

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
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SHEILA BROWN, ET AL.	:	
v.	:	CIVIL ACTION NO.
AMERICAN HOME PRODUCTS CORPORATION	:	99-20593
-----	:	
Appellant:	:	
Arbitration No.:	:	REPORT AND AWARD
Claim No.: 183/00	:	OF ARBITRATOR
	:	

**FINDINGS OF FACT**

1. [redacted] departed this earth on [redacted] On February [redacted] surviving spouse of [redacted], submitted a claim to the AHP Settlement Trust (“Trust”) as a Representative Claimant on behalf of the [redacted] and as a derivative claimant (i.e., spouse) on his own behalf. On [redacted], the Trust denied the claim of the [redacted] (sometimes hereinafter “Claimant”) for Matrix Compensation Benefits.<sup>1</sup>

2. On [redacted], the [redacted] 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 [redacted], the claim of the [redacted] was referred by

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<sup>1</sup> Although [redacted] submitted a claim in both a representative and a derivative capacity, for purposes of this Arbitration both claims are together referred to as “[redacted]”

the Court to Arbitration pursuant to Sections VI. C. 4 (h) & (I) of the Nationwide Class Action Settlement Agreement with American Home Products Corporation.

4. On [redacted], an Arbitration Hearing was held concerning the claim of the [redacted]. The Estate was represented by [redacted].

### ANALYSIS

1. This arbitration raises the issue of whether a claimant can obtain Matrix compensation if the diet drug recipient never obtained an echocardiogram. To obtain Matrix compensation, a diet drug recipient must be both eligible and qualified. Settlement Agreement, Sections IV.B.1 and IV.B.2.c. Neither eligibility nor qualification is alone sufficient. As will be more fully explained below, [redacted] was neither eligible nor qualified to receive Matrix compensation. Accordingly, the claim of [redacted] must fail.

2. There is no dispute that [redacted] was a diet drug recipient or that she ingested diet drugs in excess of sixty days. Claimant's BLUE Form (Questions 8 and 9) states that [redacted] ingested Pondimin (Fenfluramine) for two months and Redux (Dexfenfluramine) for one month. Each of these claims is confirmed by [redacted] -pharmacy records, which show that she received 60 Redux on [redacted] and 90 Pondimin on two dates: [redacted] and [redacted].

3. The parties agree that [redacted].

4. Claimant seeks compensation on the B-1 Matrix at Level V. In order to receive Matrix Compensation, a Claimant must be both eligible and qualified to receive Matrix-Level Benefits. In order to be eligible, 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 performed on or before January 3, 2003, provided the Diet Drug Recipient registered for settlement benefits by May 3, 2003; or (2) Diet Drug Recipients who by September 30, 2005 have been diagnosed by a Qualified Physician as having Endocardial Fibrosis and who have registered for Fund B Benefits by January 31, 2006. *See* 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. Representative Claimants (e.g. the Estate) and Derivative Claimants (e.g., a spouse) may be entitled to Matrix Compensation, but their claims are subject to the same requirements as those of the diet drug recipient. Settlement Agreement, Sections IV.B.1.b., IV.B.1.c., IV.B.1.e. and IV.B.1.f.

5. Claimant's GREEN Form was completed by \_\_\_\_\_, a Board-Certified Cardiologist. Because \_\_\_\_\_ passed away before obtaining an echocardiogram, she did not meet the first eligibility criterion of having been diagnosed by a Qualified Physician as FDA Positive or as having mild mitral regurgitation by an echocardiogram performed on or before January 3, 2003. This is confirmed by GREEN Form Question C.1, which states that

\_\_\_\_\_ did not have an Echocardiogram conducted in accordance with the standards and criteria as outlined in Feigenbaum or Weyman. GREEN Form Questions C.3.A and C.3.B., which inquire about the presence of mitral or aortic regurgitation, are unanswered.

6. Claimant asserts that pathological evidence in the form of \_\_\_\_\_; Autopsy Report constitutes alternative evidence of eligibility. The Autopsy Report states that

\_\_\_\_\_ mitral valve was "floppy and showed tenting with thickening of the edges." A floppy mitral valve with tenting and thickening of the edges does not, however, establish that

\_\_\_\_\_ experienced a legally sufficient level of regurgitation, that is, an amount sufficient to bring it within the terms of the Settlement Agreement. *See* Settlement Agreement, Section

IV.B.1 Even if this evidence were consistent with mitral valve regurgitation, it does not *prove* the presence of mitral valve regurgitation. Moreover, such pathological evidence does not comply with the Settlement Agreement's requirement that valvular regurgitation be measured by an echocardiographic examination performed and evaluated by qualified medical personnel following the Feigenbaum or Weyman protocol. *See* Settlement Agreement, Section I.22; *see also* Memorandum and Pretrial Order 7091 (April 5, 2007).

