

**MDL-926 Claims Office
PO Box 56666
Houston, TX 77256**

May 1999

Dear Claims Office Registrant,

After the January 11, 1999, fairness hearing, Judge Pointer approved the Inamed limited fund class action settlement. Because the settlement fund is relatively small (\$32 million with more than 45,000 potential claimants), because all notice and administrative costs must be paid out of the limited amount, and because differentiating among types of injuries and claims would greatly increase administrative costs and thereby decrease the amount available to pay claimants, the court is proposing a simple distribution plan. Each qualifying claimant will receive the same amount, calculated by dividing the amount available for distribution (after deduction of notice and administrative costs) by the number of qualifying claimants.

If, before June 1, 1993, you received at least one post-8/84 McGhan or Cox Uphoff (CUI) implant, you are eligible to file a claim. Please read the enclosed form (including all of the information on the back) carefully. Claims must be complete, properly signed, and received in the Claims Office by October 1, 1999. If you are eligible and can provide the required information, please file your claim early. Unless an excessive number of claims are filed on or just before the deadline, we anticipate that payments to qualifying claimants could be mailed as early as December 1999 if this plan is approved. A change in the plan of distribution, however, may require additional notice and you might have to file an additional form or proof.

Any alternative proposals or objections to this distribution plan must be mailed to Inamed Proceedings, PO Box 2785, Birmingham, AL 35202-2785 USA. At a July 6, 1999, hearing the court will consider all comments or objections mailed to that post office box and postmarked by June 22, 1999. If this distribution plan is approved, there will be no further written notice to class members (although information about the court's approval will be posted on the court's website: www.fjc.gov/BREIMLIT/mdl926.html). If this plan is not approved, any additional notice and administrative costs resulting from a different plan of distribution will also have to be deducted from the amount available for distribution to claimants.

Please also note information on the back of this letter about resolution of certain US government claims for reimbursement.

We are mailing this information to a large percentage of people who registered with this office, so please do not think that our sending you this letter and claim form means that we believe you are eligible to participate. *You can only file this claim form if you have had a type of implant covered by this settlement.* See the list of brand names on the back of the claim form. Unless you know that you have had one of these named brands, do not file this form.

Yours truly,

Ann Cochran
Claims Administrator

Questions and Answers About Your Notification of Status

- Q1 I do not have any implants covered by the revised settlement program. Why are you sending me a Notification of Status?**
- A These Notifications of Status are being sent to people who registered with the Claims Office but who have not yet indicated their eligibility for the revised settlement program by filing the Blue Proof of Manufacturer form. Since you say you are not eligible for the revised settlement program, this is formal notice to you that after 45 days from the date on your Notification of Status have passed you will be free to file suit against any party except Mentor, Bioplasty, Dow Corning, and the parties participating in the revised settlement program. Any applicable statutes of limitation or repose will resume running against those other parties 30 days after that 45-day opt-out period expires. If, however, you file an Opt-Out form within that 45-day period, you will also be free to pursue claims against the parties participating in the revised settlement program and your statutes of limitation or repose will not resume running until 6 months after the date that Opt-Out form is received in the Claims Office.
- Q2 I have not been able to determine what kind of implants I had. Can't I make this decision after I find out whose implants I had?**
- A No. You must decide now whether you want to participate in the revised settlement program even if you do not know who made your implants. You will not be able to change the decision you make now if it is later discovered that your implants are covered by the revised settlement program.
- Q3 I filed an Election form months ago stating that I was not eligible for the revised settlement program but that I was not ready to opt out and pursue my claims privately. If I don't file the Opt-Out form, will I still be able to postpone filing suit until I am ready to do so?**
- A You cannot postpone the resumption of any applicable statutes of limitation or repose indefinitely but you will have 6 months instead of 30 days if you file an Opt-Out form within 45 days from the date on your Notification of Status. See Q9.
- Q4 What are "applicable statutes of limitation or repose"?**
- A There are laws varying from state to state that govern how much time a person can take before filing a lawsuit. You should consult an attorney if you are concerned about how these statutes might affect your rights.
- Q5 I have a claim pending in the Dow Corning bankruptcy proceeding. What effect does this Notification of Status have on that claim?**
- A All claims against Dow Corning are pending in the Bankruptcy Court for the United States District Court for the Eastern District of Michigan. If you have questions about that proceeding, consult with an attorney or call 1/800/651-7030. Please do not call the Claims Office with questions about Dow Corning. We are not involved in the bankruptcy proceeding and do not have answers to questions about that proceeding.
- Q6 I filed a Mentor (or Bioplasty) claim with the Claims Office. What effect does this Notification of Status have on that claim?**
- A We will notify you separately about that claim. This Notification relates only to any breast implants you may have had other than those covered by the Mentor or Bioplasty distribution plans.
- Q7 I believe I am eligible and have decided I want to participate in the revised settlement program. What do I have to do now?**
- A You do not have to send anything to the Claims Office to advise us of your decision to stay in the revised settlement program. You will be a participant automatically once the 45-day opt-out period has expired. You must, however, establish your eligibility by filing the blue Proof of Manufacturer form and acceptable proof of the identity of at least one covered implant. If you need another copy of that form or of the rules relating to proof of manufacturer, call the Claims Office and ask for those materials.
- Q8 Do I have to file that Proof of Manufacturer form in the next 45 days?**
- A No. There is currently no deadline for filing either the form or acceptable proof of your covered implant, but you must file that form and proof before we can process any claim or pay any benefits.
- Q9 I am eligible for the revised settlement program but I do not want to participate. I want to opt out. What do I need to do?**
- A Included with this mailing is a white Opt-Out Form. You must complete and sign that form and return it to us within 45 days of the date on your Notification of Status. The Opt-Out form must be actually received in the

