EXHIBIT "E"

MEDICAL CONDITIONS LIST

1. The Medical Conditions set forth herein relate to making claims pursuant to the Settlement Agreement and the Claims Administration Procedures (at Exhibit "D" thereto) of the Wilson Class Action Settlement Agreement. The criteria set out herein for eligibility and qualification for settlement benefits are to be considered by the Claimant and Treating Physician in determining whether a claim should be advanced, and shall be considered by the Claims Adjudicator in determining whether a Claimant is entitled to benefits pursuant to the settlement.

2. The Parties hereto acknowledge and agree that, where reference is made in this Settlement Agreement and the Exhibits hereto to the "cause" of a disease or condition for which a claim for benefits is made, or where reference is made to any diagnostic criteria described herein, such reference is made only for the purposes of the administration and implementation of the settlement herein and is not intended to be and shall not be construed as an admission by the Defendants, or any of them, that the Products are the cause of, or contribute to, any of the injuries for which Claimants may be compensated pursuant to this Settlement Agreement.

3. Eligibility

3.1 *Valvular Heart Disease*

3.1.1 A Claimant shall be eligible to receive a benefit for Valvular Heart Disease ("VHD") if that Claimant timely and properly submits a claim for such benefit demonstrating that the Product Recipient was "FDA Positive" or greater.[1]

3.1.2 Diagnosis of VHD at an FDA Positive level or greater must have been made within seven (7) years following first use of the Products by the Product Recipient.[2]

3.1.3 If a diagnosis of VHD at an FDA Positive level or greater was made more than seven (7) years following a Product Recipient's first use of the Products, it shall be presumed that the Claimant is not entitled to a VHD Benefit. This presumption may be overcome

[1] The Parties hereto acknowledge and agree that, where reference is made in this Settlement Agreement and the Exhibits hereto to the "cause" of a disease or condition for which a claim for benefits is made, or where reference is made to any diagnostic criteria described herein, such reference is made only for the purposes of the administration and implementation of the settlement herein and is not intended to be and shall not be construed as an admission by the Defendants, or any of them, that the Products are the cause of, or contribute to, any of the injuries for which Claimants may be compensated pursuant to this Settlement Agreement.

[2] See Note 1, above.

where the Claims Adjudicator determines from a review of the Claim Package that the Product Recipient satisfies all of the criteria contained in the Medical Conditions List and where the following additional requirements are met:

(a) Where the Supporting Medical Documentation reflects that the Product Recipient sought medical attention within seven (7) years of first use of the Products in relation to the disease or condition for which a claim is being made and none of the Additional Medical Factors for Consideration for VHD as set out in section 6 herein are found in the Product Recipient's Supporting Medical Documentation, the claim shall be adjudicated in the normal course; or

(b) Where the Supporting Medical Documentation reflects that the Product Recipient sought medical attention within seven (7) years of first use of the Products in relation to the disease or condition for which a claim is being made, if the Supporting Medical Documentation reveals one or more of the Additional Medical Factors for Consideration for VHD as set out in section 6, the Claims Adjudicator shall confirm that the Additional Medical Factors have been ruled out[3] as the cause of the VHD before the Claimant is entitled to have the claim adjudicated in the normal course; or

(c) Where the Supporting Medical Documentation reflects that the Product Recipient has not sought medical attention within seven (7) years of first use of the Products in relation to the VHD, and none of the Additional Medical Factors for Consideration for VHD as set out in section 6 are found in the Product Recipient's Supporting Medical Documentation, the Claims Adjudicator shall be required to satisfy him or herself that the Products were most likely the cause of the VHD[4] before the Claimant is entitled to have the claim adjudicated in the normal course; or

[3] The recognition of any process of ruling out other alternative causes for the VHD of the Claimant is for the purposes of this settlement only and shall not be construed as an admission that the Products are the cause of, or contribute to, any of the injuries for which Claimants may be compensated pursuant to this settlement.

[4] Any determination by the Claims Administrator that other alternative causes of VHD have been ruled out as the cause of the VHD shall be for the purposes of this settlement only. Any such determination pursuant to this section, as well as the process employed in arriving at this determination pursuant to the terms of this settlement, shall not be construed as an admission that the Products are the cause of, or contribute to, any of the injuries for which Claimants may be compensated pursuant to this settlement.

(d) Where the Supporting Medical Documentation reflects that the Product Recipient has not sought medical attention within seven (7) years of first use of the Products in relation to the disease or condition for which a claim is being made, if the Supporting Medical Documentation reveals one or more alternative causes for the VHD, the Claims Adjudicator shall confirm that the Additional Medical Factors for Consideration for VHD as set out in section 6 for VHD have been ruled out[5] as the cause of the VHD before the Claimant is entitled to have the claim adjudicated in the normal course.

3.2 *Primary Pulmonary Hypertension*

3.2.1 A Claimant shall be eligible for Matrix Benefits for Primary Pulmonary Hypertension ("PPH") if the Product Recipient was diagnosed with PAH (as defined herein) within seven (7) years following first use of the Products.[6]

3.2.2 If a diagnosis of PAH was made more than seven (7) years following a Product Recipient's first use of the Products, it shall be presumed that the Claimant is not entitled to a Matrix-level Benefit for PPH.[7] This presumption may be overcome where the Claims Adjudicator determines that the Product Recipient satisfies all of the criteria contained in the Medical Conditions List. The following additional requirements also apply where a Product Recipient was diagnosed with PAH [8] more than seven (7) years following first use of the Products:

(a) Where the Supporting Medical Documentation reflects that the Product Recipient sought medical attention within seven (7) years of first use of the Products in relation to the disease or condition for which a claim is being made and none of the alternative causes for PPH listed in section 5.2.2 are found in the Product Recipient's Supporting Medical Documentation, the claim shall be adjudicated in the normal course; or

(b) Where the Supporting Medical Documentation reflects that the Product Recipient sought medical attention within seven (7) years of first use of the Products in relation to the disease or condition for which a claim is being made, if the

[5] See Note 3 and 4, above.

