UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE:	§	**CASE NO. 00-CV-00005-DT**
	§	**(Settlement Facility Matters)**
DOW CORNING CORPORATION,	§	
	§	**Hon. Denise Page Hood**
REORGANIZED DEBTOR	§	

OMNIBUS RESPONSE OF CLAIMANTS' ADVISORY COMMITTEE TO SEVEN ADDITIONAL MOTIONS SEEKING RELIEF IN THE FORM OF TOLLING AND/OR EXTENSION OF CURE DEADLINES FOR CLAIM SUBMISSIONS

AND

OMNIBUS MOTION OF CLAIMANTS' ADVISORY COMMITTEE FOR RELIEF ON BEHALF OF ALL SETTLING CLAIMANTS WHOSE CURE DEADLINE(S) HAVE ALREADY RUN OR ARE ABOUT TO RUN WITHIN THE NEXT SIX MONTHS

Seven additional motions have now been filed seeking relief based on cure deadlines which either have already run or are about to run within the next several months.[1] These motions are in addition to four other pending motions which have previously been briefed seeking the same or similar relief with regard to tolling cure deadlines and/or requests for re-review of claim deficiencies.[2] The

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[1] The seven motions are: 1) Plaintiffs' Motion For Expedited Consideration For Tolling Of Disease Deficiencies And Request For Six Month Extension For Curing Past and Future Disease Deficiencies, filed May 27, 2005 by Motley Rice; 2) Plaintiffs' Motion For Expedited Consideration For Tolling Of Disease Deficiencies And Request For Six Month Extension For Curing Past And Future Disease Deficiencies, filed May 31, 2005 by Siegel, Kelleher & Kahn; 3) Motion and Memorandum In Support of [Claimant Name Redacted] To Toll The One Year Deadline For Curing Disease Claim Deficiencies, filed June 6, 2005 by Doffermyre Shields Canfield Knowles & Devine; 4) Motion [#2] and Memorandum In Support Of [Claimant Name Redacted] To Toll The One Year Deadline For Curing Disease Claim Deficiencies, filed June 6, 2005 by Doffermyre Shields Canfield Knowles & Devine (this motion was later withdrawn); 5) Motion and Memorandum In Support Of [Claimant Name Redacted] To Toll The Six Month Deadline For Curing Rupture Deficiencies, filed June 6, 2005 by Doffermyre Shields Canfield Knowles and Devine; 6) Motion of Nita Baldwin To Toll The Six-Month Deadline For Curing Rupture Deficiency, filed June 13, 2005 by the Law Office of Thomas R. Dreiling; and 7) Motion and Memorandum In Support of To Toll [sic] The One Year Deadline For Curing Disease Claim Deficiencies, filed June 17, 2005 by Provost Humphrey Law Firm, LLP.

[2] The four pending motions are: 1) Motion of [Claimant Name Redacted] To Toll The Six Month Deadline For Curing Rupture Deficiencies, filed January 21, 2005 by Doffermyre Shields Canfield Knowles &

CAC is informed based on numerous conversations and contacts with law firms active in this litigation that additional motions are about to be filed on behalf of hundreds of other claimants whose cure deadlines are also approaching in the upcoming months. Rather than respond to each individual motion as it is filed – which will likely prove expensive and time consuming for the Settlement Trust and will undoubtedly cause a backlog for the Court's docket in this case -- the CAC believes that the best course of action is to file this Motion seeking the Court to provide relief on a global basis to all Settling Claimants whose claim has been reviewed and found deficient to date by the Settlement Facility. Specifically, the CAC requests that this Court use its inherent and explicit supervisory authority over the Settlement Trust to take the following action:

1. Void the enforcement of all cure deadlines that any Settling Claimant has received for a claim found deficient by the Settlement Facility including those cure deadlines that have already expired and those about to expire in the upcoming months;

2. Temporarily suspend the issuance of new deficiency Notification of Status letters that would trigger cure deadlines to run (nothing however would prevent the issuance of award letters and payment for approved claims);

Devine; 2) Motion of the CAC To Toll The Cure Deadline For All Requests For Re-Review That Are Pending More Than 21 Days, filed February 7, 2005 by the Claimants' Advisory Committee; 3) Motion of Deborah DeSanto For 60 Day Extension To Cure Her Explant And Rupture Deficiencies Based On Special Circumstances, filed February 25, 2005 by the Law Offices of Richard DeSanto; and 4) Motion Of Tamara Vanlandingham To Toll The Six Month Deadline For Curing Rupture Deficiencies, filed March 16, 2005 by Siegel, Kelleher & Kahn.

