UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re: SILICONE GEL BREAST IMPLANT
PRODUCTS LIABILITY LITIGATION
(MDL 926)

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Master File No. CV 92-P-10000-S

Civil Action No. CV 94-P-11558-S
HEIDI LINDSEY, et al.,
Plaintiffs; -vs.-DOW
CORNING CORPORATION, et al.,
Defendants.
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ORDER No. 27
(Approval of Revised Settlement Program and Injunctions)

It is hereby ORDERED as follows:

1. Attached to this order is the "Bristol, Baxter, 3M, McGhan & Union Carbide Revised Settlement Program," which has been submitted to the Court by such defendants in accordance with paragraph 18 of the notice that described the settlement which was approved on September 1, 1994 ("the Settlement").

(a) The Court concludes that, for eligible participants, this revised settlement program reduces the amount of "ratcheting" that would otherwise occur under terms of the Settlement and that, for persons not eligible to participate, it preserves their rights under the Settlement to opt out and, indeed, by providing some options to continue and extend the suspension of statutes of limitation and repose, it partially enhances those rights. Acting under its reserved general supervisory powers to administer the terms of the Settlement, the Court approves this program (except where inconsistent with the provisions contained in the attached Notice) as a revision in benefits authorized under paragraph 18 of the notice previously sent regarding the Settlement.

(b) Also attached to this order are the primary components of a new Notice package that, pursuant to terms of the Settlement, shall, as soon as printed, be sent to all persons who have registered with the Claims Office. It will also be sent to all other persons who, although not having registered with the Claims Office, nevertheless have given their names and addresses to the Court or to the Claims Office as possibly being breast-implant recipients, including those who have previously opted out. The provisions of the attached Notice are adopted as part of this order and, in the event of inconsistencies, the provisions of the attached Notice supersede and modify those in the revised settlement program.

(1) Where class members have indicated that they have an attorney and have asked that further information be sent only to such attorney, the Claims Office will endeavor to send the Notice package only to the attorney.

(2) Where class members have indicated they have an attorney but have not specifically requested that further information be sent only to their attorney, the Claims Office will endeavor to send the Notice package both to the class member and to the attorney.

(3) Where class members have not indicated they have an attorney, the Claims Office will endeavor to send the Notice package to the class member.

(4) Although the foregoing notice program is in accord with the requirements of the Settlement and satisfies due process requirements, if any of the settling defendants want to give further additional notice to class members regarding the revised settlement program beyond the written notice and the explanatory television program, regional orientation meetings, and national telephone conference described in the Notice package, they may do so, but must first obtain the Court's prior approval as to the method and contents of such additional notice.

(c) In a subsequent order, the Court will approve a Question and Answer Booklet and Schedule G, which are to be mailed as part of the Notice package to Lindsey class members and others identified as possibly being breast-implant recipients. The Court reserves the right to make grammatical, typographical, and other non-substantive changes in the Notice package during the printing process.

(d) Class members should not use copies of the forms contained in the attached Notice package to make elections regarding their rights and options. Rather, they should wait until these forms—with identifying name, address, social security (or MDL registration) number, and date of birth information preprinted on the Election Forms to assist in electronic "scanning" of the Election Forms—are, with the Question and Answer Booklet and Schedule G, mailed to class members.

2. The injunction contained in the Settlement enjoining Lindsey class members from instituting, asserting, or prosecuting claims against any of the entities and persons named in Exhibit B to the Settlement as Settling Defendants or Released Parties for personal injury or death allegedly due in whole or part to any breast implant remains in effect, except as follows:

(a) Such persons—whether or not they elect to opt out of the Lindsey class or to accept or reject the terms of the revised settlement program—may, subject to the automatic stay provided by bankruptcy law, now file and pursue claims against Dow Corning under and pursuant to procedures for presenting claims against Dow Corning as set by the Bankruptcy Court for the United States District Court for the Eastern District of Michigan. Any suspension of the running of statutes of limitation and repose following the

filing of bankruptcy proceedings by Dow Corning is governed by applicable provisions of bankruptcy law.

(b) Such persons—whether or not they elect to opt out of the Lindsey class or to accept or reject the terms of the revised settlement program—are, as a result of earlier bankruptcy proceedings, barred from proceeding with claims against the Bioplasty defendants. Their claims against the Bioplasty defendants will be resolved under the terms of the previously-approved Settlement by this Court and in conjunction with orders of the Bankruptcy Court for the United States District Court for the District of Minnesota.

(c) Such persons—whether or not they elect to opt out of the Lindsey class or to accept or reject the terms of the revised settlement program—are, as a result of an earlier mandatory non-opt-out class settlement which became final on September 10, 1993, barred from proceeding with claims against the Mentor defendants relating to breast implants implanted before June 1, 1993. Their claims against the Mentor defendants relating to such implants will be resolved under the terms of the previously-approved mandatory class settlement.

