

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.

v.

AMERICAN HOME PRODUCTS  
CORPORATION

CIVIL ACTION  
99-20593

Appellant: Roger E. Auger  
Arbitration No.:  
Claim No.: 183/00 1904268

REPORT AND AWARD  
OF ARBITRATOR

**FINDINGS OF FACT**

1. On 05/07/2004, the AHP Settlement Trust ("Trust") issued a Final Determination in the matter of [REDACTED]; (sometimes hereinafter "Claimant") and awarded Claimant compensation in the amount of \$58,888.88 pursuant to Matrix B-1, Level III.
2. On 07/17/2004, Claimant filed an appeal from the award of benefits by the Trust, and requested that the United States District Court ("Court") refer this matter to Arbitration. The appeal was assigned docket number 795.
3. On 08/11/2004, the claim of [REDACTED] was referred by the Court to Arbitration pursuant to VI. C. 4 (h) & (i) of the Nationwide Class Action Settlement Agreement with American Home Products Corporation.
4. On 08/19/2004, an Arbitration Hearing was held concerning the claim of [REDACTED] was represented by [REDACTED].

## ANALYSIS

1. Claimant is a Diet Drug Recipient, having ingested Redux (Dexfenfluramine). This is confirmed by claimant's pharmacy records, which confirm that he was dispensed Redux on two occasions: [REDACTED] and [REDACTED]. On each occasion claimant was given 60 Redux pills, intended to be a 30-day supply.

2. In support of his claim for Matrix compensation, [REDACTED] submitted a GREEN Form, completed by [REDACTED], a Board-Certified Cardiologist. In his GREEN Form, claimant sought compensation at Level III on Matrix A-1. This is not a dispute about Claimant's entitlement to compensation, but rather is a dispute about whether his compensation should be paid on Matrix A-1 or Matrix B-1.

3. The parties do not dispute [REDACTED]'s entitlement to compensation at Matrix-Level III. Because [REDACTED] had severe mitral regurgitation, he met the definition of FDA Positive, thus making him eligible for Matrix Compensation. See Settlement Agreement at Section I.22 and Claimant's GREEN Form, Question C.3.a. Because he had pulmonary hypertension, abnormal atrial dimensions, abnormal left ventricular end-systolic dimension, arrhythmias and medically contraindicated valvular surgery after ingestion of Redux, [REDACTED] was qualified to receive Matrix-Level III benefits. See GREEN Form, Questions F. 3, 5, 6, 7 and 10.

4. The dispute in this matter centers on whether Level III benefits should be paid on Matrix A-1 or Matrix B-1. To be eligible for compensation on Matrix A-1, a Diet Drug Recipient must have ingested Diet Drugs for 61 days or more. See Settlement Agreement, Section IV.B.2.d.(1). Diet Drug Recipients who ingested Diet Drugs for sixty days or less receive compensation on Matrix B-1. *Id.*, at IV.B.2.d.(2)(b). In his BLUE Form, claimant stated that he ingested Redux (Dexfenfluramine) for 365 days. See BLUE Form, Question 9. In

subsequently filed papers and during the Arbitration Hearing, claimant modified the time to approximately eleven months, from . . . . . Claimant's position is that because he ingested Redux for eleven months his claim should be paid on the A-1 Matrix, and that the Trust therefore erred in placing the claim on the B-1 Matrix.

5. The Settlement Agreement imposes on the claimant the burden of proving the length of time that Diet Drugs were ingested (Settlement Agreement, Section VI.C.2.d.) and requires that the proof include one of the following:

1) Pharmacy Records: 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 refill date. *Id.*, at VI.C.2.d.(1).

2) Prescribing Physician Information: 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. *Id.*, at VI.C.2.d.(2).

3) Defined Alternatives: 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). *Id.*, at VI.C.2.d.(3).