Claims Office no later than 45 days after the date on your Notification. The running of any applicable statutes of limitation or repose will resume six months after the date this form is received in the Claims Office.

Q10 When does the 45-day period for opting out begin? On the date I receive the Notification of Status?

A No. The 45-day period begins on the date that is printed on your Notification of Status.

Q11 In addition to my covered implants, I have two implants that are not covered by the revised settlement program. If I decide to participate in the revised settlement program will I be giving up any claims I have for those non-covered implants?

A After the expiration of 45 days from the date on your Notification of Status you will be free to file suit against any party except the parties participating in the revised settlement program, Mentor, Bioplasty, and Dow Corning even if you decide to participate in the revised settlement program.

Q12 I believe my implants were Surgitek but I cannot obtain the required proof of manufacturer. Can anyone help me?

A Call the Claims Assistance Office, 1/513/651-9770.

Q13 My Notification of Status says that I am classified as an "other registrant." What does that mean?

A Your registration status determines what benefits may be available to you if you are eligible and decide to participate in the revised settlement program. You are classified as an "other registrant" because you registered with the Claims Office before the March 1, 1995, registration deadline. You can receive a \$1,000 advance payment if acceptable proof of at least one Bristol, Baxter, or 3M implant is filed with the Proof of Manufacturer form and can receive \$3,000 in explantation benefits if one of those Bristol, Baxter, or 3M implants is or was explanted after March 31, 1994. (Post-8/84 McGhan participants, however, are not eligible for either advance payments or explantation benefits). After receiving an advance payment, you can make a claim under the Long-term Benefit Schedule (if your covered implants are Bristol, Baxter, or 3M) or under the McGhan Benefit Schedule (if you are eligible for post-8/84 McGhan benefits) if you have or later develop systemic sclerosis, scleroderma, lupus, polymyositis, dermatomyositis, or the combination of findings required for "general connective tissue symptoms." The precise criteria for proving those diseases and conditions are found in Exhibit E1, "Revised Disease/Symptomology Definitions and Compensation Levels." If and when you believe you are ready to make such a claim, call the Claims Office and request a copy of the appropriate claim form. You are not eligible to make a rupture claim.

Q14 My registration status is "late registrant." What rights and options will I have if I participate in the revised settlement program?

A You are classified as a late registrant because you sent your Registration Form to the Claims Office after the March 1, 1995, deadline. If you decide to participate in the revised settlement program and file sufficient manufacturer proof to establish your eligibility, you will have the same rights as "other registrants" to file a disease compensation claim should you develop one of the diseases or conditions found in Exhibit E1. If your claim is approved, however, you will be paid benefits only if, when, and to the extent the settling defendants' cumulative payments to timely registered participants do not exceed their annual funding obligations and you will not have a right to opt out at that time. You are not eligible for an advance payment, explantation benefits, or enhanced benefits for rupture.

Q15 I registered and filed a disease compensation claim before the September and October 1994 deadlines. Why am I not classified as a current claimant?

A We did not review your file to see if you could be classified as a current claimant because you did not file a Proof of Manufacturer form by the December 16, 1996, deadline. Failure to file that form by the deadline precludes you from now claiming that you should be classified as a current claimant.

Q16 I am positive that I sent my Proof of Manufacturer form to you last fall. What can I do to see if an error was made and perhaps to have it corrected?

