

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: REDACTED Arbitration No.: REDACTED Claim No.: REDACTED	REPORT AND AWARD OF ARBITRATOR

FINDINGS OF FACT

1. On **[DATE]**, the AHP Settlement Trust (“Trust”) denied the claim of **[APPELLANT]** for Matrix Benefits.

2. On **[DATE]**, **[APPELLANT]** requested that the District Court refer this matter to arbitration.

3. On **[DATE]**, **[APPELLANT’S]** claim was referred by the United States District Court for arbitration from the Trustees and/or claims administrator’s denial of benefits to **[APPELLANT]**.

4. On **[DATE]**, a hearing was held on **[APPELLANT’S]** arbitration claim. **[APPELLANT]** participated in the hearing and was represented by his/her counsel, **REDACTED**.

ANALYSIS

1. **[APPELLANT’S]** pharmacy records reflect that he/she was dispensed more than 61 (sixty-one) days’ worth of Pondimin and Phentermine.

2. [APPELLANT] stated on his/her PINK Form that he/she ingested Pondimin® (Flenfluramine) for approximately 18 months and Redux™ (Dexfenfluramine) for approximately 90 days. (PINK Form Questions 7 and 9.)

3. [APPELLANT] submitted two GREEN Forms, an original form on February 12, 2001, and a supplemental form on [DATE].

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 [APPELLANT'S] GREEN Form and his/her echocardiogram report. Question C.3 of [APPELLANT'S] supplemental GREEN Form states that he/she has a mild level of mitral valve regurgitation and does not have any aortic valve regurgitation.¹ However, [APPELLANT'S] echocardiogram reports reflect mild mitral valve regurgitation and trace or mild aortic valve regurgitation. As a result, the answers on [APPELLANT'S] GREEN Form regarding his/her aortic valve on their face do not appear to be consistent with his/her echocardiogram report.

7. An additional issue in this case is whether [APPELLANT'S] aortic valve surgery was required by stenosis or regurgitation. [APPELLANT'S] Supplemental GREEN Form indicates that he/she 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). [APPELLANT'S] medical records and echocardiogram reports, however, indicate he/she underwent elective aortic valve replacement due to aortic stenosis and experienced an associated post-operative infection requiring additional surgery.

8. 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, [APPELLANT'S] GREEN Form indicated he/she did not have such regurgitation conditions and thereby indicates the surgery indicated in the answers to Questions F9 and I1 was due to a

¹ [APPELLANT'S] Statement of the Case indicates that he/she had moderate mitral valve regurgitation. However, neither [APPELLANT'S] GREEN form nor his/her echocardiogram report support this contention. [APPELLANT'S] own cardiologists lists his/her mitral condition only as mild.

reason other than regurgitation. As a result, there is no support for [APPELLANT'S] contention that his/her 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.

9. [APPELLANT] made a representation that he/she had an appointment to meet with his/her doctor again during the week following the hearing and that perhaps his/her doctor could clear up the confusion regarding the GREEN Forms, the echocardiogram reports, and the medical records.

10. [APPELLANT] also represented that he/she intended to discuss with his/her doctor whether his/her aortic valve condition qualifies as "mild" according to the specific technical definitions of the Settlement Agreement.

11. The Attorney for the Trust indicated that if [APPELLANT'S] cardiologist considers [APPELLANT'S] condition to qualify as mild aortic under the Settlement Agreement definition as defined on the GREEN Form (or wishes to make other condition clarifications), the appropriate procedure would be to submit a supplemental GREEN Form so indicating, which would in turn be re-evaluated by the Trust.

12. If [APPELLANT] were to submit a Supplemental GREEN Form, such form would constitute new evidence. New evidence is not permitted for consideration in the appeals process. *See* Rules Governing Arbitration Process, 9a. The proper procedure for new evidence is for the arbitrator to refer the case back to the Arbitration Chair. *Id.*, 10.

13. In light of the possibility of new evidence being presented subsequent to [APPELLANT'S] scheduled meeting with his/her doctor, the arbitrator made the decision to

adjourn the hearing, leave the record open, and refer this matter back to the Arbitration Chair. Both parties agreed with the arbitrator's course of action and made no objections.

CONCLUSIONS

1. [APPELLANT'S] GREEN Forms do not indicate the same level of aortic regurgitation as indicated by his/her echocardiogram report.

2. [APPELLANT'S] GREEN Forms, echocardiogram reports, and medical records do not indicate that the reason for aortic valve replacement surgery is one covered by the Settlement Agreement.

3. [APPELLANT] has expressed the intent to meet with his/her doctor for a previously scheduled appointment and possibly submit new evidence to clarify the discrepancies in his/her records.

4. Due to the possibility of new evidence, this matter is being referred to the Arbitration Chair.

Date: March 1, 2002

REDACTED, ESQUIRE
ARBITRATOR