

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 23, 2007

Debra Blackson ("Ms. Blackson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> 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").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. James E. Blackson, Sr., Ms. Blackson's spouse, also has 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 presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (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 April 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician Arnold B. Meshkov, M.D. Based on an echocardiogram dated December 17, 1998, Dr. Meshkov attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction between 50% and 60%.<sup>4</sup> Based on such

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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.

4. Dr. Meshkov also attested that Ms. Blackson had mild aortic regurgitation. As Ms. Blackson's claim does not present any of the conditions necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$567,341.

In the report of claimant's echocardiogram, Stephen E. Weinberg, M.D., the reviewing cardiologist, stated that claimant suffered from "[m]ild to moderate mitral regurgitation," but did not specify a percentage as to the level of claimant's mitral regurgitation. 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. Weinberg also estimated claimant's ejection fraction as 60% to 65%. 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. § IV.B.2.c.(2)(b).

In June 2005, the Trust forwarded the claim for review by Siu-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Yao concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction because the "visual EF" was greater than 60%. Dr. Yao, however, found that claimant had moderate mitral regurgitation.<sup>5</sup>

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5. 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 id. § IV.B.2.c.(2)(b). As the Trust did not contest the  
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Based on Dr. Yao's diagnosis of an ejection fraction greater than 60%, the Trust issued a post-audit determination denying Ms. Blackson's claim.<sup>6</sup> Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant submitted a supplemental report from Dr. Meshkov. In his report, Dr. Meshkov stated that:

With regard to the left ventricular ejection fraction I maintain an opinion with a reasonable degree of medical certainty that Ms. Blackson's left ventricular ejection fraction was between 50 and 60%.

\* \* \*

In my experience and in my opinion, an ejection fraction over 60% is associated with evidence of hypercontractile function of the left ventricle as well as very small volume in the ventricle at the end of systole. This

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attesting physician's finding 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 Level II benefits.

6. Based on findings in audit, the Trust issues a post-audit determination regarding whether 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.

7. 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. Blackson's claim.

was not demonstrated on Ms. Blackson's echocardiogram. Therefore I have confidence in my visual assessment of an ejection fraction in this case of between 50 and 60%.

Claimant argued that the supplemental opinion of Dr. Meshkov presented a reasonable medical basis for her claim. Claimant also argued that Dr. Weinberg, the physician who prepared the report for her echocardiogram, opined that her ejection fraction "certainly could have been 60%, which supports Dr. Meshkov's finding."

The Trust then issued a final post-audit determination, again denying Ms. Blackson'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. Blackson's claim should be paid. On January 19, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5953 (Jan. 19, 2006).

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 April 19, 2006. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor<sup>8</sup> 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, Gary J. Vigilante, 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'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 between 50% and 60%. 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 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).

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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 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. 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. Blackson reasserts the arguments she made in contest. Claimant also argues, among other things, that her attesting physician's interpretation of her echocardiogram was reasonable and "based on sound, basic medical principles and techniques which are well known and accepted within the medical community." Claimant further contends that the auditing cardiologist: (1) did not apply the proper standard and instead dismissed the supportive evidence provided to the Trust; (2) found "in a very conclusory fashion" that the attesting physician's opinion had no reasonable medical basis; and (3) should have considered whether "a 5% difference in opinion in the contest of estimating left ventricular ejection fractions without more is enough to fall outside of a 'normal clinical judgment.'"

The Trust counters that the auditing cardiologist applied the proper standard and found that the attesting physician's finding "was beyond the bounds of medical reason." The Trust further argues that: (1) Dr. Meshkov is a "high Green Form filer" having attested to at least 124 Green Forms; (2) claimant bears the burden of proof and she has failed to show a reasonable medical basis for her claim; and (3) claimant's argument regarding the 5% difference in opinion is without merit as "the parties drew the line at 60% for the ejection fraction."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of

a reduced ejection fraction between 50% and 60%. Specifically, Dr. Vigilante concluded that:

The left ventricle was normal in size with good contractility and no abnormal wall motion. I digitized several representative cardiac cycles. I traced appropriate still frames of left ventricular end diastole and left ventricular end systole. Using Simpson's Rule, end diastolic and end systolic volumes were calculated and the ejection fraction was calculated. The ejection fraction values were in the range of 56%-62%. It should be noted that adequate endocardial definition was able to be determined in the measurements of left ventricular end diastolic and end systolic volumes.

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. Meshkov, reviewed claimant's echocardiogram and found that claimant had a reduced ejection fraction between 50% and 60%. Although the Trust contested the attesting physician's conclusion, Dr. Vigilante confirmed the attesting physician's findings.<sup>9</sup> Specifically, Dr. Vigilante concluded that "[t]he ejection fraction values were in the range of 56%-62%." 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). Under these

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

circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.<sup>10</sup>

For the foregoing reasons, we conclude that claimant has met her burden of 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 claims submitted by Ms. Blackson and her spouse for Matrix Benefits.

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10. Accordingly, we need not address claimant's remaining arguments.

