

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:
Arbitration No.:
Claim No.: 183/00

REPORT AND AWARD
OF ARBITRATOR

FINDINGS OF FACT

1. [REDACTED] passed away on September 26, 2000. On July 11, 2001, [REDACTED] surviving spouse of [REDACTED], submitted the first of several GREEN Forms 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 July 13, 2006, the Trust denied the claim of the [REDACTED] (sometimes hereinafter "Claimant") for Matrix Compensation Benefits.¹

2. On July 21, 2006, the [REDACTED] filed an appeal from the denial of benefits by the Trust, and requested that the United States District Court ("Court") refer this matter to Arbitration.

¹ Although [REDACTED] submitted both a representative and a derivative claim, for purposes of this Arbitration both claims are together referred to as "The Estate

3. On March 30, 2007, the claim of the Estate was referred by 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. waived his right to an Arbitration Hearing and requested that the Arbitration be decided on the basis of the written submissions of the parties.

ANALYSIS

1. Claimant seeks benefits at Level V on Matrix A-1. Claimant's first GREEN Form sought Level IV benefits without specifying which Matrix. See GREEN Form, Part 1, Questions 5 and 6, dated July 11, 2001, and received by the Trust on July 17, 2001 (hereinafter GREEN Form #1). Part II of GREEN Form #1 was not completed, and also was not signed by a Board-Certified physician. Claimant also submitted a supplemental GREEN Form, seeking Level V benefits on Matrix A-1. See GREEN Form, Part I, Questions 5 and 6, dated February 10, 2003, and received by the Trust on February 14, 2003 (hereinafter GREEN Form #2). Part II of GREEN Form #2 was also not completed, and GREEN Form #2 was not signed by a Board-Certified physician.

2. In order to be compensated at Level V on Matrix A-1, a Claimant who ingested Pondimin® ("Fenfluramine") and/or Redux™ ("Dexfenfluramine") (both hereinafter "Diet Drugs"), must demonstrate both eligibility for compensation and that she qualified to receive benefits at Level V. As will be more fully discussed below, Claimant has not demonstrated that ingested Diet Drugs or that she was both eligible and qualified to receive Matrix benefits at Level V.

3. The Settlement Class consists of persons who ingested Pondimin® and/or Redux™ (hereinafter “Diet Drug Recipients”) and their Representative or Derivative Claimants. Settlement Agreement, § II.B. Thus, only Diet Drug Recipients (and their Representative or Derivative Claimants) are eligible for Matrix compensation. Settlement Agreement, § IV.B.1. Claimants can prove that they were prescribed Diet Drugs in any of three ways. Settlement Agreement, § VI.C.2.d. If the Diet Drugs were dispensed by a pharmacy, the Claimant must provide the identity of the prescribing pharmacy and the records corroborating the dispensing of Diet Drugs. *Id.*, at VI.C.2.d.(1). If the Diet Drugs were dispensed directly by a physician or weight loss clinic, or the pharmacy record is unobtainable, the Claimant must provide the identity of the prescribing physician and a copy of the medical records(s) prescribing or dispensing the Diet Drug(s). Those medical records must identify the Diet Drug Recipient, the Diet Drug name, the date(s) prescribed, the dosage, and the duration the drug was prescribed or dispensed. *Id.*, at VI.C.2.d.(2). If the pharmacy and medical records are unavailable, the Settlement Agreement allows for the submission of an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy, identifying the Diet Drug Recipient, the Diet Drug(s) prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of Diet Drugs. *Id.*, at VI.C.2.d.(3). Alternative forms of proof are not permitted by the terms of the Settlement Agreement.

4. In the BLUE Form, Claimant stated that [redacted] ingested Pondimin® (Fenfluramine) in excess of 60 days. *See* BLUE Form, Questions 7 and 8. In that same form Claimant stated that [redacted] received the Diet Drugs directly from M.D. In such a circumstance, Claimant may prove that [redacted] ingested Diet Drugs by

providing the identity of the prescribing physician and a copy of the medical record(s) prescribing or dispensing the Diet Drug(s). Pursuant to the terms of the Settlement Agreement, those medical records must identify the Diet Drug Recipient, the Diet Drug name, the date(s) prescribed, the dosage, and the duration that the Diet Drugs were prescribed or dispensed. *See id.*, at VI.C.2.d.(2). Claimant did identify _____ as the prescribing physician, but the only documentation submitted was a copy of a prescription with _____ name and address at the top. The document is dated 6-4-97 and contains _____'s name. The prescription also contains the following handwritten notation: "Dexfenfluramine 25 mg (Redux) Sun 1. OM. M. 30." It bears the signature of _____. As stated above, where a Claimant seeks to establish proof of Diet Drug use through pharmacy or medical records, those records must include information about the dosage, and the duration for which the drug was prescribed or dispensed. *See id.* The copy of the prescription submitted by Claimant contains neither of these required pieces of information. Therefore, Claimant has not established that _____ was a Diet Drug Recipient and a member of the Settlement Class.