3. Direct the Settlement Facility to develop and release information to claimants that provides specific answers and guidelines for submitting and processing claims similar to the Q&A's that were recently promulgated by the MDL 926 Claims Administrator and Court;

4. Allow claimants who have already been notified of an alleged deficiency in their claim submission the opportunity to submit new information consistent with the agreed-upon claims criteria and new Q&A's that the Claims Administrator will promulgate in conjunction with the parties and the Court;

5. Direct that the disability "A" disease claims should be interpreted consistent with the way the these claims were processed in the Revised Settlement Program from January 1996 to October 1997; and

6. Re-review all claims previously found deficient consistent with the new Q&A's to be developed and the disability A interpretation that was applied in the RSP pre-October 1997.

MEMORANDUM IN SUPPORT OF MOTION

In support of this Response and Motion, the CAC hereby adopts and incorporates by reference herein its prior *Motion For The Disclosure of Substantive Criteria Created, Adopted And/Or Being Applied By The Settlement Facility and Request For Expedited Consideration*, its Reply brief to this *Motion*,

and the *Motion of the Claimants' Advisory Committee To Toll The Cure Deadline For All Requests For Re-Review That Are Pending More Than 21 Days* and the CAC's Reply brief to that *Motion*. The CAC states as follows:

1. Several months ago, based on growing concerns about the claims processing backlogs and activities at the Settlement Facility, the CAC and Debtor's Representatives requested that an outside claims audit be conducted. The audit was done by ARPC and a written report was recently provided to the Court, Finance Committee, Debtor's Representatives and CAC. The audit report has not been publicly released so the CAC is unable to provide specific examples in this Motion and Memorandum in support; however, we believe it is fair to state that the audit conclusions support the relief being sought herein.

2. At the April 7, 2005 hearing before the Court, argument on the pending *CAC Motion for Disclosure of Substantive Criteria* was deferred until July 21, 2005 so that the audit could proceed and the parties could have adequate time to evaluate the results and determine how best to proceed with the pending motions. We believe this schedule is achievable; however, in light of the urgency of the expiration of the one-year cure deadlines for disease claims that are being triggered in June 2005, the CAC believes that it is important for the Court to take immediate action to address the substantial harm that will result to claimants in this situation.

3. For the past several months, the CAC has been gathering data and documentation on approved RSP disease claims to compare processing outcomes with that in the Settlement Option. We believe that sufficient information exists to demonstrate that consistency in claims outcomes between the two claims office – particularly with regard to disability "A" disease claims – is not occurring.

4. Since the CAC filed its *Motion For The Disclosure Of Substantive Criteria* in January 2005, the Claims Administrator resigned and a successor Claims Administrator, David Austern, has been appointed. The successor Claims Administrator's appointment was effective May 23, 2005 – one month ago. The CAC fully supports the ongoing efforts of the successor Claims Administrator to address the myriad and seemingly herculean claims processing problems at the Settlement Facility. This motion should not be interpreted to be critical of him or his efforts in any way. We recognize that the problems at the Settlement Facility are significant and that he has not yet had adequate time to implement all of the necessary changes; however, we are compelled to file this motion now given that hundreds of cure deadlines are and will continue to run unless immediate relief is granted.

5. In the Revised Settlement Program, the Plaintiff representatives filed a *Motion adopting the CAC's Motion For Disclosure of*

Substantive Criteria and sought similar relief. Thereafter, the MDL-926 Claims Administrator promulgated a lengthy set of Q&A's concerning one of the nine disease conditions (General Connective Tissue Symptoms), which were adopted by the MDL 926 Court on April 20, 2005. A copy of the MDL Court's Order of April 20, 2005 is attached hereto as Exhibit 1. At an informal status conference on June 3, 2005, the MDL 926 Claims Administrator indicated that she was working on additional Q&A's on several Long Term Benefit Schedule diseases (or Disease Option 2 claims in the Dow Corning Settlement Option); however, she did not have a schedule for the completion of these and other Q&A's on disease claims. The CAC applauds the MDL Claims Administrator for making this information available in the MDL proceedings and her willingness to promulgate additional Q&A's. We note that MDL claimants' rights have not been prejudiced because of the lack of information on submitting disease claims in the MDL because they do not have any deadline to cure a deficiency in a claim submission. As noted below, the substantive rights of Dow Corning claimants are being adversely affected by the lack of adequate information to date on correct claim criteria.

