

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
\_\_\_\_\_) )  
THIS DOCUMENT RELATES TO: )  
SHEILA BROWN, et al. )  
v. ) CIVIL ACTION NO. 99-20593  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

May 31, 2007

Willie Barton ("Ms. Barton" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seek benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

---

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

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 medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). 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

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In December 2001, claimant submitted a Green Form to the Trust. Based on an echocardiogram dated May 23, 2001, claimant's physician, Malcolm Taylor, M.D., attested in Part II of her Green Form that claimant had severe mitral regurgitation. If accepted, claimant would be entitled to Matrix A-1, Level I benefits in the amount of \$90,967.00.<sup>3</sup>

---

2(...continued)

with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug recipients with serious VHD 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 VHD was caused solely by the use of these diet drugs.

3. Under the Settlement Agreement, a claimant is entitled to Level I benefits for damage to the mitral valve if he or she is diagnosed with severe mitral regurgitation and no complicating factors as defined in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(1)(a).

In the report of claimant's echocardiogram, Dr. Taylor stated that claimant had "severe mitral regurgitation with RJA/LAA ratio of 48%." Under the definition set forth in the Settlement Agreement, severe mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is greater than 40% of the Left Atrial Area ("LAA"). See Settlement Agreement §§ I.22 and IV.B.2.c.(1)(a).

In May 2002, the Trust notified claimant that her claim had been selected for audit.<sup>4</sup> In response, claimant submitted a letter dated June 24, 2002 from Dr. Taylor. Therein, Dr. Taylor stated that claimant "has severe mitral regurgitation with an RJA/LAA ratio of 48%. Clinically, this mitral regurgitation appears to be moderate to severe. However, the ratio is elevated because the left atrial size is small."

In July 2002, the Trust forwarded the claim for review by Donna R. Zwas, M.D., one of its auditing cardiologists. In audit, Dr. Zwas concluded that there was no reasonable medical basis for Dr. Taylor's finding that claimant had severe mitral regurgitation because "both jet size and left atrial size were not properly measured."

---

4. Under the Settlement Agreement, the Trust and Wyeth could designate for audit a certain number of claims for Matrix Benefits and identify the condition(s) to be reviewed during the audit. See Settlement Agreement § VI.F; Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. In Pretrial Order ("PTO") No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

Thereafter, the Trust issued a post-audit determination denying Ms. Barton's claim. Pursuant to the Audit Policies and Procedures, claimant disputed this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2457, Audit Policies and Procedures § VI.<sup>5</sup> The Trust then applied to the court for issuance of an Order to show cause why Ms. Barton's claim should be paid. On September 25, 2002, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2617 (Sept. 25, 2002).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 15, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor<sup>6</sup> to review

---

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Mr. Barton's claim.

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge—helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting  
(continued...)

claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. at § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had severe mitral regurgitation. See Audit Policies and Procedures § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there was a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, claimant submitted an Affidavit from Dr. Taylor. Therein, Taylor stated that:

The May 23, 2001 echocardiogram showed clinically moderate to severe mitral

---

6(...continued)

expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

regurgitation. However, it is my understanding that an RJA/LAA ratio in excess of 40% constitutes 'severe' mitral regurgitation under the definitions of the national diet drug settlement agreement and the Green Form.

Dr. Taylor also stated that he "again evaluated Ms. Barton's May 23, 2001 echocardiogram tape" and "[u]pon my re-evaluation I found the RJA/LAA to be 41% ...." Claimant also argues that the auditing cardiologist "provides no indication of what she believes the correct measurements to be" and does not "provide a calculation (or estimation) of the RJA/LAA ratio ...."

In response, the Trust argues that claimant fails to address the auditing cardiologist's finding that the attesting physician relied on inaccurate measurements. The Trust also asserts that the auditing cardiologist complied with the Settlement Agreement in the manner in which she reviewed claimant's echocardiogram.

Dr. Abramson, the Technical Advisor, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had severe mitral regurgitation. Specifically, Dr. Abramson found that:

There is no reasonable medical basis for the physician completing the diet-drug recipient's claim form to state that Willie Barton has severe MR. I measured the RJA/LAA ratios in the apical-4-chamber view which is the same view that the Attesting Physician used. I planimetered the mitral regurgitant jet area and the left atrial area using the same method that the Attesting Physician used. I measured the mitral regurgitant jet

on 3 different beats for measurements of 2.4 cm<sup>2</sup>, 2.5 cm<sup>2</sup>, and 2.7 cm<sup>2</sup>. I measured the left atrial area for measurements of 13.1 cm<sup>2</sup>, 13.5 cm<sup>2</sup>, and 14 cm<sup>2</sup>. These calculate to RJA/LAA ratios of 18.3%, 18.5%, and 19.3%.

\* \* \*

The Attesting Physician did over measure the regurgitant jet area and under trace the left atrial area, thereby resulting in an inflated level of regurgitation. He measured the jet area at 4.74 cm<sup>2</sup>, which is much greater than the jet area that I measured and averaged at 2.5 cm<sup>2</sup>. I used three consecutive heartbeats for my measurements; one beat was the same beat that the Attesting Physician used. His measurement of the left atrial area of 8.65 cm<sup>2</sup> is much less than that which I measured and averaged at 13.5 cm<sup>2</sup>. The Attesting Physician measured these areas incorrectly.

After reviewing the entire Show Cause Record, we find claimant's arguments all without merit. First, and of crucial importance, claimant does not contest the analysis provided by the either Dr. Zwas or Dr. Abramson.<sup>7</sup> Claimant does not address Dr. Zwas' conclusions that claimant's attesting physician relied on inaccurate measurements. Nor does claimant challenge Dr. Abramson's specific findings that claimant had only mild mitral regurgitation. Claimant also does not refute Dr. Abramson's finding that the attesting physician improperly overtraced the regurgitant jet area and undertraced the left atrial area. On this basis alone, claimant has failed to meet her burden of

---

7. Despite an opportunity to do so, claimant did not submit any response to the Technical Advisor Report. See Audit Policies and Procedures § VI.N.

demonstrating that there is a reasonable medical basis for her claim.

Finally, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Severe mitral regurgitation is defined as greater than 40% RJA/LAA, which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(1)(a). Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having severe mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation.

Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix benefits. There is no basis for such a revision and claimant's argument is contrary to the standards we previously have evaluated and accepted. As we explained in PTO No. 2640, "[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology."<sup>8</sup> See Memorandum and PTO No. 2640, at 15.

---

8. Claimant's argument as to measurements also is flawed because, although not necessary for resolution of this claim, the Technical Advisor provided specific measurements of her level of mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis to conclude that she had severe mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Barton's claim for Matrix benefits.

