

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.  
: 2:15MD1203  
:  
:

SHEILA BROWN, ET AL.

v.

: CIVIL ACTION NO.  
: (99-20593)  
:  
:

AMERICAN HOME PRODUCTS  
CORPORATION

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

: **REPORT AND AWARD**  
: **OF ARBITRATOR**  
:  
:

**FINDINGS OF FACT**

1. On \_\_\_\_\_, the AHP Settlement Trust (“Trust”) issued a Final Determination denying the claim of \_\_\_\_\_ (“Claimant”) for Matrix Compensation Benefits.
2. On \_\_\_\_\_ Claimant filed an appeal from the denial of the benefits by the Trust and requested 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) and (i) of the Settlement Agreement with American Home Products Corporation.
4. On \_\_\_\_\_ at \_\_\_\_\_ p.m., an Arbitration Hearing was held concerning the claim of \_\_\_\_\_ was not represented by counsel.
5. During the Arbitration Hearing, \_\_\_\_\_ confirmed that in \_\_\_\_\_ obtained a prescription for “the Fen-Phen Combination” of drugs from a doctor in Mexico,

Dr. \_\_\_\_\_, that \_\_\_\_\_ had the prescription filled in Mexico, and did not know precisely which diet drug \_\_\_\_\_ received.

6. \_\_\_\_\_ further confirmed that in \_\_\_\_\_ lived in \_\_\_\_\_ approximately two blocks from \_\_\_\_\_'s office in Mexico. \_\_\_\_\_ went to Mexico for the "Fen-Phen Combination" of drugs because \_\_\_\_\_ did not have health care coverage in the United States; \_\_\_\_\_ knew that \_\_\_\_\_ could not get a prescription from a Mexican physician filled in the United States, and because \_\_\_\_\_ spent a significant amount of time in Mexico (during \_\_\_\_\_ to help care for an ill family member.

### ANALYSIS

1. Under the Settlement Agreement, persons who are part of the Settlement Class consist of persons who ingested Pondimin ("Fenfluramine") and/or Redux ("Dexfenfluramine") (hereinafter both Pondimin and Redux are referred to as "Diet Drugs") and their Representative or Derivative Claimants. See Settlement Agreement §II.B.

2. Under the Settlement Agreement, there are two types of Matrix Compensation Benefits. Matrix A benefits, or the full compensation matrix, applies to claimants who: (a) have been diagnosed timely as FDA positive; (b) ingested Diet Drugs for sixty-one (61) days or more; and (c) have no conditions requiring a reduced payment under the terms of the Settlement Agreement. See Settlement Agreement § IV.B.2.d.(1). Matrix B benefits, or the reduced compensation benefits matrix, applies to claimants who: (a) have been diagnosed timely with Mild Mitral Regurgitation (regardless of the duration of ingestion of the Diet Drugs); or (b) were diagnosed timely as FDA Positive and ingested Diet Drugs for sixty (60) days or less; or (c) were diagnosed timely as FDA Positive, ingested Diet Drugs for sixty-one (61) or more days, and have certain conditions, identified in the Settlement Agreement, that may have caused or contributed to the claimant's heart problems. See id. § IV.B.2.d.(2).

3. To qualify for any benefits due to the ingestion of Diet Drugs, a claimant must submit “documentary proof” regarding the ingestion of Diet Drugs, as defined by the Settlement Agreement. See Settlement Agreement § VI.C.2.d.

4. If the Diet Drugs were dispensed by a pharmacy, a claimant must prove the identity of the prescribing pharmacy and the records corroborating the dispensing of Diet Drugs. See id. § 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 record prescribing or dispensing the Diet Drugs. Those medical records must identify the Diet Drug Recipient, the name of the Diet Drugs, the date(s) prescribed, the dosage, and the duration that the Diet Drugs were prescribed or dispensed. See id. § 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 Drugs prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of Diet Drugs. See id. § VI.C.2.d.(3). No alternate forms of proof are allowed under the Settlement Agreement.

5. Claimant seeks benefits at Level IV on Matrix A. In support of claim, Claimant submitted a Green Form in which claims benefits based on valvular surgery after the use of Diet Drugs. The GREEN Form was completed by , a Board-Certified Cardiothoracic Surgeon, and signed on

6. In order to be compensated for Level IV on Matrix A-1 benefits, Claimant must establish that meets the Settlement Class requirements. The Settlement Class consists of “[a]ll persons in the United States, its possessions and territories who ingested Pondimin and/or

Redux.” See Settlement Agreement § II.B. “Diet Drugs” are defined in the Settlement Agreement as “Fenfluramine marketed under the brand name Pondimin® and/or Dexfenfluramine marketed under the brand name Redux™.” See Settlement Agreement § I.20.

7. The Blue Form signed on \_\_\_\_\_ indicated that the pharmacy records were unavailable, therefore the prescribing doctor provided a Declaration.

8. Here, Claimant’s only evidence that \_\_\_\_\_ was prescribed any weight loss drug is limited to the Declaration of \_\_\_\_\_ Declaration indicates that \_\_\_\_\_ prescribed Pondimin 60 mg, to be taken once daily and Fen-Phen 15 mg to be taken twice daily for the period \_\_\_\_\_

9. For reasons which are not clear, the Trust waited until \_\_\_\_\_, to submit a Petition to Submit New Evidence. The “new evidence” was limited to a Declaration Pursuant to 28 U.S.C. § 1746 from \_\_\_\_\_, Legal Counsel for Wyeth Mexico, which is Wyeth Pharmaceutical’s Mexican affiliate responsible for marketing and selling Wyeth Products in Mexico.

10. The Trust’s Petition to submit new evidence was granted by Chairperson, \_\_\_\_\_ on \_\_\_\_\_

11. According to the Declaration of \_\_\_\_\_, Wyeth Mexico did not market or sell Fenfluramine in Mexico under the brand name Pondimin in \_\_\_\_\_, but it did market this drug under the brand name “Ponderex.” See Declaration at ¶¶ 5 and 6.

12. There is no dispute about the medical records and echocardiogram report submitted by Claimant.

13. On the issue of whether \_\_\_\_\_ ingested Diet Drugs, it is clear from the evidence presented that \_\_\_\_\_ has not established that \_\_\_\_\_ ingested Pondimin or Redux.

14. While \_\_\_\_\_ claims, if true, are unfortunate, the Trust acted appropriately in denying \_\_\_\_\_ claim since \_\_\_\_\_ could not have obtained the Diet Drugs in the United States and therefore could not have ingested Diet Drugs as required by the Settlement Agreement. Absent proof to the contrary, \_\_\_\_\_ is not entitled to Matrix Benefits. As such, it is not necessary to consider Claimant's Echocardiogram Report and medical treatment for cardiac conditions for the purpose of determining Matrix Benefits.

**CONCLUSIONS**

15. Having failed to demonstrate that \_\_\_\_\_ ingested Diet Drugs, specifically Pondimin, for any period of time while in the United States, \_\_\_\_\_ is ineligible for Matrix Benefits as established by the terms of the Settlement Agreement.

16. Based upon the information provided by \_\_\_\_\_ to the Trust of ingestion of Pondimin in the United States, the Trust's denial of benefits is not clearly erroneous.

11/19/09  
\_\_\_\_\_  
Date

\_\_\_\_\_  
Arbitrator