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. 5. : CIVIL ACTION NO. AMERICAN HOME PRODUCTS CORPORATION	:	99-20593
Appellants: REDACTED Arbitration No.: REDACTED Claim No.: REDACTED	:	REPORT AND AWARD OF ARBITRATOR

FINDINGS OF FACT

1. On **[DATE]**, the AHP Settlement Trust ("Trust") issued a Final Determination on the claim of **[APPELLANT]** for Matrix Compensation Benefits, awarding **[APPELLANT]** Matrix-Level II benefits on the B-1 Matrix in the gross amount of $122,265.00. In the same Final Determination, the Trust awarded a Derivative Claim Benefit to **[DERIVATIVE CLAIMANT]** in the gross amount of $1,235.00.

2. On **[DATE]**, **[APPELLANT]** and **[DERIVATIVE CLAIMANT]** filed an appeal from the Final Determination of Benefits by the Trust, requesting that the United States District Court ("Court") refer this matter to Arbitration.

3. On **[DATE]**, the appeal of **[APPELLANT]** and **[DERIVATIVE CLAIMANT]** was referred by the Court to Arbitration pursuant to 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 **[DATE]**, an Arbitration Hearing was held on the claim of **[APPELLANT]**

and **[DERIVATIVE CLAIMANT]**. **[APPELLANT]** and attorney **[COUNSEL]** of **[REDACTED]**, participated in the Arbitration Hearing.

5. **[APPELLANT'S]** Green Form, completed by **[DOCTOR]**, a Board-Certified Cardiologist, indicated that **[APPELLANT]** has severe mitral regurgitation (Question II.C.3). The Green Form also indicated that **[APPELLANT]** has Pulmonary Hypertension secondary to moderate or greater mitral regurgitation (Question II.F.3), abnormal left ventricular end-systolic dimension (Question II.F.6), severe regurgitation with ACC/AHA Class I surgery indications (Question II.F.10) and Class III New York Heart Association Functional Class symptoms (Question II.G). On this basis and **[APPELLANT'S]** prescription records, the Trust determined that **[APPELLANT]** should be compensated under Matrix B-1/Level II. Accordingly, **[DERIVATIVE CLAIMANT]** should receive a derivative Gross Matrix Compensation Benefit of $1,235.00.

6. In their appeal, **[APPELLANT]** and **[DERIVATIVE CLAIMANT]** seek Matrix A-1/Level II Benefits.

ANALYSIS

1. **[APPELLANT]** submitted two Pink Forms: one dated **[DATE]** and one dated **[DATE]**. Both of **[APPELLANT'S]** Pink Forms state that he/she ingested Pondimin (Fenfluramine) for sixty-one days or more. In his/her **[DATE]** Pink Form, **[APPELLANT]** stated that he/she took Pondimin for approximately 120 days (Questions 8 and 9). In his/her **[DATE]** Pink Form, **[APPELLANT]** stated that he/she took Pondimin for approximately 90 days (Questions 8 and 9). Prescription records establish that **[APPELLANT]** was dispensed ninety Pondimin pills on **[DATE]**, and another ninety Pondimin pills on **[DATE]**, for a total of

180 Pondimin pills. The prescription instructed **[APPELLANT]** to take one Pondimin pill three times each day. During the Arbitration Hearing, **[APPELLANT]** confirmed that he/she was dispensed a total of 180 Pondimin pills and that the prescription instructed him/her to take one Pondimin pill three times each day.

2. According to the terms of the Settlement Agreement, whether a claimant eligible for Matrix Compensation Benefits is placed on the A-1 Matrix or the B-1 Matrix depends on the length of diet drug usage, and/or the existence of specified medical conditions. Matrix A-1 applies when a claimant, diagnosed as FDA Positive and who has a condition eligible for Matrix payments without a disqualifying condition, ingested the Diet Drugs for sixty-one days or more. (Settlement Agreement, Section IV.B.2.d.(1)). Matrix B-1 applies if the claimant ingested the Diet Drugs for sixty days or less; was diagnosed as having mild mitral regurgitation within the specified time period; or ingested the Diet Drugs for sixty-one (61) or more days, with disqualifying conditions. (Settlement Agreement, Section IV.B.2.d.(2)).

