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.	:	CIVIL ACTION NO.
v.	:	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 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 VI.C.4(h) & (i) or VI.D.1.(f) & (g) of the Nationwide Class Action Settlement Agreement with American Home Products Corporation.

4. An Arbitration Hearing concerning the claim of was scheduled for , but had to be rescheduled. On , an Arbitration Hearing was held concerning the claim of

5. The Trust determined that was not entitled to any Matrix Compensation Benefits on the basis that failed to supply the documentation required to establish Diet Drug ingestion.

6. In statement of the case, requests benefits based on alleged medical symptoms and conditions purportedly caused by the use of the diet drugs. In Green Form, indicates that believes is entitled to Matrix B-1 Benefits with severity level III. See Green Form, Part I, page 4, questions 5 and 6.

ANALYSIS

FUND A ISSUES NOT COVERED BY ARBITRATION PROCESS

1. The Settlement Agreement provides for two funds, Funds A and B, which were established to provide benefits to class members. See Settlement Agreement, Section III.A.1; Memorandum and Pretrial Order No. 1415 (August 28, 2000) at 62. Fund A provides funding only for non-Matrix specified benefits and expenses, e.g., drug refunds and echocardiogram reimbursement. See Settlement Agreement, Section IV.A; Memorandum and Pretrial Order No. 1415 (August 28, 2000) at 62. Fund B provides funding for Matrix Compensation Benefits. See Settlement Agreement, Section IV.B; Memorandum and Pretrial Order No. 1415 (August 28, 2000) at 62.

2. The arbitration process only covers determinations made regarding Fund B and the eligibility of claimants to receive Matrix Compensation Benefits and/or the amount of Matrix Compensation Benefits they are entitled to receive.

MATRIX ELIGIBILITY AND QUALIFICATION

1. Under the Settlement Agreement, Matrix Compensation Benefits are paid according to two matrices. See Settlement Agreement § IV.B.2.d. The A Matrix, or the full compensation matrix, applies to claimants who: (1) have been diagnosed timely as FDA Positive; (2) ingested the diet drugs for sixty-one (61) or more days; and (3) have no conditions requiring a reduced payment under the terms of the Settlement Agreement. See Id. § IV.B.2.d.(1). The B Matrix, or reduced compensation matrix, applies to claimants who: (1) have been diagnosed timely with Mild Mitral Regurgitation (regardless of the duration of ingestion of the diet drugs); or (2) were diagnosed timely as FDA Positive and ingested the diet drugs for sixty (60) days or less; or (3) were diagnosed timely as FDA Positive, ingested the 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).

2. In determining the length of diet drug usage, Section VI.C.2.d of the Settlement Agreement requires the claimant to submit documentary proof concerning the period of time the diet drugs were ingested. Specifically, the claimant must submit pharmacy records documenting the claimant's name, prescribing physician information, diet drug name, date(s) prescribed, dosage and duration the drug was prescribed or dispensed. If a physician or weight loss clinic prescribed the diet drugs directly, or pharmacy records are unobtainable, a claimant must identify the prescribing physician, including the prescribing physician's name, address and telephone number, and submit a copy of the medical records prescribing or dispensing the drugs. If the pharmacy records and medical records are unobtainable, a claimant must submit an affidavit under penalty of perjury from the prescribing physician or

dispensing pharmacy identifying the claimant, the drug prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the diet drug(s) to document ingestion. See id. § VI.C.2.d.(3).

3. submitted a Green Form dated

4. In the Green Form, reference is made to an echocardiogram which was performed on (See Green Form, Part II, page 8, questions C.1 and C.2).

5. The Green Form submitted by reports mild mitral valve regurgitation and moderate aortic valve regurgitation. (See Green Form, Part II, page 8, question C.3). The Green Form also reports surgery to repair or replace the aortic and/or mitral valve. (See Green Form, Part II, page 11, question 9).

6. The answers to the questions in Part II of Green Form were completed by physician, , a Board-Certified Cardiologist. (See Green Form, Part II, page 7, Section A).

7. submitted a Pink Form dated

8. According to questions 7, 8 and 9 of Pink Form, answered that took Pondimin and Redux for 60 days.

9. failed to submit any pharmacy records documenting the claimant's name, prescribing physician information, diet drug name, date(s) prescribed, dosage and duration the drug was prescribed or dispensed. also failed to submit a copy of any medical records prescribing or dispensing diet drugs.

10. In statement of the case, states that the pharmacy records were unobtainable due to changes in the ownership of the original pharmacy, states that for this reason, no pharmacy records supporting diet drug

use were submitted to the Trust for review. Also, in statement of the case, identifies as the prescribing physician of the diet drugs ingested, but states that medical records were unobtainable for submission to the Trust since had retired, became seriously ill and passed away in

11. In statement of the case, and during the Arbitration Hearing through counsel, conceded that no pharmacy records were submitted and that no medical records were submitted as required by the Settlement Agreement to establish diet drug usage.

