

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.

June 28, 2007

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

---

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

2. Peter Harrington, Ms. Cormack's spouse, also submitted a derivative claim for benefits.

3. 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  
(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 February 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Irvin F. Goldenberg, M.D. Based on an echocardiogram dated February 2, 2002, Dr. Goldenberg attested in Part II of her Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and an ejection fraction in the range of 50% and 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$497,928.

---

3(...continued)  
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.

In the report of claimant's echocardiogram, Wesley R. Pedersen, M.D., the reviewing cardiologist, stated that: "[d]oppler examination reveals moderate mitral regurgitation, with a regurgitant jet area/left atrial area (RJA/LAA) ratio in the apical views of between 25%-35%." 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. Pedersen also found "[l]eft atrial enlargement," which he measured as 4.3 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. Pedersen estimated claimant's ejection as "55-60%." 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 September 2002, the Trust forwarded the claim for review by Keith B. Churchwell, M.D., one of its auditing cardiologists. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Goldenberg's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Churchwell also found that: "[m]ultiple measurements were

performed on the tape, all underestimated the area of LA [left atrial] size which led to a [sic] overestimate of the LA/MR ratio."<sup>4</sup> Dr. Churchwell, however, did not contest the finding that claimant's left atrial dimension was enlarged.<sup>5</sup>

Based on Dr. Churchwell's finding of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Cormack's claim. 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 (May 31, 2002), Audit Policies and Procedures § VI.<sup>6</sup> The Trust then applied to the court for issuance of an

---

4. Dr. Churchwell also concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had a reduced ejection fraction. As discussed infra, it is unnecessary to address the issue of claimant's ejection fraction.

5. 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 an abnormal left atrial dimension, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. 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

(continued...)

Order to show cause why Ms. Cormack's claim should be paid. On February 6, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2735 (Feb. 6, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. In lieu of a response, claimant submitted a letter to the Special Master's office on March 13, 2003 indicating that she was standing by the materials submitted with her Green Form.

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 moderate 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.

---

6(...continued)

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 Ms. Cormack's claim.

After reviewing the entire Show Cause Record, we find that there is no reasonable medical basis for the attesting physician's diagnosis that claimant had moderate mitral regurgitation. First, and of crucial importance, claimant chose not to respond to the Trust's statement of the case and supporting documentation.<sup>7</sup> In support of her claim, Ms. Cormack rests only on Dr. Goldenberg's check-the-box diagnosis on her Green Form and Dr. Pedersen's echocardiogram report.<sup>8</sup> Claimant did not dispute or respond to Dr. Churchwell's determination that she had mild mitral regurgitation and that: "[m]ultiple measurements were performed on the tape, all underestimated the area of LA [left atrial] size which led to a [sic] overestimate of the LA/MR ratio." Although she bears the burden of proof in show cause, claimant failed to present any arguments or factual evidence to establish that Dr. Churchwell's findings were erroneous. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

Moreover, Dr. Churchwell determined, and claimant does not dispute, that all of the measurements relied on by claimant's attesting physician to support her claim were improper and

---

7. Despite an opportunity to do so, claimant did not submit a response to the Trust's statement of the case and supporting documentation. See Audit Policies and Procedures § VI.E.

8. Part II of the Green Form, to be completed by a claimant's physician, consists of approximately 45 "yes/no" and two multiple choice questions.

overestimated the level of claimant's mitral regurgitation. Such an unacceptable practice by claimant's physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Cormack's claim for Matrix benefits and the related derivative claim submitted by her spouse.