(d) Such persons may, upon opting out of the Lindsey class before being sent the Notification of Status letter by the Claims Office, file and pursue claims against such Settling Defendants and Released Parties (other than as described in (a) - (c) above), with the running of statutes of limitation and repose with respect to such entities and persons resuming 30 days after the Claims Office receives such opt-out election.

(e) Such persons may, upon opting out within 45 days after being sent the Notification of Status letter by the Claims Office, file and pursue claims against such Settling Defendants and Released Parties (other than as described in (a) - (c) above), with the running of statutes of limitation and repose with respect to such entities and persons resuming 6 months after the Claims Office receives such opt-out election.

(f) Such persons who waive their opt-out rights under ¶ 7 of the attached Notice or do not exercise such opt-out rights within 45 days after being sent the Notification of Status letter by the Claims Office—

(1) may, upon such rights being waived or expiring, file and pursue claims against such Settling Defendants and Released Parties (other than the entities and persons described in Exhibit B1 of the Notice and other than as described in (a) - (c) above), with the running of statutes of limitation and repose with respect to such entities and persons resuming 30 days after the Claims Office receives such waiver or after such 45-day period expires; and,

(2) if they later have and exercise a right to opt-out under ¶ 20(e) of the attached Notice, may at that time file and pursue claims (other than for punitive or multiple statutory damages) against the entities and persons identified in Schedule B1 of the attached Notice, with the running of statutes of limitation and repose with respect to such entities and persons resuming 30 days after the Claims Office receives such subsequent opt-out election.

(g) Foreign claimants—whether or not they elect to opt out of the Lindsey class—may now file and pursue claims in the administrative or judicial tribunals of their own country. Such foreign claimants also, subject to potential objections based on "forum non conveniens"—

(1) may now file and pursue claims in courts of the United States against such Settling

Defendants and Released Parties (other than the entities and persons described in Exhibit B1 of the Notice and other than as described in (a) - (c) above), with any suspension of statutes of limitation and repose terminating 30 days after being sent the attached Notice; and

(2) may, upon filing an Election to Opt Out with the Claims Office no later than 45 days after being sent the Notification of Status letter by the Claims Office, file and pursue claims in the courts of the United States against the entities and persons identified in Schedule B1 of the attached Notice, with any suspension of statutes of limitation and repose terminating 30 days after the Claims Office receives such opt-out election.

(h) Children of breast-implant recipients may now file and pursue claims against such Settling Defendants and Released Parties (other than as described in (a) - (c) above) respecting their own personal injury or death allegedly due in whole or part to their mother's having had a breast implant. As described in ¶ 19 of the attached Notice, statutes of limitation or repose with respect to such entities and persons are suspended until December 15, 1997, or, if later, in accordance with applicable state law.

Persons who, having previously opted out of the Lindsey class, elect to rejoin the class in order to participate in the revised settlement program will, upon filing the Election Form, be enjoined from instituting, asserting, or prosecuting claims against any of the entities and persons named in Exhibit B1 to the attached Notice for personal injury or death allegedly due in whole or part to any breast implant. If such persons later have and exercise a right to opt out under ¶ 20(e) of the attached Notice, they may at that time file and pursue claims (other than for punitive or multiple statutory damages) against such entities and persons, with statutes of limitation and repose deemed to have been suspended from the time such persons file their Election to rejoin the class until 30 days after such subsequent Opt-Out election is filed with the Claims Office.

3. The Settling Defendants identified in Schedule B1 of the attached Notice are hereby enjoined, pending further order of the Court, from engaging in settlement negotiations and discussions relating to possible resolution of claims by persons who have previously opted out of the Lindsey class or who may hereafter opt out of the Lindsey class except on a case-by-case, individual-claimant basis in cases that were brought by persons who earlier opted out of the Settlement or that may be specifically set for trial or court-sponsored mediation or arbitration. With respect to any such settlement negotiations and discussions that are permitted, the Settling Defendants and such claimants and their counsel are alerted to the provisions of Order No. 13 and ¶ 28(b) of the attached Notice.

4. As with the Settlement approved on September 1, 1994, the court, under Fed. R. Civ. P. 54(b), expressly determines that there is no just reason for delay and expressly directs that this order, upon filing in CV 94-P-11558-S, be deemed as a final judgment.

5. Without deferring or delaying the finality of this order, this court retains exclusive, general, and continuing jurisdiction as needed or appropriate in order to administer, supervise, implement, interpret, or enforce the Settlement, including the investment, conservation, protection, allocation, and distribution of the settlement funds under the revised settlement program.

This the 22nd day of December, 1995.

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

Bristol, Baxter, 3M, McGhan & Union Carbide Revised Settlement Program

A. Eligible participants: A non-foreign class member, as defined in the global settlement, who has or had at least one implant manufactured or distributed by one of the settling defendants (or their predecessors and subsidiaries): Bristol/MEC, Baxter/Heyer-Schulte, 3M,[1] or McGhan.[2]

1. Proof of eligibility is to be provided as specified in I1 below.

2. Persons who would otherwise be eligible to participate but for having previously opted out from the global settlement may participate under the program for "Other Registrants" if, before 12/16/96 and before proceeding to trial against a settling defendant, they withdraw their exclusion and register with the Claims Office.

