

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.

May 31, 2007

Michelle Crawford ("Ms. Crawford" 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
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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 August 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Malcolm Taylor, M.D. Based on an echocardiogram dated June 18, 2001, Dr. Taylor attested in Part II of her Green Form that she suffered from moderate mitral regurgitation and a reduced 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 \$551,721.

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. Taylor stated that claimant had "[m]oderate mitral regurgitation with RJA/LAA ratio of 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. Taylor also stated that claimant had an "ejection fraction greater than 55%." 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 January 2002, the Trust forwarded the claim for review by Ernest C. Madu, M.D., F.A.C.C., one of its auditing cardiologists.³ In audit, Dr. Madu concluded that there was no reasonable medical basis for Dr. Taylor's finding that claimant had a reduced ejection fraction between 50% and 60%. Dr. Madu, however, was not asked to review claimant's level of mitral regurgitation.⁴

3. Under the Settlement Agreement, Wyeth and the Trust could each designate for audit a certain number of claims for Matrix Benefits and identify the condition(s) to be reviewed during the audit. See Settlement Agreement § VI.F; Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. In Pretrial Order ("PTO") No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

4. Under the Settlement Agreement, a claimant is entitled to
(continued...)

Based on Dr. Madu's diagnosis of a normal ejection fraction, the Trust issued a post-audit determination denying Ms. Crawford's claim.⁵ Pursuant to the 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; PTO No. 2457, Audit Policies and Procedures § VI.⁶ The Trust then applied to the court for issuance of an Order to show cause why Ms. Crawford's claim should be paid. On September 10, 2002, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2596 (Sept. 10, 2002).

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

5. Based on findings in audit, the Trust issues a post-audit determination regarding whether or not a claimant is entitled to Matrix benefits. A claimant may submit contest materials to challenge a post-audit determination. After considering any contest materials, the Trust then issues a final post-audit determination.

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 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. Crawford's claim.

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 January 15, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁷ 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 Technical Advisor, James F. Burke, M.D., 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. Id. § VI.O.

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. § 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

7. 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.

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. Crawford argues that her claim should be accepted because the attesting physician "again evaluated the June 18, 2001 echocardiogram and again found that it showed an ejection fraction of 55 to 60%."⁸ In particular, Dr. Taylor stated that "[t]his is especially apparent in the apical 4-chamber view."

In response, the Trust had Dr. Madu review claimant's echocardiogram for a second time. Based on this second review, Dr. Madu concluded that:

My review of this case confirms my prior determination that the LV ejection fraction is between 60-65% noted in my audit report of 01/21/2002.

* * *

The claimant's attesting cardiologist states that the ejection fraction is between 55 and 60% and points to the apical 4-chamber view as particularly demonstrating this finding.

8. In her show cause submissions, claimant also asserts that, based on the "re-evaluation" of her echocardiogram, Dr. Taylor found an abnormal left atrial dimension, which is another complicating factor under the Settlement Agreement. In claimant's Green Form, however, Dr. Taylor specifically attested that claimant did not have an abnormal left atrial dimension. Despite his change in position, the Affidavit prepared by Dr. Taylor does not explain why he changed his opinion about claimant's left atrial dimension. As the Trust notes, claimant also could have amended her Green Form to assert this condition, but she did not do so. We, therefore, will not consider this new complicating factor in reviewing the claim before us.

I do however disagree with this finding. Unfortunately in the apical 4-chamber view, the endocardial borders are inadequately visualized due to poor acoustic windows and therefore can not [sic] be relied upon for accurate estimation of LV ejection fraction. The LV endocardial borders are better delineated in the parasternal long axis view, the short axis view at the papillary muscle level and the apical 2-chamber view. In all of those views the estimated ejection fraction is about 65%.

Dr. Burke, the Technical Advisor, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had a reduced ejection fraction. Specifically, Dr. Burke concluded that: "[e]ven taking into account a variability in the calculation of LVEF [left ventricular ejection fraction], my evaluation yielded a result clearly not in this 55-60% range." Claimant did not refute or respond to the determination by the Technical Advisor.

After reviewing the entire Show Cause Record, we find claimant's arguments all without merit. First, and of crucial importance, claimant does not contest the analysis provided by Dr. Burke.⁹ Claimant does not challenge Dr. Burke's specific finding that claimant had a normal ejection fraction. Claimant also does not refute Dr. Burke's conclusion that, even taking into consideration reasonable ranges of variation, claimant's ejection fraction could not reasonably be found to be less than

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

or equal to 60%. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Crawford's claim for Matrix benefits.