3. There is no dispute between the parties that **[APPELLANT]** has left sided Valvular Heart Disease with complicating factors, entitling him/her to Matrix-Level II Benefits. The dispute is whether he/she is entitled to Benefits on Matrix A-1 or Matrix B-1. It is the Trust's position that the 180 Pondimin pills taken three times per day were consumed in sixty days. On this basis, the Trust placed **[APPELLANT]** on Matrix B-1. **[APPELLANT]** asserts that the evidence supports a finding that he/she took Pondimin for sixty-one days or more, entitling him/her to compensation on Matrix A-1.

4. 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 Class Member must submit pharmacy records and/or medical records documenting the claimant's name, prescribing physician information, diet drug

name, date(s) prescribed, dosage and duration the drug was prescribed or dispensed. In the event pharmacy or medical records are unobtainable, a Class Member may submit an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy identifying the claimant, the drug(s) prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the Diet Drug(s) to document ingestion. **[APPELLANT]** submitted pharmacy and prescription records which indicate that he/she was dispensed 180 Pondimin pills to be taken at the rate of one pill per day. At the prescribed rate, **[APPELLANT]** would have consumed all prescribed Pondimin pills in sixty days.

According to the Claims Processing Procedures, approved by the parties to the Settlement, "The prescription/pharmacy record creates a rebuttable presumption that the drug was ingested for the period reflected in the record." (Claims Processing Procedures: Duration of Use ¶1) (hereinafter "the Claims Procedures").

5. Paragraph 2 of the Claims Procedures provides that "[a] claimant may rebut the presumption that the claimant ingested the diet drugs for 60 days or less with credible proof that the drug was ingested on more days than shown in the prescription." (*Id.* at ¶ 2). In addition to the statements in his/her two Pink Forms, **[APPELLANT]** submitted two Declarations, both signed under penalty of perjury. In his/her **[DATE]** declaration, **[APPELLANT]** declares that he/she took Pondimin for approximately ninety days. In his/her declaration dated **[DATE]**, **[APPELLANT]** estimates that he/she took Pondimin for at least ninety days.

6. The Claims Procedures state specifically that a claimant's affidavit, "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 . . . ." (*Id*. at ¶3). The Claims Procedures continue by saying that "the Trust may consider a claimant's affidavit standing alone in the totality of the circumstances presented by that claimant to assess

its weight in the rebuttal analysis." The Claims Procedures, however, do not specify how to evaluate the totality of the circumstances in determining the weight, if any, to accord the claimant's affidavit.

7. During the Arbitration Hearing, **[APPELLANT]** pointed to several pieces of evidence to corroborate his/her Declaration that he/she ingested Pondimin for sixty-one or more days, entitling him/her to compensation on Matrix A-1.

a. First, he/she stated that he/she was prescribed three 20 mg. Pondimin per day. According to **[APPELLANT]**, the typical dosage is two 15 mg. Pondimin per day, making his/her dosage twice that which is typically prescribed.

b. Second, **[APPELLANT]** asserted that he/she took fewer than three Pondimin per day because three pills per day caused sleeplessness. As circumstantial evidence supporting this claim, **[APPELLANT]** argues that Pondimin (Fenfluramine) is known to have a stimulating effect.

c. Third, **[APPELLANT]** cited the fact that he/she had lost 12.1 pounds between his/her initial visit of **[DATE]** and his/her second visit of **[DATE]** as corroboration of his/her assertion that he/she was meeting his/her desired weight loss goal while taking fewer than three Pondimin per day. Thus, he/she would have continued taking fewer than three pills per day.

d. In a letter dated **[DATE]**, **[DOCTOR]**, **[APPELLANT'S]** prescribing physician stated that "literally hundreds of patients would come back and admit that they were not consuming three Pondimin a day. They were all taking less."

e. In Declarations dated **[DATE]** and **[DATE]** (both signed under penalty of perjury), **[APPELLANT]** stated that he/she ingested all 180 Pondimin that he/she had been prescribed, which if a single one had been ingested at a rate of fewer

than three pills per day would have taken more than sixty days to complete.

8. In determining whether the claimant's Declaration has been corroborated, there must be some evidence that corroborates the action of the claimant. As an example of credible proof sufficient to rebut the presumption established by the prescription records, the Claims Procedures state that a "medical record contemporaneous with use indicating longer-term use would be sufficient to rebut the presumption." (*Id.* at ¶ 3). No such record or any similar record was submitted in this case. More importantly, however, the example of a contemporaneous medical record cited in the Claims Procedures demonstrates a requirement that the corroborative evidence illuminate the actions of the claimant, not those of humanity in general. The evidence relied upon by **[APPELLANT]** suffers in two regards. In some instances, the evidence constituted assertions by **[APPELLANT]** without any substantiation of the assertion having been given to the Trust. In the other instances, the evidence at best corroborates the actions of people generally, but not **[APPELLANT]** specifically.

