

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:
Arbitration No.:
Claim No.: 183/00

REPORT AND AWARD
OF ARBITRATOR

FINDINGS OF FACT

1. On [REDACTED] the AHP Settlement Trust ("Trust") denied the claim of [REDACTED] for Matrix Benefits.
2. On [REDACTED] [REDACTED] requested that the District Court refer this matter to arbitration.
3. On [REDACTED] claim was referred by the United States District Court for arbitration from the Trustees and/or claims administrator's denial of benefits to [REDACTED].
4. On [REDACTED] a hearing was held on [REDACTED] arbitration claim. [REDACTED] participated in the hearing and was represented by his counsel,
5. At the arbitration hearing, [REDACTED] expressed the intent to meet with his doctor for a previously scheduled appointment and possibly submit new evidence to clarify the discrepancies in his records.

6. New evidence is not permitted in the arbitration process. Therefore, as a result of representations that he was soon scheduled to consult with his physician, the arbitrator issued a decision on _____ holding the record open pending meeting with his doctor and referring the matter back to the arbitration chair.

7. On _____ sent a letter to the arbitration chair, Gregory P. Miller, informing Mr. Miller that he had not received any additional information which would be helpful to _____ case. (Letter from _____ to Gregory P. Miller of _____ indicated that _____ had no objection to the record being closed.

Id. The arbitration chair requested the arbitrator to issue a final Decision and Award.

ANALYSIS

1. _____ pharmacy records reflect that he was dispensed more than 61 (sixty-one) days' worth of Pondimin and Phentermine.

2. _____ stated on his PINK Form that he ingested Pondimin® (Fenfluramine) for approximately 18 months and Redux™ (Dexfenfluramine) for approximately 90 days. (PINK Form Questions 7 and 9).

3. _____ submitted two GREEN Forms, an original form on _____ and a supplemental form on _____

4. The Settlement Agreement provides for eligibility as a class member and/or qualification for benefits depending on the severity of the Diet Drug recipient's condition. (Settlement Agreement IV.B.1 and B.2). The degree of severity, however, is subject to very specific definitions when applied to regurgitation terms such as "mild." *Id.* In contrast, medical reports often use terms such as "trace" or "mild" in a much looser manner. Therefore, in order to qualify under the Settlement Agreement, the terms "mild," "moderate," and "severe" have been given very specific medical definitions on the GREEN Form. *Id.*

5. The Trust bases its determinations on the cardiologist's declaration under penalty of perjury indicated on the GREEN Form as supported by information in the patient's echocardiogram report. The GREEN Form is the primary indicator of eligibility and the Trust cannot make determinations for eligibility or benefits inconsistent with the cardiologist's statements on the GREEN Form:

[T]he Trustees and/or Claims Administrator(s) shall make Matrix Benefits Determinations based upon the Medical Information provided to them by an appropriate Board-Certified physician on or with a properly and fully completed GREEN FORM. In making Matrix Benefits Determinations, if the Trustees and/or Claims Administrator(s) determine any inconsistency in the information provided in a Claim Form, the Trustee and/or Claims Administrator(s) shall review the Medical Information relating to such Claim to determine if the Medical Information resolves such inconsistency.

(Settlement Agreement VI.4.d).

6. One issue in this matter is an apparent contradiction between GREEN Form and his echocardiogram report. Question C.3 of supplemental GREEN Form states that he has a mild level of mitral valve regurgitation and does not have any aortic valve regurgitation.¹ However, echocardiogram reports reflect mild mitral valve regurgitation and trace or mild aortic valve regurgitation. As a result, the answers on GREEN Form regarding his aortic valve on their face do not appear to be consistent with his echocardiogram report.

7. Although he stated that he would consult with his doctor to clarify the discrepancy, did not provide any further clarification. Therefore, according to the strict

¹ Statement of the Case indicates that he had moderate mitral valve regurgitation. However, neither GREEN form nor his echocardiogram report support this contention. own cardiologist lists his mitral condition only as mild.

definitions of the GREEN Form, [REDACTED] has mild mitral valve regurgitation and no aortic valve regurgitation.

8. An additional issue in this case is whether [REDACTED] aortic valve surgery was required by stenosis or regurgitation. [REDACTED] Supplemental GREEN Form indicates that he underwent aortic valve replacement after ingestion of Diet Drugs and experienced post-operative complications requiring additional surgery for treatment of that complication. (Questions F9 and I1). [REDACTED] medical records and echocardiogram reports, however, indicate he underwent elective aortic valve replacement due to aortic stenosis and experienced an associated post-operative infection requiring additional surgery.

9. Under the Settlement Agreement, in order to qualify for benefits based on valve surgery, the surgery must have been required by moderate to severe aortic or mitral regurgitation. (Settlement Agreement IV.B.2.c (1), (2), (3)(a)). As discussed above, [REDACTED] GREEN Form indicated he did not have such regurgitation conditions and thereby indicates the surgery indicated in the answers to Questions F9 and I1 was due to a reason other than regurgitation. As a result, there is no support for [REDACTED] contention that his aortic valve surgery was related to Diet Drug use, and the surgery does not fall within the definition of surgery to repair or replace the aortic valve following use of Diet Drugs as provided in Section IV.B.2.c(3) of the Settlement Agreement.

10. [REDACTED] took Diet Drugs for 61 or more days and has a mild level of mitral valve regurgitation. These factors make him eligible as a class member, however, alone do not make him qualified for Matrix Benefits.

11. The GREEN Form does not indicate that [REDACTED] has any conditions which would qualify him for any Matrix Benefits. Matrix Level I Benefits must be based on severe

mitral regurgitation or on other conditions which are not indicated by GREEN Form or echocardiogram report. (Settlement Agreement, section IV.B.2.c (1)(a), (b)). There are also no conditions indicated which are prerequisite to recovery of Matrix Level II, III, IV, or V Benefits. (*Id.* at IV.B.2.c(2), (3), (4), and (5)).

12. It is possible that [REDACTED] will develop a medical condition that will entitle him to recovery of Matrix Benefits in the future. Since [REDACTED] has demonstrated mild mitral valve regurgitation, should his condition change in the future, as an eligible class member, he is entitled between now and December 31, 2015, to apply for Matrix Benefits by submitting a supplemental GREEN Form.

CONCLUSIONS

1. The Trust findings are not clearly erroneous as set forth in Rule 5 of the Rules Governing Arbitration Process.
2. [REDACTED] has demonstrated mild mitral regurgitation.
3. [REDACTED] GREEN Forms do not indicate aortic regurgitation as indicated by his echocardiogram report.
4. [REDACTED] GREEN Forms, echocardiogram reports, and medical records do not indicate that the reason for his aortic valve replacement surgery is one covered by the Settlement Agreement.
5. Based upon the findings above, [REDACTED] is not entitled to any Matrix Benefits at this time because the requisite conditions for recovery of Matrix Level I, II, III, IV, or V Benefits are not present in this claim. (Settlement Agreement, Sections IV.B.2.c (1), (2), (3), (4), and (5)).

6. As an eligible class member, should his condition change in the future, is entitled between now and December 31, 2015 to apply for Matrix Benefits by submitting a supplemental GREEN Form.

7. Based upon all of the above, the claimant is not presently entitled to any Matrix Benefits.

Date: August 14, 2002

ARBITRATOR