NORTHERN DISTRICT OF ALABAMA
UNITED STATES DISTRICT COURT

Notice of Rights under Breast Implant Litigation

To Settlement Class Members (and others identified as possibly being breast implant recipients[1]):

Enclosed for your attention and consideration are:

a Notice (white) describing the status of the previously approved global settlement; the terms of a revised "claims-made-- settlement program being offered to certain breast implant recipients by Bristol, Baxter, 3M, McGhan, and Union Carbide; your options, if eligible, to accept or reject the revised settlement; your options to remain in, exclude yourself from, or possibly rejoin the "Lindsey-- class; and the status of claims against Mentor, Bioplasty, and Dow Corning.

a "Question and Answer" Booklet (pink), answering questions frequently asked by implant recipients. [**not included in *.rtf file**]

four Forms: [**not included in *.rtf file**]

(1) an Election Form (white), to be used by all breast implant recipients to elect, at least initially, among various options. (May also be used as a Registration Form by eligible implant recipients who have not previously registered with the Claims Office or as an election to rejoin the class by eligible recipients who previously opted out of the global settlement.)

(2) a Proof of Manufacturer Form (blue), to be used (with the Election Form) if you may be eligible and may want to participate in the revised settlement.

(3) an Explantation Claim Form (yellow), to be used (with the Election and Proof of Manufacturer forms) if you may be eligible and may want to participate in the revised settlement and if you have a Bristol, Baxter, or 3M implant removed after April 1, 1994.

(4) a Rupture Claim Form (green), to be used (with the Election and Proof of Manufacturer forms) if you may be eligible and may want to participate in the revised settlement, have previously filed a Current Disease Compensation Claim under the global settlement, and can prove by December 16, 1996, the rupture of a silicone-gel Bristol, Baxter, or 3M implant.

a Synopsis (manila), briefly describing the revised settlement, highlighting important dates, and explaining the Forms. I urge you, however, to consult the Notice and the Question and Answer Booklet for more detailed information concerning your rights and options.

Before returning any forms, you should carefully read the attached Notice. If you have an attorney, you should consult with that attorney about your rights and options. If you do not have an attorney, you can call 513-651-9770 to request legal advice. To learn about regional informational meetings, call 800-938-7357. The Claims Office, at 800-600-0311 (toll-free in U.S.) or 713-951-9106, can answer questions about the forms and general processing information, but cannot provide legal advice. Save these materials (as well as a copy of any form you return) for future reference.

Sam C. Pointer, Jr.

[1] This Notice is being sent not only to all persons who have registered with the Claims Office, but also to all others who have provided the Claims Office or the Court with their names and addresses. It is also being sent to those who have previously opted out of the Lindsey class since some of them may want at this time to rejoin the class to participate in the revised settlement.

Chief Judge

SYNOPSIS OF REVISED SETTLEMENT PROGRAM

KEY FEATURES

a claims-made settlement program being offered to domestic breast implant recipients with at least one Bristol, Baxter, or 3M implant (or, under certain conditions, a post 8/84 McGhan implant).

benefits are fixed in amount, calculated without regard to how many or how few other implant recipients accept the offer.

most benefits based on medical condition during 15-year period (until December 15, 2010).

offer does not include all implant recipients who were eligible under global settlement.

benefits are substantially less than specified in Disease Compensation Schedule grid of initial global settlement —although, for most eligible participants with only Bristol, Baxter, or 3M implants, greater than the severely ratcheted grid amounts that might have been submitted under the global settlement. Negotiations are pending to eliminate reimbursement and subrogation claims by most non-governmental health-care insurers against participants under the revised settlement program.

some benefits are based on the original disease and disability/severity schedule; other benefits are based on a new, more restrictive revised disease/symptomology schedule.

special benefit options and protections for those who timely submitted claims and documentation under the Current Disease Compensation program of global settlement.

potential for special benefits for Current Claimants in event of rupture of Bristol, Baxter, or 3M silicone-gel implants before December 16, 1996.

special explantation compensation in event of removal of Bristol, Baxter, or 3M implant between April 1, 1994, and December 15, 2010.

advance payments that may expedite partial payment of benefits and provide some compensation to those without other benefits.

compensation of privately-retained attorneys to be borne by individual participants, subject to some maximum limitations, and with no reduction in scheduled benefits for common benefit attorneys' fees and expenses or administrative costs.

a person is eligible to participate in the revised settlement if she (1) is a domestic (non-foreign) breast implant recipient, (2) was implanted before June 1, 1993, with a Bristol, Baxter, or 3M implant (or, under certain conditions, with a post 8/84 McGhan silicone-gel implant), and (3) has neither settled with the settling defendants nor had her claims against such defendants resolved by final judgment.

eligible class members are not required to participate in the revised settlement. They can reject the settlement offer, and the number of rejections does not affect scheduled benefits for those who accept the offer. They can wait to make this decision until they are sent a Notification of Status from the Claims Office regarding their eligibility and potential benefits under the revised settlement. Alternatively, they can make an immediate election to opt out and proceed with breast implant litigation if they are ready to do so. Settling defendants have no withdrawal rights based on number of opt-outs, and most of their obligations are not subject to any maximum limitations.

IMPORTANT DATES

April 1, 1996: Deadline for Election Form to be filed with Claims Office by implant recipients who have not previously registered but want to preserve their Second Opt-Out Right. (Election Form filed by such persons will constitute registration.)

December 16, 1996: Deadline for Election and Proof of Manufacturer forms to be filed with Claims Office by participants wanting to preserve status as Current Claimant. Also, deadline for filing Rupture Claim Form by Current Claimants seeking rupture benefits.

DECIDING WHAT FORM(S) TO USE

Before completing any form, you should review the Notice and the Question and Answer Booklet and consult with your own lawyer. If you do not have a lawyer, you can call 513-651-9770 to request legal advice or 800-938-7357 to learn about information meetings.

1. Determine whether you are eligible to participate in the revised settlement. (See Notice ¶10)

2. **If you are eligible to participate**, complete and return the Election Form (white), marking box 1A and either box 2A, box 2B, or box 2C.

Before completing the Election Form, decide whether you definitely want to accept the settlement offer (2B), or definitely want to reject the settlement offer (2C), or want to wait to make this decision until the Claims Office, after reviewing your forms and records, sends you a Notification of Status letter concerning your potential benefits under the settlement (2A).

The Court believes that box 2A will be the best choice for most eligible implant recipients, because they will know more about their potential benefits before deciding whether or not to accept the settlement.

Box 2B is primarily intended for implant recipients who do not expect to ever file a lawsuit and want the earliest possible payment of benefits under the settlement.

Box 2C is primarily intended for implant recipients who know they want to proceed with litigation rather than accept benefits under the settlement and who have already filed a separate lawsuit or are prepared to immediately file such a lawsuit. (If you mark this option, do not return any forms other than the Election Form.)

If you do not understand the enclosed materials, you have an opportunity to learn more. The Court has anticipated that you may have questions about the choices you are to make.

To complement the written notices, there will be a televised program on Court TV, available on cable TV in many localities, on Wednesday, January 24, 1996, at 9:00 pm, CST, at which Judge Pointer and Judge Cochran will explain these forms and notices, and the rights and options of implant recipients.

In addition, the Court has selected persons not associated with plaintiffs or defendants to answer questions about what the revised settlement means and what your options are. They will conduct meetings around the country in the next several months. As agents of the Court, however, they cannot provide legal advice about individual claims.

To find the date, time, and location of the regional meetings nearest you, call 1-800-938-7357 for a recorded schedule.

If you do not have access to the Court TV channel or cannot attend one of the regional meetings, you can still learn more. The Court has also made arrangements for a national telephone meeting, at which persons can call in, hear presentations, and ask questions. To find out more about how to do this, call 1-800-938-7357.

The regional meetings and the telephone conference are intended primarily for those persons who do not have their own attorneys with whom to consult about their rights and options. Implant recipients who have their own attorneys, while expected to consult with those attorneys, may, however, also attend these meetings or participate in the telephone conference. Other meetings will be scheduled to assist attorneys in rendering advice to their clients.

SAVE THIS NOTICE FOR PERIODIC REFERENCE REGARDING RIGHTS AND AND TELEPHONE NUMBERS

THE LITIGATION

1. **Cases.** Thousands of lawsuits seeking damages for death or 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 Chief Judge Sam C. Pointer, Jr., in a proceeding known as *In re Silicone Gel Breast Implant Products Liability Litigation, MDL No. 926*, Case No. CV 92-P-10000-S. Over a dozen breast implant cases have already been tried, with considerable expense and time, in state and federal courts —with some verdicts favorable to plaintiffs and with some favorable to defendants.

THE GLOBAL SETTLEMENT

2. **Settlement Approved.** In April 1994 Judge Pointer preliminarily approved a proposed global settlement under Fed. R. Civ. P. 23(b)(3) on behalf of a broad class of persons with respect to pending or potential claims against the then settling defendants for present or future personal injury or death caused by or involving breast implant products. On September 1, 1994—after extensive notice to potential class members; after opportunity to object, comment, and opt out; and after several days of hearings—Judge Pointer approved this settlement. The settlement order was entered in a case identified as *Lindsey, et al. v. Dow Corning Corporation, et al.,* Case No. CV 94-P-11558-S, and the class was generally referred to as the Lindsey class.

