

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 )  
CORPORATION ) 2:16 MD 1203

**MEMORANDUM AND PRETRIAL ORDER NO.**

Bartle, C.J.

January 29, 2007

Marcell Croteau<sup>1</sup> ("Ms. Croteau" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,<sup>2</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>3</sup> 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>4</sup>

- 
1. Claimant is Pro Se.
  2. Prior to March 11, 2002 Wyeth was known as American Home Products Corporation.
  3. Ms. Croteau's spouse and children submitted derivative claims for benefits.
  4. Matrix benefits are paid according to two benefit matrices  
(continued...)

To seek Matrix Benefits, a claimant must 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 in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In or about July 2001, claimant submitted Part II of her Green Form to the Trust.<sup>5</sup> Based on a transesophageal echocardiogram dated April 5, 2001, claimant's physician, Dr.

---

4.(...continued)

(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 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.

5. Claimant submitted two Green Forms. The first form was completed by Paul Peterson, M.D., and was based on an echocardiogram dated March 22, 2000. The second form was completed by Edward Gibbons, M.D., and was based on an echocardiogram dated April 5, 2001. The Green Form completed by Dr. Gibbons is at issue in these proceedings.

Gibbons, attested in Part II of her Green Form that she suffered from severe aortic regurgitation. Mild or greater aortic regurgitation is defined as "regurgitant jet diameter in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable), equal to or greater than ten percent (10%) of the outflow tract diameter ("JH/LVOTH") [Jet Height/Left Ventricular Outflow Tract Height ratio]." Settlement Agreement § I.22. Severe aortic regurgitation is defined as greater than 49% JH/LVOTH. See id. § IV.B.2.c.(1)(a).

In the provider notes related to claimant's echocardiogram, Dr. Gibbons stated that the echocardiogram demonstrated "significant aortic insufficiency, greater than 3+" and "[t]here is a central orifice through which there is a moderately severe jet of aortic insufficiency. This is graded at least 3+."<sup>6</sup> If accepted, claimant would be entitled to Matrix A-1, Level I benefits in the amount of \$100,795.00.<sup>7</sup>

---

6. Dr. Gibbons also attested that claimant had mild mitral regurgitation, mild or greater aortic regurgitation with bacterial endocarditis, and an ejection fraction between 50% and 60%. In her show cause submissions, claimant agreed that she did not have bacterial endocarditis. The other two conditions do not support a claim for damage to the aortic valve.

7. In Part I of her Green Form, claimant indicated that she was seeking Level II Matrix benefits. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the aortic valve if he or she is diagnosed with moderate or severe aortic regurgitation and one of three complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(a). Part II of Claimant's Green Form does not

(continued...)

In October 2002, the Trust forwarded the claim at issue to Benjamin Citrin, M.D., one of its auditing cardiologists, for review. In audit, Dr. Citrin concluded that there was no reasonable medical basis for Dr. Gibbons' finding that claimant had severe aortic regurgitation because the "aortic insufficiency appears moderate by criteria." Dr. Citrin was not asked to review any other answers in Part II of claimant's Green Form.

Thereafter, the Trust issued a post-audit determination denying Ms. Croteau's claim.<sup>8</sup> Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant contested 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; Pretrial Order ("PTO") No. 2457, Audit Policies and Procedures § VI.<sup>9</sup> The Trust

---

7.(...continued)

indicate that she has any of the complicating factors needed to qualify for Level II benefits. A claimant, however, is eligible for Level I benefits if he or she is diagnosed with severe aortic regurgitation. See id. § IV.B.2.c.(1). Thus, given claimant's assertion that she had severe aortic regurgitation, we must determine whether she is entitled to Level I benefits.

8. Based on findings in audit, the Trust issues a post-audit determination regarding whether or not a claimant is entitled to Matrix benefits.

9. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. See 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. See PTO No. 2807 (Mar. 26, 2003).

then applied to the court for issuance of an Order to show cause why Ms. Croteau's claim should be paid. On July 31, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2950 (Jul. 31, 2003).

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 on October 26, 2003. The Trust submitted a reply on October 25, 2004. Under the Audit Policies and Procedures it is within the Special Master's discretion to appoint a Technical Advisor<sup>10</sup> to review 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 a Technical Advisor, Gary J. Vigilante, 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. Audit Policies and Procedures § VI.O.

