

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.

April 12, 2007

Gracia Becker ("Ms. Becker" or "claimant") is a class member seeking benefits from the AHP Settlement Trust ("Trust"), which was established under the Diet Drug Nationwide Class Action Settlement Agreement with Wyeth¹ ("Settlement Agreement").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. Robert Becker, Ms. Becker's spouse, has also submitted a claim for derivative 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

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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. 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 answers, have a reasonable medical basis.

In June 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Roger W. Evans,

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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. and 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.

M.D. Based on an echocardiogram dated November 29, 2000, Dr. Evans 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% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$444,159.

In the report of claimant's echocardiogram, Admassu Hailu, M.D., the reviewing cardiologist, stated that claimant had mild mitral regurgitation and that her ejection fraction was between 55% and 60%. In a second report titled "Echocardiogram Reread," which is dated December 26, 2001, Dr. Evans reported that claimant's mitral regurgitation "occupies a ratio of about 25%." 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. Evans also stated that claimant's ejection fraction was 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 September 2003, the Trust forwarded the claim for review by Ioannis P. Panidis, M.D., one of its auditing cardiologists. In audit, Dr. Panidis found that claimant's ejection fraction was between 61% and 65%, and concluded that there was no reasonable medical basis for the attesting

physician's finding of an ejection fraction of less than or equal to 60%. Dr. Panidis initially concluded that there was no reasonable medical basis for Dr. Evans' finding that claimant had moderate mitral regurgitation, but she later conceded that there was a reasonable medical basis for that finding.⁴

Based on Dr. Panidis' finding of a reduced ejection fraction, the Trust issued a post-audit determination denying Ms. Becker's claim.⁵ Pursuant to the Rules for the Audit of Matrix Compensation Benefits ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued, among other things, that Dr. Panidis failed to apply a "reasonable medical basis" standard, and instead substituted her own personal

4. 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 ultimately 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 Level II benefits.

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 Audit Policies and Procedures, as approved in Pretrial Order ("PTO") No. 2457. See 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. See PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Becker's claim.

opinions. In support, claimant also provided a supplemental opinion from Dr. Evans, in which he reconfirmed his finding of an ejection fraction between 50% and 60%.⁷

The Trust then issued a final post-audit determination, again denying Ms. Becker'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. Becker's claim should be paid. On March 26, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3380 (Mar. 26, 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 November 4, 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

7. Ms. Becker also provided opinions from Drs. Reader, Boxberger, and Francisco. Dr. Reader stated that her ejection fraction was "about 60%," Dr. Boxberger found it to be in the range of 55% and 60%, and Dr. Francisco stated that it was "approximately 60%."

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

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claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Sandra V. Abramson, 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. Id. at 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 basis for the answer in claimant's Green Form that is at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. at Rule 38(a). 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. 38(b).

In support of her claim, Ms. Becker argues in her show cause submissions that there was a reasonable medical basis for the finding that her ejection fraction was between 50% and 60%.

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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. See id.

According to claimant, inter-reader variability accounts for the differences in the opinions of her cardiologists and the Trust's auditing cardiologist.

Dr. Abramson reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of an ejection fraction between 50% and 60%. Specifically, Dr. Abramson concluded that:

Based on my review of the Special Master Record and the transthoracic echocardiogram dated 11/29/00, there is a reasonable medical basis for the Attesting Physician's assertion that [Ms. Becker] does have an ejection fraction in the range of 50%-60%.

This study is a very poor quality study which makes it difficult to interpret. By visual estimation, I found that the ejection fraction appeared to be between 50% and 60%. As the ejection fraction appeared to be close to 60%, I decided to make some measurements in order to get a more exact determination. Despite the technical limitations of the study, I measured four ejection fractions in the apical views. The range of these ejection fractions is 58%-63% with an average of 61%. This ejection fraction could reasonably be found to be within the range of 50% to 60% as stated by the Attesting Physician.

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, Dr. Evans, reviewed claimant's echocardiogram and found that claimant had a reduced ejection fraction.⁹ Although the Trust contested the

9. Although unnecessary for resolution of this claim, as noted above, claimant also submitted opinions from Drs. Reader,
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attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's findings.¹⁰ Specifically, Dr. Abramson concluded that claimant's "ejection fraction could reasonably be found to be within the range of 50% to 60% as stated by the Attesting Physician."¹¹ 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 id. at § IV.B.2.c.(2)(b). Here, Dr. Abramson measured four ejection fractions in the apical views and determined that the range of these ejection fractions was between 58% and 63%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim. 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. We will reverse the Trust's denial of the

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Boxberger, and Francisco, all of whom supported a finding of an ejection fraction of less than or equal to 60%.

10. In its show cause submissions, the Trust argues that, under Federal Rule of Civil Procedure 26(a)(2), 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 Policies and Procedures. See PTO No. 6997 (Feb. 26, 2007).

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

claims submitted by Ms. Becker and her spouse for Matrix Benefits.