3. **Opt-Outs from Global Settlement. (First or Initial Opt-Out)** A major question while the proposed global settlement was pending was whether the number of persons electing under Fed. R. Civ. P. 23(c)(2) to opt out (or exclude themselves) from the proposed settlement would be so large that the then settling defendants would exercise their reserved option not to proceed with a settlement that might obligate them to pay more than $4.2 billion to the remaining class members. Although a substantial number of potential class members (over 10,000) did opt out, the then settling defendants concluded to proceed nevertheless with the settlement. Those who did not opt out were enjoined by the Court from pursuing or instituting lawsuits against the then settling defendants pending implementation of the settlement.

4. **Registrations and Claims.** Lindsey class members were advised that, if they wanted to make claims under the Current Disease Compensation Program of the global settlement, they were required to submit claim forms (with supporting documentation) to the Claims Office by September 16, 1994. Later orders of the Court extended to October 17, 1994, the deadline for submitting supporting documentation, and to March 1, 1995, the deadline for domestic class members to register with the Claims Office to avoid being treated as late registrants. (Under terms of the settlement and notice, late registrants would receive benefits only if and to the extent settlement funds were not exhausted by benefits paid to class members who timely registered.) Eligible foreign class members who did not register with the Claims Office by March 1, 1995, were precluded from obtaining benefits under the settlement or from proceeding with litigation in courts in the United States, but retained their full rights to pursue claims in the judicial and administrative tribunals of their own countries.

5. **Current Disease Compensation Claims and Ratcheting under Global Settlement.** At the time the global settlement was approved, it could not be known whether, or to what extent, the benefits that might be approved under the Schedule of Benefits for Current Disease Compensation Claims (ranging from $105,000 to $1,400,000 for domestic claimants) would exceed the $1,200,000,000 to be set aside under the settlement for such benefits. For that reason, the settlement provided that the amounts shown in the Schedule were subject to potential reduction (or ratcheting) but that, in such event, all registered class members would be so notified and be given a second opt-out right in order to pursue litigation rather than accept reduced benefits. The defendants would, however, then have an option to withdraw from the settlement because of the number of such additional opt-outs.

Promptly after the settlement was approved, the Claims Office began processing registrations and evaluating those with current claims. However, because of the large number of registrations (approximately 260,000 were mailed by September 16, 1994) and because of the large number of those with current claims (projected to be about 100,000), it became apparent that far more time would be required to evaluate all current claims than had been initially anticipated and that benefit levels would definitely have to be ratcheted. In order not to unduly delay the determination about the extent of ratcheting, the opportunity for opting out, or the possible withdrawal by defendants, samples of these claims were selected for evaluation in a manner as to allow reasonably accurate predictions about the extent of ratcheting.

This study, a summary of which the Claims Office announced to class members in June 1995, demonstrated that, given the large amount of current claims that would be approved under the disease and severity criteria of the global settlement, the scheduled Disease Compensation benefits would be severely reduced—to perhaps less than 5% of the amounts shown in the schedule. Additionally, by that time, Dow Corning, which was obligated to make almost half of the contributions to the settlement funds, had become the Debtor in bankruptcy reorganization proceedings, and its continued participation in the settlement was uncertain. These facts led the Court to conclude not only that thousands of additional class members would opt out of the class, but also that the defendants would withdraw from the settlement as a result of these opt-outs.

6. **Efforts to Reduce Ratcheting.** As required by the global settlement, Plaintiffs Settlement Class Counsel and representatives of the more financially solvent defendants not in bankruptcy engaged in extensive conferences during the Summer and Fall of 1995 and explored various methods and options to reduce the extent of ratcheting, while preserving the rights of registered class members to opt out as had been guaranteed under the global settlement. Ultimately in November 1995 the Court was presented with a proposed revised settlement program approved by Bristol, Baxter, 3M, McGhan, and Union Carbide.

Although still providing substantially less compensation than the Schedule of Benefits contained in the original notice of settlement, this program is, in the view of the Court, far superior—for those eligible to participate—to the distribution of a conditional offer of severely-ratcheted benefits based on percentages of grid amounts in that original notice. The benefits to most participants with only Bristol, Baxter, or 3M implants under the revised settlement will be greater than the ratcheted amounts than would have been presented to class members under the original settlement. More importantly, those ratcheted amounts would, because of the projected opt-outs and withdrawal by the defendants, never have been paid to any class member, whereas the benefits offered under the revised settlement are not subject to any withdrawal right by the settling defendants even if a large number of persons opt out of the revised settlement.

Plaintiffs Settlement Class Counsel have not approved the terms of the revised settlement offer and, indeed, believe that the settling defendants should have been willing to offer greater benefits, and to more members of the Lindsey class. They do not, however, object to class members individually having an opportunity to consider and possibly accept an offer of settlement where the terms of that offer are clear and understandable—even if less than what Class Counsel personally believe would represent a fair settlement value. Nor do they dispute that, for those eligible to participate, the revised settlement provides an opportunity for settlement without litigation that, because of the defendants right to withdraw due to additional opt-outs, would not have been provided by sending notices of ratcheting under the original benefit schedule. While Class Counsel have not agreed to the terms of the revised offer, paragraph 18 of the original notice did not require agreement to a revision, such as this, that reduces the extent of ratcheting which would otherwise occur.

SECOND OPT-OUT RIGHT

7. **Opt-Out Right.** Because of the reduction in potential benefits, members of the Lindsey class now have a second right to opt out of the class and thereby be able, if desired, to pursue or institute litigation (including any rights to seek punitive or statutory multiple damages) against those who were settling defendants or released parties under the global settlement. This opt-out right is provided to all Lindsey class members—whether or not eligible to participate in the revised settlement—except for those who do not register until after April 1, 1996, or who, having previously opted out, elect to rejoin the Lindsey class.

(a) To opt out now, the individual (or her court-appointed representative) must sign and return to the Claims Office the Election Form (included with this Notice), with box 2C or 3A marked. The form can also be completed and signed by the individuals attorney. In the event of conflict between an election signed by a class member and an election signed by the persons attorney, the former will control.

(b) Those who elect to opt out now should understand that statutes of limitation and repose—which have been suspended during the pendency of the *Lindsey* case and, for most class members, during the pendency of the earlier-filed *Dante* class action—will resume

running 30 days after the Claims Office receives this election. Resumption of the running of such statutes could adversely affect the litigation rights of persons who have not already filed lawsuits or who are not prepared to file any lawsuits within that 30-day period. Accordingly, the Court cautions class members against making an immediate opt-out election unless they are sure they wont be adversely affected by such statutes.

(c) There is no fixed deadline for such persons to opt out. Registered class members can wait to make the decision whether or not to opt out until 45 days after they are individually sent a Notification of Status letter by the Claims Office explaining their potential eligibility for benefits under the revised settlement. These individual Notifications will be mailed by the Claims Office during 1996 as registrations and claims are processed and reviewed. Statutes of limitation and repose will continue to be suspended until that decision is made, and indeed for many class members as much as 6 months after such an opt-out election is made. For this reason—and to assure the most informed decision by those who may be eligible to participate in the revised settlement—the Court strongly recommends that most Lindsey class members delay any decision about opting out until they are sent this Notification by the Claims Office.

(d) Persons who opt out should understand that their rights to institute or pursue litigation claims against Mentor, Bioplasty, and Dow Corning are subject to certain restrictions. See 15-17 below. Also, they should understand that the companies that are parties to the new settlement program are prohibited from now engaging in settlement negotiations and discussions (except on a case-by-case basis involving cases that were brought by persons who earlier opted out of the global settlement or cases that may be specifically set for trial or court-sponsored mediation or arbitration), and that any recoveries through separate litigation or settlement are subject to potential sharing in the cost of services performed by counsel for the common benefit of all having breast implant claims. See 28 below.

(e) Persons wanting to obtain the Advance Payment and payment of other benefits at the earliest possible date can waive this second opt-out right.

REVISED SETTLEMENT PROGRAM

8. **General Description.** The revised settlement program can be described as a claims-made program. Rather than the settling defendants offering to make a prescribed payment into a settlement fund that then would be divided in some manner among class members electing to participate (and perhaps being subject to cancellation if too many class members elect not to participate), the amounts to be paid to individual participants are essentially unconditional, fixed, and unaffected by the number or amount of benefits paid to other participants, and the total amount to be paid by the various settling defendants will be determined by the number of, and the payments to, the persons participating in the settlement.

(a) This revised settlement is being offered by some, but not all, of the manufacturers and suppliers involved in the original settlement; and, as described in 10 below, not all Lindsey class members are eligible to participate in the revised settlement.

(b) The benefits provided are substantially less than the amounts shown in the Disease Compensation Schedule of the original settlement (which, before ratcheting, could have been as high as $1,400,000 for some class members). The maximum benefits payable under the revised settlement are $253,000 ($250,000 under Long-term Benefits Schedule plus $3,000 for explantation). Such benefits would be payable, for example, to a qualified participant who in May 1993 developed Systemic Lupus with a compensation level A under the criteria of the revised settlement program, and whose only implants, manufactured by Baxter/Heyer-Schulte, were removed in May 1994.

(c) At the lower range of benefits, however, the amount payable to some eligible participants under the revised settlement may actually exceed that described under the global settlement. For example, an Advance Payment of $1,000 would be payable to a qualified participant with a Baxter/Heyer-Schulte implant who did not make a Current Disease Compensation Program claim under the global settlement and who does not in future years either have her implants removed or develop a disease or symptomology covered under the criteria of either settlement program. Also, the amount payable ($3,000) to those who qualify for explantation benefits but who would not otherwise qualify for any benefits may exceed the amount that might have been payable to such persons under the global settlement.

