

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 Post-Audit Determination denying the claim of for Matrix Compensation Benefits on the A Matrix.

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. On an Arbitration Hearing was held concerning the claim of

5. The Trust determined that Appellant was eligible for Compensation Benefits on the B Matrix, but that was not entitled to Compensation Benefits on the A Matrix on the basis that failed to supply the documentation required to establish Diet Drug ingestion for sixty-one (61) or more days.

6. In Statement of the Case, Appellant requests benefits based on alleged medical symptoms and conditions purportedly caused by the use of the diet drugs on Matrix A-1.

### 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 § 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 § IV.A. Memorandum and Pretrial Order ("PTO") No. 1415 (August 28, 2000) at 62. Fund B provides funding for Matrix Compensation Benefits. See Settlement Agreement § IV.B, PTO 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 the 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. Under the Settlement Agreement, the burden of proving diet drug ingestion remains with the claimant. See PTO 7779 at 6.

4. In \_\_\_\_\_ Appellant submitted a Green Form Part II based upon an \_\_\_\_\_ echocardiogram, alleging, among other conditions, severe aortic regurgitation, surgery to the aortic valve following diet drug use, and ventricular fibrillation/sustained ventricular tachycardia. Pursuant to the Parallel Processing Procedures (the "PPP") in place at that time, Wyeth designated the Claim for payment at Matrix A-1, Severity Level III, based upon Appellant's aortic valve surgery. Said claim was paid at that level.

5. In \_\_\_\_\_ the Appellant submitted a new claim based upon a Supplemental Green Form received by the Trust on \_\_\_\_\_. This is the claim at issue in this appeal.

6. In the Supplemental Green Form, reference is made to the echocardiogram performed on \_\_\_\_\_ (See Supplemental Green Form, Part II, page 8, questions C.1 and C.2).

7. The Supplemental Green Form submitted by Appellant reports severe aortic regurgitation, and no mitral valve regurgitation. (See Supplemental Green Form, Part II, page 8, question C.3). The Supplemental Green Form also reports surgery to repair or replace the aortic valve following diet drug use, ventricular fibrillation or sustained ventricular tachycardia, and death as a result of valvular heart disease or valvular repair/replacement surgery. (See Supplemental Green Form, Part II, page 11, question 9; page 13, questions 4 & 5).

8. The answers to the questions in Part II of Appellant's Supplemental Green Form were completed by \_\_\_\_\_ physician, \_\_\_\_\_ a Board-Certified Cardiologist. (See Supplemental Green Form, Part II, page 7, Section A).

9. After audit, the Trust determined that the claim based upon the Supplemental Green Form was eligible for benefits on Matrix B-1, Severity Level V. Appellant's Claim was reduced to Matrix B-1 based solely upon duration of diet drug use. Because the previously paid Matrix A, Severity Level III Benefits exceeded the value of the Matrix B, Severity Level V Benefits, the Trust issued a Post-Audit Determination denying the claim on \_\_\_\_\_ Appellant submitted a Contest to the Post-Audit Determination on \_\_\_\_\_ On \_\_\_\_\_ the Trust issued a Final Post-Audit Determination denying the second claim of \_\_\_\_\_ for Matrix Compensation Benefits on the A Matrix, which led to this appeal.

10. \_\_\_\_\_ submitted a Blue Form dated \_\_\_\_\_

11. According to questions 7, 8 and 9 of \_\_\_\_\_ Blue Form, answered that \_\_\_\_\_ took Pondimin for sixty-one (61) days or more, for a total period of four (4) months.

12. According to question 10 of \_\_\_\_\_ Blue Form, the Pondimin ingested was dispensed by \_\_\_\_\_

13. The parties agree that the Settlement Agreement and the internal Claims Processing Procedures, which had been approved by the Trust and by Class Counsel, governs the Trust's determination in evaluating the length of diet drug ingestion. See PTO 3261 at 2-5.

14. submitted several documents in support of claim that took Pondimin for sixty-one (61) days or more, which the Trust evaluated by the standards set forth in the Settlement Agreement and in the Claims Processing Procedures.

15. submitted a four-page pharmacy record entitled "Medical Expenses," generated by relating specifically to for the period to The pharmacy record documents that Pondimin was dispensed on thirty (30) pills, and again on ninety (90) pills.

16. also submitted two pages of Progress Notes from (the "Progress Notes") and a one page document entitled (the "Medication Record").

17. In addition to the pharmacy and medical records, Appellant submitted a Blue Form Declaration dated completed by who was identified as the dispensing pharmacist (the "Blue Form Declaration"), a letter dated purporting to be from the prescribing physician, to Appellant's counsel, and a affidavit of the of

18. The Settlement Agreement requires the Trust, in determining the length of diet drug usage, to look first to the pharmacy records. See Settlement Agreement § VI.C.2.d.(1) and (2).

