

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ : MDL DOCKET NO.
FENFLURAMINE/DEXFENFLURAMINE) : 2:15MD1203
PRODUCTS LIABILITY LITIGATION :
:-----: :
SHEILA BROWN, ET AL. :
v. :
AMERICAN HOME PRODUCTS CORPORATION : CIVIL ACTION NO.
:-----: :
99-20593
: :
Appellant: : REPORT AND AWARD
Arbitration No: : OF ARBITRATOR
Claim No.: 183/00 :

FINDINGS OF FACT

1. On the AHP Settlement Trust (Trust) issued a Denial of Matrix Compensation Benefits for Failure to Supply Supporting Documents (Denial) on the Claim of (Claimant) for Matrix Compensation Benefits, indicating that the Claim would not be subject to audit pursuant to Pretrial Order 2662.
2. On Claimant filed an appeal from the Denial to the United States District Court (Court) requesting that the Court refer this matter to Arbitration.
3. On , the Court referred the 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).
4. An Arbitration Hearing on Claimant's claim was held on . Claimant was not represented by Counsel.

5. Claimant submitted to the Trust a Blue Form dated (Blue Form).

6. In Green Form dated (Green Form), Claimant requested Matrix Compensation Benefits based on medical symptoms and conditions allegedly caused by use of the Diet Drugs. The Green Form indicates that Claimant believed that is entitled to Matrix A-1, Level III Benefits. Green Form Part I, Questions 5-6.

7. Claimant based claim on an echocardiogram dated . The Attesting Physician stated that this echocardiogram showed that the Claimant had moderate aortic valve regurgitation. Green Form Part II, Question C.3. The Attesting Physician also stated that the echocardiogram showed evidence of aortic root dilation, abnormal left ventricular end-systolic dimension >50mm, an ejection fraction of 50-60%, and surgery to repair or replace aortic and/or mitral valve(s) after use of Pondimin® and/or Redux™. Green Form Part II, Questions D.4, F.4, F.8 and F.9.

8. The Claim was sent by the Trust to the Class Counsel Claim Office (CCCO) for evaluation. In a letter to Claimant dated the CCCO (CCCO Letter) informed Claimant that file was missing data essential to making Claim complete. This letter was sent to Claimant pursuant to the Seventh Amendment of the Settlement Agreement. The "Area of Missing Data" was designated as "Proof of drug use." The CCCO Letter further advised Claimant of the need to provide "Pharmacy records or prescribing doctor's notes indicating ingestion of Pondimin® and/or Redux™" in order to complete the Claim.

9. After reviewing the Claim file, including Claimant's responses to the CCCO Letter, the Trust concluded that Claimant had failed to provide the required proof of drug use, and issued the Denial on The Denial indicated that the CCCO had reached the same conclusion.

10. By letter dated _____ Appellant contested the Denial, and on _____ filed an Appeal to the District Court. By letter dated _____ the Chair of the Arbitration Panel permitted the Claim to proceed to Arbitration¹, and on _____ the Court referred the Claim to arbitration (Paragraph 2, supra).

ANALYSIS

1. Only persons who have ingested Diet Drugs are members of the Settlement Class eligible to submit a claim for Matrix Compensation Benefits. Settlement Agreement §II.B.

2. The Settlement Agreement provides that in order to sustain a claim for Matrix Compensation Benefits,

each 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.

Settlement Agreement §VI.C.2.d.

3. The Settlement Agreement permits the use of medical records rather than the record(s) of a dispensing pharmacy to establish proof of ingestion, but "[t]he medical record(s) must include records which identify the Diet Drug Recipient, the Diet Drug name, the date(s) prescribed, the dosage, and the duration the drug was prescribed or dispensed." Settlement Agreement §VI.C.2.d.(2).

¹Letter of JoAnne A. Epps, Chair of the Arbitration Panel, to Claimant, dated _____. The Chair permitted Claimant's Appeal to proceed even though _____ Contest of the Denial was untimely, not having been filed until almost two years after the date of the Denial. The Chair cited in support of her decision Arbitration Rule 6(a), which requires the Trust to "serve its final determination using a delivery method that verifies the date and fact of receipt." Claimant had moved from the California address to which the Denial had been delivered. The UPS Package Tracking Delivery Notification received by the Trust had verified delivery, but not the fact of receipt. The Chair thus permitted the Appeal to proceed.

4. The Settlement Agreement also contemplates that a Claimant will use pharmacy records or a physician's medical records as documentary proof of the period of ingestion of Diet Drugs, but recognizes that such records may be unobtainable. The Settlement Agreement thus provides that in those circumstances a Claimant may rely upon other documentation, as specified:

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 SVI.C.2.d.(3).

5. While the medical information on Green Form indicates that Claimant is potentially eligible for Matrix Compensation Benefits, both the CCCO and the Trust concluded that Claimant had failed to submit the documentary proof of ingestion required by Settlement Agreement SVI.C.2.d.

6. Claimant has argued that has provided sufficient proof of diet drug ingestion.

7. Claimant represented in answers to Blue Form Questions 9 and 10 that ingested Pondimin® for over 60 days, and that the Pondimin had been dispensed by ". " also stated the following in a handwritten note on Blue Form: "
 . (sold). Unknown where he went. Called CA# given by -
 unknown. Maybe 's group knows."