6. The new MDL 926 Q&A's have been provided to the successor Claims Administrator. We do not know at this time whether these

Q&A's will be recognized and accepted by the Settlement Facility. This matter is under consideration.[3]

7. There are significant backlogs in claims processing at the Settlement Facility for virtually every type of claim. Requests for re-review to cure deficiencies have also experienced significant time delays and backlogs. These backlogs and delays have seriously prejudiced the ability of claimants to fairly and effectively pursue their claims.

8. June 1, 2005 was the one-year anniversary of the Effective Date. The CAC is informed that hundreds of claimants are and will continue to see their one-year cure deadline for disease claims run out each month in June, July and continuing through the next 6 months. Simply stated, this translates to hundreds – perhaps thousands of claims which may be permanently extinguished because claimants were not provided with either adequate information about the correct claims criteria prior to the submission of their claim or were provided with partial and incomplete information, on an individual claimant-by-claimant basis to those fortunate enough to have been able to reach one of only two nurse reviewers in the Claims Assistance Program, and then received the information only after their cure deadline began to run.

[3] The CAC notes that the former Claims Administrator did not promulgate any disease Q&A's since claim form packages were mailed in February 2003. To the contrary, the CAC submitted dozens of proposed disease Q&A's and proposed questions that sought answers, but the former Claims Administrator declined to provide the answers or adopt any of the Q&A's.

9. The specific examples presented by the Motley Rice motion further heighten the CAC's concern about processing and alleged claim deficiencies for claims in the Settlement Option. For example, Exhibit 9 is a Notification of Status letter for a claimant whose disability level is approved but whose disease symptom for "documented sleep disturbances" in Atypical Connective Tissue Disease was found deficient because "the Claimants' medical record(s) must document multiple instances of interference with normal sleep pattern, or an adequate description of the interference with the normal sleep pattern." This is the only deficiency and the only thing apparently keeping the claimant from receiving compensation for $10,000. The underlying medical record that references this symptom is dated July 29, 1994 and contains a notation of "sleep disturbances" (plural). The CAC is unable to understand what more a claimant or her physician would have to include to adequately document sleep disturbances. Common sense and experience dictates that claimants have not scheduled expensive doctor's appointments to report the loss of only one night's sleep. It is also contrary to our experience in reviewing medical records to expect a treating doctor to describe in any more particularity what the sleep disturbance is. Suffice it to say that the claimant reported she was unable to sleep on multiple occasions. Indeed, the claimant's record in question used the plural of "sleep

disturbances." Moreover, we believe it is important for the Court to understand the following:

► claimants are having great difficulty getting their treating doctors to cooperate and provide the medical records and clarifying report particularly given the lengthy interval between the time the report was first written in 1994 and today – a difference of 11 years[4],

► doctors who served as QMD's previously are increasingly unwilling to do so given the problem created when the SFDCT sent out letters in early 2005 advising claimants that their QMD was, for some unknown reason, deemed "unreliable" or "unacceptable by the SFDCT,"

► there are real and often substantial costs incurred by claimants for follow-up doctor's appointment that are not related to treatment but solely to ask the doctor to write something more descriptive on sleep disturbances in the claimants' records (descriptions that the doctor would not otherwise include in the record but for the Settlement Facility's dogmatic and unreasonable insistence on over-interpreting what we believe is a straightforward symptom of "sleep disturbances",

► the claimant must also pay for a second clarifying letter and the costs of obtaining the medical records – costs which are likely to exceed several hundreds of dollars -- solely to obtain an additional sentence or

[4] The SFDCT requires both the clarifying letter from the QMD and the underlying medical records for the office visit. In instances where the QMD has simply written a clarifying report without seeing the claimant again, the SFDCT then denies the claim because it apparently requires the doctor to conduct a new examination on the sleep disturbance symptom!

two on the nature of how the claimant is unable to sleep. These expenses are not justified given the relatively modest recovery amounts in the Plan.

10. Pending the outcome of the various audits and reviews that are being conducted and pending a full evaluation of the audit and the implementation of corrective steps, the CAC urges this Court to take immediate action to afford claimants relief as described herein.