(d) For other qualified participants, benefits should fall between these limits, depending on factors such as (1) the manufacturer(s) of the implant(s), (2) the severity and disease/symptomology criteria under the global settlement and the revised settlement, (3) the time when a claim and supporting documentation are filed, (4) whether there is proof of rupture, and (5) the time when an implant is removed.

9. **Settling Defendants under Revised Settlement.** A full listing of the settling defendants participating in the revised settlement is contained in Exhibit B1. In this Notice, however, the following short descriptions of these defendants are sometimes used for convenient reference:

Bristol, meaning Bristol-Myers Squibb Co., Medical Engineering Corp. (MEC), and their affiliates, including breast implants sold under the Surgitek name.

Baxter, meaning Baxter Healthcare Corporation, Baxter International Inc., American Hospital Supply Co. (Heyer-Schulte) and their affiliates.

3M, meaning Minnesota Mining & Manufacturing Co., McGhan Medical Corp. (Dela.) and their affiliates. (For purposes of this program, 3M implants are 3M/McGhan implants manufactured wholly or partly before 8/3/84.)

McGhan, meaning McGhan Medical Corporation (Calif.) and INAMED Corporation. (For purposes of this program, post 8/84 McGhan implants are silicone-gel breast implants manufactured at or by McGhan wholly after 8/2/84.)

Union Carbide, meaning Union Carbide Chemical & Plastics Co., Union Carbide Corporation, and their affiliates.

See Exhibit G for various brand names of implants.

10. **Eligibility.**

(a) A person who does not timely opt out will be eligible to participate in the revised settlement program if she satisfies each of the following requirements:

(1) is not a foreign claimant (see 18);

(2) has not released through settlement all claims against each of the settling defendants whose implants were implanted in the person (or had such claims resolved by final judgment); and

(3) before June 1, 1993, either—

(A) was implanted with one or more breast implants manufactured by Bristol, Baxter, or 3M, or

(B) was implanted only with one or more post 8/84 McGhan silicone-gel breast implants (or only with one or more such implants and with one or more breast implants manufactured by Bioplasty, Cox Uphoff/ CUI, or Mentor).

(b) An implant recipient who would otherwise be eligible but for having earlier opted out of the global settlement may participate in the settlement (but without opt-out rights under 7 above) by filing with the Claims Office an Election Form before the person proceeds to trial against any of the settling defendants. If the form is filed after December 16, 1996, the person will be classified as a Late Registrant.

(c) As under the global settlement, participation by an implant recipient also constitutes participation by that persons estate and family members with respect to any derivative or representative claims. However, any claims by children of implant recipients with respect to their own personal injury are not covered by the revised settlement, and the pursuit of any such claims is not barred by this settlement.

11. **Registration; Proof of Manufacturer Form; Classification of Participants.**

(a) Persons eligible to participate in the revised settlement who have already registered with the Claims Office do not have to re-register (whether or not they filed any claim under the global settlement). However, they should complete and file with the Claims Office the Election Form (included with this Notice) when they are prepared to make a decision regarding possible participation in the settlement, and the failure to file this form by December 16, 1996, would preclude an otherwise eligible participant from obtaining the special benefits and protections afforded to Current Claimants.

(b) Persons eligible to participate in the revised settlement who have not already registered with the Claims Office may still participate as Late Registrants under the revised settlement, but must file with the Claims Office the Election Form (included with this Notice) by April 1, 1996, in order to preserve certain rights to opt out later.

(c) All persons who are eligible and may want to participate in the revised settlement must also complete and file with the Claims Office the Proof of Manufacturer Form (included with this Notice). Although there is no fixed deadline for filing this form, benefits cannot be paid under the revised settlement until the participant has filed this form with supporting documentation, and failure to file this form and proof by December 16, 1996, would preclude otherwise eligible participants from obtaining the special benefits and protections accorded to Current Claimants.

(d) The benefits, options, and protections given participants under the revised settlement vary based on the following classifications of participants:

Current Claimants: eligible participants who, under terms of the global settlement, (1) mailed to the Claims Office by September 16, 1994, a signed Registration Form and (2) mailed to the Claims Office by October 17, 1994, a substantially complete Current Disease Compensation Form with sufficient documentation to be classified by the Claims Office under the global settlement as a current claimant (without regard to whether any deficiencies in documentation would be classified as minor or major).

Other Registrants: eligible participants who are not Current Claimants as defined above, but (1) who registered with Claims Office by March 1, 1995, or (2) who, having previously opted out of the global

settlement, withdraw their exclusion and register with Claims Office by December 16, 1996.

Late Registrants: all other eligible participants who register with the Claims Office but are neither Current Claimants nor Other Registrants as defined above. There presently is no deadline for registration, but the Court may in the future impose a final deadline for registration, and the Second Opt-Out Right under 7 above is not provided to persons who register after April 1, 1996.

12. **Benefits for Participants Who Have Had at least one Bristol, Baxter, or 3M Breast Implant.** Participants with at least one Bristol, Baxter, or 3M breast implant are eligible to receive explantation benefits under 12(a), plus either long-term benefits under 12(b) or fixed payment benefits under 12(c). They are also entitled to receive an Advance Payment under 12(d) that will be credited against benefits under 12(b) or 12(c).

(a) Explantation Benefit: A one-time payment of $3,000 will be paid to participants (other than Late Registrants) on proof of removal of a Bristol, Baxter, or 3M implant after April 1, 1994, and before December 15, 2010 (end of 15-year program). Payment is in addition to payments under 12(b) or 12(c) below. The settling defendants obligations to pay their respective shares of these payments are unconditional and do not depend on how many or how few participants elect to participate and qualify for benefits. The Explantation Claim Form enclosed with this Notice contains detailed explanations and instructions for submitting and documenting such claims.

Long-term Benefit Schedule (Paragraph 12(b))		
Disease or Symptomology; Compensation Level (Exhibit E1 to this Notice)	Bristol, Baxter, or 3M implant	
	No Dow Corning implant	Also one or more Dow Corning implants
Scleroderma (SS) or Lupus (SLE); Compensation Level A	$250,000	$125,000
Scleroderma (SS) or Lupus (SLE); Compensation Level B	$200,000	$100,000
Scleroderma (SS) or Lupus (SLE); Compensation Level C	$150,000	$ 75,000
General Connective Tissue Symptoms (GCTS), Polymyositis (PM), or Dermatomyositis (DM); Compensation Level A	$110,000	$ 55,000
General Connective Tissue Symptoms (GCTS); Compensation Level B	$ 75,000	$ 37,500

(b) Long-term Benefits. Participants with at least one Bristol, Baxter, or 3M implant will be paid benefits under the above schedule upon proof, during the 15 years of the program (before December 15, 2010), of having developed a disease or symptomology, at the indicated compensation level, as defined in revised settlement. (See Exhibit E1.) These criteria are more restrictive than those in the original settlement program.

(1) Benefits of $100,000 or less will be paid in single lump sum payment; larger benefits may be paid in 2 or 3 annual installments. (Defendants are not required to pay more than $100,000 to a recipient in any given year.)

(2) If before the end of the 15-year period of program a participant documents a condition that would entitle her to a larger payment than previously received, she would at that time be paid the difference between the new amount and any amount previously paid under this schedule.

(3) Bristols, Baxters, and 3Ms obligations are unconditional and unlimited in amount (*i.e.*, not affected by how many or how few persons accept the revised settlement or by how much money they must pay under the settlement) with respect to their respective shares of benefits approved under the Long-term Benefit Schedule (other than under 12(b)(2))—

(A) for GCTS, PM, or DM benefits payable to a Current Claimant who had any claim under the global settlement that would have been either approved or treated as having only minor deficiencies, and

(B) for SS/SLE benefits to a Current Claimant who had a claim for SS/SLE under the global settlement that would have been either approved or treated as having only minor deficiencies.

(4) Except as stated in (3) above, the obligations of Bristol, Baxter, and 3M to pay their respective shares of payments under the above schedule are subject to certain maximum limitations. See 20(b) below. However, any failure by them to make payments will at that time give affected participants (other than Late Registrants) a right to opt out and pursue litigation against the defendants. See 20(e) below.

(c) Special Options, Benefits, and Protections for Current Claimants. As an alternative to benefits under 12(b) above, Current Claimants (defined in 11(d) above) who have had a Bristol, Baxter, or 3M breast implant may elect to receive a fixed payment under the following Fixed Amount Benefit Schedule based on disability/severity levels specified in the Disease Schedule of the global settlement for diseases described in that Schedule (rather than under the more restrictive criteria of the revised settlement).

Benefits under this Fixed Amount Benefit Schedule constitute one-time settlement compensation, and will not be increased if, after being paid benefits under this schedule, a recipient should later develop a medical condition that would otherwise qualify for higher benefits under this schedule (other than for rupture under (2) below) or for higher benefits under the long-term benefit schedule of 12(b).

Fixed Amount Benefit Schedule (Paragraph 12(c))			
Disability/severity Level for diseases under global settlement	Current Claimant with Bristol, Baxter, or 3M implant		
	No Dow Corning implant	Proof of rupture of Bristol, Baxter, or 3M implant	No ru
A		$100,000	$
B		$ 50,000	$
C or D		$ 25,000	$

(1) Benefits of $25,000 or less will be paid in single lump sum payment; larger benefits will be paid in 2 equal annual installments.