[6] See Note 1, above.

[7] *Ibid*.

[8] *Ibid*.

Supporting Medical Documentation reveals one or more of the alternative causes for the PPH listed in section 5.2.2, the Claims Adjudicator shall confirm that the alternative causes for PPH have been ruled [9] out as the cause of the PPH before the Claimant is entitled to have the claim adjudicated in the normal course; or

(c) Where the Supporting Medical Documentation reflects that the Product Recipient has not sought medical attention within seven (7) years of first use of the Products in relation to the PPH, and there is no other alternative cause for PPH listed in section 5.2.2 found in the Product Recipient's Supporting Medical Documentation, the Claims Adjudicator shall be required to satisfy him or herself that the Products were most likely the cause of the PPH [10] before the Claimant is entitled to have the claim adjudicated in the normal course; or

(d) Where the Supporting Medical Documentation reflects that the Product Recipient has not sought medical attention within seven (7) years of first use of the Products in relation to the disease or condition for which a claim is being made, if the Supporting Medical Documentation reveals one or more of the alternative causes for PPH listed in section 5.2.2, the Claims Adjudicator shall confirm that any alternative causes for PPH have been ruled out [11] as the cause of the PPH before the Claimant is entitled to have the claim adjudicated in the normal course.

3.2.3 A Claimant shall not be eligible for a PPH benefit if the Supporting Medical Documentation (as defined in the Claims Administration Procedures) identifies the presence of a diagnosis of pulmonary hypertension prior to use of the Products except where the progression of such pulmonary hypertension deviates from the

[9] The recognition of any process of ruling out other alternative causes for the PAH of the Claimant is for the purposes of this settlement only and shall not be construed as an admission that the Products are the cause of, or contribute to, any of the injuries for which Claimants may be compensated pursuant to this settlement.

[10] Any determination by the Claims Administrator that other alternative causes of PAH have been ruled out as the cause of the PAH shall be for the purposes of this settlement only. Any such determination pursuant to this section, as well as the process employed in arriving at this determination pursuant to the terms of this settlement, shall not be construed as an admission that the Products are the cause of, or contribute to, any of the injuries for which Claimants may be compensated pursuant to this settlement.

[11] See Notes 9 and 10, above.

expected course in a clinically significant manner, following ingestion of the Products.

3.3 Echocardiographic Criteria

3.3.1 Minimum Qualifications for Echocardiographic Review

(a) Where echocardiographic images are available, all echocardiographic findings that form the basis of a VHD claim must satisfy the following criteria:

(i) The echocardiogram must have been performed by an echocardiogram technician, a cardiac sonographer, or a radiographer credentialed in the performance of echocardiography or by a cardiologist or radiologist who is able to produce and evaluate ultrasonic images and related data used by physicians to render a medical diagnosis, save and except:

(1) Where the echocardiogram was performed by a radiographer not so credentialed prior to January 1, 2003, in which case the echocardiogram must have served as the basis for further monitoring or a course of treatment as demonstrated by medical records; or

(2) Where the echocardiogram was performed in Québec, in which case, it must have been performed by a physician credentialed in the performance of echocardiography by the *Collège des médecins du Québec* .

(ii) The echocardiogram must have been conducted under the supervision of, in accordance with the normal practice in the jurisdiction in which the echocardiogram was performed, and read and interpreted by, a physician with at least level 2 training in echocardiography as specified in the Recommendations of the American Society of Echocardiography Committee on Physician Training in Echocardiography, or the equivalent of level 2 training, as determined by the Claims Adjudicator; and

(iii) The echocardiogram must have been memorialized in a written report issued by the physician referred to in section 3.3.1(a)(ii) and the accompanying echocardiographic recording, where available, shall confirm a diagnosis which qualifies the Claimant for benefits.

(iv) In circumstances where only the written report is available, and the claim is for a benefit that requires the establishment of left atrial and/or ventricular dimensions, the written report must contain a record of at least left atrial and/or left ventricular dimensions. In circumstances where the written report is unavailable, the echocardiographic recording must be available.

3.3.2 Measurement and Quantification of Regurgitation

(a) To serve as the basis for a VHD claim, where echocardiographic images are available, measurement and quantification of regurgitation must be conducted in accordance with the following criteria:

(i) The colour jet must also display turbulent flow as indicated by colour mosaic. Colour gain settings must be set appropriately to minimize background speckle and a Nyquist limit must be set at greater than or equal to 50 cm/second;

(ii) The regurgitant jet must originate and be contiguous with the valve leaflets and be clearly seen in real time rather than only from a frozen image; and

(iii) To constitute a basis for a claim, the same level of severity of regurgitation must be visible for at least three consecutive beats of the heart and all measurements taken to determine the severity of regurgitation shall be taken from the same echocardiogram.

(b) **Standards for Matrix Claims**

(i) For VHD Matrix Claims, where echocardiographic images are available, they must be interpreted by the Claims Adjudicator in accordance with the standards and criteria established and published by the American Society of Echocardiography[12] (the "ASE Guidelines"). The ASE Guidelines require that, to the extent possible based on available data, specific and supportive signs be evaluated in conjunction with quantitative parameters to determine regurgitation severity.

[12] Zoghbi et al., *Recommendations for Evaluation of the Severity of Native Valvular Regurgitation with Two-Dimensional and Doppler Echocardiography,* Am. Society of Echocardiography, 16 J Am Soc Echo 777-802 (2003).

