IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE / FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2 :15 MD1203
SHEILA BROWN, ET AL. 1. AMERICAN HOME PRODUCTS CORPORATION	:	CIVIL ACTION NO. 99-20593
Appellant: REDACTED Arbitration No.: REDACTED Claim No.: REDACTED	:	REPORT AND AWARD OF ARBITRATOR

FINDINGS OF FACT

1. On **[DATE]**, the AHP Settlement Trust ("Trust") denied the claim of **[APPELLANT]** for Matrix Compensation Benefits.

2. On **[DATE]**, **[APPELLANT]** filed an appeal from the denial of benefits by the Trust, requesting that the United States District Court ("Court") refer this matter to Arbitration.

3. On **[DATE]**, the claim of **[APPELLANT]** was referred by the Court to Arbitration pursuant to Sections VI. C. 4 (h) & (i) or VI. D. 1. (f) and (g) of the Nationwide Class Action Settlement Agreement with American Home Products Corporation.

4. On **[DATE]**, an Arbitration Hearing was held concerning the claim of **[APPELLANT]**.

ANALYSIS

1. **[APPELLANT'S]** Pink Form (Questions 8 and 9) states that he/she ingested Pondimin (Fenfluramine) and Redux (Dexfenfluramine) (collectively "diet drugs") for 61 days or more. This is confirmed by **[APPELLANT'S]** pharmacy records, which show that he/she was dispensed 90 tablets of Pondimin on **[DATE]** and 90 tablets of Pondimin on **[DATE]**. His/her medical record also show that he/she was prescribed 30 tablets of Pondimin on **[DATE]** and 30 tablets of Pondimin on **[DATE]**.

2. **[APPELLANT]** submitted three Green Forms. The first, dated **[DATE]**, is signed by **[DOCTOR]**, a Board-Certified Cardiologist. The second, dated **[DATE]**, also is signed by **[DOCTOR]**. The third Green Form, dated **[DATE]**, consisting only of pages one through five, is signed only by **[APPELLANT]**. In his/her third Green Form, **[APPELLANT]** states that he/she seeks Matrix-Level II Benefits on the A-1 Matrix.

3. In order to obtain Matrix Compensation Benefits, a claimant who ingested diet drugs must first be eligible and then be qualified to receive Matrix-Level Benefits. In order to be eligible for Matrix Compensation Benefits, a Diet Drug Recipient must fit within one of two categories: (1) Diet Drug Recipients diagnosed by a Qualified Physician as FDA Positive or as having mild mitral regurgitation by an echocardiogram within a specified time period; or (2) Diet Drug Recipients diagnosed by a Qualified Physician as having Endocardial Fibrosis and who have registered for Fund B Benefits within a specified time. Settlement Agreement, Section IV.B.1. In order to be diagnosed as FDA Positive, a Diet Drug Recipient must suffer mild or greater aortic valve regurgitation and/or moderate or greater mitral valve regurgitation. Id. at Section I.22.

4. Questions C.3.A. and C.3.B. of **[APPELLANT'S]** first Green Form (dated **[DATE]**)

does not indicate that **[APPELLANT]** suffered from mitral or aortic regurgitation. Question C.3.A. of his/her second Green Form (dated **[DATE]**) states that **[APPELLANT]** had no mitral regurgitation and contains no information regarding whether he/she suffered from aortic regurgitation. The third Green Form (dated **[DATE]**), which included only pages one through five, does not provide any information regarding whether **[APPELLANT]** has mitral or aortic regurgitation. None of the Green Forms, therefore, provide a basis from which the Trust could properly have concluded that **[APPELLANT]** suffered from mitral or aortic regurgitation.

5. **[APPELLANT]** also submitted two Gray Forms. Question 6 of his/her **[DATE]** Gray Form, signed by **[DOCTOR]**, states that **[APPELLANT]** had no mitral regurgitation and no aortic regurgitation. The accompanying echocardiogram report, dated **[DATE]**, reported a finding of "probable trace mitral regurgitation" and did not mention any finding of aortic regurgitation. Question 6 of **[APPELLANT'S]** second Gray Form, dated **[DATE]**, signed by cardiologist **[DOCTOR]**, states that **[APPELLANT]** suffered mild mitral regurgitation and no aortic regurgitation. The accompanying echocardiogram report, also dated **[DATE]**, states that **[APPELLANT]** suffered from a "trace amount of mitral regurgitation." Therefore, it is questionable whether **[APPELLANT]** can even establish that he/she is eligible for Matrix Compensation Benefits.