The parties to the Settlement Agreement could have agreed that pharmacy records and affidavits were each equally acceptable means of proving Diet Drug use or that affidavits could be used to supplement medical records. But they did neither. The terms of the Settlement Agreement provide that pharmacy and medical records are preferred to affidavits, and limit affidavits to situations when pharmacy and medical records are unobtainable.

In support of his claim, . . . . . supplied pharmacy records, medical records, his

BLUE Form statement that he took Redux for 365 days, and a sworn declaration (affidavit) of his prescribing physician, [REDACTED]. Mr. Anger took Redux from [REDACTED] 1996 to August 7, 1997 (11 months).

6. Pharmacy Records: Records from the [REDACTED] pharmacy confirm that [REDACTED] was twice dispensed 60 Redux pills, each intended to be a 30-day supply. If taken in accordance with the instructions, 120 Redux would have been consumed in 60 days. Thus, if [REDACTED] can establish that he ingested Redux on one day in addition to the 60 days proven by the pharmacy records, he would be entitled to compensation on the A-1 Matrix.

Claimant asserts that his medical records are sufficient to rebut the information contained in the pharmacy records. Claimant's medical records confirm that on [REDACTED] September 13, 1996, Mr. Anger was to "start Redux 15 mg BID." Pharmacy records confirm that the following day [REDACTED] received 60 Redux intended to be a 30-day supply. Thereafter, the dates of the medical records and the pharmacy records do not coincide, so they must be analyzed separately to determine whether the medical records establish ingestion of Diet Drugs beyond the sixty days established by the pharmacy records. After the [REDACTED] 1996 entry, the next entry on Mr. Anger's medical records is dated [REDACTED] October 20, 1996, and says that Mr. Anger was "taking Redux 15 BID" and was to "continue Redux 15 BID". The next note on [REDACTED] medical records is undated, and states "on Redux." The next and final relevant entry, dated [REDACTED] August 17, 1997,

[REDACTED], states that [REDACTED] Anger was "off all meds." Thus, read in a light most favorably to [REDACTED] Anger, there are two notations in his medical records that refer to the ingestion of Redux (one on [REDACTED] and one undated) to compare to the pharmacy records.

Although the Claims Processing Procedures permit the information from prescription records to be overcome by a contemporaneous medical record indicating longer-term use, it is clear that the parties intended to restrict Matrix A-1 compensation to Diet Drug recipients who

had ingested Diet Drugs in excess of sixty days and, accordingly, to minimize the ability of claimants to use after-the-fact records to justify Matrix A-1 compensation. Dr. [redacted] would like the records to be read to prove that after [redacted] he was twice given Redux: once in October and once at some later date, and that while one of these provisions corresponds to (and legitimizes) the Redux he received in [redacted], the other establishes additional use, bringing the total in excess of 60 days. The undated entry, however, renders the medical records ambiguous. If Dr. [redacted] filled in [redacted], a prescription he received at the time of the undated entry, then the records could be read to establish use in excess of sixty days (dispensing in September and October and at the time of the “undated” entry). The records, however, are equally susceptible to a finding that Dr. [redacted] filled in [redacted], a prescription he received on [redacted] and that the undated note “on Redux” was written thereafter, while he was ingesting the sixty pills dispensed in [redacted] (dispensing in September and October). Neither reading of the medical records is more or less likely than the other. In order to overcome the sixty-day presumption established by the pharmacy records, the medical records must indicate longer term use. While Mr. [redacted]’s records are not inconsistent with longer term use, because of their ambiguity they do not *indicate* longer term use.