(c) **Standards for FDA Positive Claims**

(i) For FDA Positive Claims, where echocardiographic images are available, they must meet the following criteria:

A. Moderate MR shall mean greater than 20% RJA/LAA;

B. Mild AR shall mean greater than 10% JH/LVOTH

(ii) Notwithstanding the preceding, where the mitral or aortic regurgitant jet is eccentric and a large flow convergence area is evident, other qualitative factors shall be considered in determining severity.

3.3.3 Restrictions on Foreign Echocardiograms

(a) The echocardiogram(s) referred to herein must be performed and interpreted in Canada unless the Claimant provides evidence that the foreign echocardiogram was conducted by an individual with the equivalent qualifications and credentials and in accordance with the same criteria for performance and interpretation set out at section 3.3.1 and section 3.3.2 above and one or more of the following conditions are met:

(i) the Product Recipient normally has a temporary foreign residence and therefore has regularly sought their primary medical care in the foreign jurisdiction, including for the condition for which a claim is made;

(ii) the Product Recipient normally receives medical treatment outside of Canada, including for the condition for which a claim is made;

(iii) the Product Recipient has received treatment in Canada which indicates that he or she has a condition such that he or she may qualify for benefits under this settlement and on the basis of that treatment or diagnosis, he or she has sought and received treatment at a tertiary care cardiology clinic outside of Canada and has had an echocardiogram performed and interpreted at such a tertiary care cardiology clinic outside of Canada which echocardiogram shall be submitted as part of the Supporting Medical Documentation;

(iv) the Product Recipient has access to foreign health care through a foreign medical insurance plan or employee assistance plan and normally receives medical treatment outside of Canada, pursuant to such plan, including for the condition for which a claim is made; or

(v) the Product Recipient sought and received treatment outside of Canada in relation to the condition for which a claim is made due to a medical emergency.

4. Levels of Disease Severity Qualifying for Payment

4.1 A Claimant shall be eligible to make a claim for benefits if that Claimant timely and properly submits a Claim Package within the Claim Period, pursuant to the procedures outlined in the Claims Administration Procedures, demonstrating that the Product Recipient has been diagnosed with a compensable condition of compensable severity. The levels of disease severity which qualify eligible Claimants for settlement benefits follow below. These definitions of FDA Positive, VHD and PPH are intended solely for the purpose of describing claims entitled to benefits under the terms of this Settlement Agreement, and shall not be used, including against the Defendants, for any other reason or purpose.

4.2 In reviewing Claim Packages, the Claims Adjudicator shall make his or her own decision with respect to whether a particular level of disease severity exists pursuant to these definitions.

4.3 FDA Positive Benefits

4.3.1 "FDA Positive" means mild or greater regurgitation of the aortic valve of the heart and/or moderate or greater regurgitation of the mitral valve of the heart as measured by an echocardiographic examination and as defined above in Section 3. A diagnosis of "FDA Positive" is a condition which the physician referred to in section 3.3.1(a)(ii) above, interpreting the echocardiogram, in the ordinary course of medical treatment, has issued a written report in accordance with section 3.3.1(a)(iii) above which states that the Product Recipient has mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve. An echocardiogram is considered to be obtained in the ordinary course of medical treatment where it is deemed appropriate by the physician referred to in section 3.3.1(a)(ii) above, regardless of whether it is used to determine eligibility for this Settlement.

4.3.2 If the Supporting Medical Documentation (as defined in the Claims Administration Procedures) identifies a diagnosis of FDA positive or greater regurgitation in the valve which is the subject of the

claim prior to use of the Products, the Claimant will not be entitled to receive FDA positive benefits pursuant to the Settlement Agreement.

4.4 Matrix-Level Valvular Heart Disease Benefits

4.4.1 Where a Claimant submits more than one echocardiogram in respect of a Product Recipient, the Claims Adjudicator shall base his or her opinion on the echocardiogram which confirms the highest level of disease severity, even where the level of disease severity has regressed, provided that the Supporting Medical Documentation does not reflect that the Product Recipient's condition regressed within 18 months following the first echocardiogram with the highest severity level. However, in the event that such a Product Recipient's level of disease severity is reduced as a result of active medical intervention, the claim shall be assessed at the highest level of disease severity reflected in the echocardiograms submitted by the Claimant. In the event that such a Product Recipient's level of disease severity progresses after submission of a Claim Package but during the Administration Period, a Claimant shall only be entitled to submit a claim for progression if the Product Recipient's disease severity level exceeds the level at which a benefit was originally assessed.

4.4.2 The Claims Adjudicator shall apply the following criteria in determining for which, if any, Matrix-level VHD Benefit a Claimant qualifies.

4.4.3 Matrix Level I

(a) Matrix Level I is defined as one of the following:

(i) Hemodynamically significant MR which shall mean >30% RJA/LAA unless the echo recording is not available, in which case a written description of moderate or greater mitral regurgitation in the echocardiogram report will be sufficient, in either circumstance, with evidence of left ventricular enlargement as documented by abnormal left ventricular end-diastolic dimension of >63mm or >34 mm/m^2 by BSA Indexing (which is the calculation derived from dividing the patient's chamber dimension by the patient's body surface area using the Dubois method) and abnormal left atrial antero-posterior systolic dimension >40 mm or >22 mm/m^2 by BSA Indexing.

(ii) Hemodynamically significant AR which shall mean >45% JH/LVOTH, unless the echo recording is not available, in which case a written description of moderate or greater aortic regurgitation in the echocardiogram report will be sufficient, in either circumstance, with evidence of left ventricular enlargement as documented by abnormal left ventricular end-diastolic dimension of >65mm or 34.5 mm/m^2 by BSA Indexing, or abnormal left ventricular end-systolic dimension of >45 mm or >24 mm/m^2 by BSA Indexing.

