

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

FINDINGS OF FACT

1. On [redacted] the AHP Settlement Trust (Trust) issued a Final Determination in the form of a Final Post-Audit Determination Letter (Final PADL) on the claim of [redacted] for Matrix Compensation Benefits (Matrix Benefits) on Matrix A, denying [redacted] claim for Matrix Benefits on Matrix A, but affirming that [redacted] claim was payable on Matrix B.

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

3. The Court referred [redacted] claim 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).

REDACTED AS TO
NAME(S) AND DATE(S)

4. On an Arbitration Hearing was held on claim.

5. In Green Form dated (Green Form), requests Matrix Benefits based on medical symptoms and conditions allegedly caused by use of the Diet Drugs. The Green Form indicates that believes that is entitled to Matrix A, Level IV Benefits. Green Form at 4, Questions Nos. 5-6.

6. Green Form indicates severe mitral valve regurgitation and severe aortic valve regurgitation. Green Form, at 8 question C.3. In support of her claim, submitted a report of an echocardiogram conducted on . The report of that echocardiogram also indicates severe mitral valve regurgitation and severe aortic valve regurgitation. Green Form also indicated that she had undergone surgery to repair or replace her aortic and/or mitral valves. Id. at 11, Question No. 9.

7. In the Final PADL, the Trust determined that mitral valve replacement claim was payable on Matrix B because of the presence of mitral valve prolapse. Final PADL at 1. had previously contested whether mitral valve prolapse had been present, but that question is not at issue in this Arbitration. See Chair Arbitration No. regarding Petition to Submit New Evidence, dated (Chair Decision No.) for summary of this dispute and its resolution.

8. In the Final PADL, the Trust also found that the length of diet drug use required the payment of either or both her mitral valve replacement or aortic valve replacement claims to be paid on Matrix B. Id. Concerning the length of her diet drug use, the Trust stated that:

In order to rebut the presumption created by

medical records that she ingested Diet Drugs for 60 days or less, was required to submit credible proof of the actual number of days that she took Diet Drugs. In this case, has submitted her own affidavit to support her allegation that she ingested Diet Drugs for 61 days or more. Such an affidavit, by itself, does not constitute credible proof of 61 days or more of Diet Drug use. Therefore, the Trust does not overturn its determination that the proof of Diet Drug ingestion submitted for does not exceed 60 days.

Id. at 2.

9. Although the Trust used the term "medical records" in the just-quoted language from the Final PADL, it primarily based its conclusion on pharmacy records, which reflect that was prescribed 120 Redux tablets, to be taken two times a day. Arbitration Statement Outline and Calculation of Benefits, at 4. These records were regarded as establishing that took the pills for only 60 days, and that affidavit claiming that she sometimes took only one Redux pill per day, and hence spread her consumption beyond 60 days, did not provide "clear, supplemental documentary proof that she used Redux for 61 days or more." Id. at 4-5.

10. On filed a Petition to Submit New Evidence (the Petition). submitted as new evidence a Declaration of Appellant's Prescribing Physician, which was executed by Declaration of Prescribing Physician or Dispensing Pharmacy, Blue Form at 11, dated (Declaration). In the Petition, explained that she filled her Redux prescription on and stopped taking Redux on , pursuant to instructions. Petition at 4. In his Declaration, identifies a Redux "Approximate Start Date" of and a Redux "Approximate End Date" of Declaration. According to she has submitted Declaration to clarify the medical records

previously submitted with her Green Form because such records "are almost impossible for anyone else but [redacted] to read." Petition at 2. [redacted] argues further that "[t]he Trust apparently could not interpret [redacted] medical records correctly, without the help of his letter and his declaration." Id. at 5.

11. In reviewing the Petition, the Chair also considered an attachment to her Statement of the Case, dated [redacted] an [redacted] letter from [redacted] with attached medical records ([redacted] Letter). [redacted] Letter stated that "start date [for Redux] was [redacted] and the stop date was [redacted]."

12. In Chair Decision [redacted] the Chair of the Arbitration Panel granted [redacted] Petition and admitted as new evidence both [redacted] Declaration and [redacted] Letter, and ordered that the new evidence be submitted to the Trust for evaluation.

13. In a letter dated [redacted] at 2, the Trust stated that it had "analyzed the additional evidence submitted by counsel for the claimant [redacted] . . . and determined that the new evidence does not impact upon the final benefits determination of this claim."

ANALYSIS

1. The sole issue in this Arbitration is whether [redacted] has provided credible proof that she ingested diet drugs for 61 days or more, qualifying her for Matrix Benefits under Matrix A rather than Matrix B.

2. In order to qualify for any benefits, the Settlement Agreement requires documentary proof of ingestion of diet drugs.

As stated in Section VI.C.2.d. of the Settlement Agreement:

[E]ach Class Member must submit documentary proof to the Trustees and/or Claims Administrator(s) of the period of time for which the Diet Drugs Pondimin® and/or Redux™ were prescribed and dispensed to the Diet Drug Recipient who is the subject of the Claim. This proof must include one of the following:

- (1) If the diet drug was dispensed by a pharmacy, the identity of each pharmacy that dispensed Diet Drugs to the Diet Drug Recipient, including its name, address, and telephone number, and a copy of the prescription dispensing record(s) from each pharmacy, which should include the medication name, quantity, frequency, dosage and number of refills prescribed, prescribing physician's name, assigned prescription number, original fill date and each subsequent fill date; or,
- (2) If the diet drug was dispensed directly by a physician or weight loss clinic, or the pharmacy record(s) is unobtainable, the identity of each prescribing physician, including the prescribing physician's name, address, and telephone number and a copy of the medical record(s) prescribing or dispensing the diet drug(s). The medical record(s) must include records which identify the Diet Drug Recipient, the Diet Drug name, the date(s) prescribed, the dosage, and duration the drug was prescribed or dispensed; [or],
- (3) If the pharmacy records and medical records are unobtainable, an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy identifying the Diet Drug Recipient, the drug(s) prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the Diet Drug(s).