(2) The increase in benefit level for rupture is limited to rupture of a Bristol, Baxter, or 3M silicone-gel implant that is established by explantation and documented by December 16, 1996.

(A) A Rupture Claim Form is enclosed with this Notice for use in submitting claims for rupture benefits. To qualify for benefits, the participant must complete and mail this form, with proof of the rupture, to the Claims Office in time to be received by the Claims Office by December 16, 1996.

(B) For further details, including definition of rupture and types of acceptable documentation, see the instructions and explanation on back of Rupture Claim Form.

(3) At the time of being sent their Notification of Status, Current Claimants will be asked to chose between schedules 12(b) and 12(c) and they must make this choice before they will be paid benefits under either schedule. Those who choose compensation under schedule 12(c) may not later seek compensation under schedule 12(b). Those who choose compensation under schedule 12(b) may, before being paid benefits under schedule 12(b), elect to return to schedule 12(c) but, in such event, the benefits under 12(c) as shown above will be reduced by 25%.

(4) The obligations of Bristol, Baxter, and 3M to pay their respective shares of benefits under 12(c) are unconditional and unlimited in amount—not affected by how many or how few persons accept the revised settlement or by how much money they must pay under the settlement. As an additional protection to Current Claimants, the obligations of Bristol, Baxter, and 3M to make payments under schedule 12(b) to certain Current Claimants, as described in 12(b)(3) above, are unconditional and not subject to any maximum limitations.

(d) Advance Payments. As soon as the Claims Office can determine that a participant (other than a Late Registrant) has submitted satisfactory proof of manufacture of a Bristol, Baxter, or 3M breast implant to be eligible to participate and has waived or not timely elected to exercise her Second Opt-Out Right, the participant will be paid $5,000 if a Current Claimant or $1,000 if an Other Registrant, as those terms are defined

in 11(d) above. These are advances in that they will be credited against (and reduce) amounts later determined to be payable under 12(b) and 12(c) above but will not otherwise be refundable (in the absence of fraud).

13. **Benefits for Participants Qualifying because of post 8/84 McGhan Silicone-gel Breast Implants.** Breast implant recipients who have never received a Bristol, Baxter, or 3M implant but are eligible to participate because of having received only post 8/84 McGhan silicone-gel breast implants (or only such implants and Bioplasty, Cox Uphoff/CUI, or Mentor implants) are eligible to participate, but with more limited benefits than provided recipients with a Bristol, Baxter, or 3M implant. These more limited benefits will be paid by McGhan (20%), 3M (40%), and Union Carbide (40%) to such persons as follows:

Post 8/84 McGhan implant benefits	
Qualifying Disease or Symptomology and Disability/severity or Compensation Level	Amount
SS/SLE Comp. Level A,B, or C under revised disease schedule or Disability/severity Level A under disease schedule of global settlement (Current Claimants only)	$ 50,000
GCTS/PM/DM Comp. Level A under revised disease schedule or Disability/severity Level B under disease schedule of global settlement (Current Claimants only)	$ 20,000
GCTS Comp. Level B under revised disease schedule or Disability/severity Level C or D under disease schedule of global settlement (Current Claimants only)	$ 10,000

(a) Benefits. Such participants will be paid benefits under the following schedule upon proof, during the 15 years of the program (before December 15, 2010), of having developed a disease or symptomology, at the indicated compensation level, as defined in the revised settlement. (See Exhibit E1). Current Claimants (defined in 11(d) above) may optionally qualify for one-time benefits based on proof of a disability/severity level and disease defined in the Disease Schedule for the global settlement.

(b) Benefits will be paid in a single lump sum payment.

(c) If during the 15-year period of the program, a participant develops and documents a condition that would entitle her to a larger payment under the revised disease schedule than previously received under that schedule, she would at that time be paid the difference between the new compensation amount and the amount previously paid.

(d) The obligations of McGhan, 3M, and Union Carbide to pay their respective shares of benefits based on post 8/84 McGhan implants to qualifying Current Claimants based on the global settlement disease schedule—and to certain qualifying Current Claimants based on the revised disease schedule, as described in 12(b)((3)(A) and (B)—are unconditional and do not depend upon how many or how few other such Current Claimants elect to participate and qualify for benefits. However, post-8/84 McGhan benefits do not become payable to Current Claimants until the Courts order becomes Final and, therefore, may be delayed if there is

an appeal from approval of the revised settlement.

(e) Except as stated in (d) above, the obligations of McGhan, 3M, and Union Carbide to pay their respective shares of benefits based on post 8/84 McGhan implants are subject to certain maximum limitations. See 20(c) below. However, any failure by them to make payments will at that time give affected participants (other than Late Registrants) a right to opt out and pursue litigation against the defendants. See 20(e) below.

(f) There are no Advance Payments or rupture benefits payable to implant recipients qualifying for eligibility based on post 8/84 McGhan implants, nor does this revised settlement program provide benefits for removal of post 8/84 McGhan implants.

14. **Benefits and Options for Late Registrants.** Late Registrants, as defined in 11(d) above, are eligible for benefits only under 12(b) and 13, and not for explantation benefits or Advance Payments. Late Registrants will be paid benefits under 12(b) only if, when, and to the extent Bristols, Baxters, and 3Ms cumulative payments to Current Claimants and Other Registrants under 12(b) do not exceed their respective maximum obligations as stated in 20. Late Registrants will be paid benefits under 13 only if, when, and to the extent McGhans, 3Ms, and Union Carbides cumulative payments under 13 do not exceed their respective maximum obligations as stated in 20. As under the global settlement, Late Registrants will have no right to opt out in the event such maximum limitations result in their not receiving the full amount shown in the schedules. Late Registrants will, however, be entitled to the Second Opt-Out Right described in 7 above if they register with the Claims Office by April 1, 1996.

15. **Status of Recipients of Mentor Implants.** Implant recipients who have received one or more Mentor implants in addition to Bristol, Baxter, 3M, or post 8/84 McGhan implants, are eligible to receive the same benefits under the revised settlement as others eligible to participate in the revised settlement.

(a) There are no special benefits based on explantation or rupture of a Mentor implant.

(b) Persons who have had a Mentor implant but never had a Bristol, Baxter, 3M, or post 8/84 McGhan implant are not eligible for benefits under the revised settlement program. They will, however, be eligible to participate in distribution of the approximately $25,800,000 being paid by Mentor under terms of a limited-fund mandatory (non-opt out) class settlement with Mentor (which was not appealed and became final on September 10, 1993). The distribution formula for those benefits will be set by the Court at a later time, and it is anticipated that, because of the very limited funds set aside for such recipients, the Court will give preferential, if not exclusive, consideration to those who do not have potential claims against other implant manufacturers.

(c) Persons who have had a Mentor implant—whether or not eligible to participate in the revised settlement—have the same rights to opt out as provided to other members of the Lindsey class. They should understand, however, that, because of the earlier Mentor limited-fund settlement, they are precluded from instituting or pursuing litigation regarding breast implant 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.) for implantations occurring before June 1, 1993.

16. **Status of Recipients of Bioplasty Implants.** Implant recipients who have received one or more Bioplasty implants in addition to Bristol, Baxter, 3M, or post 8/84 McGhan implants, are eligible to receive the same benefits under the revised settlement as others eligible to participate in the revised settlement.

(a) There are no special benefits based on explantation or rupture of a Bioplasty implant.

(b) Persons who have had a Bioplasty implant but never had a Bristol, Baxter, 3M, or post 8/84 McGhan implant are not eligible for benefits under the revised settlement program. They will, however, be eligible to participate in distribution of the approximately $5,000,000 being set aside by Bioplasty under terms of bankruptcy proceeding. The distribution formula for those benefits will be set by the Court and the Bankruptcy Court for the United States District Court in Minnesota at a later time, and, because of the very limited funds set aside for such recipients, it is anticipated that the courts will give preferential, if not exclusive, consideration to those who do not have potential claims against other implant manufacturers.

(c) Persons who have had a Bioplasty implant—whether or not eligible to participate in the revised settlement—have the same rights to opt out as provided to other members of the Lindsey class. They should understand, however, that, because of the Bioplasty bankruptcy proceedings, they are precluded from instituting or pursing litigation regarding breast implant claims against the Bioplasty Defendants (Bioplasty, Inc.; Bio-Manufacturing, Inc.; and Uroplasty, Inc.).

17. **Status of Recipients of Dow Corning Implants.** Implant recipients who have had one or more Dow Corning implants in addition to Bristol, Baxter, or 3M implants may participate in the revised settlement, but will have reduced benefits under the revised settlement in view of their right to present claims related to their Dow Corning implants.

(a) Benefits for such participants under 12(b) and

12(c) are 50% of the benefits for those without Dow Corning implants. Participants in the revised settlement do not, however, waive any claims against Dow Corning, though they should understand that any claims against Dow Corning are subject to certain automatic stays and other orders that may issue from the Bankruptcy Court for the United States District Court for the Eastern District of Michigan and, to be preserved, may require presentation of a proof of claim in that court.

(b) There are no special benefits based on explantation or rupture of a Dow Corning implant.

(c) Persons who have received a Dow Corning implant but never received a Bristol, Baxter, or 3M implant are not eligible for benefits under the revised settlement program even if they received a post 8/84 McGhan implant.