5. Even if the evidence established that _____ was a member of the Settlement Class, in order to receive Matrix Compensation a member of the Settlement Class must also be both eligible and qualified to receive Matrix-Level Benefits. To be eligible, a Diet Drug Recipient must fit within one of two categories: (1) Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having mild mitral regurgitation by an echocardiogram,² provided the Diet Drug Recipient registered for settlement benefits by May 3,

² The deadline set forth by the Settlement Agreement was January 3, 2003 for echocardiograms provided by the Trust through the Screening program or by July 3, 2003, if the Claimant had an echocardiogram performed by a private provider.

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, § 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 § 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 Claimant. Settlement Agreement, §§ IV.B.1.b., IV.B.1.c., IV.B.1.e. and IV.B.1.f.

6. On December 1, 2003, Claimant submitted another GREEN Form Part II, signed by Dr. _____, a Board-Certified Cardiologist and a Board-Certified Cardiothoracic Surgeon who also indicated completion of level 2 training in echocardiography as specified in the “Recommendations of the American Society of Echocardiography Committee on Physician Training in Echocardiography.” *See* GREEN Form, Part II, dated May 16, 2003 and received by the Trust on December 1, 2003 (hereinafter GREEN Form #3). GREEN Form #3 stated that _____ had moderate aortic regurgitation and both mild and moderate mitral regurgitation, based on a May 20, 1998 echocardiogram. *See* GREEN Form #3, Questions C.2., C.3.a. and C.3.b.

7. The Settlement Agreement requires Class Members to provide appropriate documentation of the condition of the Diet Drug Recipient that forms the basis for the claim. Settlement Agreement, § VI.C.4.a. Included among the required documentation is “a copy of the videotape or disk of the Echocardiogram results which, in whole or in part, forms the basis for the Claim for Matrix Compensation Benefits.” Settlement Agreement, § VI.C.4.a.(2). Claimant

has not submitted a copy of [redacted] echocardiogram tape or disk. Instead, Claimant has submitted a letter dated June 23, 2004 with the letterhead “Memorial Herman Baptist Hospital” and bearing the signature of [redacted] of Medical Records, which states that “[redacted] had a [sic] echocardiography done on 5/28/98. There was no tape made of the echocardiography.” See Letter of [redacted], dated June 23, 2004. Claimant also submitted a typed document bearing the letterhead of Memorial Hermann Baptist Hospital, Beaumont, bearing the signature of [redacted], M.D., which states that “[t]he echocardiography tape could not be found that was done on 5-20-98.” See undated document entitled “Memorial Hermann Baptist Hospital, Beaumont,” signed by [redacted], M.D. Let it simply be noted that in the letterhead the name of the hospital differs in the two documents. In the document bearing the signature of [redacted], Herman has one “n”; in the document bearing the signature of [redacted], Hermann has two “n’s.” In addition, the signature of [redacted] on the undated Memorandum is very similar to the signature on Claimant’s May 20, 1998 Echocardiogram Report, right down to the places where the pen skipped. Held up one behind the other, the two signatures appear identical in all respects. If a Claimant is unable to provide the documentation required by the Settlement Agreement, the Trust has the right to consider other supporting documentation including but not limited to declarations of other Qualified Physician(s) under penalty of perjury setting forth opinions to a reasonable degree of medical certainty to support the claim that the Class Member’s condition entitled her to a Matrix payment. Settlement Agreement, § VI.C.4.b. Because Claimant has not submitted a copy of [redacted]’s echocardiogram tape or disk and has submitted no alternative supporting documentation, Claimant has not met the burden of establishing that [redacted] was an eligible Claimant.

8. In January 2004, Claimant submitted another GREEN Form, again signed by Dr. [REDACTED] and again based on a May 20, 1998 Echocardiogram. *See* GREEN Form, Part II, dated May 16, 2003, and received by the Trust in January, 2004 (hereinafter GREEN Form #4). Whereas in GREEN Form #3, Dr. [REDACTED] answered Questions C.3.a, C.3.b, F.3, F.6 and L.2 in the affirmative, but did not answer Questions F.1, F.2, F.4, F.5, F.7, F.8, F.11, F.12.a., F.12.b. and G, in GREEN FORM #4 Dr. [REDACTED] answered Questions C.3.a, C.3.b, E.3, E.5, E.6, F.1, F.2, F.3, F.4, F.5, F.6, F.7, F.8 and F.11.a. in the affirmative. Page 12 of GREEN Form #4 is missing from the file, so it is not possible to state with accuracy how Dr. [REDACTED] answered Questions F.12 and G on GREEN Form #4. Changes from GREEN Form #3 were not initialed or acknowledged in any way.