6. Even if **[APPELLANT'S]** Green Forms, Gray Forms and echocardiograms established that he/she suffered from mild mitral regurgitation, making him/her eligible for Matrix Compensation Benefits, he/she would not be entitled to receive Matrix A-1 Benefits. To receive benefits, a Diet Drug Recipient must have a compensable disease defined in Matrix Levels I, II, III, IV or V.

Matrix Level I is severe left sided valvular heart disease without complicating factors,

which is defined as severe aortic regurgitation and/or severe mitral regurgitation or FDA Positive valvular regurgitation with bacterial endocarditis contracted after commencement of diet drug use. Settlement Agreement, Section IV.B.2.c.(1).

Matrix Level II is left sided valvular heart disease with complicating factors, which is defined as: (1) moderate or severe aortic regurgitation with pulmonary hypertension secondary to severe aortic regurgitation with certain peak systolic pulmonary artery pressures, abnormal left ventricular end-systolic dimension, and/or an ejection fraction of <50%; and/or (2) moderate or severe mitral regurgitation with pulmonary hypertension secondary to valvular heart disease with certain peak systolic pulmonary artery pressures, abnormal left atrial supero-inferior systolic dimension >5.3 cm or abnormal left atrial antero-posterior systolic dimension >4.0 cm, abnormal left ventricular end-systolic dimension ≥ 45 mm, an ejection fraction of ≤ 60%, or cardiac arrhythmias. *Id.* at Section IV.B.2.c.(2).

Matrix Level III is left sided valvular heart disease requiring surgery or conditions of equal severity, which is defined as surgery to repair or replace the aortic and/or mitral valve(s) after the use of diet drugs, or severe regurgitation and the presence of ACC/AHA Class I indications for aortic and/or mitral valve surgery, and a statement from a qualified physician regarding the recommendations made to the patient, with the reason why the surgery is not being performed, or qualification for Matrix Levels I(b) or II and a stroke due to bacterial endocarditis after diet drug use or as a result of atrial fibrillation with left atrial enlargement that results in a permanent condition which meets the AHA Stroke Outcome Classification Functional Level II, determined six months after the event. *Id.* at Section IV.B.2.c.(3).

Matrix Level IV is defined as: (1) qualification for payment at Matrix Levels I(b), II or III, and stroke due to bacterial endocarditis after diet drug use, or as a result of chronic atrial

fibrillation with left atrial enlargement that results in a qualifying permanent condition meeting the specified criteria six months after the event; or (2) qualification for payment at Matrix Levels I(b), II or III, and a peripheral embolus due to bacterial endocarditis after diet drug use or as a result of atrial fibrillation with left atrial enlargement that results in severe permanent impairment of kidneys, abdominal organs or extremities; or (3) the individual qualifies for payment at Matrix Level III, and has New York Heart Association Functional Class I or Class II symptoms, and needs valvular repair and replacement surgery or is ineligible for surgery, and has significant damage to the heart muscle; or (4) the individual has had valvular repair or replacement surgery with complications which occur during surgery or within 30 days after surgery (renal failure; peripheral embolus resulting in severe permanent impairment to the kidneys, abdominal organs, or extremities; or quadriplegia or paraplegia resulting from cervical spine injury during valvular heart surgery); or (5) a stroke caused by aortic and/or mitral valve surgery that has caused certain permanent conditions; or (6) the individual has had valvular repair or replacement surgery and suffers from post-operative endocarditis, mediastinitis or sternal osteomyelitis requiring the reopening of the median sternotomy, or a post-operative serious infection (HIV or Hepatitis C) within six months of surgery as a result of a blood transfusion associated with the heart valve surgery; or (7) the individual has had valvular repair or replacement surgery and requires a second surgery through the sternum within 18 months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery. *Id.* at Section IV.B.2.c.(4).