(d) Persons who have received a Dow Corning implant—whether or not eligible to participate in the revised settlement—have the same opt-out rights as other members of the Lindsey class. They should understand, however, that any claims against Dow Corning are subject to certain automatic stays and other orders that may issue from the Bankruptcy Court for the United States District Court for the Eastern District of Michigan and, to be preserved, may require presentation of a proof of claim in that court.

(e) Implant recipients will likely be mailed a separate notice from the Bankruptcy Court for the United States District Court for the Eastern District of Michigan explaining procedures and possibly deadlines for presenting or preserving claims against Dow Corning.

18. **Definition and Status of Foreign Claimants.** Foreign Claimants were defined in the global settlement, and continue to be defined under this Notice, as being breast implant recipients (i) who were not citizens or resident aliens of the United States, (ii) whose breast implants were all implanted outside the United States, and (iii) who had not received any compensation from any then settling defendant or released party for breast implant injuries or expenses under the laws or procedures of a country other than the United States. Such persons were offered more limited settlement benefits under the global settlement than the domestic members of the Lindsey class, but were also provided additional guarantees regarding opt-out rights, as well as the opportunity (if they did not participate affirmatively in the global settlement) to pursue breast-implant claims in the administrative and judicial tribunals of their own countries. Foreign claimants from Australia and the Canadian provinces of Ontario and Quebec were excluded from the Lindsey class unless they affirmatively opted into the settlement.

(a) After issuance of the notice of the global settlement, this Court in several orders relating to foreign recipients who had opted out of the global settlement concluded that litigation in courts of the United States by citizens of Australia, Canada, and England is barred under the doctrine of forum non conveniens (without prejudice to pursuit of claims by such persons in Australian, Canadian, and English courts), but that litigation in the courts of the United States by some citizens of New Zealand is not barred under that doctrine. In those orders the court did not specifically address claims by opt-out foreign claimants from other countries, but indicated that such litigation rights would be resolved by applying the principles used in addressing issues relating to the Australian, Canadian, English, and New Zealand claimants.

(b) Preferring administrative resolution or litigation—in this country or in other countries—over any immediate settlement as a means to address claims of Foreign Claimants, the settling defendants under the revised settlement program are not now making any offer to settle in this forum the pending or potential claims of Foreign Claimants, and such persons are not eligible for benefits under the revised settlement program. The defendants declination to provide settlement offers to such persons at this time in this forum does not, however, preclude the possibility of their willingness to consider settlement of such claims outside the terms of this settlement offer, whether in courts of the United States or in judicial or administrative tribunals of other countries.

(c) Foreign Claimants who want to pursue or institute litigation in the United States against Bristol, Baxter, 3M, McGhan, or Union Carbide have the right—as guaranteed under terms of the global settlement—to do so (subject to any objection by those defendants under doctrines such as forum non conveniens), but, to do so, must exercise their Second Opt-Out Right as described in 7 above, either at this time or after being mailed a Notification by the Claims Office regarding their status. To eliminate any need to make this decision prematurely, they are allowed to delay making this decision until sent the Notification by the Claims Office, with statutes of limitation and repose in this country being suspended until 30 days after the time allowed in that Notification for opting out.

(d) Foreign Claimants who want to pursue or institute claims against implant manufacturers or distributors in the judicial or administrative tribunals of their own countries may do so, and need not file any further form or election with the Claims Office.

19. **Children of Breast Implant Recipients**. The revised settlement program does not provide any special benefits to children of breast implant recipients. Such children are, with respect to any claims for personal

injury or death allegedly resulting from their mothers breast implant, hereby excluded from membership in any class previously established by the Court, and any such claims may be brought before December 15, 1997, or, if later, within two years after the claim accrues or the child attains the age of majority under applicable state law.

20. **Limits on Obligations of Defendants; Additional Opt-Out Rights.**

(a) The obligations of the settling defendants to make payments under this program are several, not joint, and are limited to the approved claims involving implants from that defendant (or with respect to which that defendant is agreeing to make payments).

(b) If a claimant has had implants from more than one of Bristol, Baxter, or 3M, their obligations are divided simply on the basis of the number of such defendants whose implants the claimant had. For example, if a claimant had one or more Bristol implants, one or more Baxter implants, a post 8/84 McGhan implant, and a Mentor implant and was entitled to a $150,000 payment, then Bristol would be responsible for payment of $75,000 and Baxter for payment of $75,000. Enhancement payments for rupture and explantation benefits are the sole responsibility of the defendant whose implant ruptured or was explanted.

(1) The obligations of Bristol, Baxter, and 3M to make payments under 12(a), 12(c), and 12(d) are not subject to any maximum limitations.

(2) As explained in 12(b)(4), their obligations to make payments under 12(b) (other than to certain Current Claimants as explained in 12(b)(3)) are subject to certain limitations; namely, a maximum of $725,000,000 (less amounts paid for explantation expenses of Other Registrants), with their respective obligations for such 12(b) benefits being as follows:

Bristols cumulative obligation for such 12(b) benefits ($400,000,000) increases in the amount of $27,600,000 per year for the first 10 years and $24,800,000 per year for the next 5 years (less amounts paid by it for explantation expenses of Other Registrants)

Baxters cumulative obligation for such 12(b) benefits ($193,000,000) increases in the amount of $13,300,000 per year for the first 10 years and $12,000,000 per year for the next 5 years (less amounts paid by it for explantation expenses of Other Registrants)

3Ms cumulative obligation for such 12(b) benefits ($132,000,000) increases in the amount of $9,100,000 per year for the first 10 years and $8,200,000 per year for the next 5 years (less amounts paid by it for explantation expenses of Other Registrants)

(c) The obligations to pay benefits under 13 based on post 8/84 McGhan implants are divided between McGhan (20%), 3M (40%), and Union Carbide (40%).

(1) Their respective obligations to make payments to Current Claimants are not subject to any maximum limitations.

(2) As explained in 13(e), their obligations to make payments under 13 (other than to Current Claimants as explained in 13(d)) are subject to certain limitations; namely, a maximum of $30,000,000, with their respective obligations for such benefits being as follows:

McGhans cumulative obligation for such benefits ($6,000,000) increases in the amount of $400,000 per year for 15 years (less the amount, if any, that its payments to Current Claimants based on post 8/84 McGhan implants exceed $38,400,000)

3Ms cumulative obligation for such benefits ($12,000,000) increases in the amount of $800,000 per year for 15 years (less the amount, if any, that its payments to Current Claimants based on post 8/84 McGhan implants exceed $76,800,000)

Union Carbides cumulative obligation for such benefits ($12,000,000) increases in the amount of $800,000 per year for 15 years (less the amount, if any, that its payments to Current Claimants based on post 8/84 McGhan implants exceed $76,800,000)

(d) The settling defendants are to pay into the fund established by the Court and maintained by the Escrow Agent such amounts as, from time to time during the 15-year period of the program, are estimated by the Court with the assistance of the Claims Office and the Escrow Agent to be needed (after considering undistributed funds previously contributed to the fund by that defendant and the limitations under (b) and (c) above) to pay benefits (or installments) for which that settling defendant will become obligated to pay during the next 3 months. For further information concerning the fund, see 31.

(e) If the cumulative limitations stated in (b) and (c) above result in any year in a participant (other than a Late Registrant) not being paid the full amount (or installment) shown in the schedule, then such person would at that time have the option either (1) to accept a reduced amount based on the defendants obligated payment (with a carry forward of the unpaid portion for potential payment in future years if within the defendants obligated payments) or (2) to opt out from the settlement, with the rights to pursue litigation against the settling defendants for compensatory damages (but not punitive or statutory multiple damages). Participants electing to opt out (i) must first return any amounts previously paid

under the program (other than for explantation expenses or as an Advance Payment) and (ii) shall be given the opportunity, if they so elect, to participate in procedures to be established by the Court, in an effort to resolve their claims.

(f) If a participants claims against one settling defendant have been released or resolved by final judgment, she will be paid only the prorated benefits due from other settling defendants with respect to which her claims have not been released or resolved by final judgment.

21. **Pre-Existing Diseases; Successive Claims**.

(a) For claims under the revised settlement based on the revised disease criteria (Exhibit E1)—

(1) benefits may not be obtained for a disease or condition if the qualifying symptoms existed before the date of the first implantation; and

(2) a claimant receiving benefits under the Long-term Benefit Schedule may make an additional claim during the 15 years of the program if, as a result of additional symptoms, she can establish that she is entitled to a higher level of compensation either because of a new disease or symptomology or because of an increase in the compensation level. In such event, amounts previously paid will be subtracted from the amount otherwise payable for the new condition.

(b) For claims under the revised settlement based on the disease and disability/severity schedule of the global settlement, the provisions stated in the original notice govern the effect of symptoms and disabilities that existed before the claimants first breast implant. Under those provisions, no symptom is considered for purposes of establishing ACTD if it existed before the date of first implantation. A participant who, before her first breast implant, had another covered disease listed on the original disease schedule would, if the benefit level based on the disease or disability/severity increased after that implant, be eligible for benefits measured by the difference between the amount payable for the new disease and disability/severity level and the amount that would have been payable for the pre-existing condition.

22. **Claims of Health-care Providers.**

(a) Under current terms of the revised settlement program, reimbursement and subrogation-type claims by insurers, governmental agencies, and other health-care providers will, to the extent enforceable under applicable laws, be the responsibility of participants; the settling defendants will have no additional responsibilities to such insurers, agencies, and providers for participants electing to accept benefits under the revised settlement.