(iii) FDA Positive valvular regurgitation[13] with bacterial endocarditis in the valve upon which the claim is based.

(b) Claimants who file qualified claims within the Claim Period and who fulfill the qualification requirements herein shall be entitled to Level I benefits according to the VHD Matrix attached hereto as Exhibit "F".

(c) In addition, Claimants who filed an FDA Positive Benefit claim within the Claim Period that was approved, shall be entitled to submit a Progressed Claim in accordance with the Claims Administration Procedures where the Product Recipient's level of disease severity progresses to a Matrix Level I or higher condition during the Administration Period.

4.4.4 Matrix Level II

(a) Matrix Level II is defined as one of the following:

(i) Hemodynamically significant MR as defined in section 4.4.3(a)(i) above, with:

(1) arrhythmias, defined as chronic atrial fibrillation/flutter that cannot be converted to normal sinus rhythm, or atrial fibrillation/flutter requiring ongoing medical therapy, and the Product Recipient was under the age of 70 years at the date of diagnosis of the arrhythmia, and the arrhythmia was not caused by hyperthyroidism, previously diagnosed coronary disease, alcohol abuse or systemic hypertension

[13] See Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Services, *Cardiac Valvulopathy Associated with Exposure to Fenfluramine or Dexfenfluramine: US Department of Health and Human Services Interim Public Health Recommendations,* 46 Morbidity & Mortality Weekly Rep. 1061, 1061-1066 (1997).

(3 readings of greater than 160/95 within 2 years prior to the diagnosis of the arrhythmia); or

(2) pulmonary hypertension secondary to regurgitation with a mean systolic pulmonary artery pressure of >25mm Hg at rest or >30 mm Hg with exercise as measured by cardiac catheterization or with a peak systolic pulmonary artery pressure >45 mm Hg at rest as measured by Doppler Echocardiography, assuming a right atrial pressure of 5 mm Hg where the inferior vena cava is less than 2.0 cm and collapse is greater than 50%; assuming 10 mm Hg where the inferior vena cava is greater than 2.0 cm and collapse is less than or equal to 50%; and assuming 20 mm Hg where the inferior vena cava is greater than or equal to 2.0 cm and does not collapse; and where the inferior vena cava measurement is unavailable, a right atrial pressure of 5 mm Hg will be assumed; or

(3) left ventricular ejection fraction of <60% by echo; or

(4) abnormal left ventricular end-diastolic dimension >67 mm or >36 mm/m^2 by BSA Indexing, or end-systolic dimension ≥45 mm or ≥24.5 mm/m^2 by BSA Indexing.

(ii) MR defined as >30% RJA/LAA, unless the echo recording is not available, in which case a written description of greater than moderate mitral regurgitation in the echocardiogram report will be sufficient, with left ventricular end-diastolic dimension of >60mm or >32.5 mm/m^2 by BSA Indexing, and:

(1) a pulmonary artery systolic pressure of greater than 55 mm Hg and an abnormal left atrial antero-posterior systolic dimension >40 mm or >22 mm/m^2 by BSA Indexing; or

(2) arrhythmias, defined as chronic atrial fibrillation/flutter that cannot be converted to normal sinus rhythm, or atrial fibrillation/flutter requiring ongoing medical therapy, and the Product Recipient was under the age of 70 years at the date of diagnosis of the arrhythmia, and the arrhythmia was not caused by

hyperthyroidism, previously diagnosed coronary disease, alcohol abuse or systemic hypertension (3 readings of greater than 160/95 within 2 years prior to the diagnosis of the arrhythmia) and an abnormal left atrial antero-posterior systolic dimension >48 mm or >26 mm/m^2 by BSA Indexing; or

(3) left ventricular ejection fraction of <50% by echo.

(iii) Hemodynamically significant AR as defined in section 4.4.3(a)(ii) above, with:

(1) a left ventricular ejection fraction of <50% by echo; or

(2) Pulmonary hypertension secondary to regurgitation with a mean systolic pulmonary artery pressure of >25mm Hg at rest or >30 mm Hg with exercise as measured by cardiac catheterization or with a peak systolic pulmonary artery pressure >45 mm Hg at rest as measured by Doppler Echocardiography, assuming a right atrial pressure of 5 mm Hg where the inferior vena cava is less than 2.0 cm and collapse is greater than 50%; assuming 10 mm Hg where the inferior vena cava is greater than 2.0 cm and collapse is less than or equal to 50%; and assuming 20 mm Hg where the inferior vena cava is greater than or equal to 2.0 cm and does not collapse; and where the inferior vena cava measurement is unavailable, a right atrial pressure of 5 mm Hg will be assumed; or

(3) abnormal left ventricular end-diastolic dimension >70 mm or >37 mm/m^2 by BSA Indexing or end-systolic dimension >50 mm or >26.5 mm/m^2 by BSA Indexing.

(b) Claimants who file qualified claims within the Claim Period and who fulfill the qualification requirements herein shall be entitled to Level II benefits in accordance with the VHD Matrix attached hereto as Exhibit "F".

(c) In addition, Claimants who filed a qualified FDA Positive or Matrix Level I claim within the Claim Period shall be entitled to submit a progressed claim in accordance with the Claims Administration Procedures where the Product Recipient's

level of disease severity progresses to a Matrix Level II or higher condition during the Administration Period.

