation is to eliminate unnecessary disputes regarding admissibility of documents (rather than to arbitrarily bind parties—plaintiffs or defendants—to erroneous stipulations), any party may, for good cause shown, seek relief from or modification of this stipulation respecting FRE 803(6). However, in the interest of orderly and efficient preparation and conduct of trial, it is also essential that any such requests for relief or modification be timely raised.
 - (1) As soon as the PSC or a Signatory Defendant becomes aware of an erroneous classification in the appendices of a document as satisfying or not satisfying the standards of FRE 803(6) that should be corrected, it shall file with the MDL-926 Transferee Judge an appropriate motion for relief or modification respecting the particular document.
 - (2) If, at least 30 days before a scheduled trial, a party lists, as an exhibit that may be offered in evidence, a document classified on the appendices as satisfying FRE 803(6), then each other party in the case shall be deemed to have waived any right to object to admissibility of the exhibit under FRE 802 or 803(6) unless, within 14 days after receiving such list, it files an objection specifically challenging the satisfaction of FRE 803(6) standards respecting the particular document and asserting that the document was erroneously classified in the appendices as satisfying those standards.

- (b) Any motion for relief from or modification of the stipulations regarding business records shall be filed with the MDL-926 Transferee Judge. However, if the motion is not promptly ruled on by the Transferee Judge, the motion may be presented for an interim ruling to the court in which the case is pending, to be applicable in that case only, and the Transferee Judge shall be advised of that court's ruling for consideration in ruling on the motion with respect to other cases.
- (c) The fact that the appendices do not classify a document as satisfying all or some of the standards of FRE 803(6) does not constitute a stipulation that the document fails to satisfy one or more of those standards and does not preclude a party from attempting to satisfy those standards through appropriate evidence outside this stipulation and its appendices.
- (d) The fact that a document does not satisfy the standards of FRE 803(6) does not necessarily make the document inadmissible. Depending on the circumstances, it may, for example, nevertheless be admissible for non-hearsay notice purposes or be admissible under FRE 801(d)(2) when offered against the party creating the document. Similarly, the fact that a document satisfies the standards of FRE 803(6) does not necessarily make the document admissible; depending on the circumstances, it might, for example, be held inadmissible under FRE 402 or 403.

6. Date of Receipt.

- (a) Each Signatory Defendant asserts as an answer to a deposition question (and the PSC and such Defendant hereby stipulate) that—with respect to documents not created by that Defendant (or its affiliate) but in their custody at the date of production—
 - (1) if the document contains a "Received" (or comparable) stamp or notation identified with that company, the document was probably received, and should be rebuttably presumed as received, by such company on the date indicated in the stamp; and
 - (2) if the document does not contain such a date stamp or notation but reflects that the Defendant (or its affiliate) was an intended recipient of the document, the document was probably received, and should be rebuttably presumed as received, by such company shortly after any date indicated in the document as the date of preparation or mailing.
- (b) Except as indicated in 6(a) above, this stipulation does not give rise to any presumption as to when other documents not created by the Defendant (or its affiliate) but in their custody on the date of production were received by such company, nor does it give rise to any presumption regarding the identity or authority of the person who had custody or possession of the document. If admissibility of such a document depends on the date it was received by the company or the identity and authority of the person having custody or possession (for example on an issue of "notice"), any party may seek a hearing before the MDL-926 Transferee Judge for a determination as to the date of receipt and the identity and authority of the person having custody or possession. If such an issue arises during the trial of a case and there has been no such ruling by the MDL-926 Transferee Judge, the issue is to be decided by the trial judge, for purposes of that case only, and the Transferee Judge shall be advised of that court's ruling for consideration in ruling on the issue with respect to other cases.

7. Application to Documents Produced by Other Defendants.

(a) Each Signatory Defendant's stipulations and deposition answers as contained in paragraphs 3 through 6 apply, in general, only to the documents produced by that Defendant (or

certain of its former or current affiliates), as reflected in the appropriate appendices prepared by or adopted by such Defendant. However, solely for the purpose of entering a stipulation relating to admissibility of documents—and not to be taken in any way as evidence of the nature or duration of any relationship between such companies—the following Defendants have also entered into this stipulation with respect to documents produced from the records of companies with which they are now or have previously been affiliated:

- (1) Baxter International Inc. and Baxter Healthcare Corporation adopt each other's stipulations and deposition answers and, in addition, have provided stipulations and deposition answers respecting certain pre-March 31, 1984, "Heyer-Schulte" documents that were produced to the Depository by Mentor Corporation.
- (2) Bristol-Myers Squibb Company and Medical Engineering Corporation, including Natural Y Surgical Specialties, Inc. and Aesthetech Corporation, adopt each other's stipulations and deposition answers with respect to the admissibility of documents produced by any of them.
- (3) McGhan Medical Corporation ("McGhan") and INAMED Corporation adopt each other's stipulations and deposition answers with respect to the admissibility of documents produced by either of them.
- (4) Minnesota Mining and Manufacturing Company adopts the stipulations of McGhan Medical Corporation with respect to documents produced by McGhan bearing a date between June 1, 1977, and August 3, 1984.
- (5) The Dow Chemical Company has provided a special appendix and deposition answers (Dow Chemical Exhibit B) relating to certain documents that it acknowledges were created by Dow Chemical's employees but were produced to the Depository by its former affiliate, Marion Merrell Dow. (No such stipulation or deposition answers are provided by Dow Chemical with respect to the documents listed in its Exhibit C, but it acknowledges that those were produced to the Depository by Marion Merrell Dow.)
- (b) Each Signatory Defendant waives any objection that it did not receive proper notice of the deposition questions asked of the other Signatory Defendants under Fed. R. Civ. P. 31 or of the answers to such questions as contained in the appendices provided by such other Defendants.
 - (1) The PSC and each Signatory Defendant recognize, therefore, that under Fed. R. Civ. P. 32(a)(2) those deposition answers by a Defendants could be used by adverse parties to establish the evidentiary foundation for admissibility at trial of documents produced by such Defendant.
 - (2) Although each Signatory Defendant may object to admissibility of an exhibit that is offered as a copy of a document produced by another Defendant, nevertheless—in the interest of orderly and efficient preparation and conduct of trial—each stipulates that any ground for objection that the producing Defendant and the plaintiffs would have been precluded from raising under paragraphs 3-6 above will be waived if not raised within 14 days after being notified that the exhibit will be offered as evidence. Such objections may be made in the first instance to the court in which the case is pending, for a ruling in that case only, but the MDL-926 Transferee Judge will be notified of that court's ruling and may schedule a hearing to resolve such objection for other cases.

8. Modification and Relief.

- (a) Petitions may be made to the MDL-926 Transferee Judge for relief from these stipulations, for correction of deposition answers contained in this stipulation, or for leave to correct information shown in the various appendices. Petitions for interim relief, when justified by the exigencies of time, may be made to the trial judge before whom an action is pending, for a ruling in that case only, but the MDL-926 Transferee Judge will be notified promptly of that court's ruling and may schedule a hearing to address such requests for other cases. If a Defendant is permitted to modify its response to a deposition question, its prior response shall not thereafter be used by or against it.
- (b) It is anticipated that, subsequent to the initial submission and approval of this stipulation, there may be added similar stipulations and deposition answers from other defendants.

Approved:2

<u>/s/ Sam C. Pointer, Jr.</u> Chief Judge and MDL-926 Transferee Judge

Submitted to the Court by:

FOR PLAINTIFFS:

/s/ Dianne M. Nast June 6, 1996

Dianne M. Nast

RODA & NAST

36 East King Street
Suite 301

Lancaster, PA 17602

(717) 397-1700

On Behalf of MDL-926 Plaintiffs' Steering Committee

²The document descriptions and dates contained in the appendices were prepared by the PSC, intended to describe neutrally the document (or in some cases a series of related documents) for purposes of preparing exhibit lists. Both plaintiffs and defendants reserve the right to make appropriate corrections in these descriptions and dates.

FOR DEFENDANTS:

/s/ Debra E. Pole

Debra E. Pole or Wendy A. Tucker BROBEK, PHLEGER & HARRISON 550 Hope Street Los Angeles, CA 90071-2604 (213) 489-4060 National Breast-Implant Counsel for Baxter Healthcare Corporation and Baxter International Inc

/s/ Richard M. Eittreim

Richard M. Eittreim
McCARTER & ENGLISH
100 Mulberry Street
4 Gateway Center
Newark, NJ 07102
(201) 622-4444
National Breast-Implant Counsel for
Bristol-Myers Squibb Co.,
Medical Engineering Corporation,
Natural Y Surgical Specialties, Inc.,
Aesthetech Corporation, Sirod Corporation,
Wilshire Foam Products, Inc.,
Cooper Companies, Inc., and
CooperSurgical Inc.

