

SYNOPSIS OF BREAST IMPLANT LITIGATION SETTLEMENT

KEY FEATURES OF SETTLEMENT

- Settlement (with prior settlements) will provide up to \$4,255,070,000 to pay:
 - compensation to breast implant recipients who have — or who within the next 30 years develop — any one of several covered diseases or medical conditions. (Projected net compensation for U.S. claimants after all costs and attorneys' fees: \$105,000 to \$1,400,000, depending on disease, severity, and recipient's age at onset of qualifying disease/severity)
 - past and future expenses for medical evaluations and diagnoses
 - past and future expenses for removal of implants ("explantation")
 - compensation for past or future rupture of implants
 - compensation for other injuries and emotional distress
 - compensation for special circumstances not otherwise covered
 - attorneys' fees and expenses, and administrative costs
- Both silicone and saline breast implants are covered. The amount of a Class Member's individual benefits does not depend on the settlement contributions or financial worth of the particular manufacturer of her implants.
- Defendants include all American manufacturers of breast implants, and many suppliers of materials used in implants.

IMPORTANT DATE — December 1, 1994^{1/}

- Deadline for mailing Registration Form to Claims Administrator in order to preserve eligibility to make future claims during the 30-year period of the settlement and to be included on the mailing list for later information concerning their rights.
- "Foreign Claimants" **MUST** register by this date to be eligible for benefits under settlement. Foreign claimants from Australia, Ontario, and Quebec who want to become voluntary class members **MUST** register by this date.
- Domestic class members **SHOULD** register by this date; otherwise, they may receive significantly less benefits than Class Members who timely register.
- Persons who have previously excluded themselves from the settlement class but who now wish to withdraw that exclusion in order to become eligible to participate in the settlement **MUST** withdraw their exclusion by this date.

(over)

1. Domestic claimants who mailed a Claim Form by September 16, 1994, have until October 17, 1994, to submit the required medical documentation (and any amendment to their Claim form) to make a "Current" claim. Foreign claimants have until December 1, 1994, to submit this documentation and revised Claim form under the Current Disease Compensation Program.

Revised 9/16/94

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

Breast Implant Litigation Settlement

Dear Class Member:

Enclosed for your attention and consideration are:

- the Breast Implant Litigation Settlement Notice as revised September 16, 1994, describing the terms of the settlement and your rights and options.
- a "Question and Answer" booklet, answering questions frequently asked by Class Members.
- two Forms for use in submitting claims:
 - a Registration Form, to be used to register for benefits (now or later) under the settlement; and
 - a Disease Compensation Claim Form, to be used (with the Registration Form) by Class Members at such time as they have or develop one of the diseases or medical conditions and severity levels covered under the Disease Compensation Program.

You should carefully read the Settlement Notice. As explained in the Settlement Notice, you may wish to consult an attorney about your rights and options. You may also obtain further information and legal assistance by calling 1-800-887-6828 (toll-free in U.S.), 1-312-609-8680, or 1-513-651-9770 (Claims Assistance hot-line). You should save these materials (as well as a copy of any Form you return) for future reference.

Also enclosed is a Synopsis briefly describing the settlement, highlighting an important date, and explaining the Forms. I urge you, however, to consult the Settlement Notice and the Question and Answer booklet for more detailed information concerning your rights and options.

You may have received some information regarding the settlement before it was approved by the court. On September 1, 1994, the court approved the proposed settlement, but with some modifications. The major changes related to "foreign claimants" — those persons who, as of April 1, 1994, were neither citizens nor permanent resident aliens of the United States and whose breast implants were all performed outside the United States. In addition to some safeguards respecting the benefits of foreign claimants under the Disease Compensation Program, the revisions now allow foreign claimants to submit claims under Designated Funds I-V. Foreign Claimants from Australia and from the Canadian provinces of Ontario and Quebec will be members of the settlement class only if they voluntarily "opt in" by December 1, 1994.

The enclosed materials reflect the changes in the settlement and the items of interest to those persons who have not previously received the Settlement Notice package.

Sam C. Pointer, Jr.
Chief Judge

COMPLETING THE FORM(S)

Before completing either form, you should review the Settlement Notice and the Question and Answer booklet, and perhaps call the numbers listed for legal advice or consult with your own lawyer.

If you have not previously "opted out" of the settlement class:

1. You should complete, sign, and mail the **Registration Form** to the Claims Administrator (P. O. Box 56666, Houston, TX 77256) by December 1, 1994. This will preserve your eligibility to make claims under the Disease Compensation Program or under Designated Funds I-V during the 30-year period of the settlement. It will also ensure that you are on the list to receive future mailings regarding your rights, including procedures for filing claims under Funds I-V and any rights to "opt out" of the settlement at a later time.

If you are a "foreign claimant" from Australia or from the Canadian Provinces of Ontario or Quebec, you should send in the Registration Form if you want to voluntarily join the settlement class. By joining the settlement, you will waive any objections to the settlement, but nevertheless will preserve your right to opt out at a later date.

2. You may complete, sign, and mail the **Disease Compensation Program Claim Form** to the Claims Administrator (P. O. Box 56666, Houston, TX 77256) at any time within the next 30 years if you believe you are eligible to receive payment for — and can provide medical documentation to support — a claim under that Program. The diseases and disability criteria for this Program are described in the Disease Schedule attached as Exhibit D to the Settlement Notice. The medical documentation needed to support such a claim is described in paragraph 27(b) of the Settlement Notice.

Your claim will be processed under the Ongoing Disease Compensation Program for the year in which the required information is received. You may hear about claims being processed under the "Current Claims" portion of the Disease Compensation Program. The time for submitting claims under that portion of the Program has expired, but this does not prevent claims from being processed under the "Ongoing Claims" portion of the Program.

3. If you timely submit the Registration Form, you will be mailed information and forms for submitting claims under Funds I-V when they have been approved by the court.
4. You may hear about persons having "opted out" of the settlement class. The time for the initial opt-outs has expired (except for children of breast-implant recipients). However, there will be additional opt-out periods for foreign claimants and there may be additional opt-out periods for domestic claimants; you will be advised of any later opt-out rights if you register with the Claims Office.

If you have previously "opted out" of the settlement class:

Some persons who have previously "opted out" of the settlement class may want to withdraw their exclusion and again become members of the settlement class. Such persons should — no later than December 1, 1994 — file Registration Forms (and, optionally, their Disease Compensation Program Claim Forms) with the Claims Office, and should also by that date notify the court (MDL Exclusion; P. O. Box 13307, Birmingham, AL 35202-3307) of that decision.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

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

HEIDI LINDSEY, et al.,)
Plaintiffs;)
-vs.-) Civil Action No. CV 94-P-11558-S
DOW CORNING CORPORATION, et al.,)
Defendants.)

BREAST IMPLANT LITIGATION SETTLEMENT NOTICE

**Please read this Notice carefully.
It affects your legal rights.**

TO: All persons who have ever had a breast implant,¹ and their spouses, children, other relatives, "significant others," estates, and personal representatives

You are notified of:

- the certification of a non-mandatory worldwide class of plaintiffs, of which you may be a member
- the approval of a class action settlement under which certain manufacturers of breast implants and suppliers have agreed to pay up to \$4,225,070,000, as needed under the settlement, to resolve claims by Class Members
- your rights as a Class Member to participate in benefits of, and perhaps exclude yourself ("opt out"), from the settlement
- this important date for Class Members — December 1, 1994. This date is :
 - the registration deadline to preserve eligibility for benefits under settlement. (See paragraphs 20 and 26 for information on "Late Registration" for domestic class members)
 - the deadline for foreign claimants from Australia and the Canadian Provinces of Ontario and Quebec to voluntarily "opt in" to the settlement class
 - the deadline for persons who have previously opted out to rejoin the settlement class

1. As used in this Notice, "breast implant" means any mammary prosthesis containing silicone, silicone gel, or saline. It does not include a silicone injection.

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THE LITIGATION

1. **Cases.** Thousands of lawsuits seeking damages for injuries allegedly resulting from breast implants are pending in many state and federal courts. The federal cases are coordinated in the United States District Court for the Northern District of Alabama ("the Court") before the Honorable Sam C. Pointer, Jr., Chief Judge, in a proceeding known as *In re Silicone Gel Breast Implants Products Liability Litigation*, MDL No. 926, Case No. CV 92-P-10000-S. One or more of the Settling Defendants have been named as defendants in most of these cases.

2. **Conduct of Litigation.** The Court appointed a seventeen-person National Plaintiffs' Steering Committee ("PSC"). The PSC, assisted by numerous additional lawyers representing individual plaintiffs or groups of plaintiffs in federal and state cases, has vigorously pursued these claims on behalf of all breast-implant recipients. The various companies and individuals named as defendants have denied all liability to the plaintiffs and have vigorously defended against these claims.

3. **Court Rulings.** The Court has made no ruling as to the merits of the plaintiffs' claims or the defendants' denials and defenses (other than in an interlocutory order granting summary judgment in favor of the stockholders of Dow Corning Corporation, who had been named as defendants in some of the cases). Sending this Notice is not an expression by the Court of any opinion as to the likelihood of recovery by the plaintiffs or as to the merits of any defense asserted by the Settling Defendants. Rather, the purpose of this Notice is to inform you that a class settlement has been approved by the Court, and to inform you of your rights with respect to and under the settlement.

ABOUT CLASS ACTIONS

4. **Nature of Class Actions.** Class actions are lawsuits in which claims and rights of many people are decided in a single court proceeding brought by representative plaintiffs (the class representatives). This avoids the necessity for hundreds, or even thousands, of people to file similar individual lawsuits, enables the court system to resolve these claims in a more efficient and economical way, and seeks to assure that people with similar claims are similarly treated. In a class action, the court has a responsibility to ensure that prosecution of the class claims by the class representatives and class counsel is fair. Class members are not individually responsible for the costs or fees of class counsel, which are subject to court

award and are deducted from any recoveries from the defendants before distribution of funds to class members.

CLASS CERTIFICATION FOR SETTLEMENT PURPOSES

5. **Class Certification.** On September 1, 1994, one of the federal cases, *Lindsey, et al., v. Dow Corning Corporation, et al.*, Case No. CV 94-P-11558-S, was certified by Judge Pointer under Fed. R. Civ. P. 23(b)(3) as a class action for settlement purposes on behalf of all persons and entities who may have claims against the Settling Defendants or Released Parties for present or future personal injury or death caused by or involving breast implant products. The Settling Defendants and Released Parties are the companies, individuals, and entities listed in Exhibits A and B to this Notice.

(a) Except as provided in (b), the Settlement Class consists of:

(1) all persons, wherever located, who have been implanted before June 1, 1993, with one or more breast implants (whether or not already or later removed), with respect to any claim against a Settling Defendant or Released Party for their own personal injury or death that may be asserted as due in whole or part to any breast implant;

(2) every child, wherever located, born before April 1, 1994, whose natural mother is a person described in subparagraph (1) above and who was born after the date his or her mother had a breast implant, with respect to any claim against a Settling Defendant or Released Party for his or her own personal injury or death that may be asserted as due in whole or part to his or her mother's having had a breast implant; and

(3) all persons or entities (including estates, representatives, spouses, children, relatives, and "significant others"), wherever located, with respect to any claim against a Settling Defendant or Released Party that they may assert independently or derivatively because of their personal relationship to a person described in subparagraph (1) or (2) above.

(b) Excluded from the Settlement Class are the following:

(1) breast-implant recipients all of whose breast implants can be identified as manufactured or distributed by Porex Medical Technologies

SETTLEMENT
BENEFITS ARE
DESCRIBED IN
PARAGRAPHS 10-24

Corp., Koken Co., Ltd., or other foreign manufacturers not listed in Exhibit A or B;

(2) breast-implant recipients who, as of April 1, 1994, were not citizens or permanent resident aliens of the United States if all of their breast implantations were performed outside the United States and —

(A) they have received any compensation from any Settling Defendant or Released Party for breast-implant injuries or expenses under the laws or procedures of another country; or

(B) they as of April 1, 1994, resided or were domiciled in Australia, or resided or had received a breast implant in either the Province of Ontario or Quebec, Canada. (See, however, paragraph 23 respecting the opportunity of such persons to "opt in" voluntarily into the settlement class.)

(3) breast-implant recipients who, before June 17, 1994, shall have separately settled with a Settling Defendant, providing a general release of claims related to breast implants, unless (A) they were not represented by counsel in such settlement and the settlement involved a payment of less than \$15,000 or (B) they demonstrate by clear and convincing evidence that their settlement was induced by a Settling Defendant's fraud;

(4) breast-implant recipients who, before June 17, 1994, shall have obtained and collected a judgment against a Settling Defendant on a breast implant claim or, after a trial on the merits, shall have had a final judgment entered against them on a breast implant claim in favor of a Settling Defendant;

(5) breast-implant recipients who (during the "First Opt-Out" period) elected to exclude themselves from the Settlement Class by return of a completed Exclusion Form, received or postmarked no later than June 17, 1994, or whose Exclusion Form, though received or postmarked after that date, is accepted by the Court as timely; and

(6) any person or entity described in paragraph (a)(2) whose status as a class member depends on class membership of a recipient excluded under paragraphs (b)(1) through (b)(5).

(c) If you are covered by the above class membership definition, you are a Settlement Class Member, whether or not you have brought your own

lawsuit in federal or state court, whether or not you are a member of (or have excluded yourself from) another class action in federal or state court, and whether or not you now suffer from a medical condition associated with a breast implant. You will not be precluded from participation under paragraph (b)(1) above if, despite reasonable efforts to do so, you are unable to identify the manufacturer of your breast implants.

6. **Class Claims.** The Settlement Class claims are limited to claims against any of the Settling Defendants and Released Parties for present or future personal injury or death caused by, or involving, breast implants or breast-implant materials, whether filed or unfiled, existing or contingent, and specifically including claims for injuries or damages not yet known or manifest.

(a) Claims against the "Mentor Defendants" (Mentor Corporation; Mentor Polymer Technologies, Inc.; Mentor O&O, Inc.; Mentor H/S, Inc.; Mentor Urology, Inc.; Mentor International, Inc.; and Tecknar Corp.) have not been certified as class claims in this action. However, the \$25,800,000 to be paid by the Mentor Defendants as a result of an earlier class action settlement will be added to the funds paid under this settlement by the Settling Defendants, and members of the Mentor Settlement Class will be members of the Settlement Class in this case and will be eligible to participate in this settlement on the same basis as other Class Members. Because the earlier settlement with the Mentor Defendants was a limited-fund mandatory (non-opt out) class settlement under Fed. R. Civ. P. 23(b)(1), persons who opt out of this settlement will not generally be permitted to make any further claims against the Mentor Defendants but will be able to participate in distribution of the Mentor settlement funds if a member of the Mentor Settlement Class.

(b) Because of bankruptcy proceedings involving the "Bioplasty Defendants" (Bioplasty, Inc.; Bio-Manufacturing, Inc.; and Uroplasty, Inc.), claims against them have not been certified as class claims in this action. However, the trust funds ordered set aside for claimants of the Bioplasty Defendants by the United States Bankruptcy Court in Minnesota (consisting of \$4,000,000 in insurance proceeds, a \$1,000,000 secured promissory note from New Uroplasty, 32% of New Uroplasty stock, and 50% ownership of certain avoidance actions to be pursued by the Bankruptcy Trustee) are expected to be added to the funds paid under this settlement by the Settling Defendants, and Settlement Class Members with breast implants manufactured by the Bioplasty Defendants will be members of the Settlement Class in this case and will be eligible to participate in this settlement on the same

basis as other Class Members. Because of the stay orders of the Bankruptcy Court, persons who opt out of this settlement will not be permitted to make any further claims against the Bioplasty Defendants but will be permitted to participate in the Bioplasty trust funds if eligible under the terms of the orders of the Bankruptcy Court.

(c) Claims against any other manufacturer, distributor, or supplier of breast implants or component parts of such implants — or against doctors, hospitals, or other health-care providers not listed in Exhibit B — are not part of the proposed settlement, are not released or dismissed, and have not been certified as class claims in this action.

7. **Representative Plaintiffs.** The plaintiffs in CV 94-P-11558-S — Heidi Lindsey, Cynthia Bullock, Margaret Abner, Dorothy Dressler, Rita Thompson, Donna Dante, and Joy Bryan — have been designated as Representative Plaintiffs for the Class.

8. **Class Counsel.** Margaret Moses Branch, Elizabeth J. Cabraser, Stanley M. Chesley, Michael T. Gallagher, and Ralph I. Knowles, Jr., have been designated as Settlement Class Counsel and members of the Settlement Committee. In December 1994 the Court will add to this group an attorney who represents foreign claimants. The Court has reserved the power to designate other attorneys as additional or replacement Settlement Class Counsel and Settlement Committee members as the need arises.

SUMMARY OF SETTLEMENT

9. **The Settlement Agreement.** The Settlement Agreement consists of the initial agreement filed with the Court on March 29, 1994, and also of certain supplemental agreements and addendums filed in August 1994. Some of these terms were modified by Orders No. 15-21 and by the Opinion and Final Order and Judgment entered September 1, 1994. These documents, referred to in this Notice as the "Settlement Agreement," are even more lengthy and complex than this Notice and are available for public inspection in the Court Clerk's office in Birmingham during normal business hours. This Notice summarizes the provisions of the Settlement Agreement in sufficient detail that most people should not need to obtain a copy of the Settlement Agreement itself. Moreover, in the event of any direct conflict, the terms of this Notice take precedence over the terms of the Settlement Agreement unless language in the Notice indicates it is intended as only a general description or is subject to details contained in the Settlement Agreement.

10. **Amount and Schedule of Payments into Settlement.** The Settling Defendants have paid \$78,500,000 and, pursuant to the settlement, have been

ordered to pay, over a period of 31 years according to the schedule in Exhibit C, additional amounts of up to \$4,146,570,000 as needed to pay benefits provided under the settlement. An additional amount of approximately \$30,000,000 will be paid into the settlement fund as a result of the prior settlement with the Mentor Defendants and the reorganization proceedings in bankruptcy court involving the Bioplasty Defendants. Settlement Funds will be invested, with the net earnings increasing the funds available to pay benefits to Class Members.

11. **Nature of Benefits.** All payments will be allocated between Designated Funds I through V for the benefit of Class Members (approximately 12%), a Disease Compensation Program for Class Members (approximately 64%), and Designated Fund VI for payment of all administrative costs and legal expenses (approximately 24%). The Court has reserved the power to approve reallocation of funds among the Designated Funds and to the Disease Compensation Program as necessary and appropriate to ensure fairness to Class Members and their attorneys.

(a) Designated Funds I through V (of the approximate amount of \$520,000,000) will provide various benefits to those Class Members who are not entitled to benefits under the Disease Compensation Program. These funds will provide compensation or reimbursement for medical evaluations, expenses for removal of implants ("explantation"), implant ruptures, and other injuries or emotional distress. See paragraph 14 for details concerning these Funds.

(b) The Disease Compensation Program (of up to approximately \$2,715,070,000) has two parts. The "Current Disease Compensation Program" will provide compensation to Class Members who are currently disabled by one or more of the most serious diseases or medical conditions that, according to the plaintiffs, are associated with breast implants. The "Ongoing Disease Compensation Program" will provide compensation to Class Members who during the next 30 years become disabled by one of these diseases (or whose claim under the Current Disease Compensation Program is not timely submitted and documented). The projected net compensation (after reduction for all administrative costs and legal expenses) to Class Members with these diseases under either program ranges from \$105,000 to \$1,400,000, depending on the type of disease, level of severity or disability, and age when first manifested. See paragraphs 15-22 for details concerning this Program, including information about making claims and the possibility of adjustments in the projected net compensation amounts.

(c) Designated Fund VI (of the approximate amount of \$1,020,000,000) will pay for all costs incurred in providing notice and in the administration of the claims process, as well as to pay the fees and expenses of the many hundreds of attorneys who have or may later provide legal services to the class and individual Class Members. This will ensure that Class Members similarly situated receive the same net benefits, receiving neither more nor less depending on whether they have employed an attorney, and that attorneys will receive fair compensation for their services in representing the class and individual class members. See paragraph 24 for further details.

12. **Recommendation of Class Counsel.** Settlement Class Counsel recommended approval by the Court of the settlement as fair, adequate, and reasonable and in the best interests of the members of the Settlement Class on the grounds that (1) the continued prosecution of class and individual suits against the Settling Defendants through trial and appeals would require considerable expense and time, with intrusion into sensitive and private areas of Class Members' lives and a high degree of risk, inconsistency, and uncertain prospects for recovery; (2) the settlement of the claims against the Settling Defendants and Released Parties under the terms and conditions of the proposed settlement would be more beneficial to the Settlement Class as a whole than continued piecemeal litigation, reducing potential conflicts between those with existing injuries and those who may sustain injuries in the future, and (3) each Class Member was provided an initial opt-out right and the potential opportunity to opt out later.

13. **Defendants' Position.** Although agreeing to the settlement, the Settling Defendants continue to deny any wrongdoing or any legal liability of any kind. They have agreed to the settlement not only because of the risk of adverse judgments in some cases, but also because of the substantial time, expense, and other burdens they would incur even in successfully defending against thousands of existing cases and of cases that might be filed in the future. The defendants believe that, at the same time, the settlement will also be in the best interests of those who have been implanted with their products, in that, by taking advantage of the potential savings in "transaction costs" resulting from a class settlement, the amounts actually paid to Class Members as a whole under the settlement will, in their opinion, exceed recoveries obtained through individual claims and lawsuits. Each Settling Defendant has reserved the right to withdraw from the proposed settlement if, in its opinion, the number of persons opting out of the settlement under paragraph 18(c) would defeat these objectives.

DESIGNATED FUNDS

14. **Purposes; Procedures.** After consulting with the Claims Administrator and Settlement Class Counsel, the Court will establish procedures for making claims under these Funds and guidelines for allocating the funds to pay such claims, taking into account the number and nature of claims made and anticipated as future claims.

- **Fund I — Medical Diagnostic/Evaluation Fund** [approximately \$75,000,000 net to Class Members, after deducting potential administrative costs and legal expenses]. Fund I, to be funded from defendants' payments in the first three funding years, is designed to pay certain unreimbursed costs for medical diagnoses and evaluations of Class Members for breast implant-related medical problems, including diagnoses and evaluations for ruptures and symptoms of diseases and medical conditions that may be covered under the Disease Compensation Program. This Fund may also be used to pay expenses of medical evaluation advisors, designated by Settlement Class Counsel with the Court's approval, to provide information and assistance to Class Members' doctors in making these evaluations.

All breast-implant recipients who are Class Members (other than those who have received benefits under the Disease Compensation Program) may make claims under this Fund, both for expenses already incurred and, on an ongoing basis, for future expenses. Benefits later payable to a Class Member under the Disease Compensation Program will be reduced by benefits previously paid to such Class Member under Fund I.

This fund covers only "unreimbursed" medical costs, *i.e.*, costs neither reimbursed nor paid by a third party (*e.g.*, a private insurance company, Medicare, or Medicaid) despite the Class Member's application therefor. Class Members will assign their rights against third parties to the Fund, which can seek reimbursement as assignee.

- **Fund II — Explantation Fund** [approximately \$75,000,000 net to Class Members, after deducting potential administrative costs and legal expenses]. Fund II, to be funded from defendants' payments in the first three funding years, is designed to pay unreimbursed costs associated with any explantation of Class Members' breast implants and, within reasonable limits, related necessary surgery. This fund does not cover expenses for the removal of a breast implant implanted after June 1, 1993, or for the reimplantation of breast implants performed after June 1, 1993.

All breast-implant recipients who are Class Members (other than those who have received benefits under the Disease Compensation Program) may make claims under this Fund, both for expenses already incurred and, on an ongoing basis, for future expenses. Benefits later payable to a Class Member under the Disease Compensation Program will be reduced by benefits previously paid to such Class Members under Fund II.

This fund covers only "unreimbursed" medical costs, *i.e.*, costs neither reimbursed nor paid by a third party (*e.g.*, a private insurance company, Medicare, or Medicaid) despite the Class Member's application therefor. Class Members will assign their rights against third parties to the Fund, which can seek reimbursement as assignee.

- **Fund III — Rupture Fund** [approximately \$220,000,000 net to Class Members, after deducting potential administrative costs and legal expenses]. Fund III, to be funded from defendants' payments in the first three funding years, will provide compensation to Class Members who have had, or in the future may have, one or more ruptures of a breast implant manufactured or distributed by a Settling Defendant or by the Mentor or Bioplasty defendants.

All breast-implant recipients who are Class Members (other than those who have received benefits under the Disease Compensation Program) may make claims under this Fund. Benefits later payable to a Class Member under the Disease Compensation Program will be reduced by benefits previously paid to such Class Member under Fund III.

- **Fund IV — Breast-Implant Recipient Compensation Fund** [approximately \$75,000,000 net to Class Members, after deducting potential administrative costs and legal expenses]. Fund IV, to be funded from defendants' payments in the first three funding years, will provide some compensation — in addition to reimbursement of medical evaluation and explantation expenses under Funds I and II — to Class Members who have not had an implant rupture or a medical condition covered under the Disease Compensation Program. In light of the large number of implant recipients likely to be in this category, the amounts to be paid to the individual Class Members are expected to be relatively small in comparison with other benefits under the settlement.

All breast-implant recipients who are Class Members (other than those who have received benefits under Fund III or under the Disease Compensation Program) may make claims under this Fund. Benefits later

payable to a Class Member under Fund III or under the Disease Compensation Program will be reduced by benefits previously paid to such Class Member under Fund IV.

- **Fund V — Reserve Fund** [approximately \$75,000,000 net to Class Members, after deducting potential administrative costs and legal expenses]. Fund V, to be funded from defendants' payments in the first three funding years, will be set aside as a reserve fund, to be paid solely to Class Members in such manner as the Court, after consulting with the Claims Administrator and Settlement Class Counsel, may determine. The purpose of this Fund is to provide a mechanism to correct for unanticipated inequities among Class Members in the administration of Funds I through IV and the Disease Compensation Program, and to respond to special and unique circumstances of individual Class Members not fairly addressed in the benefits otherwise afforded under the settlement, including early payments justified by an emergency situation.

All Class Members may make claims under this Fund. The extent, if any, to which benefits paid under this Fund will reduce benefits later payable to a Class Member under other Designated Funds or under the Disease Compensation Program will be determined by the Court after consulting with the Claims Administrator and Settlement Class Counsel.