4.4.5 Matrix Level III

(a) Matrix Level III is defined as one of the following:

(i) Surgery to repair or replace the aortic and/or mitral valve(s) following use of the Products; or

(ii) Where the Product Recipient has not had surgery and would not qualify for benefits at Matrix Level I or II, the Product Recipient has greater than moderate valvular regurgitation and demonstrates, where a record is available, that his or her left ventricular end-diastolic pressure is greater than 15 mm Hg following use of the Products, and the Product Recipient has ACC/AHA Class I or greater indications for surgery to repair or replace the aortic[14] and/or mitral[15] valve(s) and there is a statement from the attending Certified Cardiac Surgeon or Certified Cardiologist supported by medical records regarding the recommendations made to the Product Recipient concerning valvular surgery, with the reason why the surgery is not being performed; or

(iii) Where the Product Recipient qualifies for benefits at Matrix Level I or II but has not had surgery, and the Product Recipient has ACC/AHA Class I or greater indications for surgery to repair or replace the aortic[16] and/or mitral[17] valve(s) and there is a statement from the attending Certified Cardiac Surgeon or Certified Cardiologist supported by medical records regarding the recommendations made to the Product Recipient concerning valvular surgery, with the reason why the surgery is not being performed; or

(iv) Qualification for payment at Matrix Level I or II and, in addition, a stroke due to Bacterial Endocarditis in the valve upon which the claim is based or as a consequence of chronic atrial fibrillation/flutter with

[14] Robert O. Bonow, et al., *Guidelines for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Patients With Valvular Heart Disease)*, 32 J. Am. C. Cardiology 1486 (1998)

[15] See *id*. at 1533-35

[16] See *id*. at 1510.

[17] See *id*. at 1533-35

left atrial enlargement in either 4.4.4. (a)(i)(1) or 4.4.4(a)(ii)(2), related to valvular heart disease and not to an unrelated heart condition, which results in a permanent condition which meets the criteria of AHA Stroke Outcome Classification[18] Functional Level II, determined at least six months after the event.

(b) Claimants who file qualified claims within the Claim Period and who fulfill the qualification requirements herein shall be entitled to Level III benefits in accordance with the VHD Matrix attached hereto as Exhibit "F".

(c) In addition, Claimants who filed a qualified FDA Positive Benefit or Matrix Level I or II Claim within the Claim Period shall be entitled to submit a progressed claim in accordance with the Claims Administration Procedures where the Product Recipient's level of disease severity progresses to a Matrix Level IIII or higher condition during the Administration Period.

4.4.6 Matrix Level IV

(a) Matrix Level IV is defined as one of the following:

(i) Qualification for payment at Matrix Level I, II or III and, in addition, a stroke due to Bacterial Endocarditis in the valve upon which the claim is based or as a consequence of chronic atrial fibrillation/flutter with left atrial enlargement as defined above in either 4.4.4.(a)(i)(1) or 4.4.4(a)(ii)(2) which results in a permanent condition which meets the criteria of AHA Stroke Outcome Classification[19] Functional Level III, determined at least six months after the event.

(ii) Qualification for payment at Matrix Level I, II or III and, in addition, a peripheral embolus due to Bacterial Endocarditis in the valve upon which the claim is based or as a consequence of atrial fibrillation/flutter with left atrial enlargement as defined above in either 4.4.4.(a)(i)(1) or 4.4.4(a)(ii)(2), which results in severe permanent impairment to the kidneys, abdominal organs, or extremities, where severe permanent impairment means:

[18] See Margaret Kelley-Hayes, et al., *The American Heart Association Stroke Outcome Classification*, 29 Stroke 1274, 1275 (1998). It should be noted that this classification was approved by the American Heart Association Science Advisory and Coordinating Committee [hereinafter "Kelley-Hayes"]

[19] See *id.*

(1) for the kidneys, severe renal failure defined as having creatinine clearance of less than 30 cc/min for greater than six months ; or

(2) for the abdominal organs, impairment requiring intra-abdominal surgery; or

(3) for the extremities, impairment requiring amputation of a major limb.

(iii) The individual has all of the following:

(1) Qualification for payment at Matrix Level III; and

(2) New York Heart Association Functional Class I or Class II symptoms as documented by the attending Certified Cardiac Surgeon or Certified Cardiologist; and

(3) Significant damage to the heart muscle, defined as: (A) a left ventricular ejection fraction < 30% with aortic regurgitation or a left ventricular ejection fraction < 35% with mitral regurgitation in Product Recipients who have not had surgery and meet the criteria of Section (1) above, or (B) a left ventricular ejection fraction < 40% persisting for at least six months after valvular repair or replacement surgery in Product Recipients who have had such surgery.

(iv) The Product Recipient has had valvular repair or replacement surgery and has one or more of the following complications which occur either during surgery, within 30 days after surgery, or during the same hospital stay as the surgery:

(1) severe renal failure defined as having a creatinine clearance of less than 30 cc/min which persists for at least six months following surgery; or

(2) Peripheral embolus following surgery resulting in severe permanent impairment to the kidneys, abdominal organs, or extremities; or

(3) Paraplegia resulting from cervical spine injury during valvular heart surgery.

(v) A stroke caused by aortic and/or mitral valve surgery and the stroke has produced a permanent condition

which meets the criteria of the AHA Stroke Outcome Classification[20] Functional Levels II or III determined at least six months after the event.

(vi) The Product Recipient has had valvular repair or replacement surgery and suffers from post operative endocarditis, mediastinitis or sternal osteomyelitis within six months of surgery, any of which requires reopening the median sternotomy for treatment, or a post-operative serious infection defined as HIV or Hepatitis other than Hepatitis A, as a result of a blood transfusion associated with the heart valve surgery.

(vii) The Product Recipient has had valvular repair or replacement surgery and requires a second surgery through the sternum due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery but not due to replacement of a valve at the end of its functional life as determined by the Treating Physician.

(viii) Death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred following use of the Products supported by a statement from the attending Certified Cardiac Surgeon or Certified Cardiologist, supported by medical records.

(b) Claimants who file qualified claims within the Claim Period and who fulfill the qualification requirements herein shall be entitled to Level IV benefits in accordance with the VHD Matrix attached hereto as Exhibit "F".

