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. v. AMERICAN HOME PRODUCTS CORPORATION	:	CIVIL ACTION NO. 99-20593
Appellant: Executor of the Estate of	:	
Arbitration No.: Claim No.: 183/00	:	REPORT AND AWARD OF ARBITRATOR

FINDINGS OF FACT

1. departed this earth on On Executor of the Estate of , submitted a claim to the AHP Settlement Trust ("Trust"). On the Trust denied the claim of Executor of the Estate of (sometimes hereinafter "Claimant"), for Matrix Compensation Benefits.

2. On 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 the claim of 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 an Arbitration Hearing was held concerning the claim of did not participate in the Arbitration Hearing; her interests were represented

by her attorney,

ANALYSIS

1. The first issue pertains to whether (deceased) ingested diet drugs for more than sixty days or for sixty days or less. Claimant's Pink Form (Questions 8 and 9) states that ingested Pondimin (Fenfluramine) for sixty days or less. In her initial Green Form, dated Claimant sought Level V Matrix Compensation Benefits on the A-1 Matrix (*See* Green Form Questions 5 & 6). On Claimant submitted a Supplemental Green Form dated The Supplemental Green Form seeks Level V Matrix Compensation Benefits on the B-1 Matrix (*See* Supplemental Green Form Questions 5 & 6) and was submitted with a cover letter, signed by which stated "Please note our revised response to Question 6 in Part I, which reflects our inability to document more than sixty days use of the diet drugs."

By letter and Affidavit both dated requested that the Supplemental Green Form be disregarded, and notified the Trust that the Claimant sought Matrix Compensation based on having ingested diet drugs for more than sixty days. affidavit contains several attachments, including the medical records of a copy of a Pondimin prescription bottle bearing the name of and an Affidavit of brother of deceased, attesting to obtaining of additional diet pills on more than one occasion.

In the Trust's Response to the Claimant's Statement of the Case, the Trust did not address the issue of whether ingested diet drugs for less than sixty days or for sixty days or more. In its submission following the Arbitration Hearing, the Trust asserted that there is

insufficient evidence to prove that ingested diet drugs in excess of sixty days. In her submission following the Arbitration Hearing, Claimant re-submitted the Affidavit of the Affidavit of and the incomplete medical records of prescribing physician, all of which had been submitted previously and referred to during the Arbitration Hearing.

The evidence supports a finding that received a 30-day supply of diet pills from the Diet Clinic and that he returned to the clinic on at least two more occasions for more pills. The evidence does not establish, however, how many pills were dispensed on those subsequent occasions, whether they were Pondimin, or whether consumed the pills he received. As will become apparent, whether ingested Pondimin for more than sixty days or for sixty days or less is immaterial.

2. In order to receive Matrix Compensation, a Claimant must be both eligible and 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.

3. Claimant is not eligible for Matrix Compensation Benefits. On the issue of whether was FDA positive, Claimant's Green Form, signed by Board-Certified Cardiologist states that had neither mitral nor aortic regurgitation. (*See* Initial Green Form Questions C.3.A. and C.3.B.) The

accompanying echocardiogram report, dated on which based his Green Form responses, does not state that suffered from either mitral or aortic regurgitation and accordingly fails to document such a condition.

Claimant asserts that pathological evidence in the form of the autopsy report, death certificate, and an Affidavit from Board-certified cardiologist constitute alternative proof that suffered at least moderate level regurgitation. The autopsy report describes aortic valve as normal. It describes his mitral valve as "abnormal. It is shortened, stenotic and insufficient, with fenestration in what is left of the anterior leaf. The chordae tendinae are thick, coarse and shortened. The left ventricle measures 1.5 cm. The myocardium is brown, firm and homogeneous." (*See* Autopsy Report of dated .) The death certificate identifies the cause of death as Cardiac Arrhythmia, due to or as a consequence of Myocardial Hypertrophy, due to or as a consequence of Mitral Valve Stenosis and Insufficiency. (*See* Commonwealth of Kentucky Certificate of Death of dated .) Though these conditions may be consistent with mitral valve regurgitation, there is nothing from which to conclude that their presence proves 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.)

Based on a review of autopsy and prior medical records, offered by affidavit his professional opinion that suffered at least moderate level regurgitation. however, does not explain why the existence of the noted pathological findings leads to a conclusion that suffered from any valvular regurgitation, let alone regurgitation at a moderate level. During the Arbitration Hearing, counsel for the Claimant

asserted that pathological evidence ought, in fairness, to be considered since had no basis from which to suspect that he had heart disease, and therefore lacked incentive to obtain a subsequent, and perhaps more accurate, echocardiogram. As Arbitrator, my evaluation of the fairness of the Trust's actions, or even the fairness of the outcome of this matter, is irrelevant. My authority is limited to determining whether the decision of the Trust violated the Settlement Agreement.