(b) However, additional settlement negotiations are presently underway between the settling defendants and many of the private health-benefit providers and insurers which attempted to intervene in the global class settlement to assert reimbursement or subrogation claims. The general nature of these discussions is that, in exchange for additional payments to such providers and insurers by the settling defendants—over and above their obligations to pay benefits to participants under the revised settlement—such providers and insurers would agree not to pursue reimbursement or subrogation claims against implant recipients participating in the revised settlement. As of the printing of this Notice, these discussions have not resulted in a final agreement approved by those parties, but they are sufficiently promising as to justify advising eligible participants of this potential supplemental agreement that would be of substantial benefit under the revised settlement program to many implant recipients. Updated information regarding the status of these negotiations will, when available, be posted on the Claims Office recorded-message telephone line (800-887-6828); and, if the negotiations are successful, you will be advised of the details in the Notification of Status letter to be sent to you by the Claims Office.

23. **Releases.**

(a) Eligible implant recipients who do not timely opt out will for themselves (and for their personal representatives and family members with respect to representative or derivative claims) waive and release, except as provided in 20(e), their rights to institute or pursue breast-implant related claims against the Settling Defendants and Released Parties identified in Exhibit B1.

(b) Claims against Dow Corning and other manufacturers, distributors, or suppliers of breast implants or component parts of such implants—or against doctors, hospitals, or other health-care providers —not listed in Exhibit B1 are not part of the revised settlement and are not released or dismissed. Claims against Mentor, Bioplasty, and Dow Corning may, however, be barred or restricted as a result of prior settlements or bankruptcy proceedings, as explained in 15-17 above.

24. **Effect of Appeals.** An appeal does not suspend the obligation of settling defendants to make payments under 12(a) or, upon receiving an executed standard-form release, under 12(c) or 12(d). Depending on the issues raised, an appeal may suspend the obligation of defendants to make payments under 13 and (unless a mutually satisfactory release is executed) under 12(b).

25. **Defendants' Position; Inadmissibility of Settlement.**

(a) Although agreeing to the revised settlement, the settling defendants continue to deny any wrongdoing or any legal liability of any kind. They have agreed to the

revised 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 cases that might be filed in the future. These 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 by expediting the time for resolving claims and that, by taking advantage of the potential savings in "transaction costs" resulting from a class settlement, the amounts actually paid to many participants under the settlement would, in their opinion, exceed recoveries that might be obtained through individual claims and lawsuits.

(b) Establishment of and negotiations leading to the revised settlement program, and Claims Office determinations and payments under the program, do not constitute any admission by the settling defendants of fault, liability, or damages and will not be admissible in evidence in any proceeding for such purposes or as evidence of ownership, control, agency, or relationship between the settling defendants and the released parties in the event an implant recipient proceeds with litigation against the defendants (except that any judgment obtained by such a person will be reduced by any payment under this settlement).

26. **Incorporation of Terms of Global Settlement.** The revised settlement program implements paragraph 18 of the notice of the global settlement by reducing—for those eligible to participate—the extent of ratcheting that would otherwise occur and by preserving—for those not eligible to participate—their rights to opt out of the class (while providing an extension of the period during which statutes of limitation and repose would be suspended). Except to the extent modified by or inconsistent with the terms of this Notice, the settlement terms announced in the April 1994 notice (including, for example, provisions relating to contribution and indemnification claims against the settling defendants and released parties) remain in effect and govern rights, obligations, and options. The benefits provided under the revised settlement supersede and are in lieu of all benefits that participants and their attorneys might have had under the global settlement. The Court retains general powers to administer and implement the settlement, including the power to interpret the terms of the settlement and to resolve on an equitable basis conflicting claims to benefits arising because of death of a participant or asserted assignments or liens relating to payment of benefits.

ATTORNEYS' FEES AND EXPENSES

27. **Privately-retained Counsel.** Fees and expenses of attorneys individually retained by Lindsey class members who have not previously opted out, whether in presenting claims under the global settlement, or in presenting claims under the revised settlement, or in instituting or pursuing claims as new opt-outs will be borne by such persons based on applicable state law and the individual arrangements made between them and their attorneys, but subject to certain limitations indicated below.

(a) The fees charged by individually-retained attorneys to an implant recipient who accepts the terms of the revised settlement shall not exceed the sum of—

(1) 10% of the first $10,000 paid to such participant under the settlement;

(2) 22.5% of the next $40,000 paid to such participant under the settlement; and

(3) 30% of the amount in excess of $50,000 paid to such participant under the settlement.

(b) Amounts paid to or on behalf of participants as explantation benefits shall not be counted as amounts paid to a participant for purposes of calculating the above limitations.

(c) The Court reserves the power to establish additional standards and limitations affecting the expenses that individually-retained attorneys may charge those participating in the revised settlement.

(d) Benefits payable to participants under 12, 13, and 14 shall not be subject to any reduction for fees and expenses of class counsel for representing the Lindsey class or for other common benefit services (or for administrative expenses of the Claims Office and others in implementing the revised settlement).

28. **Funding of Common Benefit Fees and Expenses.** Order No. 13 was entered in CV92-P-10000-S in July 1993 in order to provide for the fair and equitable sharing among breast-implant recipients who presented claims in federal court of the cost of the special services performed, and expenses incurred, by attorneys acting for the common benefit of all such claimants. Services in conducting common discovery, for example, would be beneficial not only to implant recipients who later chose to pursue litigation, but also to those who later accepted a settlement offer prompted at least in part by the existence of such discovery.

(a) As a means for complying with Order No. 13, the settling defendants under the revised settlement program will pay into the previously established fund an amount equal to 6% of the amounts paid under 12, 13, and 14. These payments will be paid as a surcharge and will not reduce the amounts payable to participants under 12, 13, or 14.

(b) Order No. 13 continues in place, and will continue to govern the resolution, whether by trial or settlement, of breast-implant claims of persons who do

not accept (or are not eligible to participate in) the revised settlement, but who either were members of the Lindsey class (and did not exercise their initial right to opt out) or, although not members of the Lindsey class (whether because they were ineligible or because they exercised their initial right to opt out) now or in the future have breast-implant claims that are filed in or properly removed to federal court. What this means is that 6% of the gross monetary recovery obtained by such persons, whether by trial or settlement, is to be withheld and paid into the common-benefit expense fund.

(c) Under terms of Order No. 13, if the amounts paid into the fund exceed the amounts ultimately approved by the Court as proper charges against the fund, the excess will be distributed to implant recipients on a pro-rata basis as the Court determines to be fair and equitable.

29. **Employment of Attorneys.** You may retain an attorney of your own choice for advice concerning your rights or to provide services either in presenting a claim under the revised settlement or in instituting litigation, but you will be responsible for the fees and expenses of such attorney as explained in 27. You are not required, however, to have private counsel in order to submit claims under the revised settlement.

CLAIMS ADMINISTRATION

30. **Claims Office.** The Claims Office will continue to process and evaluate registrations and claims as expeditiously as possible, but may give priority of consideration to claims by claimants who, through Proof of Manufacturer forms, indicate they may have had a Bristol, Baxter, 3M, or post 8/84 McGhan implant (with particular priority to claims by those who have waived Second Opt-Out Rights) and may defer consideration of submissions by those who appear to be ineligible under the revised settlement program.

(a) As claims are processed and evaluated, the Claims Office will send each person a Notification of Status indicating whether her proof of manufacturer identification is satisfactory; whether she is classified as a Current Claimant, Other Registrant, or Late Registrant; whether, if a Current Claimant, any documentation submitted in support of a rupture supplement is satisfactory; whether there are any deficiencies in the submission; and whether there is a deadline for submitting supplemental documentation relating to deficiencies. If there are deficiencies in any of the materials that are subject to correction, the Notification will so advise. This Notification, which triggers the opt out period under 7(c), will be sent to the last address provided to the Claims Office, with a copy to the persons attorney if one has been indicated.

(b) The Claims Office will continue to implement procedures designed to detect and prevent payment of fraudulent claims. 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.

(c) Under its plenary responsibilities to assure an acceptable level of reliability and quality control of claims, the Claims Office may require, without expense to the claimant, an examination or review by a physician or laboratory selected by the Claims Office.

(d) Expenses of the Claims Office will continue to be paid from the funds initially provided under terms of the global settlement, with such supplemental contributions from the settling defendants as, during the 15-year period of the program, the Court determines to be necessary for such purposes and without reducing the benefits payable to participants under the revised settlement program.

(e) Operations of the Claims Office will be subject to the continuing jurisdiction of the Court and subject to Court review.

31. **Fund Administration.** The fund into which the settling defendants payments will be made is a continuation of the MDL 926 Settlement Fund established under Order No. 15, with Texas as its domicile, location, and place of creation and administration, and with eligible participants being its beneficiaries. Ann Tyrrell Cochran, Claims Administrator, has general responsibilities for collecting, collating, processing, evaluating, and quantifying claims. Edgar C. Gentle, III, has been designated as Escrow Agent and as Chairman of the Investment Committee, with the duties approved by the Court by order dated November 23, 1994 (as modified by further Court orders). Also on the Investment Committee are Don Springmeyer (plaintiffs designee) and Todd M. Poland (defendants designee).