9. **[APPELLANT'S]** assertion that a 20 mg. dose of Pondimin is higher than normal cannot be credited because he/she pointed to no evidence, beyond his/her statement, to substantiate this assertion. The same is true for his/her claim that Pondimin causes sleeplessness. This is not the sort of generalized knowledge that can constitute evidence.

Pursuant to Rule 9.a. of the Rules Governing Arbitration Process, new evidence is not permitted to be introduced during the Arbitration Hearing. During the Arbitration Hearing, **[APPELLANT]** claimed that the loss of 12.1 pounds put him/her well on his/her way to his/her weight-loss goal. Though this may well be true, there was no evidence on which the Trust could have relied to come to this conclusion. **[APPELLANT'S]** medical records, submitted to and relied on by the Trust, contained the notation, "small frame, 114-127." Whatever **[APPELLANT'S]** goal, from the evidence available it was reasonable for the Trust to conclude

that while constituting progress, the loss of 12.1 pounds left **[APPELLANT]** closer to his/her starting point than to his/her finishing point. **[DOCTOR'S]** letter, even if credited, offered insight into weight-loss patients in general, but was notably silent with respect to **[APPELLANT]** specifically. Furthermore, **[APPELLANT'S]** declaration that he/she consumed all 180 pills cannot tip the scale in his/her favor on the question of length of Pondimin usage because it is the claimant's declaration that must be corroborated.

10. In addition to the evidence listed above offered to corroborate his/her Declaration, **[APPELLANT]** argues generally that common sense supports a finding that he/she took Pondimin for more than sixty days. He/she bases this on an assertion that while individuals may take life-preserving medication as prescribed, people are more likely to miss or skip a pill when the medication has been voluntarily sought. Even if this fact is true, at most it serves as evidence of generalized, not specific, human behavior.

11. The role of the Arbitrator is not to render a decision in the first instance, or even to review the merits of the matter *de novo*. Rather, review is limited; the decision of the Trust will not be disturbed unless that decision was clearly erroneous. Here, the Trust relied on the pharmacy and prescription records and the absence of other documentary evidence to conclude that **[APPELLANT]** was ineligible for compensation on Matrix A-1 because he/she had not established that he/she had taken Pondimin for sixty-one days or more. Thus, the Trust awarded him/her compensation based on Matrix B-1/Level II. In the absence of evidence corroborating what **[APPELLANT]** did – as opposed to what some members of the human race might do – the Trust was reasonable in concluding that **[APPELLANT]** had not ingested Pondimin for more than sixty days and, therefore, awarding him/her Matrix B-1/Level II Benefits.

12. Derivative Claimant **[DERIVATIVE CLAIMANT]** appealed his/her Derivative Claim Benefit in the amount of $1,235.00. No individualized grounds were asserted in support

of this appeal in writing or during the Arbitration Hearing. Therefore, there is no basis to conclude that the Trust erred in its determination of **[DERIVATIVE CLAIMANT'S]** Derivative Claim.

13. At the beginning of the Arbitration Hearing, Attorney **[REDACTED]** expressed a desire to preserve for further appeal the denial of his/her request for an In-Person Arbitration Hearing. As the Arbitrator, I confirmed that the denial had been a decision of the Chair of the Arbitration Panel, and that I would not take into account either the Petition for an In-Person Hearing, the denial of that Petition, or the request to further preserve the issue for appeal.

14. At the beginning of the Arbitration Hearing, Attorney **[REDACTED]** also objected to the inclusion by the Trust in its Response to **[APPELLANT'S]** Statement of the Case a redacted Report and Award from an unrelated Arbitration. As the Arbitrator, I stated that I would consider the contents of the document, as they could have been presented by the Trust in an alternative form, but that I would not be influenced by the form in which the contents appeared.

CONCLUSIONS

1. Based on the above, 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, **[APPELLANT]** is entitled to Matrix Compensation Benefits of $122,265.00 based on placement on Matrix A-1/Level II. **[DERIVATIVE CLAIMANT]** is entitled to a Derivative Claim Benefit in the amount of $1,235.00.

August 23, 2002 ______________________________________

DATE Redacted
Arbitrator