MATRIX VHD FORM

A. Patient Information

State the name of the patient ("Product Recipient") for whom you are providing the information contained in this form.

_____
(First Name) (Middle Initial) (Last Name)

_____
(Date of Birth)

_____
(Date of Diagnosis with FDA Positive Condition as defined in Section D)

B. Physician Information

State your name, office address, telephone number, e-mail address, if any and medical specialty.

_____
(First Name) (Middle Initial) (Last Name)

_____
(Office Address)

_____
(City) Prov/Terr (Postal Code)

_____
(Area Code and Telephone Number)

_____
(Medical Specialty)

C. Echocardiogram Information

List the date(s) when the Echocardiogram(s) upon which the Product Recipient's claim is based was/were performed and the Product Recipient's height and weight at the time if available.

Date: _____ Ht: _____ Wt: _____
(MM/DD/YYYY)

Date: _____ Ht: _____ Wt: _____
(MM/DD/YYYY)

Date: _____ Ht: _____ Wt: _____
(MM/DD/YYYY)

NOTE: If the Product Recipient has had more than three Echocardiograms upon which the claim is based, please provide the information on a separate sheet of paper and attach it to this Form.

D. Definitions

In answering the questions on this form, please apply the following definitions:

"Arrhythmias" or "Chronic Atrial Fibrillation" shall mean 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).

"BSA Indexing" shall mean the calculation derived from dividing the patient's chamber dimension by the patient's body surface area using the Dubois method.

"FDA Positive Regurgitation"[1] shall mean mitral regurgitation greater than 20% RJA/LAA **or** aortic regurgitation greater than 10% JH/LVOTH.

"Hemodynamically Significant MR" shall mean mitral regurgitation >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.

"Hemodynamically Significant AR" shall mean aortic regurgitation >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.

"Pulmonary Hypertension" shall mean a mean systolic pulmonary artery pressure >25 mm 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.

"Products" shall mean shall mean Ponderal, Ponderal Pacaps and/or Redux, or any one of them.

"Product Recipient" shall mean the patient who ingested the Products.

"Severe renal failure" shall mean as having creatinine clearance of less than 30 cc/min for greater than six months.

"Significant damage to the heart muscle" shall mean either 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; **or** 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.

"VHD" shall mean valvular heart disease.

E. Matrix VHD Claim

Each of the following questions identifies a condition which may serve as the basis for a claim. To the best of your knowledge, does the Product Recipient have any of the following conditions? (Check each that applies):

I. Matrix Level I – Regurgitation with Complications

1. Hemodynamically Significant MR **with** evidence of left ventricular enlargement as documented by abnormal left ventricular end-diastolic dimension of >63 mm or >34 mm/m^2 by BSA Indexing **and** abnormal left atrial antero-posterior systolic dimension >40 mm or >22 mm/m^2 by BSA Indexing?

   ❑ Yes
   ❑ No

2. Hemodynamically Significant AR **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?

   ❑ Yes
   ❑ No

3. FDA Positive Regurgitation[2] with bacterial endocarditis in the valve upon which the claim is based?

- ❑ Yes
- ❑ No

II. Matrix Level II – Regurgitation with More Serious Complications

1. Hemodynamically Significant MR **with** evidence of left ventricular enlargement as documented by abnormal left ventricular end-diastolic dimension of >63 mm or >34 mm/m^2 by BSA Indexing **and** abnormal left atrial antero-posterior systolic dimension >40 mm or >22 mm/m^2 by BSA Indexing **and** one of the following complications:

   (a) Arrhythmias?

   - ❑ Yes
   - ❑ No

   (b) Pulmonary Hypertension secondary to regurgitation?

   - ❑ Yes
   - ❑ No

   (c) Left Ventricular Ejection Fraction of <60% by echo?

   - ❑ Yes
   - ❑ No

   (d) Greater left ventricular enlargement defined as 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?

   - ❑ Yes
   - ❑ No

2. Mitral Regurgitation (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 >60 mm or >32.5 mm/m^2 by BSA Indexing **and** one of the following complications:

   (a) 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?

   - ❑ Yes
   - ❑ No

(b) Arrhythmias and an abnormal left atrial antero-posterior systolic dimension >48 mm or >26 mm/m^2 by BSA Indexing to be added to Matrix Level I?

- ❑ Yes
- ❑ No

(c) Left Ventricular Ejection Fraction of <50% by echocardiogram?