Matrix Level V is defined as: (1) Endocardial Fibrosis diagnosed by an endomyocardial biopsy and cardiac catheterization or an autopsy, and other causes have been excluded; or (2) left sided valvular heart disease with severe complications; or (3) death resulting

from a condition caused by valvular heart disease or valvular repair/replacement surgery following diet drug use; or (4) the individual otherwise qualifies for payment at Matrix Levels II, III or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise. *Id.* at Section IV.B.2.c.(5).

7. In his/her Statement of the Case and during the Arbitration hearing, **[APPELLANT]** argued that he/she is entitled to Matrix-Benefits because he/she suffers from Endocardial Fibrosis. In support, he/she referred to a saliva test that he/she believes confirms the presence of this condition. According to the Settlement Agreement, however, Endocardial Fibrosis must be diagnosed by either: (1) endomyocardial biopsy and cardiac catheterization; or (2) an autopsy. *Id.* at Section IV.B.2.c.(5)(a). Irrespective of the medical merits of the saliva test, when the parties were drafting the Settlement Agreement, they did not include a saliva test as an agreed-upon method for determining Endocardial Fibrosis. It cannot be used, therefore, to demonstrate whether **[APPELLANT]** suffers from Endocardial Fibrosis.

8. Even if **[APPELLANT'S]** Green and Gray Forms and corresponding echocardiogram reports established that he/she suffered from mild mitral regurgitation, making him/her eligible for Matrix Compensation Benefits (which they do not), and if **[APPELLANT'S]** Green Form and corresponding echocardiogram reports established that he/she suffered from a compensable disease (which they do not), **[APPELLANT]** would not be entitled to benefits on Matrix A-1. Matrix A-1 Benefits are available only to Diet Drug Recipients with qualifying conditions who ingested Pondimin and/or Redux for sixty-one days or more, who were diagnosed within the specified time by a Qualified Physician as FDA Positive by an echocardiogram and who do not have any conditions which makes Matrix B-1 applicable. *Id.* at Section IV.B.2.d. For claims based on disease of the mitral valve, mild mitral

regurgitation is a condition making Matrix B-1 the applicable Matrix. *Id*. at Section IV.B.2.d.(2).

9. In his/her third Green Form, **[APPELLANT]** asserts he/she is entitled to Level II Matrix Compensation Benefits. As explained above, to be eligible for Level II compensation, a claimant must suffer from moderate or severe aortic regurgitation and/or moderate or severe mitral regurgitation with complicating factors. None of **[APPELLANT'S]** Green Forms states that he/she suffers from these conditions.

10. The Trust has requested that the costs of Arbitration, including the fees of the Arbitrator, be taxed against **[APPELLANT]** pursuant to Rules 8(b) and 20, on the basis that the appeal was pursued in violation of the standards set forth in Rule 8(b). Rule 8(b) requires that, when filing an appeal, each appellant must certify, consistent with Federal Rule of Civil Procedure 11(b), that "the position of the Appellant is warranted under the terms of the Settlement Agreement." The Settlement Agreement also provides for the award of costs and fees if an appeal is taken contrary to the standards of Federal Rule of Civil Procedure 11(b). *Id.* at Section VI.C.4.i. While I find **[APPELLANT'S]** claim ultimately to lack merit, I find that **[APPELLANT]**, a non-lawyer, pursued his/her appeal on the good faith basis that his/her claim should be evaluated by a neutral evaluator. Based on this, I deny the Trust's request that the costs of Arbitration be charged against the Appellant.

CONCLUSIONS

1. Appellant submitted no basis on which to conclude that he/she is eligible and qualifies for Matrix Compensation Benefits. Accordingly, the findings of the Trust are not clearly erroneous, as set forth in Rule 5 of the Rules Governing Arbitration Process.

2. Based upon the findings above, **[APPELLANT]** is not entitled to any Matrix Benefits because the conditions required for recovery of Matrix-Level I, II, III, IV or V Benefits are not present. *Id.* at Sections IV.B.2.c.(1), (2), (3), (4), and (5).

October 14, 2002
DATE

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REDACTED
Arbitrator