19. The Claims Processing Procedures provide that the prescription/pharmacy record creates a rebuttable presumption that the diet drug was ingested for the period reflected in the record. Claims Processing Procedures: Duration of Use ¶ 1.

20. The Claims Processing Procedures permit a claimant to rebut the presumption established by the pharmacy record by submitting "credible proof" that the claimant ingested diet drugs for more days than as indicated by the pharmacy record. Claims Processing Procedures: Duration of Use ¶¶ 2-3.

21. The Claims Processing Procedures further provide that the proof must demonstrate by credible proof the number of days the claimant took the drug, if it differs from the duration of the prescription. The standard would not turn on the total time span in which the claimant says the drug was used, but instead on the actual number of days on which the drug was taken. Claims Processing Procedures: Duration of Use ¶ 2.

22. Here, the pharmacy record, which is corroborated by the Progress Notes, creates a rebuttable presumption that Claimant ingested Pondimin for sixty (60) days or less.

23. The pharmacy record documents that [redacted] was dispensed Pondimin on [redacted] and on [redacted] receiving a thirty-day supply each time. The entries in the pharmacy record correspond to the entries in the Progress Notes dated [redacted] ("restart diet pills ... Fastin didn't help ... Fastin 30mg + Pondimin 20mg") and [redacted] ("Pondimin 20mg tid"). The pharmacy record reflects that the prescription filled on [redacted] was written on [redacted] which corresponds to the Progress Notes.

24. In the Appellant's Statement of the Case, it is admitted that the pharmacy record and the Progress Notes reflect but two prescriptions, filled on [redacted] and on [redacted] and that each prescription reflected a thirty-day supply.

25. The Medication Record does not support any diet drug usage as it fails to set forth the dosage and duration the drug was prescribed or dispensed. See Settlement Agreement § VI.C.2.d.(2).

26. The Blue Form Declaration does not establish the use of diet drugs for a period of more than sixty (60) days. The Settlement Agreement provides that 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). Here, however, \_\_\_\_\_ pharmacy and medical records were not unobtainable, have been submitted to the Trust, and create a rebuttable presumption that the Claimant ingested Pondimin for sixty (60) days or less.

27. The remaining question regarding the Blue Form Declaration is whether it rebuts the presumption that Claimant ingested Pondimin for sixty (60) days or less. To do so, the Blue Form Declaration must constitute "credible proof" that the Claimant ingested diet drugs for more days than as indicated by the pharmacy record. Claims Processing Procedures: Duration of Use ¶¶ 2-3. Here, the Declaration asserts that Pondimin was dispensed by the Pharmacy from \_\_\_\_\_ through \_\_\_\_\_ without interruption. This assertion is contrary to the pharmacy and medical records and is contrary to Appellant's position in Appellant's Statement of the Case that Pondimin was dispensed by the Pharmacy only on \_\_\_\_\_ and on \_\_\_\_\_. In addition, there is no explanation or documentation to support this assertion. Finally, the Declaration does not speak to the number of days the Diet Drug was taken, as required by the Claims



Processing Procedures. Claims Processing Procedures: Duration of Use ¶ 2. Therefore, I find that the Blue Form Declaration does not constitute "credible proof" that the Claimant ingested diet drugs for more days than as indicated by the pharmacy record. Claims Processing Procedures: Duration of Use ¶¶ 2-3.

28. Appellant argues that the presumption of sixty (60) days of use is rebutted by the [redacted] letter purporting to be from [redacted]. The letter states that [redacted] was prescribed Pondimin on [redacted] and on [redacted] which is consistent with the pharmacy and medical records. Then the letter indicates that "[redacted] . . . was also provided with samples of Pondimin tablets at the Ambulatory Clinic as needed."

29. As noted above, the Settlement Agreement provides that 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). Here, however, [redacted] pharmacy and medical records were not unobtainable, have been submitted to the Trust, and create a rebuttable presumption that the Claimant ingested Pondimin for sixty (60) days or less.

30. Even assuming that the medical and pharmacy records were unobtainable, the [redacted] Letter could not be considered for the purpose of establishing diet drug usage, since it is not an affidavit under penalty of perjury as required by the Settlement Agreement. Indeed, the letter is not even signed. In addition, although there is a general statement that [redacted] was provided with samples of Pondimin "as needed," the letter

does not set forth the date(s), quantity, frequency, dosages thereof, and therefore, does not all speak to the number of days of usage as required by the Claims Processing Procedures. Claims Processing Procedures: Duration of Use ¶2. The credibility of the letter is further undermined by the fact that it asserts that the Claimant was still taking Pondimin in \_\_\_\_\_ after the diet drugs were recalled from the market. Therefore, the \_\_\_\_\_ letter does not constitute "credible proof" rebutting the presumption that the Claimant ingested Pondimin for sixty (60) days or less.