3. Persons are not eligible to participate if their claims against each of the settling manufacturers from which they have received implants have been released by settlement or resolved by final judgment.[3] (If their claims against a settling defendant have been released or resolved by final judgment but they also have an implant from another settling manufacturer, they may participate and be eligible for prorated benefits paid by the settling defendant(s) with respect to which there is no release or final judgment).

4. Children of breast implant recipients are not eligible with respect to claims of their own personal injury, and such claims are not released by the recipient's being in the class. As under the existing settlement, derivative and representative claims are settled if the recipient participates in the program, and personal representatives may act on behalf of deceased or incompetent class members.

B. Classification of eligible participants:

1. Current Claimants: eligible participants who mailed to the Claims Office (a) by 9/16/94 a signed Registration Form and (b) by 10/17/94 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).

2. Other Registrants: eligible participants (a) who registered with the Claims Office by 3/1/95 but are not Current Claimants under B1 above or (b) who, having previously excluded themselves from the global settlement, withdraw their exclusion and register with the Claims Office by 12/16/96.

3. Late Registrants: all other eligible participants (*i.e.*, all other non-foreign class members with a Bristol, Baxter, 3M or Post-'84 McGhan implant) who are not Current Claimants under B1 or Other Registrants under B2 above but who register with the Claims Office. As under the global settlement, it is anticipated that at some point the court will establish a final deadline for persons to register with the Claims Office.

C. Opt-out Rights of Eligible Participants

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1 For purposes of this Revised Settlement Program, 3M implants are defined as 3M/McGhan implants implanted (or manufactured in whole or in part) before 8/3/84.

2 For purposes of this Revised Settlement Program, Post-'84 McGhan implants are defined as silicone gel implants manufactured at or by McGhan wholly after 8/3/84. McGhan, 3M, and Union Carbide have agreed to provide certain benefits under this Revised Settlement Program to participants who have or had only Post-'84 McGhan implants or who have or had only such implants and implants manufactured by Bioplasty, Cox Uphoff/ CUI or Mentor.

3 Each settling defendant must provide to the Claims Office, by December 15, 1995, a list identifying all such persons.

1. Subject to the limitation in C2 below, any eligible participant may reject the settlement offer by filing an opt-out election that is received by the Claims Office not later than 45 days after date of Notification of status of the participant's registration and claim as provided in I2. Statutes of limitations and repose will remain suspended for 6 months after the Claims Office receives the opt-out election.

2. Late Registrants will not have the opt-out right described in C1 above unless they register with the Claims Office by 4/1/96.

3. Current Claimants and Other Registrants may expedite receipt of the Advance Payments provided in D1 and E3 below by waiving the opt-out right provided in C1 above.

4. Certain ongoing opt-out rights are provided in D2b(2) and E2c below.

D. Benefits for Current Claimants[4]:

1. Advance Payment. A non-refundable advance payment of $5,000 will be paid as soon as the Claims Office determines that a person has not opted out within the time permitted under C1 (or under C3 has waived the remaining time to opt out), is a Current Claimant, and has sufficient manufacturer identification information. Payment will be made without regard to the status of any appeals relating to this settlement and without regard to the existence of any deficiencies in the claim. The $5,000 payment will be credited against other amounts payable to the claimant under the settlement or awarded in a judgment recovered against settling defendants in later litigation,[5] but otherwise is not refundable unless the Claims Office determines the claim to have been fraudulently presented.

2. Compensation. Benefits (less the Advance Payment under D1 above and subject to reduction under F1 below if the claimant also has Dow implants) to be paid to a Current Claimant, at the claimant's election, under either Option One or Option Two.

a. Option One — Fixed Benefits for Current Claimants: A fixed amount (not increased or decreased by later changes in claimant's condition) based on disease definitions and severity/disability categories in the original Disease Schedule (Exhibit D to global settlement). Upon satisfying these criteria (and with satisfactory evidence respecting implant manufacturer identification), a claimant electing this option will be paid according to the following schedule based on the severity/disability level and on whether by 12/16/96 there is appropriate documentation of rupture of a Bristol, Baxter, or 3M implant. Claims will be processed by the Claims Office in accordance with all relevant provisions of the original global settlement.

Option One — Fixed Benefits (Current Claimants Only)

Disability Level	Base Amount		Supplement if rupture	
A	$ 50,000	+ $50,000	=	$100,000
B	$ 20,000	+ $30,000	=	$ 50,000
C or D	$ 10,000	+ $15,000	=	$ 25,000

4 Current Claimants with only Post-'84 McGhan implants (or only Post-'84 McGhan implants plus implants from Bioplasty, Cox Uphoff/CUI or Mentor) will receive only the benefits set forth in D3 below.