Respectfully submitted,

FOR THE CLAIMANTS'
ADVISORY COMMITTEE

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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing Omnibus Response of the Claimants' Advisory Committee To Seven Additional Motions Seeking Relief In The Form Of Tolling And/Or Extension Of Cure Deadlines For Claim Submissions and the Omnibus Motion of the Claimants' Advisory Committee For Relief On Behalf Of All Settling Claimants Whose Cure Deadline Has Already Run Or Is About To Run Within The Next Six Months has been sent via U.S.P.S. overnight mail this 25th day of June, 2005 and an electronic copy will be served on all moving parties, the Debtor's Representatives and Finance Committee on June 27, 2005.

Dianna Pendleton-Dominguez

Dianna Pendleton-Dominguez

EXHIBIT 1

IN THE UNITED STATES COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

IN RE: SILICONE GEL BREAT IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 926)	**M DL 926** **Master File Number: 2:92-cv-10000-UWC**
HEIDI LINDSEY, et al., **Plaintiffs,** **vs.** **DOW CORNING CORPORATION, et al.,** **Defendants,**	**2:94-cv-11558-UWC**

ORDER NO. 27N
(APPROVAL OF QUESTIONS AND ANSWERS ABOUT GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS) CLAIMS UNDER THE REVISED SETTLEMENT PROGRAM)

On March 17, 2005, the Claims Administrator previously appointed by the Court for the Revised Settlement Program requested that the Court consider the approval of Questions and Answers to assist claimants with possible General Connective Tissue Symptoms ("GCTS") claims.

The Court, having considered the information provided to the Court by the Claims Administrator, the Settlement Class Counsel and the Settling Defendants, and such other information as the Court deems appropriate, the Court hereby approves the attached document titled "Questions and Answers About General Connective Tissue Symptoms (GCTS) Claims" for

distribution to claimants in a manner to be determined by the Claims Administrator.

Done this 20th day of April, 2005.

U.W. Clemon

Chief United States District Judge

CLAIMS OFFICE
MDL-926 REVISED BREAST IMPLANT SETTLEMENT
P.O. BOX 56666
HOUSTON, TEXAS 77256

800/600-0311

QUESTIONS AND ANSWERS ABOUT GENERAL CONNECTIVE TISSUE SYMPTOMS (GCTS) CLAIMS

The questions and answers in this pamphlet address many issues important to claimants making a claim for benefits for General Connective Tissue Symptoms (GCTS).

Section 1	**General Questions**
Section 2	**Exclusions and Affirmative Statements**
Section 3	**Group I - Polyarthritis**
Section 4	**Group I - Keratoconjunctivitis Sicca**
Section 5	**Group I - Immune-Mediated Skin Changes or Rashes**
Section 6	**Group II - Positive ANA**
Section 7	**Group II - Abnormal Cardiopulmonary Symptoms**
Section 8	**Group II - Myositis or Myopathy**
Section 9	**Group II - Peripheral Neuropathy or Polyneuropathy**
Section 10	**Group III - Immune-Mediated Skin Changes or Rashes**
Section 11	**Group III - Serologic Abnormalities**
Section 12	**Group III - Raynaud's Phenomenon**
Section 13	**Group III – Myalgias**
Section 14	**Group III – Dry mouth**

SECTION 1 GENERAL QUESTIONS

Q1-1 What findings must I have in order to qualify for compensation for GCTS?

A There are two levels of compensation for GCTS (Level A and Level B). Each level has two possible combinations of findings:

Level A:

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

Level B:

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

Q1-2 What do Group I, Group II and Group III mean?

A The twelve findings for GCTS are divided into three groups. Group 1 includes findings 1-3, Group II includes findings 4-7 and Group III includes findings 8-12. For purposes of compensation, Group I generally carries more weight than Group II or Group III, and Group II carries more weight than Group III.

Q1-3 What is a non-duplicative finding?

A The following are among the duplications on the list of findings:

Rashes (Group I-3 and Group III-8)
Sicca (Group I-2 and Group III-12)
Serological abnormalities (Group II-4 and Group III-9)

Please note that duplicative findings that meet criteria may be credited in either Group, but not in both. The higher Group will be credited whenever possible.

Q1-4 Where can I find the exact criteria for GCTS?

A Read Exhibit E1, specifically: Section 1. General, paragraphs A & B, and Section V. General Connective Tissue Symptoms (GCTS). Read it carefully and completely. Pay particular attention to each word.

Q1-5 Where can I get a copy of Exhibit E1?

A You can call the Claims Office at 1-800-600-0311 or visit our website at www.claimsoffice-926.com.

Q1-6 What should I submit to support my GCTS claim?

