

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 IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, C.J.

August 31 , 2010

Marie Wyatt ("Ms. Wyatt" 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 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
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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. The claimant or the claimant's representative completes Part I of the Green Form. Part II is 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, claimant's attorney must complete Part III if claimant is represented.

In July, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Steven S. Gubin, M.D. Based on an echocardiogram dated February 11, 2002, Dr. Gubin attested in Part II of claimant'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 \$501,985.³

2. (...continued)

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.

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
(continued...)

In the report of claimant's echocardiogram, Dr. Gubin stated that claimant had an ejection fraction of 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 Settlement Agreement § IV.B.2.c.(2)(b)iv).

In January, 2004, the Trust forwarded the claim for review by Susan Tiukinhoy, M.D., one of its auditing cardiologists. In audit, Dr. Tiukinhoy found that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction in the range of 50% to 60%. Dr. Tiukinhoy stated that claimant's "[ejection fraction] was clearly normal in this study and is >60%." Specifically, Dr. Tiukinhoy observed that claimant's ejection fraction was "65%-70%."

Based on Dr. Tiukinhoy's finding of an ejection fraction greater than 60%, the Trust issued a post-audit determination denying Ms. Wyatt's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁴ In contest,

3. (...continued)
five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is claimant's ejection fraction, which is one of the complicating factors needed to qualify for a Level II 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
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claimant submitted a letter from Keith G. Anderson, M.D., F.A.C.C., in which he stated that "[t]he left ventricular ejection fraction is 60% as reported by the attesting cardiologist."

The Trust then issued a final post-audit determination, again denying Ms. Wyatt'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, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Wyatt's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5242 (May 20, 2005).

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 August 15, 2005, and claimant submitted a sur-reply on September 13, 2005. Under the Audit Rules, it is within the Special Master's discretion to

4. (...continued)
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. Wyatt's claim.

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 a Technical Advisor, Sandra V. Abramson, 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 Report are now before the court for final determination. See 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 is 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 is 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).

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 a case such as this, 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.

In support of her claim, Ms. Wyatt argues that rather than provide specific measurements for her ejection fraction, the auditing cardiologist stated "only the broad conclusion that it is greater than 60%." Claimant also submits that there is a reasonable medical basis for her claim because, in his letter, Dr. Anderson agreed with Dr. Gubin's findings.

In response, the Trust argues that Dr. Anderson's report does not establish a reasonable medical basis for Dr. Gubin's Green Form representation because it "merely echoes the Attesting Physician's finding that [claimant's] ejection fraction is 60%, without acknowledging or addressing any of the Auditing Cardiologist's specific findings at audit." In addition, the Trust asserts that Dr. Anderson's letter submitted with claimant's contest is improper because it was not verified in accordance with the Audit Rules.⁶

In her sur-reply, claimant submits an affidavit from Dr. Anderson. In his affidavit, Dr. Anderson stated that, "[a]fter reviewing the materials set forth above and taking my own independent measurements, I determined that Marie Wyatt

6. The Trust also argues that Dr. Anderson failed to disclose his qualifications, compensation, and a list of cases in which he has served as an expert, implying that Rule 26(a)(2) of the Federal Rules of Civil Procedure applies to show cause claims and that physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 at 7 n.10 (Feb. 26, 2007).

suffers from ... a left ventricular ejection fraction of 60%."

Dr. Anderson also verified his original report.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction in the range of 50% to 60%.

Specifically, Dr. Abramson concluded that:

In reviewing the transthoracic echocardiogram, it is obvious that the systolic function is normal. My visual estimate is that the ejection fraction is greater than 65%. The parasternal long axis view is the best view on this tape to visualize endocardium, but it is still possible to measure the ejection fraction in the apical views. Since the Simpson's Method of Disks is the preferred method to calculate an ejection fraction, I performed measurements on three cardiac cycles of the left ventricle in the apical views. The end diastolic volume/end systolic volume tracings were 105/33 ml, 98/31 ml, and 103/32 ml with ejection fractions of 69%, 68%, and 69%. All of these ejection fractions are significantly >65%.

Thus, there is no reasonable medical basis for the Attesting Physician to state that the Claimant's ejection fraction is in the range of 50%-60%, even allowing for inter-reader variability.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not contest the analysis provided by Dr. Abramson.⁷ Specifically, Dr. Abramson measured claimant's

7. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

ejection fraction in three cardiac cycles and concluded that her ejection fraction measured 69%, 68%, and 69%. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant that the affidavit of Dr. Anderson establishes a reasonable medical basis for the attesting physician's representation that Ms. Wyatt had a reduced ejection fraction. Contrary to claimant's argument, in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, Dr. Tiukinhoy reported that claimant's ejection fraction was in the range of "65%-70%." Neither claimant nor Dr. Anderson identifies any particular error in Dr. Tiukinhoy's findings. Mere disagreement with the auditing cardiologist without identifying and substantiating any specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof. On this basis as well, 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 of 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. Wyatt's claim for Matrix Benefits.