12. In lieu of pharmacy and medical records, submitted an affidavit under penalty of perjury, being a Blue Form, Page 12 Declaration, signed by to establish diet drug usage. According to the Settlement Agreement, an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy must identify the claimant, the drug prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the diet drug(s) to document ingestion. See Settlement Agreement § VI.C.2.d.(3).

13. The Trust concluded that the Declaration signed by failed to contain all of the information required by the Settlement Agreement. In particular, the Trust contends in its Statement of the Case, that the Declaration fails to set forth any dosages of the diet drugs allegedly dispensed as required by the Settlement Agreement. See id.

14. The Trust also points out in its response to the Appellant's statement of the case that, in the Declaration of states that prescribed Pondimin and Redux to , and then lists both diet drugs as having been prescribed simultaneously from through . The Trust asserts that, if both Pondimin and

Redux were prescribed simultaneously, this would have been contrary to accepted medical practice. In statement of the case, and through counsel at the Arbitration hearing, conceded that stated that prescribed Pondimin and/or Redux, and then listed both diet drugs as having been prescribed simultaneously, advising that, at the time made the Declaration, did not recall exactly which diet drug prescribed.

15. There is no dispute that the Declaration was made under penalty of perjury, that it is from the prescribing physician, that it identifies the claimant, the date(s), quantity, frequency, and number of prescriptions or refills of the diet drug(s) to document ingestion as required by the Settlement Agreement. See Settlement Agreement § VI.C.2.d.(3). The Trust contends only that the Declaration fails to sufficiently identify the drug prescribed or to set forth the dosages of the drugs.

16. It is true that Declaration does not specify which diet drug was prescribed. However, declared that diet drugs were prescribed from through . Redux was not available for marketing in the United States until June 1996. See PTO 1415 at 7. It is therefore a fair inference from the evidence, and more likely than not, that was prescribed Pondimin, which had been marketed in the United States since 1989. See PTO 1415 at 6.

17. With regard to dosage, the 1997 Physician's Handbook states that "Pondimin is available in 20 mg orange, scored, compressed tablets..." Physicians Desk Reference, 2240 (51st ed. 1997). Thus, even though Declaration does not specify the specific milligrams of Pondimin prescribed, Pondimin was only available in 20 mg tablets. See PTO 7066 at 7. did state in the Declaration that prescribed three pills per

day. Therefore, provided proof that daily dosage of Pondimin was 60 mg per day.

18. In addition, the 1997 Physician's Handbook states with regard to Redux that "The usual dosage is one 15-mg capsule twice daily, with meals. Doses above 30 mg per day are not recommended." Physicians Desk Reference, 2914 (51st ed. 1997). With regard to Pondimin, the Handbook states "The usual dose is one 20 mg tablet three times daily before meals. Id. at 2240. Since states in the Declaration that prescribed three pills per day, this provides further proof that was prescribed Pondimin.

19. For these reasons, Declaration constitutes a valid affidavit under penalty of perjury from the prescribing physician that identifies the claimant, the drug prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the diet drug(s) which documents diet drug ingestion. See Settlement Agreement § VI.C.2.d.(3). has met burden of proof as required by the Settlement Agreement. See Settlement Agreement § VI.C.2.d.

20. also submitted the following documentation as proof of diet drug use: affidavit of Appellant dated , with exhibits; affidavit of Appellant's dated ; death certificate of , a letter dated , from former pharmacist and secretary/treasurer for , two articles: "Redux to be Voluntarily Withdrawn; Pondimin also to be Withdrawn," dated January 25, 2004, published in "Obesity Meds and Research News," and "Fen Phen Nation" dated November 13, 2003 and published in "Frontline"; an affidavit dated , of ; and two signed authorizations for the release of medical records. However, none of this additional documentation constitutes an affidavit

under penalty of perjury from the prescribing physician or dispensing pharmacy identifying the claimant, the drug prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the diet drug(s) to document ingestion. See Settlement Agreement § VI.C.2.d.(3).

21. In the affidavit of indicates that was not the prescribing physician of diet drugs and the affidavit does not contain any drug prescribed or dispensed by . Therefore the affidavit does not contain any date(s), quantities, frequencies, dosages or numbers of prescriptions or refills of the diet drug(s) necessary to document ingestion. Nevertheless, because of the previous findings with regard to the Blue Form Declaration of , the additional affidavits are not at issue.

22. The Trust determined that failed to supply the required documentation needed to establish that had ingested diet drugs. I conclude that the Trust's analysis and determination were clearly erroneous.

CONCLUSIONS

1. The Claimant has met burden of providing documentary proof of diet drug ingestion to the Trust as required by the Settlement Agreement.

2. Based on the above, the findings of the Trust are clearly erroneous as set forth in Rule 5 of the Rules Governing the Arbitration Process.

3. The final determination of the Trust is reversed and the claim of , as a High Level Claim, should be processed in accordance with the terms of the Parallel Processing Procedures approved in Pretrial Order 3882.