32. **Filing of Elections, Forms, and Documentation.**

(a) All elections, forms, and documentation described in this Notice are to be filed with the Claims Office, and not with the Court. Please do not send courtesy copies to the Court. Please do not send additional copies of materials with a request for acknowledgment—handling of duplicate copies only results in increased administrative costs and delay.

(b) Deadlines for providing elections, forms, or documentation to the Claims Office are to be determined by the date such items are actually received in the Claims

Office, rather than date of mailing. Facsimile transmissions are not acceptable.

33. **Documentation.** Current Claimants, Other Registrants, and Late Registrants may, throughout the 15-year period of the program, submit documentation respecting manufacturer identification, medical conditions and disability, and other matters affecting eligibility or entitlement to benefits in accordance with governing procedures. The Claims Office may, however, establish regulations relating to the submission of medical documentation and setting reasonable periods at which to conduct evaluations or re-evaluations of a persons eligibility and benefits based on supplemental submissions and for submission of supplemental documentation after notice of deficiencies. Initial documentation showing manufacturer identification must be presented to the Claims Office no later than December 16, 1996, by participants claiming status as Current Claimants, as must documentation of a claim for rupture supplement under 12(c)(2).

34. **Court Review of Claims Office Determinations.** A claimant dissatisfied with the decision made by Claims Officers may appeal to the Claims Administrator and, if still dissatisfied, may seek a further review, on the basis of the record evidence, by the Court (or a person designated by the Court to conduct such review). No other appeals or reviews are permitted, and the settling defendants will have no right of appeal or review from determinations made by the Claims Office.

ADDITIONAL INFORMATION

35. **Court Filings and Other Documents.** 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 revised settlement program and the Courts order approving transmittal of this offer to class members) by payment of the prescribed charges. The Clerk's office is not permitted to give legal advice. The Claims Office (800-600-0311 and 713-951-9106) is authorized to answer administrative and clerical inquiries relating to claims and the claims process, but not to give legal advice. Contact the Claims Office if you need a copy of the Disease Schedule that was transmitted with the original global settlement notice.

36. **Assistance.** You should save this Notice for reference concerning your rights and benefits, the claims process, the important deadlines, and telephone numbers. In addition to the limited information available from the Claims Office (see 35 above), you may obtain further information concerning the revised 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 consulting an attorney of your own choice. (Note: the advice given by private counsel is not monitored, reviewed, or supervised by the Court.)

by watching the cable TV program on Court TV on Wednesday, January 24, 1996, at 9 pm CST. (Note: this program, intended to complement the written notice, will provide general information only and will not provide legal advice regarding particular claims.)

by attending one of the regional meetings or participating in the telephone conference to be scheduled by the Court. See insert accompanying this Notice. (Note: these meetings and this conference will provide general information only, and will not provide legal advice regarding particular claims.)

by requesting legal assistance from Settlement Class Counsel by calling 513-651-9770. (Note: although this program has been approved by the Court, the Court does not monitor, review, or supervise the advice given by such persons.)

by contacting any of the various "support groups" formed to provide assistance to breast implant recipients and their families. (Note: these support groups operate independently of the Court, and their communications and advice are not monitored, reviewed, or supervised by the Court.)

This Notice has been approved by Judge Pointer for distribution to breast-implant recipients as an official notice of the Court.

PERRY D. MATHIS
Clerk of the Court

ATTACHED EXHIBITS:

- B1 List of Settling Defendants and Released Parties
- E1 Revised Disease/Symptomology Definitions and Compensation Levels
- G List of Implant Brands and Manufacturers

FORMS (separate documents, but included in mailing):

- Election Form
- Proof of Manufacturer Form
- Explantation Claim Form
- Rupture Claim Form

EXHIBIT B1—Revised Settlement

Settling Defendants

Baxter Healthcare Corp.
Baxter International Inc.
Bristol-Myers Squibb Co.
Inamed Corp.

McGhan Medical Corp. (Calif. Corp.)
McGhan Medical Corp. (Dela. Corp.)
a/k/a McGhan Medical/3M
Medical Engineering Corp.

Minnesota Mining & Manufacturing Co.
a/k/a 3M Company
Union Carbide Chemical & Plastics Co.
Union Carbide Corporation

Released Parties

Aesthetech Corp.
American Heyer-Schulte Corp.
f/k/a Heyer-Schulte Corp.
American Hospital Supply Corp.
Franklin L. Ashley
Baxter Acquisition Sub., Inc.
Baxter Corporation
Baxter Travenol Laboratories, Inc.
Baxter World Trade Corp.
Lawrence Birnbaum
Robert Bishop
Bristol Myers Squibb Canada, Inc.
Cabot Medical Corp.
Angelo Cappozzi
CBI Medical, Inc. a/k/a
CBI Medical Electronics, Inc.
CooperSurgical, Inc.
CooperVision, Inc.
CUI Corporation
CVI Merger Corp.
CV Sub 1987, Inc.
Edwards Laboratories, Inc.
Derwood Faries
Jack Fisher
Vicki Galati

John Hartley
Robert J. Helbling
Inamed BV
Inamed Development Co.
Richard P. Jobe
Real Lappierre
Linvatec Corp.
Harold Markham
Jacqueline Markham
Lottie Markham
Markham Medical Assn
Markham Medical International, Inc.
Markham Surgical Specialties
Mark/M Surgical
Mark/M Resources, Inc.
G. Patrick Maxwell
Anita Kost McAteer
Donald K. McGhan
McGhan Limited
McGhan NuSil Corporation
MEC Subsidiary Corp. f/k/a
Surgitek, Inc.
Natural Y Surgical Specialties, Inc.
NuSil Corp.
NuSil Technology
W. John Pangman, II

Vincent R. Pennisi
Poly Plastic Silicone Products, Inc.
Schulte Medical Products
Diran M. Seropian
Paul Silverstein
Sirod Corp.
Scott Spear
Specialty Silicone Fabrications, Inc.
H. E. Sterling
Summit Medical Corp.
Surgitek, Inc.
Kuros Tabari
John P. Tebbetts
Travenol Laboratories, Inc.
Kurt Wagner
Edward Weck, Inc.
Edward Weck & Company, Inc.
John L. Williams
Wilshire Advanced Materials, Inc.
Wilshire Foam Products, Inc.
Wilshire Technologies, Inc.
Zimmer, Inc.
Zimmer International, Ltd.
3M Australia Pty
3M Canada, Inc.

The "Released Parties" mean the above-listed individuals and entities, the above-listed Settling Defendants, and their respective present and former foreign and domestic parents, subsidiaries, and affiliates; their respective foreign and domestic successors,

predecessors, 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, (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, and (3) does not include such individuals and entities to the extent their alleged liability does not arise out of any affiliation or relationship with the Settling Defendants.

EXHIBIT E1 — Revised Disease/Symptomology Definitions and Compensation Levels

I. General

A. A claimant must file with the Claims Office all medical records establishing the required findings or laboratory abnormalities. Qualifying findings must have occurred within a single 24-month period within the five years immediately preceding the submission of the claim. (Findings supplemented in response to a deficiency letter sent by the Claims Office do not have to fall within the 24-month period outlined above.)

B. If exclusions are noted for a required finding, the physician making the finding or ordering the test must affirmatively state that those listed exclusions are not present. The physician recording a GCTS finding or making a disease diagnosis must also affirmatively state that the qualifying symptoms did not exist before the date of first implantation. (This statement can be based upon patient history so long as consistent with medical records in the physicians possession.) Failure to make these affirmative statements will result in a deficiency letter. All underlying office charts, radiology/pathology reports, and test results must be supplied to the Claims Office.

II. Scleroderma (SS)

A claim for scleroderma must include a diagnosis of systemic sclerosis/scleroderma made by a board-certified rheumatologist based upon personal examination of the patient. [Exclusion: localized scleroderma] Supporting medical documentation must affirmatively reveal that the major or at least two of the minor criteria listed below are present:

A. Major criterion: Proximal scleroderma --symmetric thickening, tightening, and induration of the skin of the fingers and the skin proximal to the metacarpophalangeal or metatarsophalangeal joints. The changes may affect the entire extremity, face, neck, and trunk (thorax and abdomen). Description of this criterion is adequate if the board-certified rheumatologist records that physical examination of the patient revealed scleroderma skin thickening, and adequately describes the parts of the body where that thickened skin was found.

B. Minor Criteria:

1. Sclerodactyly: Above-indicated skin changes limited to the fingers.

2. Digital pitting scars or loss of substance from the finger pad: Depressed areas at tips of fingers or loss of digital pad tissue as a result of ischemia.

3. Bibasilar pulmonary fibrosis: Bilateral reticular pattern of linear or lineonodular densities most pronounced in basilar portions of the lungs on standard chest roentgenogram; may assume appearance of diffuse mottling or "honeycomb lung." These changes should not be attributable to primary lung disease.

Compensation Levels:

A. Death resulting from SS, or severe chronic renal involvement manifested by a glomerular filtration rate of less than 50% of the age- and gender-adjusted norm, as measured by an adequate 24-hour urine specimen collection.

B. Clinically significant cardio-pulmonary manifestations of scleroderma[2] or proximal scleroderma on the trunk (thorax and abdomen).

C. A diagnosis of scleroderma in accordance with the above criteria that does not involve the findings in A or B above.

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[2] As manifested by interstitial fibrosis (based upon physical examination findings and abnormalities seen on chest x-ray or chest CT) or pulmonary hypertension (based upon physical examination findings and 2-D Echo doppler or angiography with hemodynamic measurements showing pulmonary artery pressures of greater than 25 TORR).