In addition to Mr. [redacted]’s medical record, there is a medication sheet. Claimant asserts that the medication sheet establishes (or corroborates) ingestion of Redux for eleven months. On the medication sheet, Redux is listed as the third of four prescribed medications and an “x” corroborates that Redux was discontinued as of [redacted]. Whereas the notation, “—>”, intended as a symbol for “continue”, appears for each of the other three drugs on [redacted] medication sheet, it is notably absent from the Redux entry. There are no other notations on the medication sheet from which one could independently confirm when Redux use began or that its use continued from [redacted] until [redacted]. The Redux entry, therefore, can be

read one of two ways. Its mere existence can be read as corroborating use for eleven months or it can be seen as hopelessly ambiguous. The impediment to using the medical record as evidence of Redux use for eleven months is that Redux is a prescription product. The pharmacy records confirm that [REDACTED] filled two 30-day supplies of Redux and his medical records show no clear evidence of additional prescriptions. To accept the medical chart as establishing use for eleven months requires the conclusion that [REDACTED] received approximately 9 months (275 days) of Redux without a single prescription notation on his medical records and (at least insofar as provided to the Trust) without a single corroborating pharmacy record. During the Arbitration Hearing, claimant asserted that on some occasions his wife filled Redux prescriptions for him at a pharmacy for which he submitted no records. Rule 9 of the Rules Governing Arbitration Process disallows the submission of new evidence at the Arbitration Hearing. Thus, I am prevented from considering this assertion.

In summary, [REDACTED]'s medical records and his medication sheet are not inconsistent with use of Redux in excess of sixty days. Because of their ambiguity, however, they do not overcome the pharmacy records' presumption that Redux use was limited to sixty days.

7. Prescribing Physician Information: If the Diet Drug was dispensed directly by a physician or weight loss clinic, or the pharmacy record(s) is unobtainable, the Settlement Agreement provides that medical records of the prescribing and dispensing of Diet Drugs is allowable. Because [REDACTED]'s claim did not assert that his Diet Drugs were dispensed directly by a physician or that any of his pharmacy records were unavailable, (see BLUE Form Question 10. b.), this provision does not apply.

8. Defined Alternatives: If the pharmacy records and medical records are unobtainable, the Settlement Agreement provides for submission of an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy regarding the prescription and

dispensing of Diet Drugs. In his sworn declaration, [REDACTED] stated that [REDACTED] approximate start date for consuming Redux was [REDACTED] and that his approximate end date was [REDACTED]. See BLUE Form, page 11, signed by [REDACTED] on [REDACTED]. The Trust's position is that physician or pharmacy affidavits are allowable only when a claimant's pharmacy and medical records are unobtainable. This is corroborated by the statement at the top of the declaration form which states, "Use this form ONLY IF your pharmacy/prescription records(s) are unobtainable as described in Question 10 [of the BLUE Form.] Because both [REDACTED] pharmacy records and medical records are available, the Trust asserts that [REDACTED] affidavit should not be considered. As a matter of interpreting the Settlement Agreement, I agree.

9. This matter presents the difficult issue of distinguishing what may be true from what has been proven. During the Arbitration Hearing, [REDACTED] stated that in addition to the two prescriptions he received from [REDACTED] he also received an unspecified number of samples. He also stated that on some occasions his wife filled his Redux prescriptions at a second and different pharmacy. Inexplicably, this information was never provided to the Trust. Therefore, true or not, this evidence cannot be considered. The Arbitration process is designed to determine if the Trust erred in applying the terms of the Settlement Agreement to the evidence submitted to it. Certainly, the physical and financial circumstances in which [REDACTED] finds himself are lamentable. But the Trust cannot be faulted for failing to consider information it was never given. Based on the information provided to it, the Trust correctly applied the terms of the Settlement Agreement in concluding that the Claimant had not met his burden of establishing use of Diet Drugs for more than sixty days.


CONCLUSIONS

1. 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, ~~XXXX XXXX~~ not entitled to payment on Matrix A-1 because of the presence of conditions that mandate compensation on Matrix B-1. Settlement Agreement, Sections IV.B.2.d.(2)(b).

Accordingly, based on all of the above, I find that ~~XXXX XXXX~~ is entitled to Level III benefits payable on the B-1 Matrix.

2/14/07  
DATE

  
Anne A. Kopp  
Arbitrator