The other basis for Matrix Compensation eligibility is Endocardial Fibrosis. Claimant's GREEN Form does not allege that \_\_\_\_\_ suffered from Endocardial Fibrosis. (*See* GREEN Form, Question L.6).

For these reasons, Claimant does not satisfy the first condition – eligibility – which is necessary in order to receive Matrix Compensation benefits.

7. Even if the evidence established that \_\_\_\_\_ was eligible for Matrix Compensation Benefits, in order to obtain Matrix compensation the evidence must establish that she was also qualified. Settlement Agreement, Section IV.B.2.c. Claimant seeks Benefits on the B-1 Matrix at Level V. (*See* GREEN Form, Question 5.) Matrix Level V is defined as

a) Endocardial Fibrosis; or

b) left sided valvular heart disease, defined as either moderate mitral regurgitation or moderate aortic regurgitation, plus other severe specified complications (defined as Matrix Levels I(b), III or IV) *and* one or more of the following:

–A severe stroke caused by aortic and/or mitral valve surgery or due to bacterial endocarditis contracted after use of diet drugs and the severe stroke has resulted in a permanent condition which meets the criteria of AHA Stroke Outcome Classification Functional Levels IV or V, determined six months after the event;

–Qualification for payment at Matrix Levels III or IV;

- New York Heart Association Functional Class III or Class IV symptoms as documented by the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist;
  - Valvular repair or replacement surgery either performed or required;
  - 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 non-surgical patients or (ii) a left ventricular ejection fraction < 40% six months after valvular repair or replacement surgery;
  - Heart Transplant;
  - Irreversible pulmonary hypertension secondary to valvular heart disease;
  - Persistent non-cognitive state 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
- (c) Post diet-drug death resulting from a condition caused by valvular heart disease 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
- (d) the individual otherwise qualifies for payment at Matrix Level II, III or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise.

Settlement Agreement, Section IV.B.2.c.(5).

8.                                  did not meet the requirements of Matrix Level V.(a). She did not suffer from Endocardial Fibrosis. (*See GREEN Form, Question L.6.*)

9. [REDACTED] did not meet the requirements of Matrix Level V.(b), which requires left sided valvular heart disease, defined as either moderate mitral regurgitation or moderate aortic regurgitation. The Settlement Agreement requires that valvular regurgitation, whether of the mitral valve or the aortic valve, be established by an Echocardiogram. Settlement Agreement I.22. Because [REDACTED] did not have an echocardiogram, she cannot prove that she had either moderate mitral regurgitation or moderate aortic regurgitation. Thus, she cannot prove that she suffered from left sided valvular heart disease. Moreover, in addition to requiring left sided valvular heart disease, Matrix Level V.(b) requires the presence of other severe specified complications (defined as Matrix Levels I(b), III or IV) *and* an additional specified medical condition. [REDACTED] did not have the qualifying complications defined in Matrix Levels I(b), III or IV, nor did she have any of the additional qualifying complications.

Matrix Level I(b) requires FDA Positive valvular regurgitation, which Claimant is unable to substantiate. *See* Settlement Agreement, Section IV.B.2.c.(1)(b) and ¶ 3, *supra*.

Matrix Level III requires surgery to repair or replace the aortic or mitral valves, severe regurgitation plus surgical indications or qualification for payment at Matrix Level I(b) or II plus a stroke due to bacterial endocarditis or as a consequence of chronic atrial fibrillation with left atrial enlargement. *See* Settlement Agreement, Section IV.B.2.c.(3). Claimant's GREEN Form stated there was no surgery to repair or replace the aortic and/or mitral valve(s) after use of diet drugs and no severe regurgitation plus surgical indications to repair or replace the aortic or mitral valves where such surgery was not performed. (*See* GREEN Form Questions F. 9 & 10).