/s/ Douglas B. Schoettinger subject to
addendum
Douglas B. Schoettinger
Legal Department
Dow Corning Corporation
CO1222
Midland, MI 48686-0994
Attorney for Dow Corning Corporation

/s/ Carolyn H. Williams

Carolyn H. Williams
WILLIAMS & CONNOLLY
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000
National Breast-Implant Counsel for
General Electric Company

/s/ Lowell S. Fine

Lowell S. Fine or Susan M. Lieppe ALEMBIK, FINE & CALLNER Marquis One Tower, Fourth Floor 245 Peachtree Center Ave., N.E. Atlanta, GA 30303 (404) 688-8800 National Breast-Implant Counsel for Koken Co., Ltd.

/s/ L. Richard Rawls

L. Richard Rawls
PALMIERI, TYLER, WIENER, WILHELM
AND WALDRON
2603 Main Street, Suite 1300
Irvine, CA 92714
(714) 851-9400
National Breast-Implant Counsel for
McGhan Medical Corporation
and INAMED Corporation

/s/ Gretchen Gates Kelly

Gretchen Gates Kelly or Joseph M. Price FAEGRE & BENSON 2200 Norwest Center 90 South Seventh Street Mineapolis, MN 55402 (612) 336-3000 National Breast-Implant Counsel for

Minnesota Mining & Manufacturing Company

/s/ Robert S. Niemann

Robert S. Niemann
LYNCH, LOOFBOURROW, GILARDI &
GRUMMER
50 Francisco Street, Suite 400
San Francisco, CA 94133
(415) 397-2800
National Breast-Implant Counsel for
Porex Technologies Corp.

/s/ Barbara Bertok

Herbert L. Zarov or Barbara Bertok MAYER, BROWN & PLATT 190 South LaSalle Street Chicago, IL 60603 (312) 782-0600 National Breast-Implant Counsel for The Dow Chemical Company

Melissa J. Fassett Nusil Technology 1055-B Cindy Lane (805) 566-4124 National Breast-Implant Counsel for McGhan Nusil Corp.

> /s/ John Dames John Dames KELLEY DRYE & WARREN 303 West Madison Street, Suite 1400

Chicago, IL 60606 (312) 346-6350 National Breast-Implant Counsel for Union Carbide Corporation

ADDENDUM TO STIPULATION BETWEEN PLAINTIFFS AND DOW CORNING CORPORATION

In this Stipulation, the Plaintiffs' Steering Committee ("PSC") and Dow Corning Corporation have resolved certain issues regarding documents produced by Dow Corning Corporation in MDL-926. Dow Corning Corporation has agreed to enter into this Stipulation subject to the provisions of this Addendum to the Stipulation.

Dow Corning Corporation and the PSC agree that:

- 1. The Dow Corning Corporation response chart attached to this Stipulation is the only Dow Corning Corporation response chart governed by the terms of this Stipulation.
- 2. In MDL-926 Dow Corning Corporation served on August 31, 1993, responses to Plaintiff's Deposition Upon Written Questions, and served on November 2, 1994 responses to Plaintiffs' Request for Admissions (including later filed addenda). It is understood by the parties to this Stipulation that as to these earlier responses:
- a. Where a document of interest to a party is not listed on the chart which accompanies this Stipulation, but <u>is</u> specifically or generally referred to in one of the earlier responses, all parties are cautioned that any of earlier chart responses regarding authenticity or the business record status of Dow Corning Corporation documents is limited by the wording of the questions to which such charts respond.
- b. As to responses for documents which appear both on the chart attached to this Stipulation and on an earlier chart, the parties specifically agree that to the extent such responses appear inconsistent or conflicting:
 - i. The responses contained in the chart attached to this Stipulation between the PSC and Dow Corning Corporation supersede such earlier responses; and
 - ii. Such superseded earlier responses shall not be used by or against Dow Corning Corporation.

| APPROVED: | DATED: |
|--------------|---------|
| IN INO I LD. | DITIED. |

<u>/s/ Sam C. Pointer, Jr.</u> 6-10-96

Judge Sam C. Pointer, Jr.

FOR PLAINTIFFS:

/s/ Dianne M. Nast 6-6-96 /s/ Douglas B. Schoettinger 5-30-96

Dianne M. Nast

RODA & NAST

Seast King Street, Suite 301

Lancaster, PA 17602

Douglas B. Schoettinger

Legal Department

Dow Corning Corporation

CO1222

(717)397-1700 Midland, MI 48686-0994

On behalf of MDL-926 Attorney for Dow Corning Corporation Plaintiff's Steering Committee