In a submission subsequent to the Arbitration Hearing, the Trust asserts that while there are circumstances when it is entitled to consider pathological evidence as supplementary proof (i.e., rebutting a presumption that the reduction factor of rheumatic valve disease exists, and in support of a claim based on surgery to repair or replace the mitral and/or aortic valve), the only situation in which it is required to accept pathological evidence is in the case of claimants seeking benefits based on having been diagnosed as having Endocardial Fibrosis. *(See* Letter from Letter to dated. pages 4 and 5.) Even though necessitated by the death of the diet drug user, post mortem professional opinions do not meet the Settlement Agreement's criteria for proving valvular regurgitation and therefore I do not find that the Trust is obligated to consider such opinions. Furthermore, even if I were to consider the pathological evidence, there is no basis from which to conclude that its presence is proof of moderate mitral valve regurgitation. For all these reasons, there is no basis for concluding that was FDA positive as that term is defined in the Settlement Agreement. (*See* Settlement Agreement, Section I. 22.)

The other basis for Matrix Compensation eligibility is Endocardial Fibrosis. Claimant's Green Form does not allege that suffered from Endocardial Fibrosis. (*See* Initial Green Form, Question I.6). For these reasons, Claimant does not satisfy the first condition – eligibility – which is necessary in order to receive Matrix Compensation benefits.

4. Even if Claimant established that was FDA Positive or that Claimant were otherwise eligible for Matrix Compensation Benefits, in order to qualify for benefits the diet drug user must have suffered from a qualifying condition. On her Green Form, Claimant stated that she seeks Matrix Level V benefits. (*See* Green Form Question 5.) Matrix Level V is defined as

a) Edocardial Fibrosis;

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).

did not meet the requirements of (a), above. He did not suffer from Endocardial Fibrosis. (*See* Green Form, Question I.6.)

did not meet the requirements of (b), above. He did not suffer from left sided valvular heart disease, defined as either moderate mitral regurgitation or moderate aortic regurgitation (*see* ¶ 3, *supra*) along with other severe specified complications (defined as Matrix Levels I(b), III or IV) *and* one or more specified medical conditions. He did not have qualifying complications as defined in Matrix Levels I(b), III or IV.

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.

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. As noted above, neither Claimant's Green Form nor echocardiogram on which the Green Form is based substantiate the conclusion that he suffered either mitral or aortic regurgitation. did suffer a qualifying stroke, meeting the AHA Stroke Outcome Classification System determined six months after the event (*See* Green Form Question F.11.) Because Claimant cannot establish eligibility for payment at Matrix Level I(b), II, III or IV, however, his stroke does not qualify Claimant for Matrix Level V benefits.

did not meet the requirements of (d), above. He did not qualify for payments at Matrix Levels II, III or IV. (*See supra.*) Nor did suffer from ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise. (*See* Green Form Question I.5.)

Claimant relies most strongly on the assertion that met the requirements of (c), above, in that he suffered a post diet-drug death resulting from a condition caused by valvular heart disease. (*See* Claimant's Statement of the Case). In Claimant's Green Form, 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, it requires a detailed statement of the

attending Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon setting forth the basis of the attending physician's opinion that death resulted from a condition caused by valvular heart disease as well as supporting medical records. (*See id.*)

Claimant submitted a report by Board-certified cardiologist, that death was due to cardiac arrhythmia due to myocardial hypertrophy due to myocardial valvular stenosis and insufficiency and that his mitral stenosis and mitral insufficiency were secondary to his pondimin ingestion. (*See* Letter from to dated

Claimant also submitted an Affidavit from Board-certified cardiologist, *Inter alia*, professional opinion is that suffered at least moderate level regurgitation and his death resulted from a condition caused by valvular heart disease that developed subsequent to his fenfluramine use. (*See* Affidavit of at ¶¶ 17, 18, and 25.) offers the opinion that valvular heart disease was "consistent with" damage caused by exposure to fenfluramine (Pondimin). (*See id.* at ¶24.) He bases his opinion on medical and autopsy records and on autopsy tissue samples. 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. Settlement Agreement, Section IV.B.2.(c)(5)(c). In this case, no such Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist statement has been submitted. In her original submission, Claimant submitted a letter from dated in which offered the opinion, with reasonable medical certainty, that suffered from valvular heart disease produced by use of fenfluramine and that the valvular heart disease was a major factor in congestive heart failure and premature death. It does not appear as though is a Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist. Thus, Claimant relies on the opinions of Neither

nor were personal physician or in attendance at any of medical events. There is no evidence that either ever met During the Arbitration Hearing, asserted that the term "attending" is not defined by the Settlement Agreement and ought to be construed to include a post-death physician in those cases, such as this, where the deceased had no reason to have sought the care of a cardiologist or cardiothoracic surgeon while alive. The Trust responded that "attending" should be given its logical meaning and be construed to include only those physicians who actually provided care to the diet drug user.

I find that the Settlement Agreement does not define the term "attending". I further find, however, that in the absence of evidence thus far not presented, the term "attending" does not include a physician whose contact with the deceased is limited to a post-mortem review of evidence, even where that evidence includes tissue samples. The bases for my conclusion are several. First, it is quite possible that the drafters of the Settlement Agreement did not contemplate a situation such as the one here presented and may have drafted the Settlement Agreement to provide compensation in this circumstance if they had so considered. By incorporating the term "attending" physician, however, 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, though concededly an extension of the above arguments, 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. It was not addressed by the Settlement

Agreement and thus I cannot speculate on the wisdom of such a provision. Because neither opinion nor opinion comply with the requirement of the Settlement Agreement that claims be substantiated by a statement from an attending physician, I find that Claimant has not established that suffered from a qualifying medical condition occasioned by his ingestion of Pondimin.

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, 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).

August 16, 2004

DATE

Arbitrator