- ❑ Yes
- ❑ No

3. Hemodynamically significant AR **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** evidence of abnormal left ventricular end-systolic dimension of >45 mm or >24 mm/m^2 by BSA Indexing **and** one of the following complications:

(a) Left Ventricular Ejection Fraction of <50% by echocardiogram?

- ❑ Yes
- ❑ No

(b) Pulmonary Hypertension secondary to regurgitation?

- ❑ Yes
- ❑ No

(c) Greater left ventricular enlargement defined as left ventricular end-diastolic dimension >70 mm or >37mm/m^2 by BSA Indexing, **or** end-systolic dimension >50 mm or >26.5 mm/m^2 by BSA Indexing?

- ❑ Yes
- ❑ No

III. Matrix Level III – Surgery or Surgical Candidate

1. Surgery to repair or replace the aortic and/or mitral valve(s) following the use of the Products?

- ❑ Yes
- ❑ No

2. Qualification for benefits at Matrix Level I or II but no surgery, **and** the Product Recipient has ACC/AHA Class I or greater indications for surgery to repair or replace the aortic[3] and/or mitral[4] valve(s) **and** a statement from the attending Certified Cardiac Surgeon or Certified Cardiologist regarding why the surgery is not being performed?

- ❑ Yes
- ❑ No

3. The Product Recipient has not had surgery **and** would not qualify for benefits at Matrix Level I or II **but** 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[5] and/or mitral[6] valve(s) **and** a statement from the attending Certified Cardiac Surgeon or Certified Cardiologist regarding why the surgery is not being performed?

   - ❑ Yes
   - ❑ No

4. Qualification at Matrix Level I or II, **and** a stroke which results in a permanent condition which meets the criteria of the AHA Stroke Outcome Classification System,[7] Functional Level II, determined at least six months after the event, due to:

   (a) Bacterial endocarditis in the valve upon which the claim is based?

   - ❑ Yes
   - ❑ No

   (b) chronic atrial fibrillation with left atrial enlargement caused by VHD and not due to an unrelated heart condition?

   - ❑ Yes
   - ❑ No

IV. Matrix Level IV – Severe Complications of Regurgitation and/or Surgery

1. Qualification at Matrix Levels I, II or III, **and** a stroke which meets the criteria of the AHA Stroke Outcome Classification System,[8] Functional Level III, determined at least six months after the event, due to:

   (a) bacterial endocarditis in the valve upon which the claim is based?

   - ❑ Yes
   - ❑ No

   (b) chronic atrial fibrillation with left atrial enlargement?

   - ❑ Yes
   - ❑ No

2. Qualification at Matrix Levels I, II or III, **and** a peripheral embolus due to bacterial endocarditis in the valve upon which the claim is based, **or** as a consequence of atrial fibrillation with left atrial enlargement, **which resulted in** severe permanent impairment to the kidneys, abdominal organs, or extremities, where severe permanent impairment means:

(a) for the kidneys, severe renal failure?

- ❑ Yes
- ❑ No

(b) for the abdominal organs, impairment requiring intra-abdominal surgery?

- ❑ Yes
- ❑ No

(c) for the extremities, impairment requiring amputation of a major limb?

- ❑ Yes
- ❑ No

3. Qualification for payment at Matrix Level III, **and** New York Heart Association Functional Class I or Class II symptoms as documented by the attending Certified Cardiac Surgeon or Certified Cardiologist, **and** significant damage to the heart muscle?

- ❑ Yes
- ❑ No

4. Surgery to repair or replace the aortic and/or mitral valve(s), **and,** within 30 days after surgery, or during the same hospital stay as the surgery, one or more of the following complications occurred either during surgery:

(a) Severe renal failure?

- ❑ Yes
- ❑ No

(b) Peripheral embolus following surgery resulting in severe permanent impairment of the kidneys, abdominal organs, or extremities?

- ❑ Yes
- ❑ No

(c) Paraplegia resulting from cervical spine injury during valvular heart surgery?

- ❑ Yes
- ❑ No

5. Surgery to repair or replace the aortic and/or mitral valve(s), **and** a stroke caused by that surgery where the stroke has produced a permanent condition which meets the criteria of the AHA Stroke Outcome Classification[9] Functional Levels II or III determined at least six months after the event?

- ❑ Yes
- ❑ No

6. Surgery to repair or replace the aortic and/or mitral valve(s) **with**:

   (a) post-operative endocarditis, mediastinitis or sternal osteomyelitis within six months of surgery, any of which required reopening of the median sternotomy for treatment,

   ❑ Yes
   ❑ No

   (b) a post-operative serious infection defined as HIV or Hepatitis other than Hepatitis A, as a result of blood transfusion associated with the heart valve surgery?