A If you think we overlooked a Proof of Manufacturer form, please notify us in writing. Be sure to include your Social Security number and a daytime telephone number in that letter. We will look again to see if you did in fact file a Proof of Manufacturer form listing at least one implant covered by the revised settlement program. If you did, we will review that and any claims you have filed and provide you with a new Notification of Status that reflects those reviews. If we do not find the Proof of Manufacturer form, we will so notify you.

**MDL-926 Claims Office
P.O. Box 56666
Houston, Texas 77256
1-800-600-0311**

Implant Brands of Inamed and Affiliated Companies

Biocell	RHP (Round High Profile)
Biodimensional	RLD (Round Low Profile DRIE)
Biospan	RLP (Round Low Profile)
Cox Uphoff	RTV/RTT (Smooth/Textured)
CZV/CRS (Croissant Versafil Low Profile)	Ruiz-Cohen
DRI	RZV/SRV (Rectangular Versafil Tissue Expander)
DRIE	SCC (Cylindrical Tissue Expander)
EHP (Enhanced High Profile)	SCS (Crescent Tissue Expander)
FZV/SFV (Round Versafil LP Tissue Expander)	SEE (Mini-crescent Tissue Expander)
Gibney	SFS (Saline Fill Skin and Tissue Expander)
*Intrashiel (implanted <u>after</u> 8/2/84)	SGO (Saline Gel Oval)
Intravent	SGR (Saline Gel Round)
IOC (Cylindrical Intraoperative Tissue Expander)	SLP (Single Lumen Adjustable)
IOM (Intravent Intraoperative Expander)	SLS (Longitudinally Curved Tissue Expander)
IOS (Spherical Intraoperative Tissue Expander)	SOE (Small Oval Tissue Expander)
Magna-Site	SOS (Ear Shaped Tissue Expander)
Maxwell	SPS (Pear Shaped Tissue Expander)
*McChan (implanted <u>after</u> 8/2/84)	SRS (Rectangular Tissue Expander)
MFE (Man Facelift Expander)	SSS (Spherical Tissue Expander)
Microcell	SWS (Wedge Shaped Tissue Expander)
OHP (Oval High Profile)	SZR (Round Low Profile Sizer)
OLP (Oval Low Profile)	TLL (Triple Lumen Round)
RCP (Round Conical Profile)	Tri-Lumen
RCR (Ruiz-Cohen Expanders)	TRL (Tri-Lumen Implants)
RDD (Reserve Double Lumen DRIE)	TSO (Triple Lumen Low Profile Oval)
RDL (Reverse Double Lumen)	TSR (Triple Lumen Round Low Profile)
RDL-XPAND	UHP
RDX (Round Double Lumen)	Ultra High Performance
Reverse Double Lumen	Versafil
RHD (Round High Profile)	

*Note that Intrashiel and McChan implants qualify only if the implant date was after 8/2/84 and before 6/1/93.

Required Confirmation of Implant Brand

You must attach one of the following types of confirmation of your implant brand.

1. A page from your medical or hospital records that names one of the brands listed above as the brand of implant (or tissue expander) you received
2. A letter from your implanting physician stating that you received one of the brands listed above (and including the date of implantation)
3. Your written statement that you received one of the brands listed above. Your statement must include the brand name, the date of implantation, and an explanation of how you know that is the brand you received.

Additional Instructions for Completing Claim Form

To receive payment, you must timely complete and return this form, providing the approximate date of implantation of at least one of the brands listed above and the required brand confirmation. If you do not satisfy these requirements, your claim will not be paid. Confirmation must be attached to the form, not filed separately. Previous submissions to the Claims Office, other claim forms, proofs of manufacturer, etc., will not satisfy these requirements. Your file will not be reviewed to see if the missing information has already been provided.

The form must be personally signed (under penalty of perjury) by the claimant herself -- and not by her attorney, family member, or friend. (The only exceptions to this requirement are that the executor or administrator of a deceased recipient's estate or the legal guardian of a recipient who has been declared incompetent may sign on behalf of a deceased or incompetent implant recipient. In such situations the executor, administrator or guardian must print the nature of his/her representative role underneath the signature line. If the implant recipient has died, the date of death must be provided.) Unsigned claims, or those signed by a person who is not the implant recipient, the executor or administrator of her estate, or her legal guardian, will not be paid.

Claims must be received in the Claims Office by October 1, 1999. Late claims -- regardless of the reason -- will not be paid. Do not send a copy of this form to the court, and do not expect to receive -- even if requested -- an acknowledgment from the Claims Office of receipt of your claim. You should call the Claims Office to inquire about the status of your claim only if by February 1, 2000, you have neither received a payment nor been advised of the denial of your claim.