(c) In addition, Claimants who filed a qualified FDA Positive or Matrix Level I, II or III claim within the Claim Period shall be entitled to submit a progressed claim in accordance with the Claims Administration Procedures where the Product Recipient's level of disease severity progresses to a Matrix Level IV or higher condition during the Administration Period.

4.4.7 Matrix Level V

(a) Matrix Level V is defined as one of the following:

(i) Left sided valvular heart disease with severe complications, as described at 4.4.3(a)(iii) above or

[20] See *id.*

Matrix Levels II, III or IV above with one or more of the following:

(1) A severe stroke caused by aortic and/or mitral valve surgery or due to bacterial endocarditis in the valve upon which the claim is based, contracted after use of the Products or as a consequence of chronic atrial fibrillation/flutter with left atrial enlargement as defined in either 4.4.4(a)(i)(1) or 4.4.4(a)(ii)(2) above and the severe stroke has resulted in a permanent condition which meets the criteria of AHA Stroke Outcome Classification[21] Functional Levels IV or V, determined at least six months after the event; or

(2) Quadriplegia resulting from cervical spine injury during valvular heart surgery; or

(3) The individual has the following:

(a) Qualification for payment at Matrix Levels III or IV; and

(b) New York Heart Association Functional Class III or Class IV symptoms as documented by the attending Certified Cardiac Surgeon or Certified Cardiologist; and

(c) Significant damage to the heart muscle, defined as: (i) a left ventricular ejection fraction < 30% with aortic regurgitation or a left ventricular ejection fraction < 35% with mitral regurgitation, in Product Recipients who have not had surgery and meet the criteria in 4.4.7(a)(i)(3)(a) above or (ii) a left ventricular ejection fraction < 40% persisting for at least six months after valvular repair or replacement surgery in Product Recipients who have had such surgery; or

(4) Heart transplant as a consequence of VHD of a nature subject to benefits herein; or

[21] See *id.*

(5) Irreversible pulmonary hypertension (PAH) secondary to valvular heart disease defined as peak-systolic pulmonary artery pressure > 50 mm Hg[22] at rest by cardiac catheterization or >60 mm Hg by Doppler echocardiogram performed in accordance with the criteria set out at 3.3.1, 3.3.2 and 4.4.4(a)(i)(2) above, where cardiac catheterization is medically contra-indicated, following repair or replacement surgery of the aortic and/or mitral valve(s); or

(6) Persistent non-cognitive state[23] caused by a complication of valvular heart disease (e.g., cardiac arrest) or valvular repair/replacement surgery supported by a statement from the attending Certified Cardiac Surgeon, Certified Cardiologist or certified neurologist, supported by medical records; or

(ii) The Product Recipient otherwise qualifies at Matrix Level II, III or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise, in the absence of hemodynamically significant coronary artery disease as demonstrated by cardiac catheterization except where medically contraindicated.

(b) Claimants who file qualified claims within the Claim Period and who fulfill the qualification requirements herein shall be entitled to Level V benefits in accordance with the VHD Matrix attached hereto as Exhibit "F".

(c) In addition, Claimants who filed a qualified FDA Positive or Matrix Level I, II, III or IV claim within the Claim Period shall be entitled to submit a progressed claim in accordance with the Claims Administration Procedures where the Product Recipient's level of disease severity progresses to a Matrix Level V condition during the Administration Period.

5. Primary Pulmonary Hypertension Benefits

5.1 A Claimant shall qualify for benefits for PPH under this settlement pursuant to the definitions contained in section 5.2 or 5.3 below.

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[22] See Braunwald E, ed. *Heart Disease: A Textbook of Cardiovascular Medicine* 5th ed. 1997, at 796-98.

[23] See Adelman, G. ed., *Encyclopedia of Neuroscience* at 268 (1987).

5.2 PPH Prior to Death

5.2.1 The Product Recipient was diagnosed with PAH prior to death, where PAH is defined as:

(a) Mean pulmonary artery pressure of > 25 mm Hg at rest or > 30 mm Hg with exercise during right heart catheterization; or

(b) Peak systolic pulmonary pressure >60 mm Hg estimated during Doppler trans-thoracic echocardiogram performed in accordance with the criteria set out at 3.3.1 and 3.3.2 above where in the opinion of the attending certified cardiologist, pulmonologist or respirologist, cardiac catheterization is medically contraindicated; and

5.2.2 The Claims Adjudicator has determined that an adequate medical evaluation was performed which demonstrated that the principal cause of the PAH was not one or more of the following conditions:

a) left ventricular failure;

b) valvular heart disease;

c) congenital cardiac disease;

d) pulmonary fibrosis;

e) chronic obstructive lung disease;

f) collagen vascular disease;

g) moderate to severe obstructive sleep apnea;

h) pulmonary thrombosis;

i) Human Immunodeficiency Viral Infection (HIV);

j) portal hypertension;

k) the following factors:

i. schistosomiasis;

ii. living at high altitude;

iii. ingestion of toxic rapeseed oil, amphetamines, toxic L-tryptophan, meta-amphetamines and cocaine;

iv. sickle cell disease;

v. acute respiratory distress syndrome;

vi. veno-occlusive disease;

vii. pulmonary capillary hemangiomatosis;

viii. mediastinal masses compressing the great vessels;

ix. sarcoidosis.

5.2.3 The factors listed in section 5.2.2 shall not be considered to be the principal cause of the Product Recipient's PAH in the following circumstances:

(a) **Left Ventricular Failure**. Left ventricular failure will not be considered to be the principal cause of the Product Recipient's PAH if an accurate pulmonary capillary wedge pressure or left ventricular end-diastolic pressure less than or equal to 15 mm Hg was documented during the same cardiac catheterization during which the PAH measure in section 5.2.1(a) was taken or, in the absence of an accurate pulmonary capillary wedge pressure or left ventricular end-diastolic pressure, if there is normal left ventricular function (left ventricular ejection fraction greater than or equal to 60% by echo or greater than or equal to 50% by MUGA) and there is no Doppler evidence of elevated left ventricular end-diastolic pressures (using LV in-flow velocities and/or tissue Doppler imaging).

