b. Each Matrix describes the amount which an eligible Class Member is entitled to recover based on (1) the level of severity of a Diet Drug Recipient's disease pursuant to Section IV.B.2.c below, and (2) the age at which the Diet Drug Recipient is first diagnosed as suffering from that level of disease severity.

c. The levels of disease severity in a Diet Drug Recipient which qualify eligible Class Members for payment on the Matrices are as follows:

(1) **MATRIX LEVEL I** is severe left sided valvular heart disease without complicating factors, and is defined as one of the following:

(a) Severe aortic regurgitation (AR) > 49% jet height/left ventricular outflow tract height (JH/LVOTH)[14] and/or severe mitral regurgitation (MR) > 40% regurgitant jet area/left atrial area (RJA/LAA)[15,16] and no complicating factors as defined below;

(b) FDA Positive valvular regurgitation[17] with bacterial endocarditis contracted after commencement of Pondimin® and/or Redux™ use.

(2) **MATRIX LEVEL II** is left sided valvular heart disease with complicating factors, and is defined as:

(a) Moderate AR (25% - 49% JH/LVOTH)[18] or Severe AR (> 49% JH/LVOTH)[19] with one or more of the following:

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[14] *See* Singh, *supra* note 2.

[15] *See id*.

[16] *See* Frederick Helmcke, *et al*., *Color Doppler Assessment of Mitral Regurgitation with Orthogonal Planes*, 75 circulation 175, 177, 183 (1987) [hereinafter "Helmcke"].

[17] *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).

[18] *See* Singh, *supra* note 2.

[19] *See id*.

i) Pulmonary hypertension secondary to severe aortic regurgitation with a peak systolic pulmonary artery pressure > 40 mm Hg measured by cardiac catheterization or with a peak systolic pulmonary artery pressure > 45 mm Hg[20] measured by Doppler Echocardiography, at rest, utilizing standard procedures[21,22] assuming a right atrial pressure of 10 mm Hg;

ii) Abnormal left ventricular end-systolic dimension > 50 mm[23] by M-mode or 2-D Echocardiography or abnormal left ventricular end-diastolic dimension > 70 mm[24] as measured by M-mode or 2-D Echocardiography;

iii) Ejection fraction of < 50%[25]; and/or

(b) Moderate MR (20% - 40% RJA/LAA)[26] or Severe MR (> 40% RJA/LAA)[27] with one or more of the following:

i) Pulmonary hypertension secondary to valvular heart disease with peak systolic pulmonary artery pressure >

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20 *See* Braunwald I, *supra* note 1 at 796-98.

21 *See* Feigenbaum, *supra* note 3 at 201-03.

22 *See* Kwan-Leung Chan, *et al.*, *Comparison of Three Doppler Ultrasound Methods in the Prediction of Pulmonary Artery Disease*, 9 J. Am. C. Cardiology 549, 550 (1987) [hereinafter "Chan"].

23 *See* 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, 1511 (1998) [hereinafter "Bonow"].

24 *See id.*

25 *See id.* at 1512.

26 *See* Singh, *supra* note 2.

27 *See id.*

40 mm Hg measured by cardiac catheterization or with a peak systolic pulmonary artery pressure > 45 mm Hg[28] measured by Doppler Echocardiography, at rest, utilizing the procedures described in Section IV.B.2.c.(2)(a)(i) above;

ii) Abnormal left atrial supero-inferior systolic dimension > 5.3 cm[29] (apical four chamber view) or abnormal left atrial antero-posterior systolic dimension > 4.0 cm (parasternal long axis view) measured by 2-D directed M-mode or 2-D echocardiography with normal sinus rhythm using sites of measurement recommended by the American Society of Echocardiography;[30]

iii) Abnormal left ventricular end-systolic dimension $\geq$ 45 mm[31] by M-mode or 2-D Echocardiogram;

iv) Ejection fraction of $\leq$ 60%[32];

v) Arrhythmias, defined as chronic atrial fibrillation/flutter that cannot be converted to normal sinus rhythm, or atrial fibrillation/flutter requiring ongoing medical therapy, any of which are associated with left atrial enlargement; as defined above in Section IV.B.2.c.(2)(b)(ii).

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28 *See* Braunwald I, *supra* note 1 at 796-98.

29 *See* Weyman, *supra* note 4 at 1290-92.

30 *See* Walter L. Henry, et al., *Report of the American Society of Echocardiography Committee on Nomenclature and Standards in Two-dimensional Echocardiography*, 62 Circulation 212, 212-13 (1980) [hereinafter "Henry"].

31 *See* Bonow, *supra* note 23 at 1533-35.

32 *See id.*

(3) **MATRIX LEVEL III** is left sided valvular heart disease requiring surgery or conditions of equal severity, and is defined as:

(a) Surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™; or

(b) Severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic[33] and/or mitral[34] valve(s) and a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist supported by medical records regarding the recommendations made to the patient concerning valvular surgery, with the reason why the surgery is not being performed; or

(c) Qualification for payment at Matrix Level I(b) (as described in Section IV.B.2.c.(1)(b) above) or Matrix Level II and, in addition, a stroke due to bacterial endocarditis contracted after use of Pondimin® and/or Redux™ or as a consequence of chronic atrial fibrillation with left atrial enlargement as defined in Section IV.B.2.c.(2)(b)(ii) which results in a permanent condition which meets the criteria of AHA Stroke Outcome Classification[35] Functional Level II, determined six months after the event.

(4) **MATRIX LEVEL IV** is defined as follows:

(a) Qualification for payment at Matrix Level I(b) (as described in Section IV.B.2.c.(1)(b) above), II or III and, in addition, a stroke due to Bacterial Endocarditis contracted

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[33] *See id.* at 1510.