**Claims Administrator's Office
P.O. Box 56666
Houston, Texas 77256**

February 6, 2007

FILE COPY

Ms. Teresa L. Peake
4182 A Bougainville Circle
Kapolei, HI 96707

Registration Number: 550-31-4441

We have received your claim for General Connective Tissue Symptoms (GCTS) under the Long-Term Benefit Schedule. The purpose of this letter is to advise you of your findings that meet criteria and those which are deficient.

You meet criteria for the following general requirement: You have provided an acceptable statement excluding Classical Rheumatoid Arthritis.

Findings that meet criteria do not necessarily result in an approved claim. Your claim will be approved only if you have the required number of findings for one of the GCTS compensation levels and those findings fall within the five year, twenty-four month time period. Please refer to Exhibit E1 (Revised Disease Criteria) to understand the number of findings required to qualify under each compensation level.

You do not meet criteria for any GCTS findings at this time.

Exhibit E1 states specific requirements for establishing each GCTS finding. If exclusions are noted for a finding, then the physician making the finding or ordering the test must affirmatively state that those listed exclusions are not present. Also, the physician recording a finding must affirmatively state that the finding did not exist before the date of your first implantation. Please note that this statement may be based on the patient's history, so long as it is consistent with the medical records in the physician's possession.

Your claim has the following symptom-specific deficiencies:

Group I:

Polyarthritis: Your finding of joint pain does not meet settlement criteria. Specifically, your medical records do not reflect both swelling and tenderness in three or more joints in at least two joint groups. In addition, your medical records reflect degenerative joint disease (osteoarthritis) of the right knee joint. Joints in which osteoarthritis is present cannot be credited toward the finding of polyarthritis.

Keratoconjunctivitis Sicca: Dr. Nancy Chen must affirmatively state that your symptom of keratoconjunctivitis sicca did not exist before the date of your first implantation. Also Dr. Chen must make the statement excluding drugs known to cause dry eyes and/or dry mouth and dry eyes caused by contact lenses.

Group II:

Peripheral Neuropathy or Polyneuropathy: Dr. Jeffrey Wang, who found tingling in the extremities, is not a board-certified neurologist. Please note that the diagnosing neurologist must also make the appropriate exclusion statement and affirmatively state that the finding did not exist before your first implantation.

Group III:

Serologic Abnormalities: You need one more ANA to be documented according to settlement criteria. In addition, Dr. Arnold Seid must affirmatively state that your abnormal ANA did not exist before the date of your first implantation.

Myalgias: Either Dr. Alfonso Jimenez or Dr. Nicole Theuvenet must affirmatively state that your symptom of myalgias did not exist before the date of your first implantation. Please note we are unable to accept this statement by Dr. Ahmed Shafi because he did not make any part of this finding.

Finally, section I of Exhibit E1 to the Revised Settlement Program Notice states that all claimants must file with the Claims Office all medical records that may establish your required findings or laboratory abnormalities, including those establishing the exclusion statements. As such, please send any additional medical records you may have relating to any of your GCTS symptoms to the Claims Office including all underlying office charts, radiology/pathology reports and laboratory test results from any health care professional that provided you with medical care. Examples of health care professionals include the following:

- Medical Doctors (M.D.)
- Doctors of Osteopathy (D.O.)
- Chiropractors
- Podiatrists
- Dentists
- Nurse Practitioners
- Optometrists
- Occupational Therapists
- Physician Assistants
- Physical Therapists
- Pharmacists

If you understand the deficiencies noted in your claim and have obtained the information or documentation to correct the deficiencies, please attach that material to the enclosed "Request for Re-Review" form and send it to the Claims Office. Remember to write your Social Security number on all submitted material.

If you file documentation of a new finding, remember that all medical records establishing that finding must be attached, along with all underlying records from the physician who made that finding or ordered the test.

If you do not understand some of the deficiencies noted in your claim, the Claims Office will be glad to assist you. You must prepare for our call by having a copy of Exhibit E1 (Revised Disease Criteria), as well as copies of all medical documents you have submitted to the Claims Office. If you do not have these documents, please write the Claims Office and request copies. After you have the necessary material, complete and return the "Request for Assistance" form and a Claims Officer will call you. If at all possible, we will call during the times you have noted on your form. If we cannot reach you in three attempts, you must submit another "Request for Assistance" form to receive another call.

Yours truly,



Pam Dedmon
Claims Manager

enc: Request for Re-Review Form
Request for Assistance Form
Exhibit E1
Questions & Answers GCTS

cc: Steven R. Finch
213 E. Hobsonway
Blythe, CA 92225