   ❑ Yes
   ❑ No

7. Surgery to repair or replace the aortic and/or mitral valve(s) **and** 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?

   ❑ Yes
   ❑ No

8. Death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery following use of the Products **and** a statement from the attending Certified Cardiac Surgeon or Certified Cardiologist regarding why the surgery is not being performed?

   ❑ Yes
   ❑ No

V. Matrix Level V – Incapacitating Complications of Regurgitation and/or Surgery

1. Qualification for Matrix Level I, II, III, or IV **with** one or more of the following:

   (a) A severe stroke contracted after use of the Products which has resulted in a permanent condition which meets the criteria of AHA Stroke Outcome Classification[10] Functional Levels IV or V, determined at least six months after the event, **which was caused by** one of the following:

   (i) aortic and/or mitral valve surgery,

   ❑ Yes
   ❑ No

   (ii) bacterial endocarditis in the valve upon which the claim is based,

   ❑ Yes
   ❑ No

(iii) chronic atrial fibrillation with left atrial enlargement?

- ❑ Yes
- ❑ No

(b) Quadriplegia resulting from cervical spine injury during valvular heart surgery?

- ❑ Yes
- ❑ No

(c) Qualification for payment at Matrix Levels III or IV **and** New York Heart Association Functional Class III or Class IV symptoms as documented by the attending Certified Cardiac Surgeon or Certified Cardiologist **and** significant damage to the heart muscle[11]?

- ❑ Yes
- ❑ No

(d) Heart transplant as a consequence of valvular heart disease of a nature subject to benefits under the Settlement?

- ❑ Yes
- ❑ No

(e) Irreversible pulmonary hypertension secondary to valvular heart disease defined as peak systolic pulmonary artery pressure > 50 mm Hg at rest by cardiac catheterization or > 60 mm Hg by Doppler echocardiogram, where cardiac catheterization is medically contraindicated, following repair or replacement surgery?

- ❑ Yes
- ❑ No

(f) A persistent non-cognitive state[12] caused by a complication of valvular heart disease (e.g. cardiac arrest) or valvular repair/replacement surgery?

- ❑ Yes
- ❑ No

2. The Product Recipient otherwise qualifies for payment at Matrix Level II, III or IV and 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?

- ❑ Yes
- ❑ No

F. Valve Pathology Evidence

Does the Product Recipient have evidence of valve pathology produced on Verhoeff-Van Gieson stain or Movat pentachrome stain which demonstrates the valve pathology associated with ingestion of the Products as defined by Volmar[13]?

- ❑ Yes
- ❑ No

G. Additional Medical Factors To Be Considered

To the best of your knowledge, does the Product Recipient have any of the following conditions? (Check each that applies):

1. In the case of an **aortic valve** claim, does the Product Recipient have one of the following conditions?

   (a) Moderate or greater aortic sclerosis as defined by Otto[14] in a Product Recipients who is ≥60 years old as of the time they are first diagnosed as with an FDA Positive condition?

   - ❑ Yes
   - ❑ No

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

   - ❑ Yes
   - ❑ No

2. In the case of a **mitral valve** claim, does the Product Recipient have one of the following conditions?

   (a) Moderate or greater mitral annular calcification as defined by Otto[15]?

   - ❑ Yes
   - ❑ No

   (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?

   - ❑ Yes
   - ❑ No

(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?

- ❑ Yes
- ❑ No

3. In the case of either an **aortic valve** claim or a **mitral valve** claim, does the Product Recipient have one of the following conditions?

(a) Bacterial endocarditis prior to use of the Products in the valve which is the basis of the claim?

- ❑ Yes
- ❑ No

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

- ❑ Yes
- ❑ No

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

- ❑ Yes
- ❑ No

(d) Prior history of daily use of pergolide or bromocriptine for a continuous period of at least two years?

- ❑ Yes
- ❑ No

H. Exclusionary Conditions

To the best of your knowledge, does the Product Recipient have any of the following conditions? (Check each that applies):

1. In the case of an **aortic valve** claim, does the Product Recipient have one of the following conditions?

(a) Aortic root disease **in conjunction with** aortic root dilatation >4.5 cm measured at the ascending aorta?

- ❑ Yes
- ❑ No

(b) Aortic stenosis **and** aortic valve area <2.0 cm^2 by the Continuity Equation?