A You should submit all underlying 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 supporting 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

Q1-7 What physician can establish my GCTS findings?

A Many findings require that the physician be board-certified in a particular specialty.

Group I-1 Polyarthritis - any board certified physician

Group 1-2 Keratoconjunctivitis Sicca – any physician

Group 1-3 Immune-mediated skin changes or rashes – either a board-certified Rheumatologist or a board-certified Dermatologist

Group II-4 Positive ANA – any physician

Group II-5 Abnormal cardiopulmonary – depending on the specific finding, it may require a a board-certified Radiologist, a board-certified Cardiologist, a board-certified Internist or a board-certified Pulmonologist

Group II-6 Myositis – any physician, but the muscle biopsy must be interpreted by a pathologist

Group II-7 Peripheral neuropathy or polyneuropathy – a board-certified Neurologist

Group III-8 Other immune-mediated skin changes or rashes – either a board-certified Rheumatologist or board-certified Dermatologist

Group III-9 Serologic abnormalities – any physician

Group III-10 Raynaud's phenomenon – any physician

Group III-11 Myalgias – any physician

Group III-12 Dry mouth – any physician

Q1-8 Can my physician write a letter to summarize my symptoms?

A A letter may be written; however, it is the underlying records that are required to support your findings.

Q1-9 My physician documented all the findings, the exclusion statements and the not pre-existing statements, but he did not sign the letter that stated that my symptoms did not exist before my first implantation. Must I ask him to sign this statement?

A Yes. Your physician must sign all statements that are required to establish a disease claim, including all records establishing your symptoms, the exclusion statements, and the not pre-existing statements.

Q1-10 What is the five (5) year time frame?

A The five (5) year time frame refers to the five years preceding the submission of your claim.

Q1-11 What is the twenty-four (24) month time frame?

A All qualifying findings must have occurred within a single twenty-four (24) month period.

Q1-12 How do I get a phone call from a Claims Officer to discuss my claim?

A Send a completed and signed Request For Assistance Form to the Claims Office.

Q1-13 How do I get a re-review of my claim?

A Send a completed and signed Request For Re-review Form, together with any additional information to be reviewed to the Claims Office.

Q1-14 Where can I get these forms?

A All forms and information concerning the settlement can be obtained by calling 1-800-600-0311. In addition, many of the forms may be obtained from the Claims Office website at www.claimsoffice926.com.

Q1-15 How long do I have to send in additional information about my claim?

A Until the settlement ends on December 15, 2010.

Q1-16 Do I have to correct all the deficiencies in my GCTS letter?

A Not necessarily. It is only necessary to cure the deficiencies for those findings that are needed to meet either Compensation Level A or Compensation Level B. Refer to Exhibit E1 for the requirements for each compensation level.

Q1-17 I have not been able to establish all the findings necessary for Level A or Level B compensation. Can I receive partial compensation for the symptoms I have established?

A No. You must meet all the criteria of a particular compensation level to receive any compensation for your GCTS symptoms.

SECTION 2 EXCLUSIONS AND AFFIRMATIVE STATEMENTS

Q2-1 What is an exclusion?

A An exclusion is a condition that may exist which could disqualify a specific finding.

Q2-2 What is an exclusion statement and who can provide this statement?

A The exclusion statement is a required written statement by the medical doctor who establishes the finding. Please note, merely stating "the exclusions are not present" is not sufficient. The doctor must address all components listed in each specific exclusion.

Q2-3 Where are the exclusions found?

A Within the GCTS criteria, six (6) of the twelve (12) findings require their own specific exclusion. The six findings include:

Group I
Polyarthritis
Keratoconjuctivitis Sicca
Immune-mediated skin changes or rashes (malar rash)

Group II
Myositis
Peripheral neuropathy or polyneuropathy

Group III
Dry mouth

These exclusions are set apart by brackets within the specific part of the finding.

Q2-4 What is meant by the phrase "affirmatively state that the qualifying symptoms did not exist before the date of first implantation?"

A An affirmative statement declares that the finding did not exist before your first breast implantation. Please note that Exhibit E1 requires that these physicians' statements be affirmative. Statements that are not written affirmatively may generate a deficiency.

Q2-5 Who can make the affirmative statement?

A Only the physician making or establishing the finding can make the affirmative statement that the qualifying symptoms did not exist before the date of your first implantation.

Q2-6 How can my current physician provide this affirmation statement without having known me before I had breast implants?

A This statement can be based upon patient history or a review of existing medical records. If it is based upon patient history, it must be consistent with the medical records in the physician's possession. In addition, the Claims Office must receive a copy of the complete patient history taken by the physician.

Q2-7 What is meant by the exclusion of classical rheumatoid arthritis?

A The general overall exclusion for GCTS is classical rheumatoid arthritis. This is in the first paragraph of section V of Exhibit E1. Every claimant seeking compensation for GCTS needs an affirmative statement from a physician stating that the claimant does not have "classical rheumatoid arthritis."

There are several types of rheumatoid arthritis, such as: possible, probable, definite, and classical. A claimant may have a diagnosis of rheumatoid arthritis (possible, probable or definite) and still be eligible for compensation for GCTS. The claimant cannot have "classical" rheumatoid arthritis. If the claimant has classical rheumatoid arthritis, she is not eligible to receive compensation for GCTS.

SECTION 3 GROUP I – POLYARTHRITIS

Q3-1 For the finding of polyarthritis, what are considered to be "different joint groups"?

A The following are considered to be "different joint groups":

Wrists
Elbows
Shoulders
Hips
Knees
Ankles
Joints of the forefoot
Metatarsal phalangeal joints
Interphalangeal joints of the toes
DIP/PIP – distal/proximal interphalangeal joints
MCP – metacarpal phalangeal joints

Q3-2 I have arthritis with tenderness in the joints of my wrists, elbows, and left knee. I have swelling in the left knee and both ankle joints. Do these joints qualify as having polyarthritis?

A No. Exhibit E1 requires that synovial swelling and tenderness are present in at least three of the same joints at the same time.

Q3-3 My doctor is board-certified in Family Practice. Is this an acceptable certification for the finding of polyarthritis?

A Yes. The requirement for Group I-1, polyarthritis, is "a board-certified physician." Exhibit E1 does not require board-certification in any particular specialty, only that the physician be board-certified.

Q3-4 I have one examination for polyarthritis which meets all of the criteria. However, when I returned to my doctor, I had tenderness and swelling in three different joints. Can I ever qualify for polyarthritis if this keeps happening?

A Yes. Exhibit E1 does not require that polyarthritis be observed in the same joints on each examination.

Q3-5 For polyarthritis, provided that the two examinations are more than six weeks apart, do they need to be performed by the same board-certified physician?

A No. You may have physical examinations from two different physicians, as long as each physician is board-certified.

Q3-6 I have osteoarthritis in my right hip. In addition, I have polyarthritis in my hands, wrists and elbows. Because of the exclusion of osteoarthritis, does this mean that I cannot be credited for the symptom of polyarthritis?

A Not necessarily. Polyarthritis may be credited in the presence of osteoarthritis if the joints counted in the diagnosis of polyarthritis are not the joint(s) affected by osteoarthritis.

SECTION 4 GROUP I – KERATOCONJUNCTIVITIS SICCA

Q4-1 I have dry eyes and my doctor is sending me to an optometrist for a Schirmer's test. Shouldn't this test be performed by an ophthalmologist instead?

A Exhibit E1 does not identify who is required to perform the Schirmer's test; however, Exhibit E1 does require that the physician recording a GCTS finding must affirmatively state that the qualifying symptoms did not exist before the date of first implantation and must affirmatively state that the listed exclusions are not present. As a result, an optometrist, who is not a medical doctor (physician), cannot make these statements and cannot satisfy settlement criteria. An ophthalmologist, who is a medical doctor, can provide all documentation needed for this symptom for purposes of the settlement.

Q4-2 Keratoconjunctivitis sicca contains an exclusion for drugs known to cause dry eyes and/or dry mouth. What must my physician say to establish that I am not excluded from this symptom because of my medications?

A The physician documenting your symptom of keratoconjunctivitis sicca must affirmatively state that you are not taking any medications know to cause dry eyes and/or dry mouth.

Q4-3 I wear contact lenses. Does this mean I cannot submit a claim for keratoconjunctivitis sicca?

A No. However, your physician must affirmatively state that your dry eyes are not caused by your contact lenses. To make this statement, your physician may require you to not wear contact lenses for some period of time prior to taking any test to establish your dry eyes.

Q4-4 My physician stated that my Schirmer's test result was less than 8mm in three minutes. Will this test meet settlement criteria?

A No. Your Schirmer's test result must be less than 8mm in five minutes.

Q4-5 My physician stated that I have a positive fluorescein staining of my cornea but not my conjunctiva. Will this meet settlement criteria?

