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 IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8202

Bartle, C.J. June 23, 2009

Gloria Linman ("Ms. Linman" 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

(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 September 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Stephen Raskin, M.D. Based on an echocardiogram dated March 6, 2002, Dr. Raskin attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension 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.[3]

2(...continued)
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 II benefits for damage to the mitral valve if he or she is
(continued...)

In the report of claimant's echocardiogram, Needham E. Ward, M.D., the reviewing cardiologist, stated that claimant had "[m]oderate mitral regurgitation." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the 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. Ward also measured claimant's left atrial dimension as 4.2 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Finally, Dr. Ward estimated claimant's ejection fraction as 50% to 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. at § IV.B.2.c.(2)(b).

In September 2005, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its

---

3(...continued)
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 findings of a reduced ejection fraction and an abnormal left atrial dimension, both of which are among the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

auditing cardiologists. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for Dr. Raskin's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. According to Dr. Gradus-Pizlo, the "[t]raced area of mitral regurgitation includes large area of nonturbulent flow." Dr. Gradus-Pizlo, however, concluded that there was a reasonable medical basis for Dr. Raskin's findings of both an abnormal left atrial dimension and a reduced ejection fraction.

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Linman's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[4]

In contest, claimant submitted a declaration from Dr. Raskin, who reviewed claimant's echocardiogram for a second time and produced several still frames that purportedly demonstrated moderate mitral regurgitation. In the declaration, Dr. Raskin stated that:

---

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. Linman's claim.

> I re-reviewed the March 6, 2002 echocardiogram with particular attention to Dr. Gradus-Pizlo's concerns and respectfully disagree with her conclusions. My review of the study finds that the March 6, 2002 echocardiogram reveals a central jet *distinct* from any non-turbulent or non-regurgitant flow such as any significant entrained flow or pulmonary venous flow.
>
> . . . Dr. Gradus-Pizlo's contention that *low flow or non-turbulent flow* accounts for an inaccurate mitral regurgitant jet area (RJA) calculation is not supported by my review. Any significant over-representation of the MR jet would typically include random inclusion of light blue low velocity flow and in my analysis I paid particular attention to, and excluded, any entrained flow as well as any possible pulmonary venous flow from the RJA. The MR jet boundary in this case was traced with care to avoid including black (no color) areas. Some minor inter-observer variability in planimetry of the mitral color jet is likely but in this case such variability does not substantively change the basis for the estimate of mitral regurgitation severity based on the AHP Trust definition.

The Trust then issued a final post-audit determination, again denying Ms. Linman'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, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Linman's claim should be paid. On April 11, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6125 (Apr. 11, 2006).

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 June 23, 2006. Under the Audit Rules, it is within the Special Master's discretion to 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 a Technical Advisor, Gary J. Vigilante, 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. See 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 of moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm

---

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. Id.

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 is 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).

In support of her claim, Ms. Linman argues that Dr. Raskin verified that her echocardiogram was performed in accordance with the Settlement Agreement. Claimant further asserts that Dr. Raskin based his finding of moderate mitral regurgitation on his review of claimant's entire echocardiogram. According to claimant, the submitted still frames illustrate that her level of mitral regurgitation is moderate. Finally, claimant contends that Dr. Raskin's detailed findings provide a reasonable medical basis for her claim.

In response, the Trust argues that the auditing cardiologist found no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because the attesting physician relied on inaccurate tracings. The Trust further contends that the auditing cardiologist determined that claimant had only mild mitral regurgitation after reviewing her echocardiogram in real time. Finally, the Trust argues that the still frames submitted by claimant are not representative of her level of mitral regurgitation.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In particular, Dr. Vigilante determined that:

> The apical two chamber and apical four chamber views were reviewed in detail. Page 21 of 36 showed an apical two chamber view with moderate mitral regurgitation. The jet was directed posteriorly into the left atrium. Page 23 also demonstrated a moderate jet of mitral regurgitation traveling laterally into the left atrium in an apical four chamber view. I measured the RJA. The LAA had been accurately measured on Page 25 of this study. The RJA/LAA ratio was 25% in both the apical two chamber and apical four chamber views. The RJA measured by the sonographer on Page 24 was actually too low. Appropriate Nyquist limits were noted on this study. . . .
>
> [T]here is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of March 6, 2002 demonstrates moderate mitral regurgitation with comments as above.

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 reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation. Although the Trust challenged the attesting physician's conclusion, Dr. Vigilante confirmed the

attesting physician's finding of moderate mitral regurgitation.[6] Specifically, Dr. Vigilante concluded that claimant's echocardiogram "demonstrates moderate mitral regurgitation."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Vigilante found that claimant's "RJA/LAA ratio was 25% in both the apical two chamber and apical four chamber views." Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim. 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 A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Linman for Matrix Benefits.

---

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