

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

Verna Mays ("Ms. Mays" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,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. Bruce Mays, Ms. Mays' spouse, 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

(continued...)

To apply for 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. To obtain Matrix Benefits, a claimant must establish that there is a reasonable medical basis for his or her claim under the criteria set forth in the Settlement Agreement. Accordingly, a claimant may recover benefits if the attesting physician's reading of the echocardiogram, and thus his or her accompanying Green Form, has a reasonable medical basis.

In April 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Nanette B.

3.(...continued)

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 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.

Oscherwitz, M.D. Based on an echocardiogram dated March 22, 2002, Dr. Oscherwitz attested in Part II of Ms. Mays' Green Form that she suffered from moderate mitral regurgitation and an enlarged left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$384,221.

In the report of claimant's echocardiogram, Dr. Oscherwitz indicated, in pertinent part, that claimant had moderate mitral regurgitation with a Regurgitant Jet Area/Left Atrial Area ("RJA/LAA") ratio of 24%. Under the definition set forth in the Settlement Agreement, 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. Dr. Oscherwitz also stated that claimant's left atrium measured 5.27 cm in the parasternal long axis view. 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).

In January, 2003, the Trust forwarded the claim for review by Craig Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for Dr. Oscherwitz's finding that claimant had moderate mitral regurgitation, but that there was a reasonable

medical basis for the finding of an abnormal left atrial dimension.

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). An abnormal left atrial dimension is one of the five complicating factors. The Trust did not contest the attesting physician's finding of an abnormal left atrial dimension.

Based on Dr. Oliner's conclusion, the Trust issued a post-audit determination denying Ms. Mays' claim.⁴ 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.⁵ The Trust then applied to the court for issuance of an

4. Based on findings in audit, the Trust issues a post-audit determination regarding whether a claimant is entitled to Matrix benefits.

5. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in 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 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Mays' claim.

Order to show cause why Ms. Mays' claim should be paid. On May 19, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2861 (May 19, 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 June 24, 2003. The Trust submitted a reply on June 30, 2003. Under the Audit Policies and Procedures it is within the Special Master's discretion to appoint a Technical Advisor⁶ 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.

In support of her claim, Ms. Mays argues in her show cause submissions that the phrase "reasonable medical basis"

6. 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. (use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper).

means that an attesting physician's conclusion must be accepted unless it is "so slanted or of such obvious misleading nature it could not be accepted by a reasonable Level II trained cardiologist." Claimant also argues that the auditing cardiologist's conclusion should be disregarded because he did not make specific measurements to determine her RJA/LAA ratio and that two other doctors substantiated the findings of her attesting physician. In support, Ms. Mays relies on a September 5, 2002 Transesophageal Echocardiogram ("TEE") report, in which Dr. Poornima interprets claimant's mitral regurgitation as "mild to moderate." Ms. Mays also provided a cardiac catheterization report, prepared by Jerome E. Granato, M.D., in which her mitral regurgitation was described as "3+." Finally, claimant argues that her claim should be paid because the Trust did not comply with the deadlines set forth in the Audit Policies and Procedures.

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. The Trust also argues that the manner in which Dr. Oliner evaluated claimant's level of regurgitation complied with the Settlement Agreement and claimant cannot meet her burden of proof simply by relying on the results of her TEE and cardiac catheterization.

The Technical Advisor, Dr. Vigilante, concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Dr.

Vigilante also confirmed that claimant had left atrial enlargement.

Claimant's attesting physician, Dr. Oscherwitz, found moderate mitral regurgitation and an RJA/LAA ratio of 24%. Although the Trust contested the attesting physician's conclusion, the Technical Advisor confirmed the attesting physician's findings.⁷ Specifically, the Technical Advisor concluded that claimant's March 22, 2002 echocardiogram demonstrated moderate mitral regurgitation in the apical four chamber view. As explained by the Technical Advisor:

[i]n the parasternal long axis view, only mild mitral regurgitation was seen. However, more significant mitral regurgitation was seen in the apical four chamber view. From tape marker 15:02:08 through 15:02:11, four cardiac cycles were noted where moderate mitral regurgitation was present. RJA/LAA ratio was averaged at 22%. It should be noted that the color flow images were quite reasonable with appropriate gain settings. Tracing of the RJA and LAA were straightforward.

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. The Technical Advisor found that moderate mitral regurgitation was visible in the apical four chamber view and that claimant's echocardiogram exhibited reasonable color flow images and appropriate gain settings. Under these circumstances, claimant

7. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor's Report. See Audit Policies and Procedures § VI.N.

has met her burden in establishing a reasonable medical basis for her claim.

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 moderate mitral regurgitation. Therefore, we will reverse the Trust's denial of the claims submitted by Ms. Mays and her spouse for Matrix benefits.

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AND NOW, on this 29th day of January, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the post-audit determination of the AHP Settlement Trust is REVERSED and that the Level II claims submitted by claimants Verna Mays and her spouse, Bruce Mays, are GRANTED. 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.