DISEASE COMPENSATION PROGRAM

15. **Summary of Program.** The Disease Compensation Program will provide, upon timely application and supporting documentation, as much as approximately \$2,715,070,000 in net compensation (after deduction for potential administrative costs and legal expenses) to Class Members who now are disabled by one or more covered diseases or medical conditions ("Current Disease" claims) and to Class Members who become so disabled from such a disease or condition within the next 30 years ("Ongoing Disease" claims). The covered diseases are the more serious medical conditions that plaintiffs contend — though defendants deny — can be caused by breast implants. To receive compensation Class Members will not have to show that their disease was caused by a breast implant, so long as the qualifying symptoms for that disease were not manifested prior to their first implant. Current Disease claims will be funded with the first \$1,200,000,000 paid into the Program; Ongoing Disease claims will be funded by any amounts in the Program not needed to pay Current Disease claims and by the later payments to be paid annually by defendants into the Program during the remainder of the 30-year period. In general, and subject to the provisions of the Settlement

Agreement, the existence of a "surplus" at any time during the Ongoing Disease Compensation Program will not reduce the total potential obligations of the defendants under the Program, but may be used to reduce temporarily their annual payments unless and until such surplus is needed to pay qualified claims in following years.

16. **Covered Diseases; Additions.** The diseases currently covered under this Program are listed and defined, along with classifications defining the level of severity or disability, in the Disease Schedule attached as Exhibit D to this Notice. Evolving medical and scientific evidence may in the future demonstrate that diseases or conditions not currently listed on the Disease Schedule are caused by breast implants. As more fully described in the Settlement Agreement, these may be added to the Disease Schedule — and an appropriate compensation level established — by the

Claims Administrator with the Court's approval after such a determination by a Court-appointed Medical Panel. Class Members may request the Plaintiffs' Settlement Committee to submit additional diseases for possible addition to the covered diseases under the Ongoing Disease Compensation Program. Inclusion of additional diseases would not increase the total or maximum annual obligations of Settling Defendants under the settlement.

17. **Projected Net Compensation.** The projected amount of net compensation to be paid to qualifying Class Members either as a Current Disease claim or an Ongoing Disease claim is set forth in the following schedule, and depends on the type of covered disease or condition, the level of severity or disability, and the Class Member's age as of the onset of qualifying symptoms. These amounts are subject to adjustment as described in paragraph 18.

SCHEDULE OF BENEFITS

DISEASE OR CONDITION (as defined in Exhibit D)	Severity or Disability	NET COMPENSATION (U.S. Dollars after costs and legal expenses)					
		AGE (as of date of onset of qualifying symptoms)					
		Under 36	36-40	41-45	46-50	51-55	56 or older
Systemic Sclerosis or Scleroderma; Systemic Lupus Erythematosus	A	\$1,400,000	\$1,330,000	\$1,260,000	\$1,190,000	\$1,120,000	\$1,050,000
	B	\$1,050,000	\$980,000	\$910,000	\$840,000	\$770,000	\$700,000
	C	\$700,000	\$630,000	\$560,000	\$490,000	\$420,000	\$350,000
Localized Scleroderma; Mild Lupus	D	\$140,000	\$140,000	\$122,500	\$122,500	\$105,000	\$105,000
Atypical Neurological Disease Syndrome; Mixed Connective Tissue Disease; Overlap Syndromes; Polymyositis; Dermatomyositis	A	\$1,050,000	\$980,000	\$910,000	\$840,000	\$770,000	\$700,000
	B	\$700,000	\$630,000	\$560,000	\$490,000	\$420,000	\$350,000
	C	\$350,000	\$315,000	\$280,000	\$245,000	\$210,000	\$175,000
Atypical Connective Tissue Disease; Atypical Rheumatic Syndrome; Non-specific Autoimmune Condition; Primary Sjogren's Syndrome	A	\$700,000	\$665,000	\$630,000	\$595,000	\$560,000	\$525,000
	B	\$455,000	\$420,000	\$385,000	\$350,000	\$315,000	\$280,000
	C	\$210,000	\$196,000	\$182,000	\$168,000	\$154,000	\$140,000

18. **Reduction in Scheduled Benefits; "Second Opt-out" rights.** If the total amount of qualifying Current Disease claims exceeds the \$1,200,000,000 set aside for such claims, the projected amounts shown in the above schedule will be subject to reduction to the extent necessary to reduce the total amount of qualifying Current claims to the amount of funds available in the Program. Before any such reductions are made, Settlement Class Counsel and the Settling Defendants will confer and in good faith explore methods and options to minimize or eliminate the need for such reductions. Any such reduction in scheduled benefits during the processing of Current Disease claims will apply to the amount of compensation payable under the Program both for Current Disease claims and for Ongoing Disease claims. If there is a reduction, all registered Class Members will be so notified and provided a "Second Opt-out" right described in subparagraph (c) below.

SAVE THIS NOTICE FOR PERIODIC REFERENCE REGARDING RIGHTS AND BENEFITS, THE CLAIMS PROCESS, DEADLINES, AND TELEPHONE NUMBERS

(a) The first reduction will be in the amounts shown in the schedule for Severity/Disability level B or C for Atypical Neurological Disease Syndrome, Atypical Connective Tissue Disease, Atypical Rheumatic Syndrome, and Non-specific Autoimmune Condition. These amounts will be reduced pro rata, up to 25% of the amounts shown, until either the amount of the qualifying claims for such diseases and severity-disability level does not exceed 50% of the total amount of all other qualifying claims or the total amount of all qualifying claims (with such adjustments) does not exceed the funds available in the Program.

(b) If still further reductions are needed, these will be made pro rata in the benefit levels for all diseases and severity levels (including those already reduced under the preceding paragraph) to the extent necessary to reduce the total amount of qualifying claims to the amount of funds available for such claims in the Program.

(c) All registered Class Members will be notified of any reduction in scheduled benefits and, during an appropriate period and under procedures to be set by the Court, be afforded a "Second Opt-Out" right from the settlement. Persons who exclude themselves at that point will retain all rights under applicable law that existed prior to April 1, 1994, including the right to seek punitive or multiple statutory damages in addition to compensatory damages.

19. **Current Disease Claims.** Current Disease claims had to be filed with, or mailed to, the Claims Office by September 16, 1994, with supporting documentation provided as prescribed in paragraphs 27 and 28 and Order No. 21. Untimely claims, although not eligible for payment as Current Disease claims, will automatically be treated as Ongoing Disease claims.

20. **Ongoing Disease Claims; Registration; Potential Reductions; and Later Opt-out Rights.** The Ongoing Disease claim process will provide compensation for otherwise eligible Class Members whose Current Disease claims were not received or postmarked by the September 16, 1994, deadline (or documented as prescribed

in paragraphs 27 and 28), and for other Class Members who become disabled by one or more of the covered diseases during the 30-year period of the Disease Compensation Program. Benefits for the covered diseases and medical conditions are as shown in the schedule, subject to any reduction in comparable benefits for Current Disease claims under paragraph 18. Benefits may also be provided for additional diseases or medical conditions as indicated in paragraph 16. Depending on the availability of funds in the Program (and without increasing the total or maximum annual obligations of the Settling Defendants as set forth in the Settlement Agreement), the Claims Administrator may, with the Court's approval, increase the amounts payable to Ongoing Disease claimants based on a "cost of living" adjustment. In general —

(a) To be eligible for priority consideration under the Disease Compensation Program for Ongoing Diseases, Class Members must file with, or mail to, the Claims Office a Registration Form by December 1, 1994. Class Members who fail to register by that date may participate in settlement benefits only as "Late Registrants." Claims of Late Registrants will be recognized and processed by the Claims Office in the order in which they are received after the December 1, 1994, deadline and only to the extent payment of such claims would not diminish benefits payable to those who timely register. It is anticipated that the Court will in the future establish a final deadline for Class Members to register to maintain eligibility for future benefits under the settlement.

(b) Ongoing Disease claims are subject to conditional reduction to the extent the funds available in the Disease Compensation Program in a particular

year are insufficient to pay the full amount of qualifying claims for that year. In general, the funds available for payment of Ongoing Disease claims submitted in a particular year will be the amounts to be paid into the Disease Compensation Program for that year plus any amounts remaining in that Program after payment of earlier claims (whether Current Disease claims or earlier Ongoing Disease claims). Further details are contained in the Settlement Agreement.

(c) The method for making reductions under paragraph (b) above will be the same as prescribed in paragraphs 18(a) and 18(b) for reductions during Current Disease claims administration. Reductions under paragraph 20(b), however, are conditional; these conditional reductions may be abated or lessened if other Class Members elect at that point to opt out as described in paragraph (d) below, thereby reducing the claims for that year, and any unpaid portions of the claims will be treated as additional claims under the Program in the next and following years as necessary. Appropriate adjustments may be made in the payment of such later years' claims in an effort to ensure that reductions under 20(b) in one year do not result in that year's claims being ultimately paid at a lesser level than similar claims made in later years.

(d) Class Members who would be adversely affected by a conditional reduction under paragraph 20(b) in the year in which their claims are first submitted will be notified of the amount of the potential reduction and be afforded the right to opt out of the settlement within a period, and under procedures, to be established by the Court, or to remain in the Program, with the unpaid portion carried forward for potential payment in later years as described in paragraph (c) above. Those electing to exclude themselves from the settlement will be permitted to pursue claims against the Settling Parties for compensatory damages, but not for statutory multiple or punitive damages (except for wrongful death in a state where only such damages are allowed), and, as a precondition to commencing or reactivating a lawsuit, they must participate in non-binding mediation under procedures to be established by the Court. Further details, such as the effect of payments previously obtained under this settlement and the nature of the defendants' waiver of defenses based on statutes of limitation and repose, are contained in the Settlement Agreement.

21. Pre-Existing Diseases; Successive Claims. Benefits may not be obtained under the Disease Compensation Program for a disease and severity level where the requisite qualifying symptoms existed before the first breast implant, except as follows:

(a) A Class Member who before the first breast implant had a covered disease, but who after an implant develops another covered disease, may obtain benefits under the Disease Compensation Program for the later disease.

(b) A Class Member who before the first breast implant had a covered disease may, if the severity level increases after an implant, obtain benefits under the Disease Compensation Program measured by the difference between the amount payable for the new severity level and that for the former severity level.

(c) Class Members who receive benefits under the Disease Compensation Program may make additional claims under the Program if, as a result of additional symptoms developing after receipt of benefits, they would be entitled to a higher level of compensation, either because of an increase in the severity level or a new disease. Amounts previously paid will be subtracted from the amount otherwise payable for the new condition.

22. Children of Breast-Implant Recipients; Special Opt-Out Rights. The Disease Compensation Program does not presently provide any special benefits to children of breast-implant recipients. Under the procedure for adding diseases described in paragraph 16, the Disease Schedule may later be amended to permit Ongoing Disease claims on behalf of children who have or develop diseases or medical conditions demonstrated to be caused by their mother's breast implant.

(a) If such benefits are added, they would be available only to a Class Member described in paragraph 5(a)(2) who does not himself or herself opt out as described in (b) below.

(b) Children of implant recipients may opt out of the settlement within two years after manifestation of symptoms of any disease or medical condition they claim is related to their mother's breast implants (or, if later, within two years from the date of majority under the laws of the state of residence). By so doing, they would be permitted to seek any remedy available for compensatory and punitive damages based on a disease for which they have not received compensation under the Ongoing Disease Compensation Program, and — provided the action is thereafter brought within the time allowed under the Settlement Agreement — the defendants would waive any defenses based on statutes of limitations or repose.

FOREIGN CLAIMANTS.

23. Foreign Claimants; Limitations on Benefits; Other Remedies. "Foreign Claimants" are those Class

Members who are not citizens or permanent resident aliens of the United States and whose breast implants were all implanted outside the United States. Claims in United States courts by such persons are subject to strong and unique procedural and substantive defenses. Many Foreign Claimants have national health and medical care programs that pay costs of diagnosis and treatment and either do not have access to indigenous tort systems or are significantly limited, in comparison with United States claimants, in the compensation they may recover. The benefits provided Foreign Claimants under the Disease Compensation Program are less than those provided to other Class Members, and the total benefits payable to Foreign Claimants under this Program and under Designated Funds I-V are limited to 3% of the amounts paid by the defendants into that Program and those Funds.

(a) To be eligible for benefits under the Disease Compensation Program, a Foreign Claimant must register with the Claims Administrator by December 1, 1994 — there is no "Late Registration" for Foreign Claimants. A Class Member who is a Foreign Claimant and does not register by December 1, 1994, will be precluded from filing or pursuing a claim relating to breast implants in the federal or state courts of the United States and will be permitted to file or pursue such claims only in the courts or administrative tribunals of other countries. Foreign Claimants from Australia or the Canadian Provinces of Ontario and Quebec are not members of the settlement class unless they voluntarily "opt in" by filing a registration with the Claims Administrator by December 1, 1994.

(b) The amounts payable to Foreign Claimants for covered diseases under the Disease Compensation Program will, subject to the availability of funds, range from 40% to 90% of the amounts payable to similarly-situated domestic claimants. This percentage will be determined by the Court on a country-by-country basis, after consulting with the Claims Administrator and counsel representing foreign claimants, in a manner that takes into account the types of compensable injuries and the amount of compensation typically awarded for similar injuries in the country where the implantation was performed.

(c) Three percent of the amounts paid into the Disease Compensation Program and Designated Funds I-V will be set aside and held for the benefit of Foreign Claimants during the 30-year period of the settlement unless and until the Court, based on a review of the claims and registrations, determines that further separation of these amounts is not necessary to protect the interest of Foreign Claimants in future years of the settlement period.

(d) All Foreign Claimants who register by the December 1, 1994, deadline will be notified of the amounts payable to Foreign Claimants under the Disease Compensation Program as calculated under subparagraphs (b) and (c) above and be afforded a special period in which to opt out at that time from the settlement. A Foreign Claimant electing to opt out at that time will have such rights, if any, that the person may have to file or pursue claims against the Settling Defendants and Released Parties in the federal and state courts of the United States and in the courts or administrative tribunals of other countries, and such defendants will not include, in measuring the statute of limitations or repose in any such jurisdiction, the period of time between March 23, 1994 (the date of filing of the Lindsey action) and 30 days after the date such Foreign Claimant opts out of the Lindsey settlement class.