Matrix Level IV requires qualification for payment at Matrix Level I(b), II or III plus a qualifying stroke. [REDACTED] did not qualify for payment at Matrix Levels I(b) or III. (*See supra.*) Matrix Level II is left sided valvular heart disease with complicating factors, defined as either moderate mitral regurgitation or moderate aortic regurgitation plus other complicating

factors, all requiring proof by echocardiography. As noted above, Claimant's lack of an echocardiogram prevents her from substantiating the conclusion that she suffered either mitral regurgitation, aortic regurgitation or the accompanying qualifying complications.

Even if [redacted] had proven the existence of left sided valvular heart disease and other severe specified complications, compensation at Matrix-Level V requires proof of an additional specified medical condition. [redacted] did not have any of the additional medical conditions. GREEN Form Question F.8, F.11, G.1 were unanswered. And GREEN Form Questions F.9, F.10, L.1., L.2. and L.3. were answered in the negative.

10. [redacted] did not meet the requirements of Matrix Level V.(d), which applies if the individual otherwise qualifies for payment at Matrix Level II, III or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise. [redacted] did not qualify for payments at Matrix Levels II, III or IV. See ¶ 9, *supra*. Although Claimant's GREEN Form stated that [redacted] suffered from ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise, (*see* GREEN Form Question L.5.) that fact becomes relevant only if [redacted] first qualifies for payments at Matrix Levels II, III or IV. She does not. (*See* ¶ 9, *supra*.)

11. The provision most closely fitting Claimant's circumstances is Matrix Level V.(c). If Claimant presented evidence, supported by medical records and a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, that [redacted] death followed ingestion of diet drugs and resulted from a condition caused by valvular heart disease, Claimant would qualify for Matrix Level V benefits. In Claimant's GREEN Form, [redacted] responded in the affirmative to the question which asked whether the diet drug recipient died from a condition caused by valvular heart disease. (*See* GREEN Form, Question L.4.) When GREEN Form Question L.4. is answered in the affirmative, the Settlement

Agreement requires a detailed statement from the attending Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon setting forth the basis of that attending physician's opinion that death resulted from a condition caused by valvular heart disease as well as supporting medical records. Settlement Agreement, Section IV.B.2.c.(5)(c).

Claimant relies on the Autopsy Report, completed by \_\_\_\_\_ on behalf of the County Coroner's Office, as proof that \_\_\_\_\_ death was caused by valvular heart disease. The Settlement Agreement, however, requires that such a claim be supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist. *Id.* There is no evidence that \_\_\_\_\_ is a Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist. And \_\_\_\_\_, who completed claimant's GREEN Form and who is a Board-Certified Cardiologist, concedes in his letter of \_\_\_\_\_, that he was not the attending cardiologist in \_\_\_\_\_ case.

Although the Settlement Agreement does not define the term "attending", I conclude that the term "attending" does not include a physician whose opinion is based on a post-mortem review of evidence. My reasons for this conclusion are several. First, by incorporating the term "attending" physician, the Settlement Agreement clearly excludes consulting physicians as acceptable sources of evidence. Second, if "attending" physicians were to include physicians whose bases of information were purely clinical rather than personal, it would render meaningless the use of the word "attending". Finally, to permit the term "attending" to include physicians who never delivered medical care to the deceased would create an uncontrollable slippery slope, essentially opening the door for any physician to review medical records and offer opinions binding on the Trust. Whether this would be a good outcome or not, or whether it is desirable and just in death cases is not for me to decide.

12. Because the evidence from \_\_\_\_\_ and \_\_\_\_\_ does not comply with the



requirement of the Settlement Agreement that claims be substantiated by a statement from an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, I find that Claimant has not established that \_\_\_\_\_, even if eligible, was qualified for Matrix-Level V benefits.

13. In resolving the Diet Drug lawsuit, the parties to the Settlement Agreement could have included a provision for diet drug recipients who died before obtaining an Echocardiogram. But they did not. However wise or fair, the Settlement Agreement is unequivocal in its requirement that qualifying conditions be corroborated by an Echocardiogram conducted in accordance with the protocols established by Feigenbaum or Weyman.

14. Sad though it may be, Claimant's inability to establish that \_\_\_\_\_ was an eligible claimant and that she suffered from a qualifying medical condition is fatal to its claim.

For these reasons, I find that Claimant is not eligible for Matrix compensation.

### CONCLUSIONS

1. Appellant submitted no basis on which to conclude that \_\_\_\_\_ was eligible and qualified for Matrix-Level 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, Claimant 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. Settlement Agreement, Sections IV.B.2.c.(1), (2), (3), (4), and (5).

\_\_\_\_\_  
DATE

\_\_\_\_\_  
Arbitrator