9. In March 2004, Claimant submitted another GREEN Form, again signed by Dr. [REDACTED], and again based on a May 20, 1998 Echocardiogram. *See* GREEN Form, Part II, dated May 16, 2003 (hereinafter GREEN Form #5). Questions C.3.a, C.3.b, F.2, F.3, F.6, G.2 and L.2 were answered in the affirmative. Question E.3 was answered in both the affirmative and the negative. Questions E.5, F.1 and F.11.a., which were answered in the affirmative in GREEN Form #4, were now answered in the negative. Questions F.7 and F.8, which were answered in the affirmative in GREEN Form #4, were left unanswered. Changes from GREEN Form #4 were not initialed or acknowledged in any way.

10. In June 2004, Claimant submitted another GREEN Form, again based on a May 20, 1998 Echocardiogram. *See* GREEN Form, Part II, dated June 23, 2004 (hereinafter GREEN Form #6). GREEN Form #6 was signed by [REDACTED], a Board-Certified Cardiologist who also indicated completion of level 2 training in echocardiography as specified in the

“Recommendations of the American Society of Echocardiography Committee on Physician Training in Echocardiography”. See GREEN Form, Part II (hereinafter GREEN Form #6). In GREEN Form #6, Dr. [redacted] asserted mild mitral regurgitation, moderate aortic regurgitation, pulmonary hypertension secondary to severe aortic regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, abnormal left ventricular end-systolic dimension, ejection fraction of 50-60%, stroke resulting in a permanent condition meeting criteria for Functional Level II of the AHA Stroke Outcome Classification System determined six months or later after the event, and NYHA Class II Symptoms. See GREEN Form #6, Questions C.3.a, C.3.b., F.2, F.3, F.6, F.8, F.11.a. and G.2. Question E.3, which had been answered in the affirmative in GREEN Form #4 and, inexplicably, in both the affirmative and the negative in GREEN Form #5, was answered in GREEN Form #6 in the negative. Questions E.6, F.1, F.4, F.5 and F.7, which had been answered in the affirmative in GREEN Form #4 were answered in the negative in GREEN Form #6. Question F.11, answered in the negative in GREEN Form #5, was answered in the affirmative in GREEN Form #6. Question L.2, answered in the affirmative in GREEN Form #3, in the negative in GREEN Form #4, and in the affirmative in GREEN Form #5, was once again answered in the negative in GREEN Form #6.

Simply stated, though GREEN Forms #3, #4, #5 and #6 allege the presence of assorted qualifying conditions, none is accompanied by the required documentation.

11. On or about September 16, 2004, consistent with the Parallel Processing Procedures (“PPP”) which were approved by Court at PTO 3882, Claimant’s case was transferred to the Class Counsel Claims Office (“CCCO”). The PPP provided that “Class

Counsel shall review each claim to determine if it is sufficiently complete within the meaning of §§ VI.C.2 [pp. 90-94] and VI.C.4 [pp. 103-111] of the Settlement Agreement to permit making a determination of eligibility for Matrix Compensation Benefits as a High Level Claim. Missing information shall be considered a deficiency that renders a claim incomplete only if material to making that determination.” Pretrial Order Number 3882, § 8.(a). Section 8.(b) of PTO 3882 continues “. . . Class Counsel shall continue to work with the Class Member to obtain the [required] information until such time as Class Counsel determines that the information cannot be obtained and that it should not process the claim further. Upon Class Counsel’s determination that the information cannot be obtained . . . Class Counsel shall not process the claim further and shall return the claim and its records of all written and oral contacts with the Class Member to the Trust. The Trust shall close the claim and not process it further, unless the Class Member establishes to the Trust good cause to reopen the claim.” *Id.* at § 8.(b). CCCO worked with Claimant in an effort to assist Claimant in providing the necessary documentation. *See e.g.*, June 7, 2004 letter from Class Counsel Claims Office to Estate of _____, in care of _____

Based on Claimant’s failure to supply documentation necessary to complete the Claim, CCCO recommended that the claim be closed. On May 30, 2006, the Trust closed the Claim and issued a Denial of Matrix Compensation benefits. *See Tentative Determination*, dated May 30, 2006.