(e) If in any year the 3% limitation would have the effect of reducing the amount otherwise payable to Foreign Claimants under the Disease Compensation Program, such Foreign Claimants will be afforded an election either to opt out of the settlement as under paragraph (d) above or to "carry forward" the amount of such reduction into the following year or years for inclusion as Ongoing Claims of Foreign Claimants under the Program.

ATTORNEYS' FEES AND EXPENSES

24. **Fund VI.** The Court has ruled that all fees and expenses of attorneys representing the class or individual class members should be compensated or reimbursed out of Fund VI and not otherwise diminish the net benefits payable to Class Members. The Court has also indicated that the total amount of such fees and expenses, as well as the costs of notice to Class Members and of administration of the claims program over the next 30 years, should not exceed 25% of the total funds to be paid by the defendants. Consistent with these principles, the Court has directed that up to approximately \$1,020,000,000 (24% of the total amount that may be payable under the settlement by the defendants during the 30-year settlement period) be set aside into Designated Fund VI to cover projected administrative costs and the fees and expenses of all attorneys providing services to the settlement class or to individual members of the class. (Moneys recovered under Order No. 13 against persons who opt out of the settlement but later obtain recoveries against defendants — assessed as a means to assure that the cost of services enuring to the common benefit of all plaintiffs be equitably shared by all — will be used to support services, such as the document depository and employment of a Special Master to assist in coordination of federal and state cases, that may reduce

litigation costs in cases pursued by persons who opt out of the settlement.)

(a) The procedures for submitting, processing, and paying claims for attorneys' fees and expenses will be established by the Court in subsequent orders. The Claims Office may be used to receive and collate claims for such fees and expenses, but it is anticipated that the Claims Office will not be responsible for the evaluation and approval of such claims. Approved payments may be made in installments as the moneys funding Fund VI are received.

(b) Subject to the availability of funds in Fund VI, attorneys for the plaintiff class and for individual members of the class will be compensated, and their reasonable expenses reimbursed, as follows:

(1) for reimbursement of reasonable out-of-pocket costs and expenses incurred for the benefit of the plaintiff class or individual plaintiffs, as approved by the Court;

(2) for services already or later performed for the "common benefit" of the plaintiff class or groups of plaintiffs in federal or state court (including services in achieving this settlement or in pursuing federal or state litigation that directly or indirectly contributed to achieving this settlement), determined in accordance with applicable standards for such fees, including as appropriate consideration of the results achieved and the contingencies involved in such services;

(3) for services provided to individual members of the plaintiff class, whether in filing and pursuing lawsuits in federal or state court, in providing advice regarding rights and options under this settlement, or in providing assistance in presentation of claims under this settlement, measured by reasonable hourly rates; and

(4) for such additional compensation as might be accorded under "contingent fee" contracts based on benefits obtained by such clients under this settlement, arising from contacts and relationships with individual members of the plaintiff class before March 1, 1994 (the date when information concerning potential acceptance of this settlement — with its defined benefits for class members and assurance of payment of attorneys' fees — became generally known). To afford equity among counsel, the Court reserves the power to set maximum limits on the contingency percentages that may be recognized and to make appropriate reductions in such contingent fee amounts for the cost of "common

benefit" services provided by other attorneys that contributed to the amount of benefits obtained by the client.

(c) If you have already employed an attorney, there is no need to discharge such person since his or her fees and expenses will not reduce the amount you receive under the settlement and you may benefit from the attorney's advice regarding your rights or assistance in submitting claims.

(d) Should the total amount of administrative costs and attorneys fees and expenses approved by the court be less than the funds available in Fund VI, the excess would be distributed pro rata to Class Members as the Court directs.

CLAIMS ADMINISTRATION

25. **Claims Administrator; Claims Office.** After consulting with the parties, the Court has appointed Ann Tyrrell Cochran of Houston, Texas, formerly Judge of the 270th District Court of Texas, as Claims Administrator. The Claims Administrator will, with the assistance of her agents or employees, including Claims Officers, be responsible for processing and evaluating claims under Designated Funds I through V and under the Disease Compensation Program in a fair, inexpensive, and timely manner. Procedures shall be adopted that, consistent with the responsibility to reject fraudulent or otherwise meritless claims, minimize the burdens and personal intrusion on Class Members imposed by the claims process. Operations of the Claims Office will be subject to the continuing jurisdiction of the Court and subject to Court review. Expenses of the Claims Office will be paid from Designated Fund VI.

26. Registration and Claims.

(a) To be eligible to file a Claim (and to be placed on the mailing list for information that may affect your rights), you must register with the Claims Office, using the enclosed Registration Form. Foreign Claimants must send this Registration Form by December 1, 1994, and domestic Class Members should send this Registration Form by December 1, 1994. (Domestic Class Members who do not register until after December 1, 1994, will be treated as "Late Registrants," and their claims will be recognized and processed by the Claims Office in the order in which they are received after December 1, 1994, and only to the extent payment of such claims would not diminish benefits to those Class Members who have timely registered.) It is anticipated that the Court will in the future establish a final deadline for Class Members to register to maintain eligibility for future benefits under the settlement.

(b) The deadline for filing a claim under the Current Disease Compensation Program expired September 16, 1994.

(c) Claims under the Ongoing Disease Compensation Program may be filed at any time during the 30-year period of the Program that the claimant satisfies — and can support with the required medical documentation — the disease and severity criteria under that Program. Claims under the Program are to be submitted to the Claims Administrator, using the enclosed Claim Form.

(d) There is no deadline for filing claims under Designated Funds I-VI; indeed, the procedures and forms for filing such claims have not yet been determined by the court. Information concerning such claims will be mailed to registered class members when those procedures and forms are approved.

(e) Registration Forms and Claim Forms (with documentation) must be mailed to:

Claims Administrator
P. O. Box 56666
Houston, TX 77256

Do NOT send these to the Clerk of the Court.

(f) The Claims Administrator will acknowledge receipt of your Registration Form. Inquiries — in English — about your claim or the claims process can be mailed to the above address or be made by telephone to 1-800-600-0311 (toll-free U.S. and Canada) or to 1-713-951-9106. The Claims Office is not permitted to give legal advice.

(g) To deter potential fraud, all claims must be signed under penalties of perjury. Since the Postal Service will be used in the processing and payment of claims, submission of fraudulent claims will violate the criminal laws of the United States and subject those responsible to criminal prosecution in the federal courts.

27. Forms and Documentation.

(a) Only the enclosed Forms (or other Court-approved forms) may be used to submit claims or register. Additional copies can be obtained from the Claims Office. Forms must be completed in English.

(b) Claims under the Disease Compensation Program must be accompanied by either —

(1) a Statement or Diagnosis from a Qualified Medical Doctor (a Board-certified Specialist), together with the medical records on which it is based, that will enable the Claims

Office to place the claimant in a category on the Disease Schedule; or

(2) medical records that, by themselves, demonstrate that the claimant should be placed in a category on the Disease Schedule.

Claimants are responsible for seeing that required medical documentation in other languages are translated into English.

(c) You will not be precluded from benefits if, despite reasonable efforts to do so, you are unable to identify the manufacturer of your implants.

28. **Claims Processing; Appeals.** Each claim will be reviewed by a Claims Officer as soon as possible. If the Claims Administrator has a reasonable basis to believe a claim or series of claims may be fraudulent, she shall so advise the Court.

(a) The Claims Officer may challenge or ignore the diagnosis of a Qualified Medical Doctor only if the signs, symptoms, or findings in the medical records (or in the Statement or Diagnosis) do not satisfy the eligibility requirements in the Disease Schedule. In this event, the Claims Officer will seek additional information on which to base his or her decision.

(b) If there are minor deficiencies in the medical documentation, the Claims Administrator will send a notice to the claimant (and, if applicable, to the claimant's attorney), indicating the deficiencies and the additional information needed. Information so submitted by the claimant within 30 days after this deficiency notice was mailed will be considered by the Claims Office in classifying the claim for that same year of the Disease Compensation Program. Information submitted after that time will be considered in reevaluating the Claim in the next or later years of the Ongoing Disease Compensation Program, as appropriate.

(c) Before being finally certified for payment under the Disease Schedule, the claim will be reviewed by a second Claims Officer. Unless the reviewing Claims Officer determines that there is no basis in fact for the original placement on the Disease Schedule, the claim will be approved and certified as eligible for payment. A claimant contemporaneously suffering from more than one of the diseases on the Disease Schedule will be compensated based on the disease, severity level, and onset age providing the highest level of compensation.

(d) An adversely affected claimant may appeal the final claims classification first to the Claims Administrator, and then, under procedures to be

established, to the Court. Settling Defendants will have no right of appeal from claims classifications.

29. **Payments.** Claims will be paid, either as a single payment or in installments, as soon as possible after final approval of all claims during the year or period that may affect the amount to be paid. To avoid undue delay in payment caused by the need to evaluate all submitted claims, the Claims Administrator may authorize, on request, advance payment of part of an approved claim upon condition that the recipient waive any opt-out rights that may arise from subsequent reduction of benefits payable.

30. **Maintenance of Records; Privacy.** The Claims Office will maintain all documents and records relating to the submission and review of claims under Designated Funds I through V and the Disease Compensation Program.

(a) Submission and review of records in the claims process shall not constitute a waiver of any claimant's physician-patient privilege.

(b) Identification of claimants, including information contained on claim forms and in medical records, will be treated as confidential and will not be disclosed except to persons with a "need to know" to assure the integrity of claims processing and administration of the settlement. Defendants and their insurers, at their expense and pursuant to procedures approved by the Court, may inspect these records, but must maintain the confidentiality of this information to protect the identity and privacy of individual claimants.

DEFENDANTS' OBLIGATIONS AND OPTIONS

31. **Amount and Timing of Defendants' Obligations.** The Settlement Agreement governs the amount and timing of the Settling Defendants' obligations to make payments under this settlement. In general —

(a) Each Settling Defendant is responsible only for making its own payments at the times and in the maximum amounts shown in the column for such defendant in Exhibit C, and is not in any way a guarantor or a joint or conditional obligor for the obligations of other Settling Defendants.

(b) The Settlement Agreement required the Settling Defendants to provide guarantees or financial assurances of their obligations. The Court has reviewed the adequacy of these guarantees or financial assurances in considering the fairness, adequacy, and reasonableness of the settlement.

(c) The dates when the amounts shown in Exhibit C for Funding Years 1-31 must be paid are prescribed in the Settlement Agreement, which has been drafted to

cover a number of possible contingencies. The most likely circumstance is that the amounts for Funding Year 1 would be due 5 business days after the Court's order approving the settlement (dated September 1, 1994) has (after any appeals) become final and that the amounts for Funding Years 2-31 would be payable at the times set forth in the Funding Agreement.

(d) Should a Settling Defendant default in its payment obligations, the Settlement Agreement explains the rights of Class Members both to sue the defendant in default and to continue to receive benefits provided under the settlement by the other defendants.

(e) Under the Settlement Agreement, the amount of annual payments to be made by defendants after the first three years depends in part on whether there is a "surplus" in the Disease Compensation Program from prior years' payments (*i.e.*, more money has been contributed by the defendants than needed to pay claims). Such a surplus may temporarily reduce the amount of their following year's payment, but will not reduce permanently their potential obligations (since such amounts would become payable if and when needed for payment of later claims). To the extent the defendants' annual payment obligations under the Settlement Agreement depend upon the amount of benefits payable in a given period or year under the Ongoing Disease Compensation Program, such obligations are based on "gross" benefits rather than the net amounts shown in the schedule of benefits in this Notice (which represent only 70% of such gross benefits).

32. **Defendants' Options.** Each Settling Defendant has reserved the right to withdraw from the settlement if, in its opinion, the number of Class Members opting out during any additional Opt-Out period is excessive. Should a defendant elect to withdraw, benefits attributable to further settlement contributions by that defendant would be eliminated, Class Members would have full rights to file or pursue claims against that defendant (in addition to receiving benefits from the remaining defendants under the settlement and without reduction for benefits already received under the settlement), and Settlement Class Counsel would have the right to cancel the settlement with respect to all Settling Defendants, restoring to Class Members full rights to file or pursue claims against all defendants. Details are contained in the Settlement Agreement, including an additional right of withdrawal by some defendants under certain conditions if there is no second Opt-Out period.

33. **Further Settlements.** Registered Class Members will be given appropriate notice should there be a proposed

settlement with any manufacturers, suppliers, or health care providers not currently parties to this settlement.

OPT-OUT RIGHTS OF CLASS MEMBERS

34. **Opt-Out Rights.** As a class action certified under Fed. R. Civ. P. 23(b)(3), Settlement Class Members were afforded an opportunity to exclude themselves from the settlement class if they desired to do so. This initial opt-out period has now expired. Class Members may, however, have additional opportunities to opt out later as explained in this Notice; for example, if the projected benefits under the Disease Compensation Program are less than those shown in the schedule of benefits in this Notice.

(a) Additional opt-out rights are provided to children of Class Members with respect to claims for their own personal injury or death asserted as caused in whole or part by their mother's having had a breast implant. See paragraph 22.

(b) Additional opt-out rights are also provided to Foreign Claimants. See paragraph 23.