5 Under certain conditions claimants may have later rights to opt out and pursue litigation against settling defendants. (See D2b(2)). To exercise such an opt-out right, the claimant would first have to return any amounts previously paid (other than the Advance Payment and explantation payments).

(1) On electing to proceed under Option One, Current Claimants will, upon satisfying the criteria and approval by the Claims Office, be paid the specified amount (less the advance payment) upon full release of all claims against all settling defendants (and other released parties). The obligation of settling defendants to pay both the base amount and the increased amount for ruptures is not affected by the number or amounts of claims or by the number of opt-outs. Payments will be made as soon as the claim is approved and upon execution of a standard-form release, without regard to the pendency of any appeals. A Current Claimant initially qualifying only for the base amount will be paid the rupture supplement (maximum one per claimant) on proof by 12/16/96 of rupture.

(2) Payments of $25,000 or less will be paid in a single lump sum; payments of more than $25,000 will be paid in two equal annual installments.

(3) "Rupture" of a Baxter, Bristol, or 3M implant — which, if documented by 12/16/96, affects benefit levels for Current Claimants under Option One — refers to the failure of the elastomer envelope(s) surrounding a silicone-gel implant to contain the gel (resulting in contact of the gel with the body), not solely as a result of "gel bleed", but due to a tear or other opening in the envelope(s) after implantation and prior to the explantation procedure. To qualify for a rupture supplement, the Claimant must have undergone an explantation operation at which the rupture was confirmed and must submit a contemporaneous operative and/or pathology report (and related statements) documenting the rupture in accordance with the protocol in Exhibit F. For explantations after 1/1/96, the claimant shall use her best efforts to cause the removed implant to be preserved and, if requested by the Claims Office, to provide the removed implant to the Claims Office or to an examiner designated by the Claims Office to resolve or report on the issue of rupture.

b. Option Two: As an alternative to Option One, Current Claimants may choose Option Two for long-term benefits under E2 below. Benefits under Option Two depend on satisfying during the 15 year period of the program the more restricted disease and severity criteria specified in Exhibit E (rather than the disease and severity/disability categories specified in the Disease Schedule attached as Exhibit D to the original global settlement notice). Upon satisfying these criteria and approval by the Claims Office, the claimant will be paid in accordance with the schedule shown in E2 below, depending on the new disease/severity criteria.

(1) The obligation of defendants to pay approved SS/SLE benefits under Option Two to a Current Claimant whose claim for SS/SLE under the global settlement would have been either approved or treated as having only minor deficiencies (and to pay approved GCTS/PM/DM benefits under Option Two to a Current Claimant with any claim that under the global settlement would have been approved or treated as having only minor deficiencies) is not affected by the number or amounts of claims, by the number of opt-outs, or by the maximum cumulative obligations of settling defendants under E2c below; and, upon execution of mutually satisfactory releases with individual claimants, the settling defendants will pay these amounts without regard to the pendency of any appeals relating to this settlement.

(2) Current Claimants who elect and qualify for compensation under Option Two will be treated as also eligible, during the 15 years of the program, for additional compensation in the same manner as for Other Registrants and subject to the provisions of E2c. That is, if a Current Claimant who receives a payment under Option Two later develops during the 15 years of the program a condition that would entitle her to a larger amount, she would at that time be entitled to the difference between the new compensation amount and any amount previously paid. If at that time she does not receive this increase because of the maximum cumulative obligations of the defendants under E2c below, she would have the same opt-out right as stated in E2c.

(3) Current Claimants electing Option Two may, at any time during the 15 year period of the program before being awarded benefits under Option Two, elect to return to Option One but with a 25% reduction in the amount they would otherwise receive under Option One.

3. Post-'84 McGhan implants. Current Claimants with only Post-'84 McGhan implants (or only Post-'84 McGhan implants plus implants from Bioplasty, Cox Uphoff/CUI or Mentor) shall be eligible for Option One benefits as set forth in D2a above, excluding rupture supplements. Payments to such claimants are not payable until 30 days after the Court's Final Order with respect to this Revised Settlement Program becomes Final as defined in the global settlement. Thereafter, payments will be made to claimants with approved claims upon execution of a standard form release.

E. General Benefits for Participants

1. Explantation expenses. Although not recommending explantation absent some specific medical reason to do so, the settling defendants will pay $3,000 to Current Claimants and Other Registrants who, after 4/1/94 and within the 15 years of the program, have a Bristol, Baxter, or 3M implant removed (without the surgery also involving reimplantation of a silicone-gel implant).

a. The obligation of settling defendants to make this payment is not affected by the number or amounts of claims or by the number of opt-outs, or by the amount of money paid as benefits under E2 below. This $3,000 payment is not subject to refund (unless the participant later elects to opt-out under C1), but would be credited against any judgment against settling defendants in subsequent litigation by the participant.[6]

b. Payment of these expenses does not reduce the amount of a participant's benefits under E2 (or the amount of benefits for Current Claimants under Option One).

c. Explantation expenses are not payable to "Late Registrants".

d. Although intended only as means to defray medical costs of explantation, the amount will not be reduced as a result of the person actually incurring less than $3,000 in expenses, whether as a result of a smaller charge for the explantation procedure or as a result of insurance or governmental health programs.

e. In addition, as an optional alternative to the $3,000 assistance offer, the settling defendants in the future may provide a list of surgeons willing to perform explantations, if the claimant so chooses, without any charge personally to the claimant.