- ❑ Yes
- ❑ No

(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?

- ❑ Yes
- ❑ No

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

- ❑ Yes
- ❑ No

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

- ❑ Yes
- ❑ No

2. In the case of a **mitral valve** claim, does the Product Recipient have one of the following conditions?

(a) Mitral Valve Prolapse of the degree defined by Freed[16] 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, and as determined by a Certified Cardiologist?

- ❑ Yes
- ❑ No

(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?

- ❑ Yes
- ❑ No

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

- ❑ Yes
- ❑ No

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

- ❑ Yes
- ❑ No

(e) Chordae rupture with flail leaflet?

- ❑ Yes
- ❑ No

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

- ❑ Yes
- ❑ No

(g) Dilated cardiomyopathy diagnosed prior to use of the Products?

- ❑ Yes
- ❑ No

(h) Chronic, inadequately treated, severe systemic hypertension (greater than 160/110) of at least ten years duration with LVEF of 40% or less?

- ❑ Yes
- ❑ No

3. In the case of either an **aortic valve** claim or a **mitral valve** claim, does the Product Recipient have one of the following conditions?

(a) Heart valve surgery on the valve that is the basis of the claims **prior to use** of the Products?

- ❑ Yes
- ❑ No

(b) A diagnosis of Systemic Lupus Erythematosis or a diagnosis of Rheumatoid Arthritis as defined by Harrison[17] or a diagnosis of Ehler's Danlos syndrome, **and** valvular abnormalities of a type associated with those conditions as defined by Otto [18]?

- ❑ Yes
- ❑ No

(c) End-stage renal disease diagnosed **prior to use** of the Products?

- ❑ Yes
- ❑ No

(d) No evidence of the valve pathology alleged to be associated with ingestion of the Products as defined by Volmar[19] where such pathology is available on Verhoeff-Van Gieson stain or Movat pentachrome stain?

- ❑ Yes
- ❑ No

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

- ❑ Yes
- ❑ No

(f) Mucopolysaccharidoses?

- ❑ Yes
- ❑ No

(g) Gross or microscopic pathology of explanted valves diagnostic of VHD attributable to another cause listed in sections G or H?

- ❑ Yes
- ❑ No

I. Declaration

I declare under penalty of perjury that it is my opinion, to a reasonable degree of medical certainty, and to the best of my knowledge, that:

(a) the Product Recipient has been diagnosed with the medical condition(s) specified in Section E above which serves as the basis of the claim;

(b) the specific medical condition which serves as the basis of the claim was not present in the Product Recipient prior to his or her first use of the Products;

(c) the Product Recipient does or does not have the conditions listed in Sections G and H, as indicated above;

(d) if one of the conditions listed in Sections G or H is present, there is nevertheless a possibility that the Product Recipient's condition was caused by ingestion of the Products;

(e) the echocardiogram(s) that serve as the basis of this claim meet the criteria set forth in the Appendix attached to this form.

_____ _____

(Date: MM/DD/YYYY) (Signature of Treating Physician)

This form is an official Court document sanctioned by the Court and submitting it to the Ponderal/Redux Settlement Administrator is equivalent to filing it with a Court.

[1] 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).
[2] *See supra, note 1*
[3] 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) at 1510-14.
[4] *See supra, note 3* at 1533-35.
[5] *See supra,* note 2.
[6] *See supra,* note 3.
[7] M. Kelley-Hayes, *et al., The American Heart Association Stroke Outcome Classification*, 29 Stroke 1274-80, (1998). (Note: approved by the American Heart Association Science Advisory and Coordinating committee).
[8]*See supra,* note 6.
[9] *See supra,* note 6.
[10]*See supra,* note 6.
[11] *See supra,* note __ (16).
[12] Adelman, G. ed., *Encyclopedia of Neuroscience* at 268 (1987).
[13] 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).
[14] Otto, C.M. et al., *Association of Aortic Valve Sclerosis with Cardiovascular Mortality and Morbidity in the Elderly*, 341 New Eng. J. Med., 142-147 (1999).
[15] Otto, C.M., *The Practice of Clinical Echocardiography* 808 (2d Ed. 2002).
[16] Lisa A. Freed, et al., *Prevalence and Clinical Outcomes of Mitral Valve Prolapse*, 341 New Eng J. Med.1, 2 (1999).
[17] *Harrison's Principles of Internal Medicine* 1878, 1885 (14th ed. 1998).
[18] *See supra,* note __ (26 at 589-93).
[19] *See supra,* note 13.