(c) Persons who elected to opt out during the initial opt-out period may, for a limited period of time, withdraw their exclusion and rejoin the Settlement Class and thereby become eligible for benefits under the settlement. To withdraw an earlier exclusion, the person must so notify the court by December 1, 1994, at the following address:

MDL 926 Exclusion
P. O. Box 13307
Birmingham, AL 35202-3307

Do NOT send this notification to the Clerk of the Court.

35. **Personal and Individual Choice; Effect on Others.** The decision whether — if you are given a later opportunity to opt out — to exclude yourself (and your family members) from the settlement class would be yours alone. It should be made only after considering the effects of that decision on your rights and the possible derivative rights or claims of your family members. You should be aware, however, that, if a Settling Defendant concludes that too many persons exclude themselves from the settlement under paragraph 18(c), it would have the option to withdraw from the settlement — which would affect the benefits afforded to persons wanting to participate in the settlement and could even lead to cancellation of the settlement.

IF YOU LATER OPT OUT

36. **Effects of Exclusion.** This Notice, in paragraphs 22 and 23, explains the consequences if a child of a breast-implant recipient or a foreign claimant elects to opt out. If

other Class Members are afforded an additional period in which they exclude themselves (and their family members) from the settlement, they will be notified at that time of the consequences of opting out.

IF YOU REMAIN IN THE CLASS

37. **Effects of Being a Class Member.** By not having opted out of the settlement during the initial opt-out period:

- you and your family members are members of the Settlement Class whose rights are determined by the terms of the settlement and judgment, and you —
- are entitled to receive benefits provided to Class Members as described in this Notice, which may include benefits under the Disease Compensation Program and under Designated Funds I through V (medical evaluation, explantation expenses, damages for implant ruptures, other injuries, and potential compensation).
- are deemed to have released (subject to later opt-out rights) any further claims against the Settling Defendants and Released Parties, while, however, retaining any rights to file and pursue (at your own expense) any claims or lawsuits against other persons and entities. State laws may limit the time within which suits against such other persons and entities must be filed.
- may submit claims under the Ongoing Disease Compensation Program and Designated Funds I through V as they arise.
- may register by the December 1, 1994, deadline to preserve eligibility to make claims under the Ongoing Disease Compensation Program and Designated Funds I through V.
- will have your attorney's fees paid from the settlement (Designated Fund VI).
- will have a further opportunity to opt out of the settlement if benefit levels under the Disease Compensation Program must be reduced because of the number of claims.

FAIRNESS HEARING

38. **Hearing; Purposes.** Before approving the settlement, the Court conducted a hearing in Birmingham, Alabama, on August 18, 19, and 22, 1994. Based on that hearing, the court determined that the settlement was fair, reasonable, and adequate, was in the best interests of the class, and should be approved.

REPRESENTATION

39. **Employment of Attorneys.** You may retain an attorney of your own choice for advice concerning your rights and for assistance in submitting claims. As noted in paragraph 24, Fund VI will — if the settlement takes effect — provide funds for payment of attorney's fees of individual Class Members. Settlement Class Counsel have arranged for representation of Class Members who do not have their own attorneys (unless requested not to do so), and will, at the request of otherwise unrepresented Class Members, provide assistance in the submission of their claims. The telephone number of the Claims Assistance Office is 1-513-651-9770.

ADDITIONAL INFORMATION

40. **Court Filings.** You may inspect documents on file with the Court at the office of the Clerk, 1729 Fifth Avenue North, Birmingham, Alabama, 35203, during regular business hours and may obtain copies of these documents (such as the Settlement Agreement, Orders No. 15-21, and the Opinion and Final Order and Judgment) by payment of the prescribed charges. The Clerk's office is not permitted to give legal advice. The Claims Office is authorized to answer administrative and clerical inquiries relating to claims and the claims process, but not to give legal advice.

This Notice was approved by Judge Pointer, after consulting with Settlement Class Counsel and the Settling Defendants, for distribution to putative Class Members after September 16, 1994, as an official notice of the Court.

PERRY D. MATHIS
Clerk of the Court

ATTACHED EXHIBITS:

- A List of Settling Defendants
- B List of Released Parties
- C Schedule of Payments
- D Disease Schedule

FORMS (separate documents, but included in mailing):

- Registration Form
- Disease Compensation Program Claim Form

41. **Assistance.** You should save this Notice for reference concerning your rights and benefits, the claims process, the important deadlines, and telephone numbers. You may obtain further information concerning the proposed settlement and your rights and options in any one or more of the following ways:

- by reading the enclosed booklet, entitled "Questions and Answers," which has been approved by the Court
- by requesting legal assistance from Settlement Class Counsel through use of the 24-hour Settlement Information Line: 1-800-887-6828 (toll-free in the United States), 1-312-609-8680, or 1-513-651-9770, or by writing to:

MDL 926
P. O. Box 11683
Birmingham, AL 35202-1684

- by consulting an attorney of your own choice
- by contacting any of the various "support groups" formed to provide assistance to breast-implant recipients and their families

EXHIBIT A
Settling Defendants

Aesthetech Corporation
American Heyer-Schulte Corporation
f/k/a Heyer-Schulte Corporation
American Hospital Supply Corporation
Applied Silicone Corporation
Baxter Healthcare Corporation
Baxter International Inc.
Bristol-Myers Squibb Canada, Inc.
Bristol-Myers Squibb Company
Cabot Medical Corporation
CBI Medical, Inc.
a/k/a CBI Medical Electronics, Inc.
CooperSurgical, Inc.
CooperVision, Inc.
CUI Corporation
f/k/a Cox-Uphoff Int'l Corp.
a/k/a Cox-Uphoff Corporation
CVI Merger Corp.
CV Sub 1987, Inc.
Dow Corning Corporation
Dow Corning STI
Dow Corning Wright Corporation
Dow Corning Wright/Medical Materials
Hazleton Biotechnologies, Inc.
Hazleton Corporation
Hazleton Washington, Inc.
HRP, Inc.
INAMED Corporation
Linvatec Corporation
Markham Medical Association
Markham Medical International, Inc.

Markham Surgical Specialties
Mark/M Resources, Inc.
Mark/M Surgical
McGhan, Ltd.
McGhan Medical Corp. (Calif. corp.)
McGhan Medical Corp. (Dela. corp.)
a/k/a McGhan Medical/3M
McGhan NuSil Corporation
MEC Subsidiary Corporation
f/k/a Surgitek, Inc.
Medical Engineering Corporation
Minnesota Mining and Manufacturing Company
a/k/a 3M Company
Natural-"Y" Surgical Specialties, Incorporated
NuSil Corporation
NuSil Technology
Poly Plastic Silicone Products, Inc.
Sirod Corporation
Summit Medical Corporation
Surgitek, Inc.
3M Canada Inc.
Union Carbide Chemical and Plastics Company Inc.
Union Carbide Corporation
Edward Weck, Incorporated
Edward Weck & Company, Inc.
Wilshire Advanced Materials, Inc.
Wilshire Foam Products, Inc.
Wilshire Technologies, Inc.
Wright Manufacturing, Inc.
Zimmer, Inc.
Zimmer International, Ltd.

EXHIBIT B
Released Parties

ACME Engineering
Louis Argenta
Franklin L. Ashley
Baxter Acquisition Sub., Inc.
Baxter Corporation
Baxter Travenol Laboratories, Inc.
Baxter World Trade Corporation
John Beernick
Bio-Manufacturing, Inc.
Bioplasty, Inc.
Lawrence Birnbaum
Robert Bishop
Ralph Blocksma
Garry S. Brody
Boyd Burkhardt
Angelo Cappozzi
Thomas Cronin
Eugene Courtiss
Corning Incorporated
CVI Merger Corp.
The Dow Chemical Company
Edwards Laboratories, Inc.
Derwood Faries
Jack Fisher
Vicki Galati
Frank Gerow
Ben Gregory
John Hartley
Hazleton Research Corporation
Hazleton Wisconsin, Inc.
Robert J. Helbling
Inamed, B.V.
Inamed Development Company

Innovative Surgical Products, Inc.
Ron E. Iverson
Richard P. Jobe
Harold Markham
Jacqueline Markham
Lottie Markham
G. Patrick Maxwell
Anita Kost McAteer
Donald K. McGhan
Kathy Montgomery
Real Lappierre
W. John Pangman, II
Vincent R. Pennisi
Marie Pletsch
Robert Reeder
W. Ian Rogers
Diran M. Seropian
Schulte Medical Products
Silicone Engineering, Inc.
Paul Silverstein
Scott L. Spear
Specialty Silicone Fabricators, Inc.
H. E. Sterling
Kuros Tabari
John B. Tebbetts
Travenol Laboratories, Inc.
Uroplasty, Inc.
Charles Vinnick
Kurt Wagner
John L. Williams
R. Alastair Winn
Wright Medical Technologies

The "Released Parties" mean the above-listed individuals and entities; the Settling Defendants listed in Exhibit A; their respective present and former foreign and domestic parents, subsidiaries, and affiliates; their respective foreign and domestic predecessors, successors, sales representatives, independent sales representatives, distributors, transferees, insurers, and assigns; and their respective present, former, and subsequent officers, directors, agents, servants, proprietors, owners, shareholders, and employees, except that the term "Released Parties" (1) does not include doctors, hospitals, and other health-care providers who furnished medical services directly to a Class Member unless they are specifically named above and (2) does not include doctors specifically named above with respect to claims against them based upon their furnishing medical services directly to a Class Member.

EXHIBIT C

**Payment Obligations of Settling Defendants
(in U.S. Dollars)**

Funding Year	Dow Corning Corporation	Baxter Healthcare Corp.; Baxter Int'l, Inc.	Medical Engineering Corporation; Bristol-Myers Squibb	Minnesota Mining & Mfg Co.	Others ^{1/}	Cumulative Obligations All Defendants ^{2/}
Preliminary Payment	\$42,500,000	\$11,700,000	\$24,300,000		\$250,000	\$78,750,000
YEAR 1	\$275,000,000	\$152,100,000	\$315,900,000	\$109,000,000	\$54,000,000	\$984,750,000
YEAR 2	\$275,000,000	\$64,350,000	\$133,650,000	\$108,000,000	\$46,000,000	\$1,611,750,000
YEAR 3	\$275,000,000	\$64,350,000	\$133,650,000	\$108,000,000	\$46,000,000	\$2,238,750,000
YEAR 4	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$2,326,920,000
YEAR 5	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$2,415,090,000
YEAR 6	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$2,503,260,000
YEAR 7	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$2,591,430,000
YEAR 8	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$2,679,600,000
YEAR 9	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$2,767,770,000
YEAR 10	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$2,855,940,000
YEAR 11	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$2,944,110,000
YEAR 12	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$3,032,280,000
YEAR 13	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$3,120,450,000
YEAR 14	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$3,208,620,000
YEAR 15	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$3,296,790,000
YEAR 16	\$51,170,000	\$11,700,000	\$24,300,000		\$1,000,000	\$3,384,960,000
YEAR 17	\$38,380,000	\$8,780,000	\$18,230,000		\$1,000,000	\$3,451,350,000
YEAR 18	\$38,380,000	\$8,780,000	\$18,230,000		\$1,000,000	\$3,517,740,000
YEAR 19	\$38,380,000	\$8,780,000	\$18,230,000		\$1,000,000	\$3,584,130,000
YEAR 20	\$38,380,000	\$8,780,000	\$18,230,000		\$1,000,000	\$3,650,520,000
YEAR 21	\$38,380,000	\$8,780,000	\$18,230,000		\$1,000,000	\$3,716,910,000
YEAR 22	\$38,380,000	\$8,780,000	\$18,230,000		\$1,000,000	\$3,783,300,000
YEAR 23	\$38,380,000	\$8,780,000	\$18,230,000		\$1,000,000	\$3,849,690,000
YEAR 24	\$38,380,000	\$8,780,000	\$18,230,000		\$1,000,000	\$3,916,080,000
YEAR 25	\$25,570,000	\$5,850,000	\$12,150,000		\$1,000,000	\$3,960,650,000
YEAR 26	\$25,570,000	\$5,850,000	\$12,150,000		\$1,000,000	\$4,005,220,000
YEAR 27	\$25,570,000	\$5,850,000	\$12,150,000		\$1,000,000	\$4,049,790,000
YEAR 28	\$25,570,000	\$5,850,000	\$12,150,000		\$1,000,000	\$4,094,360,000
YEAR 29	\$25,570,000	\$5,850,000	\$12,150,000			\$4,137,930,000
YEAR 30	\$25,570,000	\$5,850,000	\$12,150,000			\$4,181,500,000
YEAR 31	\$25,570,000	\$5,850,000	\$12,150,000			\$4,225,070,000
TOTALS	\$2,018,740,000	\$555,790,000	\$1,154,290,000	\$325,000,000	\$171,250,000	\$4,225,070,000

1. Applied Silicone Corp. is to pay by April 18, 1994, the \$250,000 shown in this column as the Preliminary Payment; Wilshire Technologies, Inc. is to pay \$8,000,000 of the amount shown for Funding Year 1; Union Carbide Corporation is to pay \$46,000,000 in Funding Years 1-3; McGhan Medical Corp. is to pay the \$1,000,000 shown for Funding Years 4-28. These payments are shown in the same column for convenience of display and not to indicate that they are joint obligors.

2. These amounts do not reflect the additional amount of approximately \$30,000,000 to be received from the Mentor Defendants and the Bioplasty Defendants.

present clinical symptoms or laboratory findings atypical of SLE but who nonetheless have a systemic lupus erythematosus-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles mixed connective tissue disease (MCTD), ACTD, or any other disease or condition defined below.