2. Compensation. On proof of satisfying, during the 15-year period of the program, the revised disease and severity criteria specified in Exhibit E, eligible participants will be paid (subject to reduction under F1 below if the participant also has Dow implants) compensation under the following schedule,[7] depending on the new disease/severity criteria.

Option Two — Long-Term Benefits

Disease — Severity Level	Amount
SS/SLE--A	$250,000
SS/SLE--B	$200,000
SS/SLE--C	$150,000
GCTS/PM/DM--A	$110,000
GCTS--B	$ 75,000

a. Benefits are to be paid in annual installments (as needed) of $100,000. These benefits are in addition to any payment related to explantation under E1 above.

b. If during the 15 years of the

6 Under certain conditions the participant may have the later right to opt out and pursue litigation against settling defendants. (See E2c below.)

7 Other Registrants with only Post-'84 McGhan implants (or only Post-'84 McGhan implants plus implants from Bioplasty, Cox Uphoff/CUI, or Mentor) will be eligible for Option Two benefits as follows: SS/SLE-A,B, or C — $50,000; GCTS/PM/DM -A — $20,000; and GCTS-B — $10,000.

program the person develops a condition that would entitle her to a larger amount than she has previously received, she would at that time be entitled to the difference between the new compensation amount and any amount previously paid.

c. The maximum obligation of the defendants to make payments under this program (E2) is $755,000,000 (less amounts paid for explantation expenses of Other Registrants under E1 above[8]), with obligated payments as follows:

Bristol's cumulative obligation under E2 ($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 under E1)

Baxter's cumulative obligation under E2 ($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 under E1)

3M's cumulative obligation under E2 for 3M implants ($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 under E1)

3M's cumulative obligation under E2 for Post-'84 McGhan implants ($12,000,000) increases in the amount of $800,000 per year for 15 years (less the amount, if any, that its payments under D3 for Post-'84 McGhan implants exceed $76,800,000)

McGhan's cumulative obligation under E2 for Post-'84 McGhan implants ($6,000,000) increases in the amount of $400,000 per year for 15 years (less the amount, if any, that its payments under D3 for Post-'84 McGhan implants exceed $38,400,000)

Union Carbide's cumulative obligation under E2 for Post-'84 McGhan implants ($12,000,000) increases in the amount of $800,000 per year for 15 years (less the amount, if any, that its payments under D3 for Post-'84 McGhan implants exceed $76,800,000)

If these cumulative limitations in any year result in any participant 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 defendant's obligated payment (with a carry forward of the unpaid portion for potential payment in future years if within the defendant's 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 (a) must first return any amounts previously paid under the program (other than for explantation expenses or, for Current Claimants, as an Advance Payment) and (b) shall be given the opportunity, if they so elect, to participate in non-binding mediation, in accordance with procedures to be established by the court, in an effort to resolve their claims.

d. Benefits to Late Registrants under this program will, as under the terms of the global settlement, be paid only if, when, and to the extent the defendant's cumulative payment obligations under this program exceed the payments to other participants claiming under this program; and such Late Registrants will have no right to opt out because of failure to receive the full amount shown in the schedule.

3. Advance Payment. A non-refundable advance payment of $1,000 will be paid as soon as the Claims Office determines that a person has not opted out within the time permitted under C1 (or under C3 has waived the

8 In the event the settling defendants provide a list of surgeons to perform explantation without charge to claimants (under E1e above), the settling defendants shall be entitled to a $3,000 credit per operation.

remaining time to opt out), is an Other Registrant, and has sufficient manufacturer identification information of having had a Bristol, Baxter, or 3M implant. Payment will be made without regard to the status of any appeals relating to this settlement and without regard to the existence of any deficiencies in the claim. The $1,000 payment will be credited against other amounts payable to the claimant under the settlement or awarded in a judgment recovered against settling defendants in later litigation,[9] but otherwise is not refundable unless the Claims Office determines the claim to have been fraudulently presented.