---

10. 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. See id. 863 F.2d at 158 (use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper).

The sole 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 aortic 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, Ms. Croteau primarily relies on two letters prepared by Dr. Gibbons, which are dated June 1, 2004 and December 6, 2004. In the letter dated June 1, 2004, Dr. Gibbons stated, in pertinent part, that:

I find unequivocal evidence that the degree of aortic insufficiency is severe and that the echocardiograms done under my supervision on April 4, 2001 and April 5, 2001; the latter a transesophageal study demonstrate [sic] the left ventricular outflow tract aortic insufficiency greater than 80% of the left ventricular outflow tract. The pressure half-time of decay of aortic insufficiency was 235 msec, and that there was flow reversal in the descending thoracic aorta. Moreover, the ejection fraction was 69%, hyperdynamic, consistent with the stimulus of volume overload from the aortic insufficiency ... the patient has had no evidence for endocarditis or congenital valvular disease  
....

Dr. Gibbons' Jun. 1, 2004 Letter, at ¶¶ 2, 5 (attached to Claimant's Show Cause Response).

The Technical Advisor, Dr. Vigilante, concluded that there was a reasonable medical basis for the attesting physician's finding of severe aortic regurgitation. A claimant seeking Matrix benefits must provide an echocardiogram that meets specific and defined criteria. See Settlement Agreement § VI.C.1. An attesting physician's opinion has a reasonable medical basis if the underlying echocardiogram supports the conclusions reflected in Part II of the Green Form.

Claimant's attesting physician, Dr. Gibbons, found that claimant had severe aortic regurgitation. Although the Trust contested the attesting physician's conclusion, the Technical Advisor confirmed that claimant had severe aortic regurgitation. Based upon his review of claimant's April 5, 2001 echocardiogram, the Technical Advisor explained that:

The TEE<sup>11</sup> of April 5, 2001 had 17 images. This demonstrates that the aortic valve is trileaflet without vegetation seen. There is incomplete closure during diastole. Color flow particularly in image 13 is consistent with severe aortic insufficiency with a JH/LVOTH of 65%.

---

11. "TEE" stands for transesophageal echocardiogram. As described in Echocardiography by Harvey Feigenbaum, M.D., which is referenced in the Settlement Agreement, transesophageal echocardiography examinations are invasive and provide "an excellent view of the heart because the ultrasonic beam is unobstructed by lung or chest wall." Harvey Feigenbaum, M.D., Echocardiography 106, 107 (5th ed. 1994).

Dr. Vigilante also reviewed four other echocardiograms submitted with Ms. Croteau's claim, dated April 4, 2001, August 16, 2001, March 22, 2000, and April 28, 2000. He concluded that, in addition to the April 5, 2001 TEE, claimant's April 28, 2000 TEE also demonstrated severe aortic regurgitation and that: (1) the April 4, 2001 echocardiogram, which contained 49 images, suggested moderate to severe aortic insufficiency; (2) the August 16, 2001 echocardiogram, which contained 59 images, demonstrated moderate to severe aortic insufficiency; and (3) the March 22, 2000 echocardiogram demonstrated moderate aortic insufficiency.

Although the Settlement Agreement contemplates the submission of a transthoracic echocardiogram, the Trust did not object to the use of the TEE submitted by claimant and forwarded the TEE to its auditing cardiologist for review.<sup>12</sup> See, e.g., Settlement Agreement §§ I.22.b., VI.C.1.b. In the particular context of this claim, it is appropriate to consider claimant's TEE in conjunction with the other echocardiograms she has submitted. Based on the Technical Advisor's conclusions regarding these echocardiograms, claimant has met her burden in establishing a reasonable medical basis for her attesting physician's conclusion that she had severe aortic regurgitation.

---

12. In addition, it should be noted that we previously authorized the use of transesophageal echocardiograms in the context of the Parallel Processing Program. See PTO No. 3882, Ex. A, § 7.

Based on our review of the entire Show Cause Record, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim. Therefore, claimant is entitled to Matrix A-1, Level I benefits and her spouse and children are entitled to derivative benefits to the extent provided by the Settlement Agreement.

