

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.

CIVIL ACTION NO.

v.

99-20593

AMERICAN HOME PRODUCTS
CORPORATION

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

REPORT AND AWARD
OF ARBITRATOR

FINDINGS OF FACT

1. On [redacted] the AHP Settlement Trust ("Trust") issued a Final Determination regarding the claim of [redacted] awarding Matrix B Compensation Benefits, but denying Matrix A Compensation Benefits.

2. On [redacted] [redacted] filed an appeal from the denial of Matrix A Compensation Benefits by the Trust, requesting that the United States District Court ("Court") refer this matter to Arbitration.

3. On [redacted] the claim of [redacted] was referred by the Court to Arbitration pursuant to VI.C.4(h) & (i) or VI.D.1.(f) & (g) of the Nationwide Class Action Settlement Agreement with American Home Products Corporation.

4. On [redacted] at 3:00 p.m., an Arbitration Hearing was held concerning the claim of [redacted]

5. The Trust determined that _____, was entitled to Compensation Benefits on the B Matrix, but that _____ was not entitled to Compensation Benefits on the A Matrix.

6. In _____ Green Form dated _____, indicates that _____ believes _____ is entitled to Matrix A-1 Benefits with severity level III. See Green Form, Part I, page 4, questions 5 and 6. In _____ Statement of the Case, _____, is requesting that the Arbitrator remand _____ claim back to the Trust to be submitted to audit pursuant to Pretrial Order No. 3882.

ANALYSIS

FUND A ISSUES NOT COVERED BY ARBITRATION PROCESS

1. The Settlement Agreement provides for two funds, Funds A and B, which were established to provide benefits to class members. See Settlement Agreement, Section III.A.1; Memorandum and Pretrial Order No. 1415 (August 28, 2000) at 62. Fund A provides funding only for non-Matrix specified benefits and expenses, e.g., drug refunds and echocardiogram reimbursement. See Settlement Agreement, Section IV.A; Memorandum and Pretrial Order No. 1415 (August 28, 2000) at 62. Fund B provides funding for Matrix Compensation Benefits. See Settlement Agreement, Section IV.B; Memorandum and Pretrial Order No. 1415 (August 28, 2000) at 62.

2. The arbitration process only covers determinations made regarding Fund B and the eligibility of claimants to receive Matrix Compensation Benefits and/or the amount of Matrix Compensation Benefits they are entitled to receive.

MATRIX ELIGIBILITY AND QUALIFICATION

1. Under the Settlement Agreement, Matrix Compensation Benefits are paid according to two matrices. See Settlement Agreement § IV.B.2.d. The A Matrix, or the full compensation matrix, applies to claimants who: (1) have been diagnosed timely as FDA Positive; (2) ingested the diet drugs for sixty-one (61) or more days; and (3) have no conditions requiring a reduced payment under the terms of the Settlement Agreement. See Id. § IV.B.2.d.(1). The B Matrix, or reduced compensation matrix, applies to claimants who: (1) have been diagnosed timely with Mild Mitral Regurgitation (regardless of the duration of ingestion of the diet drugs); or (2) were diagnosed timely as FDA Positive and ingested the diet drugs for sixty (60) days or less; or (3) were diagnosed timely as FDA Positive, ingested the diet drugs for sixty-one (61) or more days, and have certain conditions, identified in the Settlement Agreement, that may have caused or contributed to the claimant's heart problems. See id. § IV.B.2.d.(2).

2. [redacted] submitted a Pink Form dated [redacted]

3. According to questions 7 and 8 of [redacted] Pink Form, answered that [redacted] took Pondimin and Redux and for 61 days or more.

4. [redacted] submitted a Green Form dated [redacted]

5. In the Green Form of [redacted], reference is made to an echocardiogram which was performed on [redacted]. (See Green Form, Part II, page 8, questions C.1 and C.2).

6. The [redacted] Green Form submitted by [redacted] reports moderate mitral valve regurgitation and no aortic valve regurgitation. (See Green Form, Part II, page 8, question C.3).

7. The [redacted] Green Form submitted by [redacted] also reports Mitral Valve Prolapse, heart valve surgery to replace/repair the mitral valve prior to Diet Drug use, moderate or greater mitral regurgitation prior to Diet Drug use and surgery to replace/repair the mitral valve following Diet Drug use. (See Green Form, Part II, page 9, questions D.7, E.1 and E.5; page 11, question F.9).

8. The answers to the questions in Part II of [redacted] Green Form were completed by [redacted] physician, [redacted], a Board-Certified Cardiologist. (See Green Form, Part II, page 7, Section A).

9. The parties agree that the claim of [redacted] was subject to the Procedures of the Parallel Processing Program for High Level Claims (PPP), pursuant to Pretrial Order No. 3882. However, they disagree as to whether the Trust complied with these Procedures in determining the within claim.

10. Pursuant to Section 10 of the PPP Procedures, after its review of the claim forms and Medical Information, and no later than 30 days after determining that the claim is complete, Wyeth is required to notify the Trust and Class Counsel that the Matrix claim, and/or any associated claims, are designated as either (a) Payable; or (b) Payability Disputed.

11. Pursuant to Section 11(a) of the PPP Procedures, with regard to all claims designated as Payable by Wyeth, Wyeth is required to notify Class Counsel and the Trust

of the benefit level and the amount of the claim based on the documentation and information reviewed by Wyeth. Pursuant to Section 11(b) of the Procedures, with regard to all claims designated as Payability Disputed by Wyeth, Wyeth is required to notify Class Counsel⁴ and the Trust as to why payability is disputed. Further, Section 11(b)(2) of the Procedures provides that if Wyeth disputes the payability of a claim because it disputes the medical diagnosis set forth in Part II of the Green Form (or due to other proof deficiencies), Wyeth is to specify which questions in Part II of the Green Form it disagrees with, and these questions alone are to be submitted to the Auditing Cardiologist for review during the audit.

12. Section 12(a) of the PPP Procedures governs "The Trust Actions on Designated Matrix Claims." Pursuant to Section 12(a) of the Procedures, for any claim designated by Wyeth as Payable, the Trust is required to perform a review of the claim limited to determining that a Green Form has been filed and that the name and claim number are consistent as designated by Wyeth. After its review, the Trust shall issue a determination letter to the Claimant, and provide the Claimant with an opportunity to accept the amount without prejudice to have the right to contest the Matrix designation or the severity level. It is further provided by Section 12(a) that the Trust shall not run the Green Form algorithm, require additional information to complete the claim, or conduct any additional review of the claim, but instead shall process the claim at the level and in the amount specified in Wyeth's designation.

13. Section 12(a) of the PPP Procedures, 2nd paragraph, also provides that if the Claimant contests the Matrix designation or the severity level of the claim, "the claim

will be deemed a Medical Disagreement under Section 11(b)(2) of these Procedures and shall be processed in accordance with Sections 11(b)(2), 12(b) and 13 of these Procedures." As noted above, Section 11(b)(2) of the Procedures provides that if Wyeth disputes the payability of a claim, Wyeth's designated questions alone are to be submitted to the Auditing Cardiologist for review during the audit. Section 12(b) directs the Trust to forward any Payability Disputed claim under 11(b)(2) to the Auditing Cardiologist, without reviewing the claim for completeness prior to sending the disputed claim to audit. Section 13, entitled "Contest Following Audit," specifically outlines the procedures to be followed by the Trust, Wyeth and Class Counsel "[i]f the Claimant contests an audit finding in accordance with Audit Rule 18(b)..."

14. On or about [redacted], the Trust transmitted [redacted] Green Form Claim to Class Counsel Claim Office ("CCCO"). Thereafter, pursuant to Section 11(a) of the PPP Procedures, Wyeth notified Class Counsel and the Trust that [redacted] claim was designated as Payable, and of the benefit level and the amount of the claim based on the documentation and information reviewed by Wyeth.

15. On [redacted], the Trust issued a Determination to [redacted] that [redacted] was entitled to Matrix Compensation Benefits on the Matrix B, based upon Wyeth's designation of the claim as Payable pursuant to the PPP Procedures.

16. As noted above, the B Matrix, or reduced compensation matrix, applies to claimants who: (1) have been diagnosed timely with Mild Mitral Regurgitation (regardless of the duration of ingestion of the diet drugs); or (2) were diagnosed timely as FDA Positive and ingested the diet drugs for sixty (60) days or less; or (3) were diagnosed timely as

FDA Positive, ingested the diet drugs for sixty-one (61) or more days, and have certain conditions, identified in the Settlement Agreement, that may have caused or contributed to the claimant's heart problems. See Settlement Agreement, § IV.B.2.d.(2).

17. Here, the Trust points out that, based on Green Form was diagnosed timely as FDA Positive, ingested diet drugs for sixty-one (61) or more days, and had conditions, identified in the Settlement Agreement, that may have caused or contributed to the claimant's heart problems, to wit: Mitral Valve Prolapse, surgery to replace/repair the mitral valve prior to Diet Drug use, and moderate or greater mitral regurgitation prior to Diet Drug use. See id. § IV.B.2.d.(2)(c)ii and iii. The Trust determined that, for these reasons, Matrix Compensation Benefits on the B Matrix were the proper designation for claim.

18. In response to the determination of the Trust, sent letters dated , and , contesting the determination of the Trust. The sole issue raised in the letters was whether claim should have been on the A Matrix as opposed to the B Matrix. The basis for contest was an assertion that incorrectly answered questions D.7, E.1 and E.5 on page 9 of Part II of the Green Form.

19. In support of contest, also submitted to the Trust an amended page 9 of Part II of the Green Form, containing handwritten corrections by , as well as medical records from the Hospital of . While amended the answers to questions E.1 and E.5 on page 9 of Part II of the Green Form,

did not amend answer to question D.7, which affirmed that suffered from Mitral Valve Prolapse.

20. On the Trust issued a Final Determination, acknowledging the letters dated and from contesting the initial Determination, but denying the claim of for Matrix A Compensation Benefits.

21. Section 12 of the PPP Procedures clearly states that if the claimant contests the Matrix designation or the severity level of a claim, the claim will be deemed a Medical Disagreement under Section 11(b)(2) of the Procedures and "shall be processed in accordance with Sections 11(b)(2), 12(b) and 13 of these Procedures."

22. letters dated and were correctly recognized by the Trust as a contest by of the Matrix designation made by Wyeth, within the meaning of Section 12 of the PPP Procedures. Therefore, argues that the claim should have been deemed a Medical Disagreement under Section 11(b)(2) of the Procedures by the Trust, and should have been sent by the Trust to audit in accordance with Sections 11(b)(2), 12(b) and 13 of the Procedures. The Trust argues that only Wyeth, and not a claimant, can declare a claim as Payability Disputed.

23. However, that issue need not be resolved in this appeal since, the record in this case establishes that the remedy sought by Appellant, i.e., to have claim submitted to audit, has already been provided.

24. In submitted a Supplemental Claim for Matrix Compensation Benefits. In support of Supplemental Claim, submitted a Second Green Form dated ("Second Green Form"). In Second Green

Form, indicates that believes is entitled to Matrix A-1 Benefits with severity level V. See Second Green Form, Part I, page 4, questions 5 and 6.

25. In the Second Green Form, reference is made to the same echocardiogram performed on that was referenced in the original Green Form. (See Second Green Form, Part II, page 8, questions C.1 and C.2).

26. The Second Green Form submitted by reports severe mitral valve regurgitation and no aortic valve regurgitation. (See Second Green Form, Part II, page 8, question C.3). The Second Green Form also reports surgery to replace/repair the mitral valve following Diet Drug use, but does not report Mitral Valve Prolapse, surgery to replace/repair the mitral valve prior to Diet Drug use, or moderate or greater mitral regurgitation prior to Diet Drug use. (See Second Green Form, Part II, page 9, questions D.7, E.1 and E.5; page 11, question F.9).

27. The answers to the questions in Part II of Second Green Form were completed by physician,), a Board-Certified Cardiologist. (See Second Green Form, Part II, page 7, Section A).

28. The Appellant's Supplemental Claim for Matrix Compensation Benefits was submitted to audit, and the entirety of the Claim, including the underlying Level III Mitral Valve Surgery Claim, and the echocardiogram, were reviewed by an Auditing Cardiologist.

29. The Auditing Cardiologist agreed with the findings of the Attesting Physician to the Second Green Form that did not have Mitral Valve Prolapse. However, the Auditing Cardiologist found only mild mitral valve regurgitation on the

echocardiogram, with no reasonable medical basis for the Attesting Physician's representation of severe mitral valve regurgitation.

30. As noted above, a finding of mild mitral valve regurgitation, in between the commencement of Diet Drug use and the close of the screening period, places an otherwise payable mitral valve claim on the B Matrix. See Settlement Agreement, § IV.B.2.d.(2)(a).

31. Because the value of Appellant's Supplemental Claim is exceeded by the previously paid Matrix B-1, Severity Level III Benefit, the Trust determined that Appellant was not due any additional Matrix Benefits, and on [redacted], issued a Post-Audit Determination denying the Supplemental Claim on that basis.

32. [redacted] failed to contest the findings of the Auditing Cardiologist, that the [redacted] echocardiogram demonstrates only mild mitral regurgitation. Accordingly, the determination became final upon the expiration of the contest period, on or about [redacted]. See Audit Rule 18 (a), Pretrial Order No. 2807 at 10 (“...Claimant shall be deemed to have accepted the Trust’s Post-Audit Determination ... by failure to deliver to the Trust a written contest ... postmarked no later than sixty days after the date of the post-audit Determination”).

33. The relief prayed for by the Appellant has already been provided via the audit of her Supplemental Claim for Matrix Benefits. Appellant has accepted the determination that the [redacted] echocardiogram demonstrates mild mitral valve regurgitation. Any remand for audit on the issue of Mitral Valve Prolapse is therefore rendered moot, as

the finding of mild mitral valve regurgitation limits Appellant's mitral valve Claim to Matrix B.

34. For these reasons, I conclude that the Trust's analysis and determination were not clearly erroneous.

CONCLUSIONS

1. Through this appeal, the Appellant seeks a complete audit of claim pursuant to the Procedures as established by Pretrial Order No. 3882.

2. The Appellant's request for remand for an audit is rendered moot, since an audit of Appellant's entire claim was completed in 2008 when the Claimant submitted a Supplemental Claim for Matrix Compensation Benefits.

3. Based on the above, the findings of the Trust are not clearly erroneous as set forth in Rule 5 of the Rules Governing the Arbitration Process.

4. The final determination of the Trust is affirmed.