

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

FINDINGS OF FACT

1. On **[DATE]** the AHP Settlement Trust (Trust) issued a Final Determination on the claim of **[APPELLANT A]** for Matrix Compensation Benefits, awarding a Matrix B-1/Level II award to **[APPELLANT A]** in the total amount of \$85,383.00. In that same Final Determination the Trust denied the claim of **[APPELLANT B]** for a Derivative Claim Benefit.

2. On **[DATE]** **[APPELLANTS]** filed an appeal from the Final Determination to this Court requesting that the United States District Court (Court) refer this matter to Arbitration.

3. On **[DATE]** the claim of the **[APPELLANTS]** was referred by the Court to Arbitration pursuant to sections VI.C.4(h) & (i) or VI.D.1.(f) & (g) of the Nationwide Class Action Settlement Agreement with American Home Products Corporation (Settlement Agreement).

4. On **[DATE]** an Arbitration Hearing was held on the claim of the **[APPELLANTS]**.

5. According to Part II of **[APPELLANT A'S]** GREEN FORM, attested

to by Board-Certified Cardiologist Michael Mancina, M.D. on [DATE], [APPELLANT A] had moderate mitral valve regurgitation and no aortic valve regurgitation (question II.C.3). The GREEN FORM also indicated that [APPELLANT A] experiences pulmonary hypertension secondary to moderate or greater mitral valve regurgitation (question II.F.3).

6. The Trust determined that [APPELLANT A] should be compensated under Matrix B-1/Level II, and the Final Determination awarded compensation to [APPELLANT A] on that basis. The Trust stated no basis in its Final Determination as to why [APPELLANT B] was not entitled to a Derivative Claim Benefit.

7. In his/her appeal, [APPELLANT A] argues that he/she is entitled to benefits under Matrix A-1/Level II. In his/her appeal, [APPELLANT B] argues that the application of the criteria set forth in the Settlement Agreement should result in the approval of his/her claim.

ANALYSIS

1. According to the terms of the Settlement Agreement, there are circumstances which determine whether Matrix A-1 or Matrix B-1 is applicable for a claim for Matrix Compensation Benefits. The length of usage, and/or the presence of specified medical conditions, limit a claimant to a particular Matrix. Basically, Matrix A-1 applies when a claimant diagnosed as FDA Positive, without disqualifying conditions, ingested the diet drugs for sixty-one (61) or more days. Section IV.B.2.d.(2)(c) of the Settlement Agreement outlines the conditions that would disqualify a claimant for placement on Matrix A-1 and, ultimately, move a claimant to Matrix B-1. A claimant eligible for Matrix Compensation Benefits is limited to Matrix B-1 if the claimant ingested the diet drugs for

sixty (60) days or less and/or received a diagnosis of having mild mitral regurgitation within the prescribed time period. (Settlement Agreement, Section IV.B.2.d).

2. The Settlement Agreement requires the claimant to submit documentary evidence of the period of time for which Diet Drugs were prescribed and distributed to the claimant. (Settlement Agreement, section VI.C.2.d). **[APPELLANT A]** indicated on his/her PINK FORM dated **[DATE]** (question 8) that he/she ingested Diet Drugs for 61 days or more. **[APPELLANT A]** also later submitted an Affidavit, dated **[DATE]**, stating that he/she was "certain" that he/she took Redux for 61 days or more. **[APPELLANT A]** stated that he/she obtained a prescription for Redux on **[DATE]** and another prescription for Redux on May 16, 1997. He/she further stated that each prescription contained 60 pills. According to the pharmacy records included in the claim file, prescriptions for 60 15 mg capsules of Redux were filled on **[DATE]** and **[DATE]** for a total of 120 pills. He/she was instructed to take one pill twice a day, creating the inference that he/she ingested the pills for only 60 days. **[APPELLANT A]** submitted no other documentary evidence relating to the period of time in which he/she ingested Redux.

3. The Trust relied on the pharmacy records, and the absence of any other documentary evidence, in reaching the conclusion that **[APPELLANT A]** had not established that he/she had ingested Redux for 61 days or more.

4. Section VI.C.2.d(1) and (2) of the Settlement Agreement requires the Trust, in determining the length of usage, to look first to the pharmacy records. Furthermore, the Claims Processing Procedures, approved by the Parties to the Settlement, and attached to the Trust's Response to Appellant's Statement, provide that "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) (the Procedures). Accordingly, **[APPELLANT A'S]** pharmacy records establish a rebuttable presumption that he/she ingested Redux for 60 days or less.

5. The Procedures permit the claimant to rebut the presumption established by the pharmacy records by submitting "credible proof" that the claimant ingested the Diet Drugs for more days than the number indicated by the pharmacy records. (Id. at ¶¶ 2-3). The Procedures point out that a "medical record contemporaneous with use indicating longer-term use would be sufficient to rebut the presumption." (Id. at ¶3). No such medical record has been proffered by **[APPELLANT A]**.