On June 9, 2006, Claimant contested the denial of Matrix benefits and submitted various correspondence and records, including what appeared to be a signature page from GREEN Form #6, and other documents already on file, including the death certificate, various drug and medical records, and the 1998 Echocardiogram Report. By letter dated June 21, 2006, Claimant was

notified that the contest information had been forwarded to CCCO. After reviewing the contest information, CCCO advised the Trust that the claim should be closed, and on July 13, 2006, the Trust issued a Final Determination, denying Matrix compensation. Appellant subsequently appealed.

12. The parties agree that _____ died on September 26, 2000.

13. Even if the evidence established that _____ was a Class Member and eligible for Matrix Compensation Benefits, which the evidence does not establish, in order to obtain Matrix compensation the evidence must establish that she was also qualified. Settlement Agreement, § IV.B.2.c. Claimant seeks Benefits at Level V on Matrix A-1. See GREEN Form #2, Question 5 and Question 6. 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; or
 - 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) 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, § IV.B.2.c.(5).

did not meet the requirements set forth in Section IV.B.2.5.a. of the Settlement Agreement, to establish a claim for Matrix Level V benefits. None of the GREEN Forms submitted by Claimant stated that she suffered from Endocardial Fibrosis. See GREEN Forms #3-6, Question L.6. 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. As stated above, Claimant has failed to submit the tape or disk of [REDACTED]'s May 20, 1998 echocardiogram. This is particularly crucial since the Echocardiogram report states that [REDACTED] had normal left ventricular function. Thus, there is no evidence from which to conclude that [REDACTED] had left sided valvular heart disease. Moreover, in addition to requiring left sided valvular heart disease, the requirements set forth in Section IV.B.2.5.b. of the Settlement Agreement to establish a claim for Matrix Level V benefits require 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, § IV.B.2.c.(1)(b) and ¶ 7, *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, § IV.B.2.c.(3). None of Claimant's GREEN Forms stated there was 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 Forms #3-6, Questions F. 9

and F.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 tape or disk prevents substantiation of the conclusion that [redacted] suffered either mitral regurgitation or aortic regurgitation. Thus Claimant cannot establish that [redacted]

[redacted] qualified for payment at Matrix Level II. Because Claimant did not qualify for payment at Matrix Level I(b), II or III, Claimant did not qualify for payment at Matrix Level IV.

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. Although GREEN Forms #4 and #6 allege a reduced ejection fraction, (*see* Questions F.8) and stroke due to bacterial endocarditis contracted after use of Diet Drugs (*see* Questions 11), GREEN Forms #3 and #5 allege irreversible pulmonary hypertension secondary to valvular heart disease (*see* Question L.2), and GREEN Forms #5 and #6 allege Class II New York Heart Association Functional Class Symptoms, (*see* Questions G.2), Claimant submitted no medical evidence to support these allegations. Nor did [redacted] have any of the additional medical conditions. On every GREEN Form, Questions F.9, F.10, L.1 and L.3 were answered in the negative. Therefore, Claimant did not meet the requirements of Matrix-Level V.(b).

14. Nor does Claimant meet the requirements set forth in Section IV.B.2.5.c of the

Settlement Agreement to establish a claim for Matrix Level V benefits. If Claimant presented evidence, supported by medical records and a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, that death followed ingestion of Diet Drugs and resulted from a condition caused by valvular heart disease, Claimant would qualify for Matrix Level V benefits. 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, § IV.B.2.c.(5)(c). None of Claimant's GREEN Forms contains an affirmative response to the question which asked whether the diet drug recipient died from a condition caused by valvular heart disease. *See* GREEN Forms #3-6, Question L.4.

15. Claimant did not meet the requirements set forth in Section IV.B.2.5.d. of the Settlement Agreement to establish a claim for Matrix Level V benefits, 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. did not qualify for payments at Matrix Levels II, III or IV. *See* ¶ 13, *supra*. None of Claimant's GREEN Forms states that suffered from ventricular fibrillation or sustained ventricular tachycardia resulting in hemodynamic compromise, (*see* GREEN Forms #3-6, Question L.5.)

16. Because Claimant did not provide a basis for concluding that was a member of the Settlement Class, that she was eligible for Matrix compensation or that she was

qualified for Matrix benefits, I find that Claimant is not eligible for Matrix compensation.

CONCLUSIONS

1. Claimant submitted no basis on which to conclude that _____ was eligible and qualified for Matrix-Level Benefits. Accordingly, the Trust did not err in denying Matrix Benefits and 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 Compensation Benefits because the conditions required for recovery of Matrix-Level I, II, III, IV or V Benefits are not present. Settlement Agreement at Sections IV.B.2.c.(1), (2), (3), (4), and (5).

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DATE

Arbitrator