A No. You must have fluorescein staining of both the cornea and the conjunctiva to meet settlement criteria for keratoconjunctivitis sicca.

Q4-6 My physician stated that I have a positive Rose-Bengal and provided the exclusion statements but did not state in my record that I have keratoconjunctivitis sicca. Will my claim be deficient because he did not make that diagnosis?

A No. You do not need a diagnosis of keratoconjunctivitis sicca to meet settlement criteria.

SECTION 5 GROUP I – IMMUNE-MEDIATED SKIN CHANGES OR RASHES

Q5-1 My physician, who is board-eligible, but not board-certified, in Rheumatology, has diagnosed me with discoid lupus and I have had a biopsy showing that. Do I have to see another Rheumatologist or Dermatologist?

A Yes. The discoid lupus must be observed by a board-certified rheumatologist or a board-certified dermatologist to meet settlement criteria even if you already have had a biopsy.

Q5-2 What is a malar rash? Is it any rash on my cheeks?

A The language for the settlement's GCTS finding of malar rash contemplates observation of the classic butterfly rash that is used as a diagnostic criteria by Rheumatologists to diagnose lupus and was taken verbatim from the ARA revised Criteria for Systemic Lupus Erythematous, found in Table 61-11 of Kelley's Textbook of Rheumatology, 4th Ed., p. 1037. The authors of that text call this the "classic butterfly rash" (p. 1020). It is clearly not just any rash or redness that happens to appear on the cheek area. The revised disease criteria requires that this rash is immune-mediated. In addition, your physician must make certain additional statements excluding rosacea and sunburn.

Q5-3 Does my malar rash have to be on both cheeks?

A Yes. The settlement specifies that the malar rash be observed over the "malar eminences" which means both cheeks.

SECTION 6 GROUP II – POSITIVE ANA

Q6-1 Does the laboratory performing the ANA need to report the use of Hep2 as the substrate used?

A No. However, evidence should be provided that the sensitivity of the assay used was in the same range. An ANA reported by immunofluorescence (FANA) would be acceptable; however, an ANA reported using mouse kidney as the substrate is not acceptable.

Q6-2 Concerning the positive ANA finding, does the ANA have to be reported in a titer, or can it be reported in international units (IU/ml)?

A IU/ml is an acceptable method of reporting an ANA; however, the laboratory performing the test must supply their conversion table which converts IU/ml to a titer.

Q6-3 I have two positive ANAs, both in a titer of 1:80; however, the laboratory record does not contain any reference range. Where will these laboratory results be credited?

A Group II-4 requires that all "findings must be outside the performing laboratory's reference ranges." Therefore, provided that the two positive ANAs are at least two months apart, they may be credited in Group III-9, serologic abnormalities, but they would not be credited in Group II-4.

Q6-4 I meet the requirements for Group II-4, positive ANA, with two ANA's of 1:40 (with reference range and Hep2), done two months apart. After my second ANA was positive, I then had the C3 and C4 done, both of which were decreased. Will this finding be credited in Group II?

A No. Exhibit E1 requires that, in order for the ANA to be credited in Group II, one of the positive ANA's must be "accompanied by at least one test showing decreased compliment levels of C3 and C4". In other words, the C3 and C4 must be performed on the same date as one of the ANA tests. However, this finding may be credited in Group III-9, serologic abnormalities.

SECTION 7 GROUP II – ABNORMAL CARDIOPULMONARY SYMPTOMS

Q7-1 I smoked some in college, over twenty years ago. I have recently been diagnosed with interstitial lung disease. Am I barred from this symptom?

A Not necessarily. If you quit smoking many years before your diagnosis of interstitial lung disease, you may still be able to be credited with this symptom. However, your physician should clearly indicate that the interstitial lung disease was not related to your history of smoking. If you were a long-term heavy smoker who quit shortly before receiving the diagnosis, you would not be eligible to be credited with this symptom.

SECTION 8 GROUP II – MYOSITIS OR MYOPATHY

Q8-1 I have an elevated CPK on two separate occasions at least six weeks apart. My EMG records reflect short duration, small, low amplitude polyphasic potential, and fibrillation potentials, but they do not reflect bizarre high-frequency repetitive discharges. Will this meet criteria for myopathy?

A No. Your EMG must also have bizarre high-frequency repetitive discharges to meet the criteria for Group II(a).