(b) **Valvular Heart Disease**. Valvular heart disease will not be considered to be the principal cause of the Product Recipient's PAH if an accurate pulmonary capillary wedge pressure is less than or equal to 15 mm Hg or where trans-thoracic or trans-esophageal echocardiography fails to demonstrate moderate or greater mitral valvular stenosis (mitral valve area less than 2cm or transvalvular gradient greater than 5 mmHg) or greater than moderate MR or AR.

(c) **Congenital Cardiac Disease**. Congenital cardiac disease will not be considered to be the principal cause of the Product Recipient's PAH if there is no evidence of congenital cardiac lesions associated with PAH. The presence of a patent foramen ovale alone is not associated with PAH.

(d) **Pulmonary Fibrosis**. Pulmonary fibrosis will not be considered to be the principal cause of the Product Recipient's PAH if there is no greater than mild to moderate fibrosis on high-resolution computerized tomography of the chest (HRCT) and a total lung capacity greater than 80% predicted on pulmonary function testing.

(e) **Chronic obstructive lung disease.** Chronic obstructive lung disease will not be considered to be the principal

cause of the Product Recipient's PAH if FEV1 is greater than 80% predicted and a FEV1/FVC ratio greater than 70% on pulmonary function testing. The presence of asthma is not considered to be associated with pulmonary hypertension.

(f) **Collagen vascular disease.** Collagen vascular disease will not be considered to be the principal cause of the Product Recipient's PAH if the Product Recipient has neither clinical nor serological evidence of underlying scleroderma, systemic lupus erythematosis, vasculitis, or mixed connective tissue disease.

(g) **Obstructive Sleep Apnea**. Obstructive sleep apnea will not be considered to be the principal cause of the Product Recipient's PAH if it is less than moderate as determined by either overnight oximetry or polysomnography, or if neither study has been completed, where there is no clinical evidence to support the presence of moderate or greater obstructive sleep apnea.

(h) **Pulmonary thromboembolic disease**. Pulmonary thromboembolic disease will not be considered to be the principal cause of the Product Recipient's PAH if there is a ventilation perfusion lung scan demonstrating normal or low probability of pulmonary embolism, or a normal CT angiogram or normal pulmonary angiogram**.**

(i) **Human Immunodeficiency Viral Infection (HIV)**. HIV will not be considered to be the principal cause of the Product Recipient's PAH if it has been excluded by appropriate serological testing or in the absence of risk factors for HIV.

(j) **Portal Hypertension**. Portal hypertension will not be considered to be the principal cause of the Product Recipient's PAH if there is no evidence of either an elevation of portal pressures (splenomegaly, ascities, esophageal varicies) or demonstration of a trans-hepatic pressure gradient (5 mm Hg) obtained during catheterization of the hepatic vein.

(k) The following factors will not be considered to be the principal cause of the Product Recipient's PAH, based on exposure, clinical history and/or appropriate non-invasive, laboratory evaluation:

(i) Schistosomiasis if there is no history of residence in an endemic area or prior documented infection;

(ii) Living at high altitude – alveolar hypoxemia: in the absence of evidence supporting prolonged residence at elevations exceeding 10,000 feet above sea-level;

(iii) Ingestion of toxic rapeseed oil, amphetamines, toxic L-tryptophan, meta-amphetamines and cocaine based on clinical history;

(iv) Sickle cell disease based on no evidence on clinical history of recurrent crisis or positive sickle cell screen;

(v) Acute respiratory distress syndrome ("ARDS") where PAH does not persist following resolution of ARDS;

(vi) Veno-occlusive disease based on clinical, hemodynamic and radiographic data. Lung biopsy will not be required;

(vii) Pulmonary capillary hemangiomatosis based on clinical, hemodynamic and radiographic data. Lung biopsy will not be required;

(viii) Mediastinal masses compressing the great vessels based on CT scan or MRI;

(ix) Sarcoidosis based on standard radiological, clinical or serological testing;

5.2.4 Notwithstanding the existence of evidence of one or more of the factors listed in section 5.2.2, the Claimant shall be entitled to benefits where the Claims Adjudicator determines that such factor(s) were not the principal cause of the Product Recipient's PAH.

5.3 Diagnosis after death:

5.3.1 Where the claim is based on a diagnosis of PAH made after the Product Recipient's death, the Claimant must provide, in addition to the Supporting Medical Documentation, an autopsy report for the Product Recipient which:

(a) demonstrates histopathological changes in the lung consistent with PAH; and

(b) includes gross and microscopic examination of the heart and lungs.

5.3.2 Where the autopsy report or the Supporting Medical Documentation reveals the presence of one or more of the factors listed in section 5.2.2, the Claims Adjudicator shall determine whether the factor(s) present were the principal cause of the Product Recipient's PAH, having regard to the provisions of sections 5.2.3 and 5.2.4.

5.3.3 Where an autopsy report is not available, but there is sufficient evidence to determine that the Product Recipient had PPH as established by application of the criteria in section 5.2, the Claimant shall be entitled to benefits.

