

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.)
) CIVIL ACTION NO. 99-20593
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

August 24, 2007

Janet Gray ("Ms. Gray" 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").² 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").³

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

2. Clifford C. Gray, Ms. Gray's spouse, also has 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 contributed to a claimant's valvular heart disease ("VHD"). See (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, Edward M. Gilbert, M.D. Based on an echocardiogram dated May 8, 2002, Dr. Gilbert attested in Part II of Ms. Gray's Green Form that she suffered from severe aortic regurgitation and moderate mitral regurgitation.⁴ Based on such findings, claimant would be

3. (...continued)

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 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.

4. Ms. Gray's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her mitral valve. Thus, her level of mitral regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(b).

entitled to Matrix A-1, Level I benefits in the amount of \$89,910.⁵

The report of claimant's echocardiogram, prepared by David Kemp, M.D., stated that claimant suffered from "[s]evere aortic insufficiency." Under the definition set forth in the Settlement Agreement, severe aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable), is greater than 49% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22. & IV.B.2.c.(1)(a).

In October 2003, the Trust forwarded the claim for review by James Mathewson, M.D., one of its auditing cardiologists. In audit, Dr. Mathewson found that claimant had only mild aortic regurgitation. The auditing cardiologist explained that the "jet length is consistent with only 2+ or mild AI."

Based on Dr. Mathewson's diagnosis of mild aortic regurgitation, the Trust issued a post-audit determination denying Ms. Gray's claim. Pursuant to the Rules for the Audit of

5. Under the Settlement Agreement, a claimant is entitled to Level I benefits for damage to the aortic valve if he or she is diagnosed with severe aortic regurgitation. See Settlement Agreement § IV.B.2.c.(1)(a).

Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶

In contest, claimant submitted a verified statement from Dr. Gilbert. Based on Dr. Gilbert's verified statement, claimant argued that the auditing cardiologist made a "crucial error" because the attesting physician "was able to discern the anterior leaflet of the mitral valve and the leaflets of the aortic valve and measure the height of the aortic regurgitant jet to exceed 50% of the LV outflow track." Claimant also argued that "there was no clinical evidence of cardiac illness prior to the fen phen use." Additionally, claimant submitted a second echocardiogram, dated November 24, 2003, which was performed by Dr. Kemp.⁷ In reviewing this second echocardiogram, Dr. Kemp again found that claimant suffered from severe aortic regurgitation.

The Trust then issued a final post-audit determination, again denying Ms. Gray's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See

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 approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Gray's claim.

7. The Green Form was based on the echocardiogram dated May 8, 2002.

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. Gray's claim should be paid. On September 13, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3927 (Sept. 13, 2004).

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, requesting that the matter be referred to a Technical Advisor. The Trust submitted a reply on December 28, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ 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, 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. Id. Rule 35.

8. 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 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 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 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 for the answers, 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. Gray relies on her contest materials. Claimant also requests that her November 24, 2003 echocardiogram be considered in this determination. In response, the Trust argues that claimant has not established a reasonable medical basis for her claim. In addition, the Trust argues that the November 24, 2003 echocardiogram was not claimant's "echocardiogram of attestation, and was only submitted to the Trust in January 2004, well after Dr. Mathewson had completed his audit of the claim in October, 2003."

The Technical Advisor, Dr. Vigilante, reviewed claimant's May 8, 2002 echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's

finding of severe aortic regurgitation.⁹ More specifically, Dr. Vigilante found that:

... [A]lthough this study was suboptimal, the apical long axis view did allow for accurate determination of left ventricular outflow tract and aortic regurgitation jet height. I determined that the LVOTH was 2.0 cm in the apical long axis view. The JH was 1.1 cm. Therefore, the JH/LVOTH was 55%. This was noted in several cardiac cycles in the apical long-axis view.

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 May 8, 2002 echocardiogram and found severe aortic regurgitation. Although the Trust contested the attesting physician's conclusion, Dr. Vigilante confirmed the attesting physician's finding.¹⁰ Specifically, Dr. Vigilante concluded that "[i]n response to Question 1, there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.2.b."

As stated above, severe aortic regurgitation is present where the regurgitant JH in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable), is greater than 49% of the LVOTH. See Settlement

9. Although unnecessary for resolution of this claim, Dr. Vigilante also reviewed claimant's November 24, 2003 echocardiogram and concluded that claimant had severe aortic regurgitation.

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

Agreement §§ I.22. & IV.B.2.c.(1)(a). Here, Dr. Vigilante found that claimant's "JH/LVOTH was 55%."¹¹

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for finding that she had severe aortic regurgitation and is entitled to Matrix A-1, Level I benefits. Therefore, we will reverse the post-audit determination by the Trust and order that claimant and her spouse be paid in accordance with the Settlement Agreement.

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