Settlement Agreement §VI.C.2.d.

3. If a claimant's documentary proof establishes that the claimant ingested diet drug for 60 days or less (rather than 61 days or more), the claimant will receive Matrix Benefits determined under Matrix A rather than Matrix B. Settlement Agreement §IV.B.2b.2.d(2)(b).

4. In the Final PADL the Trust relied on pharmacy records, and the absence of any other documentary evidence, in reaching the conclusion that had not established that she had ingested Redux for 61 days or more. Final PDAL at 2.

5. 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 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 (Procedures). Accordingly, the Trust was correct in concluding in the Final PADL that pharmacy records establish a rebuttable presumption that she ingested Redux for 60 days or less.

6. 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. Procedures at ¶¶2-3. The 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 medical record had been proffered by prior to the issuance of the Final PDAL. conceded that certain arguably relevant medical records provided by her Prescribing Physician, , and submitted with her Green Form, "are almost impossible for anyone

else but to read." Petition at 2. The Trust was thus correct in its apparent conclusion in the Final PADL that those records were insufficient to rebut the presumption, although it did not state that conclusion explicitly.

7. What did proffer to rebut the presumption was her own Affidavit. In that Affidavit states the following:

1. I received at least 2 prescriptions of Redux. There were 60 pills per prescription which I was to take before eating. My prescribing physician instructed me to take no more than 2 pills per day and less than 2 pills per day if I ever experienced any side effects such as nervousness or nausea.

2. I took the pills for more than 61 days. There were several days that I only took 1 pill a day as I either forgot to take 2 or I wasn't hungry and didn't think it necessary to take a Redux pill if I wasn't eating. I had lost weight on Redux and there were also times that I didn't take 2 pills a day because I didn't really think I needed to.

3. I took every pill that I received for a total of 120 pills.

Affidavit of

(the Affidavit).

8. The Affidavit was prepared solely for the purpose of substantiating 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 . . ." Procedures at ¶3. had not proffered any such affirmation by another person before the Trust's issuance of the Final PDAL.

9. 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." Id.

Unfortunately, the Procedures offer no guidance for determining how the "totality of the circumstances" might influence what weight a claimant's affidavit should be given. In making that determination, however, the Arbitrator should consider the following four principles: (i) An affidavit prepared solely for the purpose of substantiating an claim must be recognized as inherently self-interested. The affidavit's taint of self-interest cannot be eliminated solely by its status as a document affirmed under oath. (ii) The "totality of the circumstances" must reveal some fact that corroborates the affidavit. (iii) 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. (iv) 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.

10. In applying these principles to Affidavit, I would conclude that the Affidavit was inherently self-interested. At the time the Trust issued the PDAL, the "totality of the circumstances" did not reveal any fact that the Trust could have regarded as corroborating the Affidavit. The Trust was not obliged to prove that had ingested diet drugs for 60 days or less. The Trust's conclusion in the Final PDAL that the Affidavit, *standing alone*, was not sufficient to rebut the presumption created by the pharmacy records, was not clearly erroneous.

11. The Chair's decision to admit as new evidence Letter and Declaration, however, raises the question of whether there is now credible proof sufficient to rebut the presumption in the form of either "a medical record

contemporaneous with use indicating longer term use," or "a reliable affirmation of another person with knowledge of the subject matter" sufficient to corroborate Affidavit.

12. Declaration and Letter are consistent in identifying the Redux start date as and the end date as . Petition asserts that she bought her Redux prescription on , and was still taking the diet drugs when told her to stop, for a total of 64 days. Petition at 4.

13. The medical records attached to Letter, entitled "Pulmonary Medicine Flow Chart" (Medical Records) include handwritten notations made by after examining On he noted "Redux sheet." On he noted "cont Redux," and on he noted "pt told to Dic Redux now per FDA" (all underlining apparently in the original). I interpret the notation as "continue Redux," and the notation as "patient told to discontinue Redux now per FDA."

14. The Medical Records constitute a "medical record contemporaneous with use indicating longer-term use . . . sufficient to rebut the presumption" (Procedure at ¶3) created by pharmacy records that she ingested the diet drugs for less than 61 days. The Medical Records, it should be emphasized, were contemporaneous with use of the diet drugs, and were not produced after she became a claimant.

15. Similarly, Letter and Declaration, each based on the contemporaneous Medical Records, constitute "reliable affirmation[s] of another person with knowledge of the subject matter" (Procedures at ¶3) and are credible proof corroborating affidavit. As such, they

rebut the presumption created by the pharmacy records.

16. In sum, the Chair's admission of the new evidence has enabled [redacted] to provide credible proof that she ingested diet drugs for 61 days or more, thereby qualifying her for Matrix Benefits under Matrix A rather than Matrix B.

CONCLUSION

1. The Trust's Final Determination assigning [redacted] claim for Matrix Benefits to Matrix B was clearly erroneous as a matter of law.

2. [redacted] claim for Matrix Benefits shall be determined under Matrix A, and is hereby remitted to the Trust for the purpose of calculating [redacted] award under Matrix A.

01/03/06

DATE

ARBITRATOR