6. Additional Medical Factors for Consideration for Matrix Level VHD

6.1 Where one or more of the following conditions is present, the Claims Adjudicator shall determine whether it is more likely than not that the Products were the cause of the Matrix Level VHD. If the Claims Adjudicator's opinion is that one of the conditions listed below is more likely than not the principal cause of the Matrix Level VHD, the Claimant shall not be entitled to a benefit except where there was evidence of diet-drug induced VHD, in which case the Claimant shall be entitled to a benefit for Matrix Level VHD pursuant to this settlement.[24]

6.1.1 With respect to an aortic valve claim:

a) Moderate or greater Aortic sclerosis[25] in Product Recipients who are $\geq$60 years old as of the time they are first diagnosed as FDA Positive; or

b) Diseases of the aortic root in conjunction with aortic root dilatation of 3.7- 4.4 cm measured at the ascending aorta.

6.1.2 With respect to a mitral valve claim:

a) Moderate or greater mitral annular calcification[26]; or

[24] Any determination by the Claims Adjudicator regarding the cause or causes of a Claimant's VHD shall be for the purposes of this settlement only. Any such determination of the Claims Adjudicator pursuant to this section, as well as the process employed in arriving at this determination, shall not be construed as admitting or implying that the Products are the cause of, or contribute to, any of the injuries for which the Claimants may be compensated pursuant to this settlement.

[25] Otto, C.M. et al., *Association of Aortic Valve Sclerosis with Cardiovascular Mortality and Morbidity in the Elderly*, 341 New England Journal of Medicine 142-147 (1999),

[26] Catherine Otto, The Practice of Clinical Echocardiography 808 (2d. Ed. 2002).

b) Chronic, inadequately treated, severe systemic hypertension (greater than 160/100) of at least five years duration with left ventricular ejection fraction of 40% or less; or

c) Evidence of greater than or equal to Grade III systolic murmur on auscultation that was not refuted by echocardiography and that was attributed by the Treating Physician to mitral regurgitation prior to use of the Products.

6.1.3 With respect to both aortic and mitral valve claims:

a) Bacterial Endocarditis prior to use of the Products in the valve that is the basis of the claim; or

b) FDA Positive regurgitation (confirmed by echocardiogram) prior to use of the Products for the valve that is the basis of the claim; or

c) Prior history of daily use of methysergide or ergotamines for a continuous period of longer than 120 days;

d) Prior history of daily use of pergolide, or bromocriptine for a continuous period of at least 2 years.

6.2 Where one or more of the following conditions is present, the Claimant shall be excluded from recovery for benefits for VHD pursuant to the Settlement Agreement:

6.2.1 With respect to an aortic valve claim:

a) Aortic root disease in conjunction with aortic root dilatation > 4.5 cm measured at the ascending aorta; or

b) Aortic stenosis and aortic valve area <2.0 square centimeter by the Continuity Equation; or

c) Evidence of diastolic murmur on auscultation that was not refuted by echocardiography and that was attributed by the Treating Physician to aortic insufficiency or to aortic valve disease prior to use of the Products; or

d) The following congenital aortic valve abnormalities: unicuspid, bicuspid or quadricuspid aortic valve, ventricular septal defect associated with aortic regurgitation; or

e) Aortic dissection involving the aortic root and/or aortic valve.

6.2.2 With respect to a mitral valve claim:

a) Mitral Valve Prolapse, of the degree defined as a condition where (a) the echocardiogram recording includes the parasternal long axis view and (b) that echocardiographic

view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border prolapsing into the left atrium during systole, and >5mm mitral leaflet thickening during diastole, as determined by a Certified Cardiologist[27];

b) M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), except where a Certified Pathologist has examined mitral valve tissue and provided a statement confirming that he/she has determined that there was no evidence of rheumatic valve disease; or

c) Evidence of mitral valve obstruction with a mitral valve area of < 2.0 cm^2 as measured by the Continuity Equation; or

d) The following congenital mitral valve abnormalities: parachute valve, cleft of the mitral valve; or

e) Chordae rupture with flail leaflet; or

f) Acute myocardial infarction associated with papillary muscle dysfunction or rupture; or

g) Dilated cardiomyopathy diagnosed prior to use of the Products; or

h) Chronic inadequately treated severe systemic hypertension (greater than 160/110) of at least ten years duration with left ventricular ejection fraction of 40% or less.

6.2.3 With respect to claims for the aortic and/or mitral valve(s):

a) Heart valve surgery prior to use of the Products on the valve that is the basis of the claim; or

b) A diagnosis of Systemic Lupus Erythematosus or a diagnosis of Rheumatoid Arthritis[28] or a diagnosis of Ehler's Danlos syndrome and valvular abnormalities of a type associated with those conditions;[29] or

c) End-stage renal disease diagnosed prior to use of the Products; or

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[27] Lisa A. Freed, et al*., Prevalence and Clinical Outcomes of Mitral Valve Prolapse*, 341 New Eng. J. Med. 1, 2 (1999).

[28] See *Harrison's Principles of Internal Medicine* 1878, 1885 (14rh ed. 1998).

[29] See *Supra.* note 28 at 589-93.

d) No evidence of the valve pathology alleged to be associated with ingestion of the Products where such pathology is available on Verhoeff-Van Gieson stain or Movat pentachrome stain and where one of the conditions listed in this section exists; or

e) Carcinoid tumor of a type associated with aortic and/or mitral valve lesions or carcinoid syndrome; or

f) Mucopolysaccharidoses; or

g) Gross or microscopic pathology of explanted valves diagnostic of VHD attributable to another cause listed in section 6.

6.3 Notwithstanding the preceding, with the exception of section 6.2.3 e), where valve pathology produced on Verhoeff-Van Gieson stain or Movat pentachrome stain is available and demonstrates evidence of the valve pathology associated with ingestion of the Products,[30] the Claimant shall be entitled to benefits.

[30] Volmar et al., *Aortic and Mitral Fenfluramine-Phentermine Valvulopathy in 64 Patients Treated with Anorectic Agents,* 125 Arch. Pathol. Lab. Med. 1555-61 (Dec. 2001).