F. Multiple Implants

1. Amounts payable are, in general, not diminished by a person's having one or more implants manufactured by other companies in addition to implants from the settling defendants. However —

a. If a participant has received one or more Dow implants in addition to one or more Bristol, Baxter, or 3M implants, the benefits provided under Option One and Option Two (but not the amount of the Advance Payment or the amount for explantation expenses) will be reduced by 50%. For example, if a Current Claimant qualifying under Option Two for a payment of $200,000 had one or more Bristol implants, one or more Dow implants, a Mentor implant, a McGhan implant manufactured after 8/3/84, and an implant whose manufacturer could not be identified, her compensation would be reduced to $100,000.

b. Persons who have received one or more Post-'84 McGhan implants and one or more implants from manufacturers other than Bristol, Baxter, 3M, Bioplasty, Cox Uphoff/CUI, or Mentor are not eligible to participate under this Revised Settlement Program.

c. Participation in this program does not release claims a participant may have against entities and persons that are not the settling defendants or Released Parties under Exhibit B1. Participants are, however, cautioned that bankruptcy rules provide a stay at the present time against institution or pursuit of claims against Dow Corning, and, to preserve claims against Dow Corning, participants may need to file appropriate claims in the bankruptcy court.

2. 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.

a. If a person has 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.[10] For example, if a person had one or more Bristol implants, one or more Baxter implants, a Post-'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.

b. The obligations of McGhan, 3M, and Union Carbide with respect to payments to persons who have only Post-'84 McGhan implants (or only Post-'84 McGhan implants and implants from only Bioplasty, Cox Uphoff/ CUI, or Mentor) are also several. 3M and Union Carbide shall each be obligated to make 40% of each such payment, and McGhan shall be obligated to make 20% of each such payment.

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9 Under certain conditions claimants may have later rights to opt out and pursue litigation against settling defendants. (See E2c). To exercise such an opt-out right, the claimant would first have to return any amounts previously paid (other than the Advance Payment and explantation payments).

10 Enhancement payments for rupture, however, remain the sole responsibility of the settling defendant(s) whose implant(s) ruptured.

G. Attorney Fees and Administrative Expenses

1. Fees and expenses of attorneys representing an individual participant in the program are to be paid by the participant (or from benefits payable to her under this program) in accordance with the arrangements made between the participant and the attorney, but the court is reserving the power to set some appropriate standards and limitations on those arrangements (such as precluding the inclusion of explantation reimbursement from the calculation of a recovery-based contingent fee). Amounts payable to participants will not be subject to any reduction for fees and expenses of attorneys for representing the plaintiff class or for other "common benefit" services.

2. Pursuant to Order No. 13, an amount equal to 6% of the amounts paid to participants under this program will be paid by defendants as a surcharge (in addition to benefits paid to participants) into the previously established fund as a means for compensating and reimbursing counsel providing "common benefit" services. Under terms of that order, participants would receive on a pro-rata basis an increase in individual benefits should the court determine that the amount of the fund exceeds the reasonable fees and expenses chargeable against it.

3. Amounts previously paid by defendants under the global settlement to support operations of the Claims Office and for other administrative purposes will remain under the court's jurisdiction for those purposes. Settling defendants will pay such additional sums for operations of the Claims Office during the 15-year period of the program as determined by the court (in consultation with the settling defendants) to be necessary for that purpose. Allocation among settling defendants of the amounts paid for Claims Office and administrative expenses shall be based upon the number of claimants applying for benefits allocable to each of the settling defendants, and shall be adjusted on an on-going basis as necessary by the Court.

H. 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 person's 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 12/16/96 by participants claiming status as Current Claimants, as must documentation of a claim for rupture supplement under Option One.

I. Claims Office Procedures. The Claims Office will continue to process and evaluate all domestic registrations and claims submitted to it as expeditiously as possible, but will give priority of consideration to claims in which the claimant has indicated having a Bristol, Baxter, or 3M implant.

1. Protocols governing the required identification of manufacturers of claimants' implants are included in the attached Exhibit F. In order to be processed as a Current Claimant, a form to be provided by the Claims Office regarding proof of manufacturer identification must be received by the Claims Office by 12/16/96; earlier presentation of the form will expedite processing of Current Claims. The manufacturer defendants agree to provide reasonable assistance (including access to their records) to claimants who have difficulties in identifying the manufacturer of their implants from their own medical records. At their request, defendants shall be afforded access to documentation and other supporting evidence submitted by a claimant to identify manufacturers of her implants (but redacted to preserve the confidentiality of the claimant's identity), and shall bring to the Claim Administrator's attention any submissions not covered by existing protocols. In such instances, defendants and Settlement Class Counsel shall have the opportunity to submit to the Claims Administrator written suggestions for amendments or additions to the existing protocols to address the questions raised by the claimants' offers

of proof. Any amendments or additions to the promulgated protocols will be published on the Claims Office computer bulletin board and be made available on request to any class member or attorney.

2. Processing of Claims: As claims are processed and evaluated, the Claims Office will send each participant 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 any documentation submitted in support of a rupture supplement under Option One is satisfactory; whether she is entitled to any Option One payment (and, if so, the amount of such payment); 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 C1, will be sent to the last address provided to the Claims Office, with a copy to the person's attorney if one has been indicated.

3. The Claims Office will continue to implement procedures designed to detect and prevent payment of fraudulent claims. It should be recognized, however, that these procedures cannot be fully implemented preceding Advance Payments under D1 and E3 above in view of the goal to make such payments as soon as possible.