3. Severity/Disability Compensation Categories:

- A. Death or total disability resulting from SLE or an SLE-like condition. An individual will be considered totally disabled based on either the functional capacity test set forth in Severity/Disability Category A for ACTD/ARS/NAC or severe renal involvement.
- B. SLE with major organ involvement defined as SLE with one or more of the following: glomerulonephritis, central nervous system involvement (i.e., seizures or Lupus Psychosis), myocarditis, pneumonitis, thrombocytopenic purpura, hemolytic anemia (marked), severe granulocytopenia, mesenteric vasculitis. See Immunological Diseases, Max Samter, Ed., Table 56-6, at 1352.
- C. Non-major organ SLE requiring regular medical attention, including doctor visits and regular prescription medications. An individual is not excluded from this category for whom prescription medications are recommended but who, because of the side effects of those medications, chooses not to take them.
- D. Non-major organ SLE requiring little or no treatment. An individual will fall into this category if she is able to control her symptoms through the following kinds of conservative measures: over-the-counter medications, avoiding sun exposure, use of lotions for skin rashes, and increased rest periods.

ATYPICAL NEUROLOGICAL DISEASE SYNDROME (ANDS)

1. A diagnosis of Atypical Neurological Disease Syndrome (ANDS) shall be based on the clinical findings and laboratory tests set forth below. The clinical and laboratory presentation of these neurological syndromes will have an atypical presentation from the natural disease and will also have additional neuromuscular, rheumatic, or nonspecific autoimmune signs and symptoms.
2. Eligibility for Atypical Neurological Disease Syndrome requires both:
 - satisfying the requirements for one of the four neurological disease types set forth in paragraph 5 below, and
 - any three additional (nonduplicative) neuromuscular, rheumatic, or nonspecific symptoms or findings set forth in the definition for Atypical Connective Tissue Disease (ACTD).
3. An individual will fit into this category if her primary symptoms are characteristic of a neurological disease as diagnosed by a board-certified neurologist or by a physician board-certified in internal medicine.
4. If the individual's Qualified Medical Doctor determines that a symptom is clearly and specifically caused by a source other than breast implants, that symptom will not be utilized in the diagnosis of Atypical Neurological Disease Syndrome unless the Claims Office determines that other submissions indicate that the symptom should be utilized. A symptom that may be caused only in part by a source other than breast implants is not excluded from such utilization.
5. Neurological disease types:

Polyneuropathies. This disease category requires a diagnosis of a polyneuropathy that is confirmed by one or more of the following:

- Objectively-demonstrated loss of sensation to pinprick, vibration, touch, or position
- Proximal or distal muscle weakness
- Tingling and/or burning pain in the extremities

EXHIBIT D
Disease Schedule

MEDICAL CONDITIONS AND CHARACTERISTICS
OUTLINE OF DEFINITIONS AND CLASSIFICATION CRITERIA

The Disease Compensation Program of the Breast Implant Litigation Settlement will compensate Class Members who meet the diagnostic criteria for the diseases and symptom complexes listed herein. Class Members who meet the diagnostic criteria will be classified in accordance with the various Compensation Categories.

If the Class Member's Qualified Medical Doctor determines that her death or total disability is clearly and specifically caused by a disease or occurrence other than the compensable disease, she will not be eligible for compensation in Severity/Disability Category A.

SYSTEMIC SCLEROSIS/SCLERODERMA (SS)

1. A diagnosis of systemic sclerosis shall be made in accordance with the criteria established in Kelley, et al., Textbook of Rheumatology (4th ed.) at 1113, et seq.
2. Application of these diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of classical systemic sclerosis but who nonetheless have a systemic sclerosis-like (scleroderma-like) disease, except that an individual will not be compensated in this category if her symptomology more closely resembles MCTD, ACTD, or any other disease or condition defined below. A "systemic sclerosis-like" or "scleroderma-like" disease is defined as an autoimmune/rheumatic disease that fulfills most of the accepted standards for the diagnosis of systemic sclerosis but is in some manner atypical of systemic sclerosis or scleroderma.
3. Severity/Disability Compensation Categories
 - A. Death or total disability resulting from SS or an SS-like condition. An individual will be considered totally disabled if the individual satisfies the functional capacity test set forth in Severity/Disability Category A for ACTD/ARS/NAC or if the individual suffers from systemic sclerosis with associated severe renal involvement manifested by a decrease in glomerular filtration rates.
 - B. Cardio-pulmonary involvement or diffuse (Type III) scleroderma as defined by Barnett, A Survival Study of Patients with Scleroderma Diagnosed Over 30 Years (1953 - 1983): The Value of a Simple Cutaneous Classification in the Early Stages of the Disease, 15 The Journal of Rheumatology 276 (1988), and Masi, Classification of Systemic Sclerosis (Scleroderma): Relationship of Cutaneous Subgroups in Early Disease to Outcome and Serologic Reactivity, 15 The Journal of Rheumatology 894 (1988).
 - C. Other, including CREST, limited, or intermediate scleroderma, except that any Class Member who manifests either severe renal involvement, as defined above, or cardio-pulmonary involvement, will be compensated at either category A or B as appropriate.
 - D. Not covered above, including localized scleroderma.

SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

1. A diagnosis of systemic lupus erythematosus (SLE) shall be made in accordance with the 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus, 25 Arthritis and Rheumatism No. 11 (November 1982) adopted by the American College of Rheumatology (ACR). See Kelley, et al., at 1037.
2. Application of the ACR diagnostic criteria is not intended to exclude from the compensation program individuals who

- Signs of dysesthesia
- Loss of tendon reflex

plus one or more of the following laboratory findings:

- Abnormal levels of anti-mag or anti-sulfatide or anti-GM1 antibodies
- Abnormal sural nerve biopsy
- Abnormal electrodiagnostic testing (EMG or nerve conduction studies, etc.).

Multiple Sclerosis-like Syndrome. This disease category requires definite evidence of central nervous system disease, with history and physical findings compatible with Multiple Sclerosis or Multiple Sclerosis-like syndrome, involving one or more of the following signs and symptoms:

- Weakness in the pyramidal distribution
- Evidence of optic neuritis documented by ophthalmologist
- Increased Deep Tendon reflexes
- Absent superficial abdominal reflexes
- Ataxia or dysidiadochokinesia as the sign of cerebellar involvement
- Neurologically induced tremors
- Internuclear ophthalmoplegia and/or bladder or speech involvement secondary to central nervous system disease.

plus one or more of the following:

- Abnormal Brain MRI with foci of increased signal abnormality suggestive of demyelinating lesions
- Delayed visual-evoked responses or abnormal-evoked potentials
- Abnormal CSF with oligoclonal bands

ALS-like Syndrome. This disease category requires documented evidence of progressive upper and widespread lower motor neuron disease and/or bulbar involvement, plus one or more of the following:

- Neurological autoantibodies such as anti-mag, anti-sulfatide, anti-GM1
- Abnormal sural nerve biopsy
- Chronic inflammation on muscle or nerve biopsies
- Abnormal EMG
- Documentation on neurological exam of both upper and lower motor neuron disease and/or bulbar involvement

Disease of Neuromuscular Junction. This disease category requires a diagnosis of Myasthenia Gravis or Myasthenia Gravis-like syndrome or disorders of the NMJ, made by a board-certified neurologist and confirmed by abnormal EMG showing typical findings of decrement on repetitive stimulation testing and/or elevated acetylcholine receptor antibodies.

6. **Severity/Disability Compensation Categories.** The compensation level for ANDS will be based on the degree to which the individual is "disabled" by the condition, as the individual's treating physician determines in accordance with the following guidelines. The determination of disability under these guidelines will be based on the cumulative effect of the symptoms on the individual's ability to perform her vocational,^{1/} avocational,^{2/} or usual self-care^{3/} activities. In evaluating the effect of the individual's symptoms, the treating physicians will take into account the level of pain and fatigue resulting from the symptoms. The disability percentages appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the physician in the exercise of his or her professional judgment.

-
1. "Vocational" means activities associated with work, school, and homemaking.
 2. "Avocational" means activities associated with recreation and leisure.
 3. "Usual self-care" means activities associated with dressing, feeding, bathing, grooming, and toileting.

- A. Death or total disability due to the compensable condition. An individual shall be considered totally disabled if she demonstrates a functional capacity adequate to consistently perform none or only few of the usual duties or activities of vocation or self-care.
- B. A Class Member will be eligible for category B compensation if she is 35% disabled due to the compensable condition. An individual shall be considered 35% disabled if she demonstrates a loss of functional capacity which renders her unable to perform some of her usual activities of vocation, avocation, and self-care, or if she can perform them only with regular or recurring severe pain.
- C. A Class Member will be eligible for category C compensation if she is 20% disabled due to the compensable condition. An individual shall be considered 20% disabled if she can perform some of her usual activities of vocation, avocation, and self-care only with regular or recurring moderate pain.

MIXED CONNECTIVE TISSUE DISEASE (MCTD) / OVERLAP SYNDROME

- 1. A diagnosis of mixed connective tissue disease (MCTD) shall be based on the presence of clinical symptoms characteristic of two or more rheumatic diseases (systemic sclerosis, SLE, myositis, and Rheumatoid Arthritis), accompanied by positive RNP Antibodies. See, e.g., Kelley, et al., Table 63-1, at 1061.
- 2. Overlap Syndrome is defined as any one of the following three: (a) diffuse cutaneous scleroderma, (b) limited cutaneous scleroderma, or (c) Sine scleroderma, occurring concomitantly with diagnosis of systemic lupus erythematosus, inflammatory muscle disease, or rheumatoid arthritis. See Kelley, et al., Table 66-2, at 1114.
- 3. The application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of MCTD but who nonetheless have an Overlap Syndrome, except that an individual will not be compensated in this category if her symptomology more closely resembles an atypical connective tissue disease condition/atypical rheumatic syndrome/nonspecific autoimmune condition.
- 4. Severity/Disability Compensation Categories
 - A. Death or total disability resulting from MCTD or Overlap Syndrome. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A of Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.
 - B. MCTD or Overlap Syndrome, plus major organ involvement or major disease activity including central nervous system, cardio-pulmonary, vasculitic, or renal involvement or hemolytic anemia (marked) or thrombocytopenic purpura or severe granulocytopenia.
 - C. Other.

POLYMYOSITIS/DERMATOMYOSITIS

- 1. A diagnosis of polymyositis or dermatomyositis shall be made in accordance with diagnostic criteria proposed by Bohan and Peter, i.e., (a) symmetrical proximal muscle weakness; (b) EMG changes characteristic of myositis including (1) short duration, small, low amplitude polyphasic potential, (2) fibrillation potentials, (3) bizarre high-frequency repetitive discharges; (c) elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT, and LDH); (d) muscle biopsy showing evidence of necrosis of type I and II muscle fibers, areas of degeneration and regeneration of fibers, phagocytosis, and an interstitial or perivascular inflammatory response; (e) dermatologic features including a lilac (heliotrope), erythematous, scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli, and Gottron's papules. A diagnosis of dermatomyositis requires presence of three of the criteria plus the rash (fifth criterion). A diagnosis of polymyositis requires the presence of four criteria without the rash. See Kelley, et al., at 1163.

2. Application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of polymyositis or dermatomyositis but who nonetheless have a polymyositis or dermatomyositis-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles an Atypical Connective Tissue Disease.
3. Severity/Disability Compensation Categories:
 - A. Death or total disability resulting from polymyositis or dermatomyositis. An individual will be considered totally disabled based on the functional capacity test set forth for Severity/Disability Category A for Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.
 - B. Polymyositis or dermatomyositis with associated malignancy and/or respiratory muscle involvement.
 - C. Other, including polymyositis or dermatomyositis with muscle strength of Grade III or less.

PRIMARY SJOGREN'S SYNDROME

1. A clinical diagnosis of Primary Sjogren's Syndrome shall be made in accordance with diagnostic criteria proposed by Fox, et al. See Kelley, et al., Table 55-1, at 932, or Fox, RI et al. "Primary Sjogren's Syndrome: Clinical and Immunopathologic Features," Seminars Arthritis Rheum., 1984; 4: 77-105.
2. Application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of Primary Sjogren's Syndrome but who nonetheless have a Primary Sjogren's-like disease.
3. Severity/Disability Compensation Categories:
 - A. Death or total disability due to the compensable condition. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A for Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.
 - B. Primary Sjogren's with associated central nervous system or severe cardio-pulmonary involvement or primary Sjogren's with pseudolymphoma or associated lymphoma.
 - C. Other.

ATYPICAL CONNECTIVE TISSUE DISEASE (ACTD) ATYPICAL RHEUMATIC SYNDROME (ARS) NONSPECIFIC AUTOIMMUNE CONDITION (NAC)

1. This category will provide compensation for Class Members experiencing symptoms that are commonly found in autoimmune or rheumatic diseases but which are not otherwise classified in any of the other compensable disease categories. This category does not include individuals who have been diagnosed with classical rheumatoid arthritis in accordance with ACR criteria, but will include individuals diagnosed with undifferentiated connective tissue disease (UCTD). However, such inclusion is not intended to exclude from this category persons who do not meet the definition of UCTD, it being intended that individuals not meeting the classic definitions of UCTD will be compensated pursuant to the provisions contained herein relative to ACTD, ARS, and NAC.
2. As with other individuals who fit within this disease compensation program, the fact that a breast implant recipient has been in the past misdiagnosed with classic rheumatoid arthritis or the fact that the symptoms of classic rheumatoid arthritis may coexist with other symptoms will not exclude the individual from compensation herein. Persons who meet the criteria below and may have a diagnosis of atypical rheumatoid arthritis will not be excluded from compensation under

this category.