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

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

after use of Pondimin® and/or Redux™ or as a consequence of chronic atrial fibrillation with left atrial enlargement as defined in Section IV.B.2.c.(2)(b)(ii) which results in a permanent condition which meets the criteria of AHA Stroke Outcome Classification[36] Functional Level III, determined six months after the event; or

(b) Qualification for payment at Matrix Level I.b, II, or III and, in addition, a peripheral embolus due to Bacterial Endocarditis contracted after use of Pondimin® and/or Redux™ or as a consequence of atrial fibrillation with left atrial enlargement as defined in Section IV.B.2.c.(2)(b)(ii) which results in severe permanent impairment to the kidneys, abdominal organs, or extremities, where severe permanent impairment means:

i) for the kidneys, chronic severe renal failure requiring hemodialysis or continuous abdominal peritoneal dialysis for more than six months;

ii) for the abdominal organs, impairment requiring intra-abdominal surgery;

iii) for the extremities, impairment requiring amputation of a major limb; or

(c) The individual has the following:

i) Qualification for payment at Matrix Level III; and

ii) New York Heart Association Functional Class I or Class II symptoms as documented by the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist; and

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[36] *See id*.

iii) Valvular repair and replacement surgery or ineligibility for surgery due to medical reasons as documented by the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist; and

iv) 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 patients who have not had surgery and meet the criteria of Section IV.B.2.c.(3)(b) above or (b) a left ventricular ejection fraction < 40% six months after valvular repair or replacement surgery in patients who have had such surgery; or

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

i) Renal failure, defined as chronic, severe renal failure requiring regular hemodialysis or continuous abdominal peritoneal dialysis for greater than six months following aortic and/or mitral valve replacement surgery;

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

iii) Quadriplegia or paraplegia resulting from cervical spine injury during valvular heart surgery; or

(e) 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[37] Functional Levels II or III determined six months after the event;

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

(g) The individual has had valvular repair or replacement surgery and requires a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery.

(5) **MATRIX LEVEL V** is defined as:

(a) Endocardial Fibrosis (1) diagnosed by (a) endomyocardial biopsy that demonstrates fibrosis and cardiac catheterization that demonstrates restrictive cardiomyopathy or (b) autopsy that demonstrates endocardial fibrosis and (2) other causes, including dilated cardiomyopathy, myocardial infarction, amyloid, Loeffler's endocarditis, endomyocardial fibrosis as defined in Braunwald (involving one or both ventricles, located in the inflow tracts of the ventricles, commonly involving the chordae tendinea, with partial obliteration of either ventricle commonly present)[38], focal fibrosis secondary to valvular regurgitation (*e.g.*, "jet lesions"), focal fibrosis secondary to catheter instrumentation, and hypertrophic

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37 *See id.*

38 *See* Braunwald I, *supra* note 1 at 1433-34.

cardiomyopathy with septal fibrosis, have been excluded; or

(b) Left sided valvular heart disease with severe complications, defined as Matrix Levels I(b) (as described in Section IV.B.2.c.(1)(b) above), III or IV above with one or more of the following:

i) A severe stroke caused by aortic and/or mitral valve surgery or due to bacterial endocarditis contracted after use of Pondimin® and/or Redux™ or as a consequence of chronic atrial fibrillation with left atrial enlargement as defined in Section IV.B.2.c.(2)(b)(ii) and the severe stroke has resulted in a permanent condition which meets the criteria of AHA Stroke Outcome Classification[39] Functional Levels IV or V, determined six months after the event;

ii) 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 Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist; and

c) Valvular repair or replacement surgery or ineligibility for surgery due to medical reasons as documented by the attending Board-Certified Cardiothoracic Surgeon or

[39] *See* Kelley-Hayes, *supra* note 35.

Board-Certified Cardiologist; and

d) 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 patients who have not had surgery and meet the criteria in Section IV.B.2.c.(3)(b) above or (ii) a left ventricular ejection fraction < 40% six months after valvular repair or replacement surgery in patients who have had such surgery; or

iii) Heart transplant;

iv) Irreversible pulmonary hypertension (PH) secondary to valvular heart disease defined as peak-systolic pulmonary artery pressure > 50 mm Hg[40] (by cardiac catheterization) at rest following repair or replacement surgery of the aortic and/or mitral valve(s);

v) Persistent non-cognitive state[41] caused by a complication of valvular heart disease (e.g., cardiac arrest) or valvular repair/replacement surgery supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records; or

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[40] *See* Braunwald I, *supra* note 1 at 796-98.

[41] *See* Encyclopedia of Neuroscience 268 (George Adelman ed., 1987).

(c) Death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records; or

(d) The individual otherwise qualifies for payment at Matrix Level II, III, or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

d. The circumstances which determine whether Matrix A-1 or Matrix B-1 is applicable to a claim for Matrix compensation benefits are as follows:

(1) **FOR MATRIX A-1**: Diet Drug Recipients who ingested Pondimin® and/or Redux™ for sixty-one (61) or more days, who were diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, whose conditions are eligible for Matrix payments but who do not have any condition or circumstance which makes Matrix B-1 applicable, or their Representative Claimants, shall be entitled to receive Matrix Compensation Benefits determined by application of Matrix A-1, provided that such Diet Drug Recipients or Representative Claimants have registered (or are deemed to have registered) for settlement benefits by Date 2.

(2) **FOR MATRIX B-1**: Diet Drug Recipients who are eligible for Matrix Compensation Benefits and to whom one or more of the following conditions apply, or their Representative Claimants, will receive Matrix Compensation Benefits determined by application of Matrix B-1, provided that such Diet Drug Recipients or Representative Claimants have registered (or are deemed to have registered) for settlement benefits by Date 2: