

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. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS
CORPORATION

NO. 99-20593

THIS DOCUMENT RELATES TO:

Claimant: Lidya N. Goldstein:
Claim No.: 183/00 8009457

2:15 MD 1203

PRETRIAL ORDER NO. 9295

AND NOW, this 18th day of June, 2014, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the appeal of claimant Lidya N. Goldstein from the July 5, 2013 Report and Award of the Arbitrator related to her claim for Matrix Benefits under the Nationwide Class Action Settlement Agreement is DENIED and the Report and Award of the Arbitrator is AFFIRMED.

BY THE COURT:


J.

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MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9295

Bartle, J.

June 18, 2014

Lidya N. Goldstein ("Ms. Goldstein" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Under the Settlement Agreement, Matrix Compensation Benefits ("Matrix Benefits") are awarded to compensate claimants for medical conditions caused by Pondimin® or Redux™ ("Diet Drugs").²

1. Prior to March 11, 2002, Wyeth was American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

In March 2012 claimant submitted a Green Form seeking Matrix Benefits. The attesting physician, Dr. Andres Tamayo, represented in Part II of the Green Form that Ms. Goldstein had ingested the Diet Drugs Pondimin (Fenfluramine) and Redux (Dexfenfluramine) for at least 61 days. He further stated that Ms. Goldstein suffered from severe aortic regurgitation, an ejection fraction of 50-60%, and New York Heart Association Functional Class II Symptoms. Based on Dr. Tamayo's conclusion that Ms. Goldstein had severe aortic regurgitation, The Trust determined that the Green Form stated a Matrix A, Severity Level I claim.

On March 22, 2012, the Trust issued a tentative denial and advised Ms. Goldstein that the Seventh Amendment to the Settlement Agreement barred her from pursuing the Severity Level I claim asserted on the Green Form. There is no dispute that Ms. Goldstein did not opt-out of the Seventh Amendment.

2. (...continued)

medical conditions, their ages when diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease. See Settlement Agreement, §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious valvular heart disease who took the drugs for 61 days or longer and who did not have any of the alternative causes of the disease that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious valvular heart disease who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their heart disease was caused solely by the use of these Diet Drugs.

Ms. Goldstein contested the denial and submitted a second Green Form, which she calls in her papers an "Amended Green Form," as well as previously provided medical records. Ms. Goldstein now claimed that she had a Matrix Severity Level III condition which was "diagnosed and occurred by the earlier of December 26, 2011" and 14 ½ years after the date of her last ingestion of Diet Drugs. Each page of the "Amended Green Form" appears to be an exact copy of the respective page of the original Green Form except for pages 11 and 14. On page 11 of the "Amended Green Form," the answer to Questions F.9 and F.10,³ which relate to surgery, is now "yes," while on page 11 of the original Green Form the answer is "no" to both questions. Page 14 of the "Amended Green Form", the signature page, appears to be an exact copy of the original Green Form page 14 except that a handwritten, unsigned notation now appears below the original signature. It states, "The patient needs to postpone surgery until her BP is well controlled, cholesterol, triglycerides are controlled and until she loses ~50 lbs." Since page 14 is otherwise the same as in the previous submission, Dr. Tamayo's signature date on the "Amended Green Form" remains unchanged from the original Green Form, and he did not sign or initial the handwritten note below his signature.

3. Question F.9 reads, "Surgery to repair or replace the aortic and/or mitral valve(s) after use of Pondimin and/or Redux?" Question F.10 reads, "Severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valve(s) where such surgery was not performed?"

On May 14, 2012, the Trust issued a Final Determination denying Ms. Goldstein's claim on the ground that she had not stated a claim under the terms of the Settlement Agreement as amended by the Seventh Amendment because (1) she did not have a valvular repair/replacement surgery prior to the Seventh Amendment deadline of December 31, 2011; and (2) she is barred from pursuing a Level III claim based upon the need for surgery which was not performed.

Ms. Goldstein appealed the Trust's determination on May 25, 2012, and we referred the matter to arbitration pursuant to §§ VI.C.4(h) and (i) of the Settlement Agreement. Both parties agreed to waive an arbitration hearing. The arbitrator issued a Report and Award dated July 5, 2013, concluding that Ms. Goldstein "is not currently entitled to Matrix Level Benefits because the conditions that are required for recovery of Matrix Level III, IV or V Benefits, as described in the Settlement Agreement and modified by the Seventh Amendment, are not present in this claim."

Claimant has now appealed to this court as permitted under the Settlement Agreement. See id. We apply a clearly erroneous standard of review to the Arbitrator's findings of fact and conduct a plenary review of conclusions of law. First Options of Chicago, Inc. v. Kaplan, 514 U.S. 938, 947-49 (1995). The decision of this court is final and binding. See Settlement Agreement, § VI.C.4.1.

On appeal, Ms. Goldstein asserts that, as a Category Two Class Member,⁴ she is entitled to Matrix benefits based upon the High Matrix Qualifying Factors set forth in the Seventh Amendment. According to claimant, she is entitled to compensation because she was told she needed aortic valve surgery, even though that surgery was not actually performed because of her other medical conditions.

The Seventh Amendment to the Settlement Agreement provides that a Category Two Class Member may seek Seventh Amendment Matrix Compensation Benefits from the Trust. Seventh Amendment, §§ I.B.64, IX.A. Seventh Amendment Matrix Compensation Benefits are defined as "those Matrix Compensation benefits which may be paid or claimed for 'High Matrix Level Qualifying Factors.'" High Matrix Level Qualifying Factors means "that the Diet Drug Recipient actually had surgery to repair or replace the valve or valves that were found to have FDA Positive regurgitation or Mild Mitral regurgitation before the end of the Screening Period and that is/are the basis of the claim." Seventh Amendment, § I.30.a. The Seventh Amendment also provides, "Upon final judicial approval of the Seventh Amendment,

4. The Trust does not dispute that Ms. Goldstein is a Category Two Class Member. Section III.2.a. of the Seventh Amendment provides a lengthy definition of a Category Two Class Member. Pertinent to this matter is the fact that Ms. Goldstein filed a Blue Form prior to May 3, 2003, seeking benefits under the Settlement Agreement; that she was diagnosed as having FDA Positive regurgitation after Diet Drug use by the end of the Screening Period; and that she did not opt-out of the Seventh Amendment.

no Class Member may pursue or receive Matrix Compensation Benefits on Matrix Level I or Matrix Level II." Seventh Amendment, § XI.B.

Finally, § IV.B.2.c.(3)(b) of the Settlement Agreement, on which Ms. Goldstein relies to claim Matrix Level III benefits, provides that a claimant is entitled to Level III benefits if he or she presents "severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valve(s) and a statement from the attending Board-Certified Cardiothoracic Surgeon... with the reason why the surgery is not being performed." However, § I.30.c. of the Seventh Amendment states, "High Matrix Level Qualifying Factors do not include the circumstances described in section IV.B.2.c.(3)(b) of the Settlement Agreement except to the extent to qualify for Matrix Benefits at Matrix Level IV or Matrix Level V" (emphasis added).

In the first Green Form, Dr. Tamayo stated that Ms. Goldstein had not had surgery to repair or replace either her aortic or mitral valves after Diet Drug use. While in the second or so-called amended Green Form, which is of questionable provenance, claimant included a notation that she required surgery but needed to postpone it based on other medical conditions, she has submitted no documentation of any valvular repair or replacement surgery. As such, any Matrix Level III claim is barred by § IV.B.2.(3)(b) of the Seventh Amendment. Furthermore, claimant has presented no evidence of a Level IV or

Level V claim. In fact, the original Green Form submitted by Ms. Goldstein supports only a Matrix Level I claim, which is barred by § XI.B. of the Seventh Amendment.

We conclude that the Arbitrator's determination was not clearly erroneous as to her findings of fact, and she did not err as to her conclusions of law. The Report and Award of the Arbitrator will be affirmed.