6. In addition to his/her response to question 8 on the PINK FORM, **[APPELLANT A]** has proffered an Affidavit under oath that was prepared solely for the purpose of substantiating his/her claim. The Procedures state specifically that such an 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). **[APPELLANT A]** has not proffered any such affirmation by another person.

7. In the sentence just quoted, however, the Procedures go on to say 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 Procedures offer no guidance, however, to determine how the "totality of the circumstances" might influence what weight, if any, the claimant's Affidavit should be given.

8. In evaluating **[APPELLANT A'S]** Affidavit in light of the

"totality of the circumstances," the Arbitrator should take into account the following four points: (1) An Affidavit prepared solely for the purpose of substantiating a claim must be recognized as inherently self-interested. The Affidavit's taint of self-interest cannot be eliminated solely by the reference to its status as a document affirmed under oath. The sworn nature of testimony is never conclusive of credibility; such testimony is routinely assessed for self-interestedness and credibility in judicial and other legal proceedings. (2) The "totality of the circumstances" must reveal some fact that corroborates the Affidavit, even if there is no reliable affirmation by a knowledgeable third party or a contemporaneous medical record. (3) It is not the Trust's obligation to prove that the claimant ingested the Diet Drugs for 60 days or less; it is the claimant's obligation to rebut any presumption created by the pharmacy records that the claimant ingested the Diet Drugs for 60 days or less. (4) The Trust's conclusion that in the "totality of the circumstances" the Affidavit does not rebut the presumption should not be disturbed by the Arbitrator unless clearly erroneous as a matter of law.

9. **[APPELLANT A]** has made two related arguments that purport to substantiate his/her claim that he/she ingested Redux for 61 days or more. First, he/she argues that "Experience tells us that it is extremely uncommon for a person, who has been prescribed a medication, to take the medication exactly as prescribed." (Appellant's Statement of the Case, at 1, dated **[DATE]**) (emphasis in the original). Physicians and pharmacists recognize this reality, he/she argues, and instruct patients who miss one of the two daily doses to not take two pills together, but skip the dose. Patients then, presumably, would take the skipped pill on another day. **[APPELLANT]** claims that he/she did just that, thereby raising the number of days he/she ingested Redux to at least 61. In his/her second argument, he/she asserts that he/she first picked up his/her prescription in the evening after work. Knowing that he/she should

not take two pills simultaneously, but eager to begin the treatment program, he/she carefully followed his/her pharmacist's instructions, and took only one pill, leaving an extra pill to be ingested on the 61st day.

10. The difficulty with **[APPELLANT A'S]** arguments, however, is that there is no way to determine what actually happened. A vague reference to what "[e]xperience" tells about how patients take medication has no scientific weight, and does not explain what **[APPELLANT A]** actually did in this case. "Experience" also tells us that some people take their medication religiously as prescribed. We have no way of knowing how **[APPELLANT A]** actually behaved. Similarly, it is equally plausible that after picking up his/her pills too late in the day to take two doses, **[APPELLANT A]** would have waited until the next morning to begin the prescribed regimen of twice a day dosages. The decision maker simply cannot know which course of action was more likely.

11. In short, **[APPELLANT A]** has produced little beyond an inherently self-interested assertion and hypothetical rationales for what might have happened. He/she certainly has not established the kind of fact that, when viewed in the "totality of the circumstances," would corroborate his/her Affidavit and overcome the presumption of the pharmacy records. It was thus reasonable for the Trust to conclude on the basis of **[APPELLANT A'S]** pharmacy records that he/she ingested Diet Drugs for 60 days or less, and to award him/her a Matrix B-1/Level II Benefit.

12. The Final Determination also denied **[APPELLANT B'S]** claim to a Derivative Claim Benefit. It did so without explanation of the basis for the Trust's denial. Appellant's Statement of the Case, however, offers no argument in support of the Derivative Claim beyond the assertion that "application of the criteria set forth in the Settlement Agreement to the information submitted by **[APPELLANT B]** should result in **[APPELLANT B'S]** claim being approved." There

was no provision of the Settlement Agreement cited in support of this assertion.

13. **[APPELLANT A'S]** PINK FORM indicates that **[APPELLANT B]** is claiming Derivative Benefits based on a "Loss of Service" and "Loss of Support" (question 4.e). The PINK FORM also indicates, however, that **[APPELLANT B]**, while **[APPELLANT A'S]** son/daughter, was born in 1964 (question 4.a), and that he/she lived at a separate address in a separate zip code. No argument in writing or at the Arbitration Hearing was proffered to overcome the Trust's reasonable assumption that **[APPELLANT B]** was an independent adult and, therefore, not dependent on his/her mother for "service" or "support."

CONCLUSION

1. The Trust's Final Determination assigning **[APPELLANT A'S]** claim for Matrix Compensation Benefits to Matrix B-1/Level II was not clearly erroneous as a matter of law.

2. The Trust's Final Determination denying **[APPELLANT B'S]** claim for a Derivative Claim Benefit was not clearly erroneous as a matter of law.

July 10, 2002

DATE

REDACTED, ESQUIRE
ARBITRATOR