III. Lupus (SLE)

A claim for SLE must include a diagnosis of SLE (lupus) made by a board-certified rheumatologist based upon personal examination of the patient. [Exclusion: mild lupus (SLE not requiring regular medical attention including doctor visits and regular prescription medications)] Supporting medical documentation must affirmatively reveal that at least four of the following 11 criteria are present:

Criterion	Definition
1. Malar rash	Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds
2. Discoid rash	Erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions
3. Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by patient history or physician observation
4. Oral ulcers	Oral or nasopharyngeal ulceration, usually painless, observed by a physician
5. Arthritis	Nonerosive arthritis involving two or more peripheral joints, characterized by tenderness, swelling, or effusion [exclusion: erosive arthritis]
6. Serositis	a) Pleuritis -- convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion, or b) Pericarditis -- documented by ECG or rub or evidence of pericardial effusion
7. Renal disorder	a) Persistent proteinuria greater than 0.5 grams per day or greater than 3+ if quantitation not performed, or b) Cellular casts -- may be red cell, hemoglobin, granular, tubular, or mixed
8. Neurologic disorder	Seizures -- in the absence of offending drugs or known metabolic derangements, *e.g.*, uremia, ketoacidosis, or electrolyte imbalance
9. Hematologic disorder	a) Hemolytic anemia -- with reticulocytosis, or b) Leukopenia -- less than 4,000/mm total on two or more occasions, or c) Lymphopenia -- less than 1,500/mm on two or more occasions, or d) Thrombocytopenia -- less than 100,000/mm in the absence of offending drugs
10. Immunologic disorder	a) Positive LE cell preparation, or b) Anti-DNA: antibody to native DNA in abnormal titer, or c) Anti-Sm: presence of antibody to Sm nuclear antigen, or d) False positive serologic test for syphilis known to be positive for at least 6 months and confirmed by Treponema pallidum immobilization or fluorescent treponemal antibody absorption test
11. Antinuclear antibody	An abnormal titer or antinuclear antibody by immunofluorescence or an equivalent assay at any point in time and in the absence of drugs known to be associated with "drug-induced lupus" syndrome

Compensation Levels:

A. Death resulting from SLE, or severe chronic renal involvement manifested by a glomerular filtration rate of less than 50% of the age- and gender-adjusted norm, as measured by an adequate 24-hour urine specimen collection.

B. SLE with involvement of one or more of the following: glomerulonephritis, seizures in the absence of offending drugs or known metabolic derangements, Lupus Psychosis, myocarditis, pneumonitis, thrombocytopenic purpura, hemolytic anemia (with hemoglobin of 10 grams or less), severe granulocytopenia (with a total white cell count less than 2000), or mesenteric vasculitis.

C. A diagnosis of lupus in accordance with the above criteria that does not involve the findings in A or B above. (Default compensation level.)

IV. Polymyositis (PM) /Dermatomyositis (DM)

A claim for polymyositis or dermatomyositis must include a diagnosis of the disease made by a board-certified rheumatologist based upon personal examination of the patient. Supporting medical documentation must affirmatively reveal that the following criteria are present:

-for polymyositis, the first four criteria without the rash;
-for dermatomyositis, three of the first four criteria, plus the rash (#5).

Criteria:

1. symmetrical proximal muscle weakness;
2. EMG changes characteristic of myositis including (a) short duration, small, low-amplitude polyphasic potential, (b) fibrillation potentials, (c) bizarre high-frequency repetitive discharges;
3. elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT, and LDH);
4. 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;
5. 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 Gottons papules.

Compensation Level:

All confirmed PM/DM diagnoses will be compensated at the GCTS/PM/DM--A level.

V. General Connective Tissue Symptoms (GCTS):

A claim for GCTS does not have to include a diagnosis for "General Connective Tissue Symptoms," but the medical documentation must establish that the combination of findings listed below are present. [Exclusion: classical rheumatoid arthritis diagnosed in accordance with the revised 1982 ACR classification criteria.]

For compensation at Level A:

(1) any two findings from Group I; or
(2) any three non-duplicative findings from Group I or Group II.

For compensation at Level B:

(1) one finding from Group I plus any four non-duplicative findings from Group II or Group III; or
(2) two findings from Group II plus one non-duplicative finding from Group III.

The following duplications exist on the list of findings:

-rashes (#3 and #8)
-sicca (#2 and #12)
-serological abnormalities (#4 and #9)

In addition to the medical verification of the required findings, a claim for GCTS must include the affirmative physician statements outlined in General Guidelines above.

GROUP I FINDINGS

1. Polyarthritis, defined as synovial swelling and tenderness in three or more joints in at least two different joint groups observed on more than one physical examination by a board-certified physician and persisting for more than six weeks. [Exclusion: osteoarthritis.]

2. Keratoconjunctivitis Sicca, defined as subjective complaints of dry eyes and/or dry mouth, accompanied (a) in the case of dry eyes, by either (i) a Schirmers test less than 8 mm wetting per five minutes or (ii) a positive Rose-Bengal or fluorescein staining of cornea and conjunctiva; or (b) in the case of dry mouth, by an abnormal biopsy of the minor salivary gland (focus score of greater than or equal to two based upon average of four evaluable lobules). [Exclusions: drugs known to cause dry eyes and/or dry mouth, and dry eyes caused by contact lenses.]

3. Any of the following immune-mediated skin changes or rashes, observed by a board-certified rheumatologist or board-certified dermatologist: (a) biopsy-proven discoid lupus; (b) biopsy-proven subacute cutaneous lupus; (c) malar rash --fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds [exclusion: rosacea or redness caused by sunburn]; or (d) biopsy-proven vasculitic skin rash.

GROUP II FINDINGS

4. Positive ANA greater than or equal to 1:40 (using Hep2), on two separate occasions separated by at least two months and accompanied by at least one test showing decreased complement levels of C3 and C4; or a positive ANA greater than or equal to 1:80 (using Hep2) on two separate occasions separated by at least two months. All such findings must be outside of the performing laboratorys reference ranges.

5. Abnormal cardiopulmonary symptoms, defined as (a) pericarditis documented by pericardial friction rub and characteristic echocardiogram findings (as reported by a board-certified radiologist or cardiologist); (b) pleuritic chest pain documented by pleural friction rub on exam and chest x-ray diagnostic of pleural effusion (as reported by a board-certified radiologist); or (c) interstitial lung disease in a non-smoker diagnosed by a board-certified internist or pulmonologist, confirmed by (i) chest x-ray or CT evidence (as reported by a board-certified radiologist) and (ii) pulmonary function testing abnormalities defined as decreased DLCO less than 80% of predicted.

6. Myositis or myopathy, defined as any two of the following: (a) EMG changes characteristic of myositis: short duration, small, low amplitude polyphasic potential; fibrillation potentials; and bizarre high-frequency repetitive discharges; (b) abnormally elevated CPK or adolase from the muscle (outside of the performing laboratorys reference ranges) on two separate occasions at least six weeks apart. (If the level of the initial test is three times normal or greater, one test would be sufficient.) [Exclusions: injections, trauma, hypothyroidism, prolonged exercise, or drugs known to cause abnormal CPK or aldolase]; or (c) muscle biopsy (at a site that has not undergone EMG testing) showing evidence of necrosis of type 1 and 2 muscle fibers, phagocytosis, and an interstitial or perivascular inflammatory response interpreted as characteristic of myositis or myopathy by a pathologist.

7. Peripheral neuropathy or polyneuropathy, diagnosed by a board-certified neurologist, confirmed by (a) objective loss of sensation to pinprick, vibration, touch, or position; (b) symmetrical distal muscle weakness; (c) tingling and/or burning pain in the extremities; or (d) loss of tendon reflex, plus nerve conduction testing abnormality diagnostic of peripheral neuropathy or polyneuropathy recorded from a site that has not undergone neural or muscular biopsy. [Exclusions: thyroid disease, antineoplastic treatment, alcoholism or other drug dependencies, diabetes, or infectious disease within the last three months preceding the diagnosis.]

GROUP III FINDINGS

8. Other immune-mediated skin changes or rashes, observed by a board-certified rheumatologist or board-certified dermatologist: (a) livedo reticullaris; (b) lilac (heliotrope), erythematous scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli; (c) Gottons sign, pink to violaceous scaling areas typically found over the knuckles, elbows, and knees; or (d) diffuse petechiae.

9. Any of the following serologic abnormalities: (a) ANA greater than or equal to 1:40 (using Hep2) on two separate occasions separated by at least two months; (b) one or more positive ANA profile: Anti-DNA, SSA SSB, RNP, SM, Scl-70, centromere, Jo-1 PM-Scl, or double-stranded DNA (using ELISA with standard cutoffs); (c) anti-microsomal, anti-cardiolipin, or RF greater than or equal to 1:80.

10. Raynauds phenomenon, evidenced by a physician-observed two (cold-related) color change as a progression, or by physician observation of evidence of cold-related vasospasm, or by physician observation of digital ulceration resulting from Raynauds phenomenon.

11. Myalgias, defined as tenderness to palpation, performed by a physician, in at least three muscles, each persisting for at least six months.

12. Dry mouth, subjective complaints of dry mouth accompanied by decreased parotid flow rate using Lashley cups with less than 0.5 ml per five minutes. [Exclusion: drugs known to cause dry mouth]