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

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

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J. August 30, 2007

Patricia A. Maccarino ("Ms. Maccarino" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks 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").[2]

---

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. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients 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

(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 July 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Steven S. Gubin, M.D. Based on an echocardiogram dated March 16, 2002, Dr. Gubin attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $476,887.

In the report of claimant's echocardiogram, Dr. Gubin reported that claimant's level of mitral regurgitation was moderate. Under the definition set forth in the Settlement Agreement, moderate mitral regurgitation is present where the

---

2(...continued)
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.

Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Gubin also estimated claimant's ejection fraction as 55%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b).

In January 2004, the Trust forwarded the claim for review by Robert A. Skotnicki, D.O., one of its auditing cardiologists. In audit, Dr. Skotnicki concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction because claimant's ejection fraction "was normal or visually greater than 60%." Dr. Skotnicki, however, found that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.[3]

Based on Dr. Skotnicki's diagnosis of a normal ejection fraction, the Trust issued a post-audit determination denying Ms. Maccarino's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this

---

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is whether claimant has a reduced ejection fraction, which is one of the conditions needed to qualify for Level II benefits.

adverse determination.[4] In contest, claimant submitted an expert report by Stephen R. Cuddy, M.D., F.A.C.C. Therein, Dr. Cuddy stated that claimant's ejection fraction was 60%. Claimant argued that Dr. Cuddy's expert report provided a reasonable medical basis for Dr. Gubin's finding that claimant's ejection fraction was less than or equal to 60%.

The Trust then issued a final post-audit determination, again denying Ms. Maccarino's claim. Claimant disputed this final 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. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Maccarino's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5243 (May 20, 2005).

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 August 15, 2005. Under the Audit Rules, it is within the Special Master's discretion to

---

4. 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 Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Maccarino's claim.

appoint a Technical Advisor[5] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. 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 to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.

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 a reduced ejection fraction. See id. Rule 24. 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 affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). 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. Rule 38(b).

---

5. 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 critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting 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. See id.

In support of her claim, Ms. Maccarino argues that the auditing cardiologist only visually assessed her ejection fraction and did not take any measurements in making his determination. Claimant also contends that the findings of Drs. Gubin and Cuddy provide a reasonable medical basis for her claim.

In response, the Trust argues that there is no reasonable medical basis for Dr. Gubin's finding of a reduced ejection fraction because the auditing cardiologist determined that it was greater than 60%. The Trust also asserts that claimant failed to rebut the auditing cardiologist's finding of a normal ejection fraction.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. In particular, Dr. Abramson determined that:

> In reviewing the transthoracic echocardiogram, it is a technically difficult study which would preclude making any reliable measurements. It is obvious that the systolic function is normal. My visual estimate is that the ejection fraction is approximately 60%. All of the physicians reviewing this study agree that there is normal systolic function with a normal ejection fraction. Clinically, a normal ejection fraction is ≥55% which is present in this study. Since this ejection fraction could reasonably be read as 60%, this falls within the range of 50%-60%. Therefore, there is a reasonable medical basis for the Attesting Physician to state that the Claimant's ejection fraction is in the range of 50%-60%.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Gubin, reviewed claimant's echocardiogram and found that claimant had a reduced ejection fraction.[6] Although the Trust contested the attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's finding of a reduced ejection fraction.[7] Specifically, Dr. Abramson concluded that claimant's ejection fraction "could reasonably be read as 60%," and, as such, "there is a reasonable medical basis for the Attesting Physician to state that the claimant's ejection fraction is in the range of 50%-60%." As stated above, an ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b). Here, Dr. Abramson estimated that claimant's ejection fraction was "approximately 60%." Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.[8]

---

6. Similarly, claimant's additional expert, Dr. Cuddy, also concluded that claimant had a reduced ejection fraction. Contrary to the Trust's argument, claimant's additional expert sufficiently rebutted the auditing cardiologist's finding of a normal ejection fraction.

7. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report. See Audit Rule 34.

8. Accordingly, we need not address claimant's remaining arguments.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix Benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Maccarino for Matrix Benefits.

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

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

PRETRIAL ORDER NO._____

AND NOW, on this 30th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimant Patricia A. Maccarino is entitled to Matrix A-1, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805 and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III
C.J.