3. Eligibility criteria and compensation levels for eligible Class Members are set forth below in the Compensation Categories, which classify individuals in accordance with the following groups of symptoms. If the Class Member's Qualified Medical Doctor determines that a symptom is clearly and specifically caused by a source other than breast implants, that symptom will not be utilized in the diagnosis of Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome unless the Claims Office determines that other submissions indicate that the symptom should be utilized. A symptom that may be caused only in part by a source other than breast implants is not excluded from such utilization.
4. A diagnosis of ACTD, ARS, or NAC must satisfy one of the following sets of criteria:
 - any two of the three signs and symptoms listed in 5(a) (Group I)
 - any one of the three signs and symptoms listed in 5(a) (Group I), plus any one of the ten signs and symptoms listed in 5(b) (Group II)
 - any three of the ten signs and symptoms listed in 5(b) (Group II)
 - any two of the ten signs and symptoms listed in 5(b) (Group II), plus any one additional (nonduplicative) sign or symptom from the eighteen listed in 5(c) (Group III)
 - five nonduplicative signs or symptoms listed in 5(a) (Group I), 5(b) (Group II), or 5(c) (Group III)
5. Symptom Groupings:
 - (a) Group I Signs and Symptoms:
 - Raynaud's phenomenon evidenced by the patient giving a history of two color changes, or visual evidence of vasospasm, or evidence of digital ulceration
 - Polyarthritis, defined as synovial swelling and tenderness in three or more joints lasting greater than six weeks and observed by a physician
 - Keratoconjunctivitis Sicca: subjective complaints of dry eyes and/or dry mouth, accompanied by any one of the following —
 - lacrimal or salivary enlargement
 - parotid enlargement
 - abnormal Schirmer test
 - abnormal Rose-Bengal staining
 - filamentous keratitis
 - abnormal parotid scan or ultrasound
 - abnormal CT or MRI of parotid
 - abnormal labial salivary biopsy
 - (b) Group II Signs and Symptoms:
 - Myalgias determined by tenderness on examination
 - Immune mediated skin changes or rash, as follows:
 - changes in texture or rashes that may or may not be characteristic of SLE, Systemic Sclerosis (scleroderma), or dermatomyositis
 - diffuse petechiae, telangiectasias, or livedo reticularis
 - Pulmonary symptoms or abnormalities, which may or may not be characteristic of SLE, Systemic Sclerosis (scleroderma), or Sjogren's Syndrome, as follows:
 - pleural and/or interstitial lung disease
 - restrictive lung disease
 - obstructive lung disease as evidenced by characteristic clinical findings and either:
 - characteristic chest X-ray changes, or
 - characteristic pulmonary function test abnormalities in a non-smoker (e.g. decrease DLCO or abnormal arterial blood gases)
 - Pericarditis defined by consistent clinical findings and either EKG or echocardiogram
 - Neuropsychiatric symptoms: cognitive dysfunction (memory loss and/or difficulty concentrating) which may be characteristic of SLE or MCTD as determined by a SPECT scan or PET scan or MRI or EEG or

neuropsychological testing

- Peripheral neuropathy diagnosed by physical examination showing one or more of the following:
 - loss of sensation to pinprick, vibration, touch, or position
 - tingling, paresthesia, or burning pain in the extremities
 - loss of tendon reflex
 - proximal or distal muscle weakness (loss of muscle strength in extremities or weakness of ankles, hands, or foot drop)
 - signs of dysesthesia
 - entrapment neuropathies.
- Myositis or myopathy:
 - diagnosed by weakness on physical examination or by muscle strength testing
 - abnormal CPK or aldolase
 - abnormal cybex testing
 - abnormal EMG
 - abnormal muscle biopsy
- Serologic abnormalities--any one of the following:
 - ANA > or equal to 1:40 (using Hep2)
 - positive ANA profile such as Anti-DNA, SSA, SSB, RNP, SM, Scl-70, centromere, Jo-1, PM-Scl or dsDNA (preferable to use ELISA with standard cutoffs)
 - other autoantibodies, including thyroid antibodies, anti-microsomal, or anti-cardiolipin, or RF (by nephelometry with 40 IU cutoff)
 - elevation of immunoglobulin (IgG, IgA, IgM)
 - serologic evidence of inflammation such as elevated ESR, CRP
- Lymphadenopathy (as defined by at least 1 lymph node greater than or equal to 1x1 cm) documented by a physician
- Dysphagia with positive cine-esophagram, manometry or equivalent imaging

(c) Group III Signs and Symptoms:

- Documented arthralgia
- Documented Myalgias
- Chronic fatigue (> 6 months)
- Documented Lymphadenopathy
- Documented Neurological symptoms including cognitive dysfunction or paresthesia
- Photosensitivity
- Documented Sicca symptoms
- Documented dysphagia
- Documented Alopecia
- Documented sustained balance disturbances
- Documented sleep disturbances
- Documented easy bruisability or bleeding disorder
- Documented chronic cystitis or bladder irritability
- Documented colitis or bowel irritability
- Persistent low grade fever or night sweats
- Mucosal ulcers confirmed by physician
- Burning pain in the chest, breast, arms, or axilla, or substantial loss of function in breast due to disfigurement or other complications from implants or explantation
- Pathological findings: granulomas or siliconomas or chronic inflammatory response, or breast infections

6. Severity/Disability Compensation Categories

The compensation level for ACTD/ARS/NAC will be based on the degree to which the individual is "disabled" by the condition, as the individual's treating physician determines in accordance with the following guidelines. The determination of disability under these guidelines will be based on the cumulative effect of the symptoms on the individuals's ability to

perform her vocational,⁴ avocational,⁵ or usual self-care⁶ activities. In evaluating the effect of the Class Member's symptoms, the treating physicians will take into account the level of pain and fatigue resulting from the symptoms. The disability percentages appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the physician in the exercise of his or her professional judgment.

- A. Death or total disability resulting from the compensable condition. An individual will be considered totally disabled if she demonstrates a functional capacity adequate to consistently perform none or only few of the usual duties or activities of vocation or self-care.
- B. A Class Member will be eligible for category B compensation if she is 35% disabled due to the compensable condition. An individual shall be considered 35% disabled if she demonstrates a loss of functional capacity which renders her unable to perform some of her usual activities of vocation, avocation, and self-care, or she can perform them only with regular or recurring severe pain.
- C. A Class Member will be eligible for category C compensation if she is 20% disabled due to the compensable condition. An individual shall be considered 20% disabled if she can perform some of her usual activities of vocation, avocation, and self-care only with regular or recurring moderate pain.

4. "Vocational" means activities associated with work, school, and homemaking.

5. "Avocational" means activities associated with recreation and leisure.

6. "Usual self-care" means activities associated with dressing, feeding, bathing, grooming, and toileting.

Revised 9/16/94

BREAST IMPLANT LITIGATION SETTLEMENT

QUESTIONS AND ANSWERS

The information contained in this booklet in Q1-Q94 has been approved by the Court and is intended to answer questions frequently asked by Class Members. For details, Class Members should read the Settlement Notice (the "Notice") or the Settlement Agreement itself. These Questions and Answers are patterned upon those contained in the booklet originally distributed to Class Members, but have been modified to relate to matters affecting Class Members receiving the Settlement Notice package after September 16, 1994.

GENERAL INFORMATION

- Q1. What is the breast implant litigation settlement?**
- A.** It is a class action settlement, funded by potential contributions from the defendants of approximately \$4.25 billion. It will provide financial and medical benefits during a 30-year period to breast-implant recipients and their families (the "Class"). Benefits include substantial monetary compensation for implant recipients who now have (or in the next 30 years develop) a disability from a disease or condition covered by the settlement, plus funds to pay past or future medical evaluation and explantation expenses, to

compensate for past or future ruptures or other injuries including emotional distress, and to pay attorneys' fees and expenses. In exchange, the settling defendants (and companies and individuals associated with them) are released from further possible liability to members of the Class. See paragraphs 9 through 23 of the Notice for details.

Q2. Who are members of the Class covered by the settlement?

A. Paragraph 5 of the Notice, defining the "Class," describes who is covered by the Settlement. The Class will **NOT** include persons who timely exclude themselves ("opt out") of the settlement. Q10-Q25 provide information about eligibility and Q30-Q36 provide information relating to exclusion. Australians and certain Canadians are not class members unless they "opt in."

Q3. What must I do to be a member of the Class?

A. If you are covered by the definition of the Class, you do not need to do anything to become a part of the Class — if you do nothing, you will automatically be part of the Class. As a Class Member, you will be entitled to claim benefits for which you are eligible under the settlement. To receive benefits, you must file certain forms, as explained in Q51.

Q4. Are there any implant manufacturers and suppliers not participating in the settlement?

A. Yes. Although all American implant manufacturers are parties to the settlement, some foreign manufacturers — such as Koken — are not. In addition, some suppliers of materials used in implants — such as

General Electric — are not parties to the settlement. The settlement does not affect your rights to pursue claims or lawsuits against such companies (or any other company or individual not listed in Exhibits A and B to the Notice). Note that you are not eligible to participate in the settlement unless at least one of your implants was manufactured by a company listed on Exhibit A to the Notice or by the Mentor or Bioplasty defendants.

- Q5.** I want to participate in the settlement, but I also want to be able to sue my plastic surgeon. Can I still do that?
- A.** Yes. At the present time, neither doctors nor hospitals are parties to the settlement, so you will be free to sue them directly without giving up your right to benefits under the settlement.
- Q6.** I don't want to do anything that might harm my plastic surgeon. Can I participate without harming my doctor?
- A.** Yes. Participating in the settlement will not affect your doctor.
- Q7.** Since this settlement is being presented to a federal court in Birmingham, will it be necessary for me to go Alabama to file a claim, to obtain medical evaluations, to undergo an explantation, etc.?
- A.** No. You will be able to submit your claims by mail and you will be able to receive the medical services covered by the settlement near your home.
- Q8.** It is important to me that no one know I have a breast implant or am filing a claim under the settlement. Can you keep my identity confidential?

A. Through special coding and other procedures, every effort will be made to keep the identity of Class Members and their medical information confidential.

Q9. How can I get more information?

A. There are two ways established by the Court for you to get more information concerning the proposed settlement and your rights.

(1) You can write to MDL 926, P.O. Box 11683, Birmingham, AL, 35202-1683 and request information.

(2) You can call 1-800-887-6828 (toll-free from the United States or Canada). Leave your name and address, and information will be sent to you. In addition, by calling this number, you can leave a message asking to speak with someone directly to get answers to your questions; leave a telephone number and someone will call you back. (Settlement Class Counsel will make attorneys available to answer the questions of unrepresented settlement class members.) If you live outside the United States and Canada, you can call the U.S. access code plus 1-312-609-8680, and leave your name and address; information will be mailed to you. You can also call the Claims Assistance hot-line directly at 1-513-651-9770.

You may also consult with an attorney of your own choice, or communicate with one of the "support groups" formed to assist implant recipients and their families.

ELIGIBILITY

- Q10.** I have saline-filled implants. Can I participate?
A. Yes. The settlement covers all breast implants containing silicone, silicone gel, or saline.
- Q11.** I have implants with a polyurethane coating. Can I participate?
A. Yes. The settlement covers silicone or saline implants that have polyurethane coatings.
- Q12.** Does it matter whether my implants were part of reconstructive surgery or were for augmentation/cosmetic reasons?
A. No. Settlement benefits are the same regardless of the reason for implantation.
- Q13.** Does it matter whether I still have my implants or that they have been removed?
A. No. The Class covers both persons whose implants are still in place and persons whose implants have been removed.
- Q14.** I have had silicone injections. Can I participate?
A. If you have had only silicone injections, you cannot participate in this settlement. However, if you have had silicone injections as well as one or more breast implants, you can participate.
- Q15.** I do not have a breast implant, but do have a silicone implant in my chin. Can I participate?
A. No, the settlement covers only breast-implant products. However, a person who, in another part of the body, was implanted with a product that was generally

distributed for breast-implant purposes would be a class member and eligible to participate in the settlement.

Q16. Can I participate in the settlement if I have not had any problems with my implants?

A. Yes. The settlement covers persons without any known problems concerning their implants. The settlement provides funds to reimburse persons for the cost (if not paid by insurance or government-sponsored medical plans) of periodic medical examinations and of removing implants. You also may qualify for a payment for emotional distress or other injuries not covered in the Disease Compensation Program. In addition, if you should later have a rupture of an implant or develop one of the listed diseases, you would be eligible for appropriate benefits at that time.

Q17. I received breast implants in 1971 but had them removed in 1973. Since this happened so long ago, am I still eligible?

A. Yes. The settlement covers all persons who have ever had a breast implant manufactured by any of the settling defendants. "Statutes of limitation" that might bar bringing a lawsuit will not prevent recovery of benefits under the settlement.

Q18. I haven't filed a lawsuit about my implants. Am I eligible?

A. Yes. The Class covers persons who have not filed any lawsuit or otherwise made any claim about their implants.

Q19. I have already filed a lawsuit about my implants. Am I still eligible?

A. Yes. You are eligible to participate in the settlement even if you have filed a lawsuit. If you have a lawsuit pending in federal or state court, you will automatically be treated as part of the Class unless you filed the Exclusion Form during the first opt-out period (generally, by June 17, 1994). See Q84 for information on what would happen to your lawsuit if you remain in the Class. If you have settled a lawsuit, or if you have already had a trial, you may be excluded from the Class. Paragraph 5 of the Notice and Q20 and Q21 describe circumstances under which a previous trial or settlement may exclude you from this settlement.