SECTION 9 GROUP II – PERIPHERAL NEUROPATHY OR POLYNEUROPATHY

Q9-1 Does the neurologist need to specify how the "loss of sensation" was documented?

A Yes. The neurologist must specify whether the loss of sensation was by pinprick, vibration, touch, or position.

Q9-2 What is meant by symmetrical distal muscle weakness?

A Symmetrical means that the weakness is found in the same distal muscle group on opposite sides of the body, e.g., weakness in the left and right gastrocnemiums (calf) muscles. Distal means a muscle group furthest from the center or from the trunk.

Q9-3 Concerning the exclusion statement for peripheral neuropathy or polyneuropathy, does the "within the last three months" statement apply to infectious disease only?

A Yes.

Q9-4 I have diabetes. Does this make me ineligible to be credited with peripheral neuropathy?

A Yes.

Q9-5 I am a recovering alcoholic and have not had a drink in over ten years. Am I still ineligible to be credited with polyneuropathy?

A Yes.

Q9-6 Does the requirement for "nerve conduction testing abnormality diagnostic of peripheral neuropathy or polyneuropathy recorded from a site that has not undergone neural or muscular biopsy" apply only if I have "loss of tendon reflex"?

A No. For this finding, the word "plus" indicates that, in addition to one of the criteria of (a), (b), (c) or (d), the nerve conduction testing is also required.

Q9-7 My doctor told me I have carpal tunnel syndrome. Is this a creditable finding under peripheral neuropathy or polyneuropathy?

A No. Group II-7 requires more than mere identification of a symptom; rather, it requires an acceptable diagnosis of peripheral neuropathy or polyneuropathy by a board-certified neurologist. Carpal tunnel syndrome, like other entrapment neuropathies, is itself a specific diagnosis that is different than a diagnosis of peripheral neuropathy or polyneuropathy.

SECTION 10 GROUP III – OTHER IMMUNE-MEDIATED SKIN CHANGES OR RASHES

Q10-1 My rheumatologist diagnosed me with livedo reticularis. Must I have a biopsy to prove it?

A No. You are not required to have a biopsy for Group III immune-mediated skin changes or rashes.

Q10-2 I have petechiae in one spot. Is this diffuse petechiae?

A No. Diffuse indicates that the petechiae is not localized to one area.

SECTION 11 GROUP III – SEROLOGIC ABNORMALITIES

Q11-1 My laboratory report for SSA SSB does not indicate that this test was performed by ELISA. My doctor told me the lab always performs this test using the ELISA method. Can my doctor write a letter saying that this was the method used for my SSA SSB?

A No. A written statement from your physician is not acceptable. The laboratory performing the SSA SSB test must provide a written statement regarding the method used to perform the test.

Q11-2 Can the lab result for RF (Rheumatoid Factor) be reported in a "quantitative method", i.e. IU/ml?

A In addition to the criteria in Exhibit E1, an acceptable RF includes a positive finding of Rheumatoid Factor according to the nephelometric method of measuring serum concentrations, where the lab value is above the range considered positive in the lab performing the test (and in no event less than 21 IU/ml).

SECTION 12 GROUP III – RAYNAUD'S PHENOMENON

Q12-1 My medical records clearly show two color changes whenever my doctor sees my Raynaud's. However, he never writes this to be in response to cold. Must the record indicate that, when the doctor sees the color changes, this was in response to cold, or can the "cold-related" be from my history as my records show?

A Exhibit E1 requires that Raynaud's phenomenon be observed by a physician and that he must indicate that he has observed the two color changes to be cold-related.

SECTION 13 GROUP III – MYALGIAS

Q13-1 I have a diagnosis of fibromyalgia and I see a chiropractor at least once a month. Can I use his records which show "tenderness to palpation, in at least three muscles"?

A No. Exhibit E1 requires that tenderness to palpation be performed by a physician. Therefore, we are unable to credit myalgias when the documentation is performed by a chiropractor, physical therapist, nurse practictioner, or physician's assistant.

Q13-2 Does the statement in Group III-11 "each persisting for at least six months" mean that I must have myalgias in the same three muscles for at least six months?

A Yes. Your physician must identify that the tenderness to palpation has persisted in the same three muscles for at least six months.

SECTION 14 GROUP III – DRY MOUTH

Q14-1 My physician stated that my parotid flow rate was less that 0.5 ml but does not state the time frame. Will this test meet settlement criteria?

A No. The physician must state that the parotid flow rate was less than 0.5 ml per five minutes.