4. 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.

J. Funding. Each settling defendant will pay into the fund established by the court 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 to be needed (after considering undistributed funds previously contributed to the fund by that defendant) to pay benefits (or instalments) for which that settling defendant will become obligated to pay during the next 3 months. The fund will maintain appropriate records defining amounts contributed and disbursed with respect to each settling defendant and with respect to the Current Claimant and Other Registrant programs. The obligations of the defendants to contribute to funding of Option Two under E2 (except as specified in D2b(1)) are limited to annual cumulative amounts indicated in E2c above. As an initial reserve, Bristol, Baxter, and 3M will each pay into the fund by January 15, 1996, at least $125,000,000.

K. Miscellaneous.

1. Establishment of and discussions leading to the settlement program, and payments under the program, do not constitute any admission by 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 among and between the settling defendants and the released parties in the event a person who was eligible to participate in the global settlement] at some point opts out and proceeds with litigation against the defendants (except that any judgment obtained by such person will be reduced by any payment under this settlement).

2. All of the Released Parties identified by the settling defendants in Exhibit B1 are released to the same extent as are the settling defendants.

3. Subject to appropriate conditions to protect claimant confidentiality, insurers for settling defendants will be afforded access to appropriate records of the Claims Office as may be necessary for defendants to

receive benefits under such insurance policies.[11]

4. Subrogation-type claims by insurers or governmental agencies based on payment of medical expenses of participants will, to the extent enforceable under applicable laws, be the responsibility of eligible participants; settling defendants will have no additional responsibilities to such insurers and agencies and will be protected by participants against such claims.

5. Where this program establishes deadlines for filing elections, supporting materials, etc. with the Claims Office, the materials must be actually received at the Claims Office by 5pm, central time, on that date. Fax transmissions will not be acceptable.

6. The various elections under this program may be made either by the participant or by the participant's previously designated attorney. In the event of a conflict between elections made by a participant and the participant's attorney, the participant's election controls.

7. The court shall appoint an independent public accounting firm to (a) conduct an annual financial audit of the Claims Office in accordance with Generally Accepted Auditing Standards and (b) conduct an audit or audits of the processing of claims by any outside claims evaluators. Reports will be made available to the parties subject to appropriate conditions to protect claimant confidentiality.

8. Settling defendants and Released Parties will—subject to the provisions of this program—be fully, completely, and forever released from all claims of non-foreign class members who have at least one breast implant manufactured by one of the settling defendants or their predecessors or subsidiaries, including derivative claims of their spouses, children, parents, and others; and such class members, including those with derivative claims (but excluding the claims of children for their own injury), will be permanently enjoined from asserting, instituting, or prosecuting any breast implant-related claim against a settling defendant or released party.

9. This program will continue to be subject to the court's previous orders concerning contribution and indemnification claims against the settling defendants and Released Parties.

10. This settlement program resolves — subject to its terms — all breast-implant related claims (including derivative claims of spouses, parents, children, and others) against the settling defendants (and their respective Released Parties) by non-foreign class members who have at least one breast implant manufactured by one of the settling defendants or their predecessors or subsidiaries unless such class members (a) opted out of the settlement class under the global settlement during the 1994 opt-out period (and do not withdraw their exclusion under A2), (b) opt out of this settlement program under C1 above , or (c) exercise an additional opt-out right as provided in sections D2b(2) and E2c above. All claims for compensation must be made by the end of the fifteenth year of the program (12/15/2010). Any claim by such a class member not made during that period would be forever barred.

11. Unless otherwise provided, the terms used herein are as defined in the Breast Implant Litigation Settlement Notice, the Breast Implant Litigation Settlement Agreement, and the Court's Final Order and Judgment dated September 1, 1994, together with any prior orders incorporated therein by reference. Benefits under this program are in lieu of all other benefits that participants and their attorneys might

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11 The court finds that the amounts to be paid under this revised settlement program by each settling defendant will, from the defendant's standpoint, represent a reasonable settlement of compensatory bodily injury claims from breast implants.

have had under the global settlement.

12. The obligations of Bristol, Baxter, and 3M to fund Option Two benefits for both Current Claimants and Other Registrants will be suspended if the provisions of A, B, C, D, E, J, K1, K2, K4, K8, or K10 are challenged on appeal and will be cancelled (together with McGhan's, 3M's, and Union Carbide's obligations to provide payments for Post-'84 McGhan implants) if any of those provisions are disapproved on appeal.