Q20. I already had a trial against the manufacturer of my implants. Can I participate?

A. Yes, unless you have collected a judgment against a settling defendant or your lawsuit has resulted in a final judgment in favor of a settling defendant after a trial.

Q21. Two years ago I signed an agreement with the manufacturer of my implants and had them removed at the manufacturer's expense. Will this prevent me from being part of the Class? Can I participate in the settlement?

A. If you have settled your claim or lawsuit and signed a general release of any claims involving implants, you may be precluded from participating in the settlement. If more than \$15,000 was paid by the manufacturer or you were represented by a lawyer in connection with the settlement, you would not be eligible to participate in the settlement if you signed a general release of all breast-implant claims unless you can demonstrate that the settlement was induced by fraud. You can participate in this settlement if you settled your claim

for less than \$15,000 and were not represented by a lawyer. The amount paid would be subtracted from any benefits you might otherwise be entitled to under the settlement.

Q22. In 1992 I received a notice about a class action involving breast implants and returned a form excluding myself from that Class. Am I still eligible to participate in this settlement?

A. Yes. Regardless of whether you participated in or excluded yourself from any other class, you are eligible to participate in this settlement. In fact, unless you filed a new Exclusion Form during the first Opt-Out period, you will automatically be treated as part of this Class.

Q23. What if my implants were manufactured by Mentor (which earlier settled) or by Bioplasty (which went into bankruptcy)? Am I eligible to participate in this settlement, or will I be limited to some share of the funds that Mentor or Bioplasty contribute to the settlement funds?

A. You will be able to participate in the settlement in the same manner as those who received implants manufactured by more solvent settling defendants. The monies to be paid by Mentor under its earlier settlement and by Bioplasty under the bankruptcy reorganization are expected to be part of the funds used to support this settlement. If you exclude yourself from this settlement, you should understand that you will probably be prohibited from pursuing any lawsuit against either of these two companies. See paragraph 6 of the Notice for more details.

Q24. I don't know what company manufactured my implants. Can I still participate in the settlement?

A. Yes. You must make reasonable efforts to identify the manufacturer of your implants, but, if you still cannot determine which company made them, you will be eligible to participate. The Claims Administrator will determine what constitutes "reasonable efforts."

Q25. I am not a citizen of the United States. Will I be eligible for any benefits under the settlement?

A. Yes. The settlement will provide benefits to all persons - wherever they may live and whatever their citizenship - who before June 1, 1993, received implants made by one or more of the defendants listed on Exhibit A. However, the benefits provided to "Foreign Claimants" (implant recipients who are not citizens or permanent resident aliens of the United States and whose implantations all were performed outside the United States) are limited in comparison with those to other Class Members. Foreign claimants from Australia or the Canadian provinces of Ontario and Quebec will not be class members unless they "opt in." See Q36 and Q77 and paragraph 23 of the Notice for more information concerning the options and rights of foreign claimants.

EXCLUSION (OPT OUT)

Q30. [Omitted — obsolete.]

Q31. [Omitted — obsolete.]

Q32. [Omitted — obsolete.]

Q33. I earlier excluded myself and my family from the settlement. Can we get back into the settlement?

A. Requests to withdraw an exclusion (and thereby rejoin the settlement class) will be honored if mailed to the court by December 1, 1994.

Q34. The Notice says that the initial opt-out period has expired. Will there be any additional opportunities to opt out?

A. Class Members may have two additional periods in which to opt out:

(1) If payments of the Current Disease Compensation Claims must be reduced because the claims exceed the funds available for such claims, all registered Class Members (not just current claimants) will have an opportunity to exclude themselves from the settlement at that point. (This is the Second Opt-Out).

(2) If during the 30-year period of the program an Ongoing Disease Compensation Claim would be subject to tentative reduction because qualified claims for that year exceeded the funds available, claimants in that year would be so notified and be given an additional opportunity to opt out at that point or to have the unpaid portion of the claim carried forward to future years. (This is sometimes referred to as the Ongoing Opt-Out).

There are additional opt-out rights for children of breast-implant recipients and Foreign Claimants. See Q76.

Q35. What is the effect if I exclude myself from the settlement during any of these different opt-out periods?

- A. If you exclude yourself from the settlement during the Second Opt-Out Period, you will not be eligible to participate in or receive any benefits from the settlement, but you will keep whatever rights you had before the settlement was reached to bring a lawsuit against any of the settling defendants. If you exclude yourself from the settlement during the Ongoing Opt-Out Period, you will not receive benefits available for the disease for which you have made a claim, but you will be entitled, subject to certain restrictions, to file a lawsuit against any of the settling defendants. Paragraphs 18 and 20 of the Notice explain the effect on your rights and obligations of opting out of the settlement at these two stages. The effect of opting out by a child of a breast-implant recipient or by a Foreign Claimant are explained in paragraphs 22 and 23 of the Settlement Notice.

Q36. What rights do Foreign Claimants have to exclude themselves from the settlement?

- A. Foreign Claimants who remain in the class and register by December 1, 1994, will have the right to exclude themselves from the settlement after determination by the Court of payment levels for the Disease Compensation Program (see Q77). A Foreign Claimant opting out at that point could pursue claims in a foreign country as well as in courts in the United States. See paragraph 23 of the Notice for details. Additionally, Foreign Claimants adversely affected by the "3% cap" for Ongoing Disease Compensation Claims would have the option either to opt out at that point or to have the portion of their claims affected by the cap carried forward to future years of the Disease Compensation Program.

APPROVAL PROCESS

- Q40. How and when will it be determined whether the settlement becomes final?**
- A.** If there is no appeal from Judge Pointer's order of September 1, 1994, approving the settlement, the settlement would become final in early October 1994. If there are timely appeals, the settlement order would not become final until such appeals are resolved and the settlement order affirmed. In general, no benefits can be paid to Class Members until the settlement has become final. Note, however, that whether the settlement takes effect depends not only on whether the settlement order becomes final, but also on whether there is an additional opt-out period resulting from insufficiency of funds to pay the full amount of qualified claims under the Current Disease Compensation Program.
- Q41. [Omitted — obsolete.]**
- Q42. [Omitted — obsolete.]**
- Q43. What if there is an appeal from Judge Pointer's order approving the settlement?**
- A.** The Court of Appeals would decide whether to affirm Judge Pointer's settlement approval order. While no one can predict how long the appeals process would take, the claims administration process would continue during this time to avoid delay in distributing payments if the settlement is upheld by the appellate court.
- Q44. [Omitted — obsolete.]**

BENEFITS and CLAIMS

Q50. What are the benefits of the settlement?

A. Settlement Benefits are described in paragraphs 9-23 of the Notice. Specific questions are addressed below.

Q51. How do I make a claim for benefits from the settlement?

- A. (1) To be eligible for any benefits, you must submit to the Claims Administrator a Registration Form (enclosed with this mailing). Failure to return this Form by December 1, 1994, will result, for Foreign Claimants, in a loss of all benefits under the settlement, and, for other Class Members, may cause a loss of benefits since the claims of timely-registered claimants will be given first priority and consideration. The Court may later set a final deadline by which Registration Forms must be filed to remain eligible for benefits.
- (2) In addition to the Registration Form, the Class Member must submit to the Claims Administrator a claim form designed for the particular part of the settlement under which benefits are claimed. Enclosed with this mailing is the Disease Compensation Claim Form, to be used in making a claim under that Program. Claim forms for other parts of the settlement (such as medical expenses, compensation for ruptures, and attorney's fees) are in the process of being designed, and, when available, will be sent to registered Class Members.

Additional copies of these Forms can be obtained from the Claims Office.

Q52. I have not had any problems with my implants. What benefits do I get under the settlement?

A. You will be entitled to participate in (1) the fund providing for medical diagnosis/evaluation (Fund I), (2) the fund providing reimbursement for expenses of explantation (Fund II) should you choose to have your implants removed, and (3) the fund providing general compensation for injuries not covered by the Disease Compensation Program, including emotional distress (Fund IV). Should you in the next 30 years have an implant rupture or develop any of the covered diseases or medical conditions, you would at that time be entitled to participate in Designated Fund III or the Ongoing Disease Compensation Program.

Q53. How much will I be paid in reimbursement for medical diagnoses and evaluations from Fund I?

A. \$75,000,000 is to be paid into Fund I to pay for expenses involving diagnosis and evaluation for implant-related medical problems not paid for by health insurance or other governmental or third-party programs. The amount individual Class Members would be able to receive under this Fund has not been determined. The Court will establish payment schedules for these evaluations and diagnoses. These medical services will be provided by physicians of the Class Members' own choosing, and will be subject to reimbursement whether rendered before or after approval of the settlement. Claim forms will be mailed to registered Class Members after they have been developed.

Q54. How much will I be paid under Fund II for having my silicone implants removed? Can I receive

reimbursement for replacing them with the saline implants that I understand are still being used?

- A. \$75,000,000 is to be paid into Fund II to pay for expenses of explantation not paid by health insurance or governmental or third-party payments. The amount individual Class Members would be able to receive under this Fund has not been determined. The Court will establish payment schedules for these reimbursements. Claim forms will be mailed to registered Class Members after they have been developed. A replacement (reimplantation) or expenses related to a replacement (reimplantation) after June 1, 1993, will not be subject to reimbursement.

Q55. I have had two sets of implants. How will this affect the benefits I will receive under the settlement?

- A. The number of implants you have had will not affect benefit levels under the Disease Compensation Program or under Funds I, III, IV, or V. In determining possible reimbursement for the expenses of explantation under Fund II, the aggregate of explantation expenses may be considered.

Q56. I need to have my implants removed now. Do I have to postpone their explantation until benefits begin to be paid from the settlement funds?

- A. You may have your implants removed at any time. Expenses you incur (to the extent not recovered from health insurance or from governmental or third-party payers) will be subject to reimbursement from Fund II once those funds become payable. The Court may also provide for emergency payments for individual Class Members.

Q57. How much will I be paid under Fund III (the "rupture fund") for my problems if my implants have ruptured but my problems haven't developed into one of the listed medical conditions?

A. \$220,000,000 is to be paid into Fund III for such claims. The specific dollar amounts to be paid to individual claimants from this Fund will be determined by the Court in consultation with the Claims Administrator and Settlement Class Counsel and will depend on the number and extent of claims made. Claim forms will be mailed to registered Class Members after they have been developed.

Q58. How much will I be paid under Fund IV (the "Breast-Implant Recipient Compensation" Fund) if I do not have any of the listed medical conditions and have not had a "rupture" of my implant?

A. \$75,000,000 is to be paid into Fund IV for such claims. The specific dollar amounts to be paid to individual claimants from this Fund will be determined by the Court in consultation with the Claims Administrator and Settlement Class Counsel. The amount to be paid to any individual will depend upon the number and extent of those claims submitted to this Fund. Claim forms will be mailed to registered Class Members after they have been developed.

Q59. How do I determine how much money I am likely to get under the Disease Compensation Program?

A. To determine the projected net amount payable under the Disease Compensation Program, you look to the Schedule of Benefits found at paragraph 17 of the Notice. Payment levels depend on the particular disease or medical condition and its severity (based on

the Disease Schedule, attached as Exhibit D to the Notice) and the person's age at the onset of her qualifying symptoms. Note that the amounts shown are "net" — after reduction for potential administrative costs and attorneys' fees. The actual amount to be paid may vary from the scheduled amount, depending on the number of qualifying claims and whether savings in administrative costs and attorneys' fees can be achieved. See paragraphs 18 and 24 of the Notice for details. Amounts payable under this Program to Foreign Claimants will be a percentage, developed on a country-by-country basis, of the amounts payable to domestic claimants and will be subject to availability of funds under the 3% "set-aside" for Foreign Claimants.

Q60. I am a United States citizen; at age 35 I received breast implants; and 8 years later I became totally disabled as a result of Polymyositis. What compensation does the Schedule provide for me?

A. The Scheduled Benefit for a domestic claimant totally disabled from Polymyositis, 43 years old at the onset of her qualifying symptoms, is \$910,000. This figure is a "net" amount, after payment of administrative costs and attorneys' fees.

Q61. What would I have to do to show this condition and the extent of my disability?

A. To apply for benefits under the Disease Compensation Program, you must fill out and return both the Registration Form and the Disease Compensation Claim Form. In addition, you must provide the Claims Administrator with appropriate medical documentation of your condition — ordinarily a Statement or Diagnosis from a qualified medical doctor (a Board-certified

specialist), together with the medical records on which this Statement or Diagnosis is based. If you cannot obtain such a Statement or Diagnosis, you may, as an alternative, provide all your medical records and request the Claims Administrator to place your claim within a category on the Disease Compensation Schedule.

Q62. What if there is a question as to whether I have one of the listed diseases or what the extent of my disability is?

A. You will be notified if the Claims Office determines that the signs, symptoms, or findings in the Statement or Diagnosis and/or your medical records do not satisfy the requirements of the Disease Schedule. For minor deficiencies in this documentation, you would be given 30 days to submit further medical evidence, and the Claims Office would consider additional information submitted during that period in classifying your claim for that year of the Disease Compensation Program. For more substantial deficiencies (or if you do not timely provide the information needed), the claim would be carried over to the following year of the Program for supplementation. If dissatisfied with the final determination by the Claims Office, you could appeal the decision to the Claims Administrator and to the Court.

Q63. Will I have to show that my disease or condition was caused by the implant?

A. No. You are required to show that you have had an implant and have one of the covered diseases, but you are not required to show that your condition was caused by your implant, so long as its symptoms did not manifest themselves until after an implant. See Q66 regarding pre-existing conditions.