31. Finally, the Appellant argues that the presumption of sixty days of use is rebutted by the affidavit of \_\_\_\_\_ signed on \_\_\_\_\_. In the affidavit, \_\_\_\_\_ confirms that \_\_\_\_\_ only received two prescriptions, each with a thirty (30) day supply of Pondimin. However, \_\_\_\_\_ further states that \_\_\_\_\_ received samples "several times," and that \_\_\_\_\_ did not take the medication as prescribed, but in fact stretched the medication out over a period of at least 120 days, as late as \_\_\_\_\_.

32. The affidavit of \_\_\_\_\_ was submitted solely to support the claim that \_\_\_\_\_ took Pondimin for 61 days or more. The Claims Processing Procedures specifically state that an affidavit under oath from the Claimant, "if not corroborated by other credible evidence, such as a reliable affirmation of another person with knowledge of the subject matter, would not be sufficient to rebut the written prescription. . . ." See Claims Processing Procedures at ¶3. Assuming the affidavit of \_\_\_\_\_ were to be considered as the affidavit of the Claimant, the statements therein are not corroborated by other credible evidence.

33. The Claims Processing Procedures also state "the Trust may consider a claimant's affidavit standing alone in the totality of circumstances presented by that

claimant to access its weight in the rebuttal analysis." See Claims Processing Procedures at ¶ 3. Implicitly, there must be other "circumstances" that corroborate a claimant's affidavit in order to give the affidavit any weight. Here, there are no other such circumstances.

34. I find that the affidavit of \_\_\_\_\_ is not corroborated by any other credible evidence and, therefore, the affidavit is not sufficient to rebut the presumption created by the prescription record. In addition, I find that an affidavit of this nature, from an interested party, i.e., the \_\_\_\_\_ of the Claimant, submitted solely to support of the claim that \_\_\_\_\_ took Pondimin for sixty-one (61) days or more, to be self-serving and lacking in credibility, regardless of the presumption that applies. See PTO 3261 at 5-6.

35. Finally, the Appellant argues that the Trust should be estopped from contending that Appellant failed to establish proof of diet drug use in excess of sixty (60) days on the basis that the Trust "conceded" use of more than sixty (60) days when Appellant's first claim was paid according to the PPP, and again when Appellant received CMS benefits in 2007. There is no merit to this argument.

36. Pursuant to Section 10 of the PPP, after its review of the claim forms and Medical Information, and no later than 30 days after determining that the claim is complete, Wyeth is required to notify the Trust and Class Counsel that the Matrix claim, and any associated claims, are designated as either (a) Payable; or (b) Payability Disputed. Pursuant to Section 11(a) of the PPP, with regard to all claims designated as Payable by Wyeth, Wyeth is required to notify Class Counsel and the Trust of the benefit level and the amount of the claim based on the documentation and information reviewed by Wyeth.

37. Section 12 of the PPP governs "[t]he Trust Actions on Designated Matrix Claims." Pursuant to Section 12(a), for any claim designated by Wyeth as Payable, the

Trust is required to perform a review of the claim limited to determining that a Green Form has been filed and that the name and claim number are consistent as designated by Wyeth. After its review, the Trust shall issue a determination letter to the Claimant, and provide the Claimant with an opportunity to accept the amount without prejudice to have the right to contest the Matrix designation or the severity level. It is further provided by Section 12(a) that the Trust shall not run the Green Form algorithm, require additional information to complete the claim, or conduct any additional review of the claim, but instead shall process the claim at the level and in the amount specified in Wyeth's designation.

38. Regarding Appellant's first claim, a Determination Letter - Matrix A was issued on \_\_\_\_\_ pursuant to Wyeth's designation of the Claim as payable according to the PPP, which expressly provides that "With respect to each claim designated by Wyeth as payable . . . [t]he Trust shall not run the Green Form algorithm, require additional completeness steps, or conduct any additional review of the claim, but instead shall process the claim at the level and amount specified in Wyeth's designation." See PPP, PTO 3882 at ¶ 12(a). Therefore, as to the first claim, no analysis or determination was made by the Trust with regard to the length of diet drug use.

39. The current appeal constitutes a wholly separate claim from the first claim paid through the PPP. Accordingly, the Trust reviewed this claim in its entirety, including documentation of diet drug use. Further, when Appellant was paid CMS Benefits from Fund A, it was with express notification that any determination of entitlement to Fund B Matrix benefits would be made separately.

40. Based upon all of the above, it was reasonable for the Trust to conclude that \_\_\_\_\_ ingested Pondimin for sixty (60) days or less, and therefore, to deny

Compensation Benefits on the A Matrix. I conclude that the Trust's analysis and determination were not clearly erroneous.

### CONCLUSIONS

1. The Claimant has not met the burden of providing documentary proof of diet drug ingestion of sixty-one (61) days or more to the Trust as required by the Settlement Agreement.

2. Based on the above, the findings of the Trust are not clearly erroneous as set forth in Rule 5 of the Rules Governing the Arbitration Process.

3. The final determination of the Trust is affirmed.