EXHIBIT B1

Settling Defendants

Baxter Healthcare Corp.
Baxter International Inc.
Bristol-Myers Squibb Co.
Inamed Corp.
McGhan Medical (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.
Anita Kost McAteer
Harold Markham
Jacqueline Markham
Lottie Markham
Markham Medical Ass'n
Markham Medical International, Inc.
Markham Surgical Specialties
Mark/M Surgical
Mark/M Resources, Inc.
G. Patrick Maxwell
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
Scott Spear
Specialty Silicone Fabrications, Inc.
Sirod Corp.
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 E — Revised Disease and Severity Definitions

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 physician's 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 of 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[12] 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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12 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. SLE (Lupus): 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
Malar rash	Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds
Discoid rash	Erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions
Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by patient history or physician observation
Oral ulcers	Oral or nasopharyngeal ulceration, usually painless, observed by a physician
Arthritis	Nonerosive arthritis involving two or more peripheral joints, characterized by tenderness, swelling, or effusion [exclusion: erosive arthritis]
Serositis	a) Pleuritis -- convincing history of pleuritic pain or rub hears by a physician or evidence of pleural effusion , or b) Pericarditis -- documented by ECG or rub or evidence of pericardial effusion
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
Neurologic disorder	Seizures -- in the absence of offending drugs or known metabolic derangements, *e.g.*, uremia, ketoacidosis, or electrolyte imbalance
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
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
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.)

III. 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 Gotton's papules.

Compensation Level:

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

IV. 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 findings 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 Schirmer's 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 laboratory's 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 laboratory's 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) Gotton's 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. Raynaud's 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 Raynaud's 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]

EXHIBIT F — Protocols for Manufacturer
Identification and Proof of Rupture

I. General

The following protocols shall govern the methods of proving (1) the identity of a particular settling defendant as the manufacturer of a claimant's implant[13] and (2) the fact that a claimant experienced a rupture in one of the settling defendant's implants.

II. Manufacturer Identification

A. Acceptable Proof

The following methods of proof, absent fraud, shall be clearly acceptable for purposes of establishing that a claimant's implant (s) were (was) manufactured by one of the settling defendants:

1. contemporaneous hospital or surgeon operative records specifying that the claimant was implanted with a settling defendant's implant (s);

2. certified copy of claimant's medical records containing the implant package label; or

3. where proof specified under 1 and 2 above is unavailable: (a) an affirmative statement from the medical doctor who performed the implantation or from a responsible person at the treating facility, attesting that the claimant was implanted with a settling defendant's implants and providing the basis for that conclusion (which cannot rest upon unacceptable proof (see IIB below)); and (b) a statement from the claimant describing the steps taken to secure proof under methods 1 and 2 above and the reasons for the unavailability of such proof.

B. Unacceptable Proof

Statements from medical personnel describing their typical or general practices concerning implant usage during a given time period, or a statement from the claimant (or a claimant's relative or friend) that seeks to identify the manufacturer based upon recollection, shall be unacceptable as proof of manufacturer identity.

C. Additional Methods of Proof to be Accepted

The settling defendants anticipate that there may be other methods of acceptable proof of manufacturer identity in addition to those set forth under IIA above. Accordingly, counsel for the settling defendants shall consult with the Claims Administrator and Settlement Class Counsel to consider additional acceptable methods of proof to be incorporated into this protocol. Any such methods shall require the consent of the affected settling defendant(s).

III. Proof of Rupture

A. Acceptable Proof

The following methods of proof, absent fraud, shall be clearly acceptable for purposes of establishing that a claimant experienced a rupture in one of the settling defendant's implants.

1. With respect to ruptures documented by explant operations that occurred on or before 1/1/92, a

13 The methods of proof set forth in Part II below apply only to the identification of settling defendant manufacturers. Each claimant also must provide a complete implant history. If a claimant is unable to identify another manufacturer, she must describe the reasonable steps she took to so identify and state why she was unable to do so.

contemporaneous operative or pathology report documenting the rupture.

2. With respect to ruptures documented by explant operations that occurred after 1/1/92, a contemporaneous operative report and, if available, a contemporaneous pathology report, together with a statement as to whether the ruptured implant (s) has (have) been preserved and, if so, the name and address of the custodian.

3. In addition to the reports described in IIIA2 above, for explantations after 1/1/96 the claimant shall use her best efforts to cause the removed implant to be preserved and the explanting surgeon or other appropriate professional approved by the Claims Office shall provide a statement affirming that, in his or her opinion, the rupture did not occur during the explantation procedure (or thereafter). The statement must describe the results of the inspection and provide a factual basis for the opinion (*e.g.*, in light of silicone granuloma formation on the exterior of the biologic capsule, or findings concerning the nature of the destruction of the elastomer envelope).

B. Unacceptable Proof

Non-contemporaneous statements from medical personnel recalling that a claimant's implant was ruptured upon explantation, or a similar statement from the claimant (or a claimant's relative or friend), shall be unacceptable as proof of a ruptured implant.

C. Additional Methods of Proof to be Accepted.

The settling defendants anticipate that there may be other methods of acceptable proof of rupture in addition to those set forth in IIIA above. Accordingly, counsel for the settling defendants shall consult with the Claims Administrator and Settlement Class Counsel to consider additional acceptable proposed methods to be incorporated into this protocol. Any such proposed methods shall require the consent of the settling defendants.