

EXHIBIT D  
Disease Schedule

MEDICAL CONDITIONS AND CHARACTERISTICS  
OUTLINE OF DEFINITIONS AND CLASSIFICATION CRITERIA

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

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

SYSTEMIC SCLEROSIS/SCLERODERMA (SS)

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

SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

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

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

3. Severity/Disability Compensation Categories:

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

**ATYPICAL NEUROLOGICAL DISEASE SYNDROME (ANDS)**

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

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

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

- Signs of dysesthesia
- Loss of tendon reflex

plus one or more of the following laboratory findings:

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

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

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

plus one or more of the following:

- Abnormal Brain MRI with foci of increased signal abnormality suggestive of demyelinating lesions<sup>1</sup>
- Delayed visual-evoked responses or abnormal-evoked potentials
- Abnormal CSF with oligoclonal bands

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

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

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

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

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

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

#### MIXED CONNECTIVE TISSUE DISEASE (MCTD) / OVERLAP SYNDROME

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

#### POLYMYOSITIS/DERMATOMYOSITIS

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

Application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of polymyositis or dermatomyositis but who nonetheless have a polymyositis or dermatomyositis-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles an Atypical Connective Tissue Disease.

3. Severity/Disability Compensation Categories:

- A. Death or total disability resulting from polymyositis or dermatomyositis. An individual will be considered totally disabled based on the functional capacity test set forth for Severity/Disability Category A for Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.
- B. Polymyositis or dermatomyositis with associated malignancy and/or respiratory muscle involvement.
- C. Other, including polymyositis or dermatomyositis with muscle strength of Grade III or less.

### PRIMARY SJOGREN'S SYNDROME

- 1. A clinical diagnosis of Primary Sjogren's Syndrome shall be made in accordance with diagnostic criteria proposed by Fox, *et al.* See Kelley, *et al.*, Table 55-1, at 932, or Fox, RI *et al.* "Primary Sjogren's Syndrome: Clinical and Immunopathologic Features," *Seminars Arthritis Rheum.*, 1984; 4: 77-105.
- 2. Application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of Primary Sjogren's Syndrome but who nonetheless have a Primary Sjogren's-like disease.

3. Severity/Disability Compensation Categories:

- A. Death or total disability due to the compensable condition. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A for Atypical Connective Tissue Disease/Atypical Rheumatic Syndrome.
- B. Primary Sjogren's with associated central nervous system or severe cardio-pulmonary involvement or primary Sjogren's with pseudolymphoma or associated lymphoma.
- C. Other.

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

- 1. This category will provide compensation for Class Members experiencing symptoms that are commonly found in autoimmune or rheumatic diseases but which are not otherwise classified in any of the other compensable disease categories. This category does not include individuals who have been diagnosed with classical rheumatoid arthritis in accordance with ACR criteria, but will include individuals diagnosed with undifferentiated connective tissue disease (UCTD). However, such inclusion is not intended to exclude from this category persons who do not meet the definition of UCTD, it being intended that individuals not meeting the classic definitions of UCTD will be compensated pursuant to the provisions contained herein relative to ACTD, ARS, and NAC.

As with other individuals who fit within this disease compensation program, the fact that a breast implant recipient has been in the past misdiagnosed with classic rheumatoid arthritis or the fact that the symptoms of classic rheumatoid arthritis may coexist with other symptoms will not exclude the individual from compensation herein. Persons who meet the criteria below and may have a diagnosis of atypical rheumatoid arthritis will not be excluded from compensation under

this category.

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

neuropsychological testing

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

(c) Group III Signs and Symptoms:

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

6. Severity/Disability Compensation Categories

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

perform her vocational,<sup>4</sup> avocational,<sup>5</sup> or usual self-care<sup>6</sup> activities. In evaluating the effect of the Class Member's symptoms, the treating physicians will take into account the level of pain and fatigue resulting from the symptoms. The disability percentages appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the physician in the exercise of his or her professional judgment.

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

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

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

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