8. In several letters submitted in connection with the Claim, Claimant included or referred to specified documents that considers sufficient to establish proof of ingestion as required by the Settlement Agreement. Letter to , dated
(with attachments); Letter to ,
(with attachments); Letter to
dated ; Letter to ,
(with enclosure).

9. Among the documents relied upon by Claimant are the following documents, which Claimant indicates were retrieved from stored medical records of Dr. _____ :

- Several undated facsimile cover pages from Dr. _____ 's office to Claimant's cardiologist, "Dr. _____ ;"
- A blank "Patient Insurance Verification" form with a copy of a _____ insurance card bearing a social security number corresponding to that provided by Claimant;
- An undated information sheet captioned "Welcome to our office," bearing Dr. _____ 's name in the letterhead, and partially completed by Claimant;
- A page captioned "Nurses Notes," including a chart with columns bearing preprinted entries for "PHEN 30mg" and "PON 20mg;"
- A photocopy of a _____ EKG report, along with EKG strips;
- A message slip dated " _____ " and
- An appointment information slip dated _____ .

10. Claimant also argues that a group of medical records submitted at various times to the Trust establish proof of ingestion as required under the Settlement Agreements. These records report Diet Drug use in one form or another. Among those records are:

- A "Health History Questionnaire" headed " _____ , MD, FACC," which includes "Pondimin" in the "Medicines" section;
- A photocopy of a note purportedly written by Dr. _____ which reads "I spoke with _____ ... I know well, _____ was on phen/fen back in _____ ... please clarify this with pt ... I hope we did not give _____ wrong info ... _____ ;"
- A record of "CARDIOPULMONARY SERVICES" from _____ Medical Center, dated " _____ " ordered by " _____ " indicating in the "History" section that "This is a _____ who has been on the Phen Fen diet in the past....;"

- An "EMERGENCY DEPARTMENT REPORT" from Medical Center, dated " ,," which refers in the "PAST MEDICAL HISTORY" section to Claimant's "six-month course of fen/phen diet pills;"
- A "PATHOLOGY CYTOLOGY REPORT," dated " ,," stating "PERTINENT HX:/CANCER HX Took Phen-Fen."

11. Claimant did not submit any pharmacy records to establish proof of ingestion. relied exclusively on medical records. For medical records to establish proof of ingestion they must meet the specific requirements of Settlement Agreement §VI.C.2.d.(2), quoted supra in paragraph 3.

12. None of the documentation submitted by Claimant satisfy those requirements. None, in particular, identify "the date(s) prescribed, the dosage, and the duration the drug was prescribed." Settlement Agreement §VI.C.2.d.(2). None, furthermore, are a record of a prescription of Diet Drugs to the Claimant. They are, instead, notations of current or past medications, as reported by the patient.

13. For example, the "Health History Questionnaire" submitted by Claimant contains no information about the dates prescribed, the dosage or the duration the drug was prescribed or dispensed. Furthermore, the inclusion of "Pondimin" under the category of "Medicines" is apparently based on a statement by the Claimant, and is not itself a record of a prescription of Diet Drugs to Claimant.

14. The various other medical records submitted by Claimant suffer from similar deficiencies. The notations on the records of Diet Drug use do not set forth the required information regarding date of prescription, dosage and duration. They also reflect self-reporting by the Claimant, and are not themselves records of prescription(s) of Diet Drugs to Claimant. Prior Reports and Awards under the Settlement Agreement have reached the same conclusion with respect to notations of Diet Drug Use on medical records. See 46th Report & Award, at 3. See also 94th Report & Award, at 4, which

stated explicitly that "the notation on the ... echocardiogram is insufficient because it does not provide the information required under the Settlement Agreement ... and because it is not a medical record of the prescription of Diet Drugs."

15. The other documents submitted by Claimant are similarly deficient. The "Nurses Notes" contains a preprinted chart with column headings referencing Diet Drugs and dosages, but contain no information about who the Diet Drug recipient was or who prescribed the Diet Drugs, let alone any information about the date or duration of prescription.

16. In addition, Claimant did not submit, in the absence of probative pharmacy or medical records, an affidavit under penalty of perjury from the prescribing physician containing the information specified by Settlement Agreement §VI.C.2.d.(3), quoted supra in Paragraph 4. The photocopy of a note purportedly written by Dr. does not constitute such an affidavit. Dr. was not the prescribing physician; the note was not created or provided under penalty of perjury; and the note contains none of the required information regarding the date of prescription, dosage or duration of prescription. It is also not a medical record of prescription.

17. The Settlement Agreement sets out highly specific requirements for proof of ingestion. It does not explicitly or implicitly establish a standard of preponderance of the evidence, probability or likelihood as sufficient for establishing proof of ingestion. It also does not contemplate the use of circumstantial evidence of Diet Drug usage to establish an inference that the Claimant ingested Diet Drugs in the amounts or for the period of time defined by the Settlement as prerequisites for eligibility for Matrix Compensation Benefits. Finally, it does not regard self-reporting of Diet Drug use by Claimants (or documents reflecting such reporting) as sufficient to prove ingestion. The documentation submitted by Claimant all falls into one or more of those categories, and none of it meets the requirements of Settlement

Agreement §§VI.C.2.d.(2) or (3).

CONCLUSION

1. The Trust's Denial is not clearly erroneous.
2. The Trust's Denial is affirmed. The Claim is not subject to audit pursuant to Pretrial Order 2662.

Date

Arbitrator