

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.

August 24, 2007

Michelle L. McGeeney ("Ms. McGeeney" 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
(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 March 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, John P. Orchard, M.D., F.A.C.C. Based on an echocardiogram dated November 30, 2001, Dr. Orchard attested in Part II of Ms. McGeeney's Green Form that she suffered from moderate mitral regurgitation 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 in the amount of \$574,011.

2(...continued)
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.

In the report of claimant's echocardiogram, Dr. Orchard stated that claimant had "[m]oderate mitral regurgitation - ratio 34%." 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. Orchard also estimated claimant's ejection fraction as 56%. 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 2003, the Trust forwarded the claim for review by Susan D. Tiukinhoy, M.D., one of its auditing cardiologists. In audit, Dr. Tiukinhoy concluded that there was no reasonable medical basis for Dr. Orchard's finding of a reduced ejection fraction. Specifically, Dr. Tiukinhoy noted that claimant's ejection fraction was "clearly normal, >65%." Dr. Tiukinhoy, however, concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.³

3. 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 findings of moderate mitral regurgitation, the only issue is whether claimant has a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim.

Based on Dr. Tiukinhoy's diagnosis, the Trust issued a post-audit determination denying Ms. McGeeney'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 an affidavit and letter from Dr. Orchard, in which he attested that claimant had an ejection fraction between 50% and 60%. Claimant also submitted an affidavit from Allen L. Dollar, M.D., wherein he stated that, based upon his review of claimant's echocardiogram and his experience in the field of echocardiography, he found that claimant's ejection fraction was between 55% and 60%. Based on these submissions, claimant asserted that she had established a reasonable medical basis for her attesting physician's Green Form response regarding a reduced ejection fraction.

The Trust then issued a final post-audit determination, again denying Ms. McGeeney'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 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. McGeeney's claim

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. McGeeney's claim.

should be paid. On March 11, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3358 (Mar. 11, 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. The Trust submitted a reply on July 13, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁵ 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, James F. Burke, M.D., 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.

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 a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical

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 a Technical Advisor to reconcile such opinions. The use a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

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 answer, 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. McGeeney argues, among other things, that there is a reasonable medical basis for her claim because an "independent cardiologist with level III training in echocardiography" reached the same conclusions as to her medical condition as did the attesting physician. Claimant also contends that she is unable "to adequately address Dr. Tiukinhoy's opinion with any degree of certainty since she never fully explains her reasoning."

In response, the Trust argues that claimant has not met her burden because she merely has provided cumulative information. The Trust also contends that Dr. Tiukinhoy properly applied the reasonable medical basis standard and provided an explanation for her findings in accordance with the Settlement Agreement and the Audit Rules.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of an ejection fraction in the range of 50% to 60%. Specifically, Dr. Burke concluded that "[b]ased on my calculations, and my visual

assessment of global left ventricular systolic function, I estimate the left ventricular ejection fraction is in the range of 50 to 60%."

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 a reduced ejection fraction in the range of 50% to 60%. Although the Trust contested the attesting physician's conclusion, Dr. Burke confirmed the attesting physician's finding of a reduced ejection fraction. Specifically, Dr. Burke concluded that "there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question F.8., which states that the Claimant's ejection fraction is in the range of 50 to 60%."⁶

As stated above, 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 Settlement Agreement § IV.B.2.c.(2)(b). Here, Dr. Burke found that claimant's ejection fraction was in the range of 50% to 60%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.⁷

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

7. 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. McGeeney for Matrix Benefits.

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PRETRIAL ORDER NO. _____

AND NOW, on this 24th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimant Michelle L. McGeeney is entitled to Matrix A-1, Level II benefits. 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.