

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 IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, C.J.

September 2, 2010

Judy Holmes ("Ms. Holmes" 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").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. Larry G. Holmes, claimant'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
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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 April, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Bradley C. Banks, M.D., F.A.C.C. Based on an echocardiogram dated April 26, 2002, Dr. Banks attested in Part II of claimant's Green Form that Ms. Holmes suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left atrial dimension.⁴ Based on

3. (...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.

4. Dr. Banks also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition,
(continued...)

such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$501,985.⁵

In the report of claimant's echocardiogram, Dr. Banks stated that claimant's "[e]stimated [pulmonary artery systolic pressure] is in the 35 mmHg range." Pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic pulmonary artery pressure greater than 40 mmHg measured by cardiac catheterization or greater than 45 mmHg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mmHg. See Settlement Agreement § IV.B.2.c.(2)(b)I). Dr. Banks also measured claimant's left atrial dimension as 3.4 cm and noted "[n]ormal intracavitary dimensions." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii).

4. (...continued)
however, is not at issue in this claim.

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 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 issues are claimant's pulmonary hypertension and abnormal left atrial dimension, each of which is one of the complicating factors needed to qualify for a Level II claim.

In October, 2003, the Trust forwarded the claim for review by Eduardo A. Arazoza, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Arazoza determined that there was no reasonable medical basis for the attesting physician's finding that claimant had pulmonary hypertension secondary to moderate or greater mitral regurgitation or an abnormal left atrial dimension. Specifically, Dr. Arazoza measured claimant's pulmonary artery systolic pressure at 35 mmHg and stated that there was "[n]o evidence of pulmonary hypertension by the echo[cardiographic] study." Dr. Arazoza also determined that claimant's left atrium was not enlarged, measuring claimant's left atrial dimension at 3.4 cm in the parasternal long-axis view and 4.5 cm in the apical four-chamber view. In addition, Dr. Arazoza observed that claimant's ejection fraction was in the range of 50% to 60%,⁶ but concluded that there was a reasonable medical basis for the attesting physician's finding that claimant did not have a reduced ejection fraction.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷

6. A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim. Under the Settlement Agreement, 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)iv).

7. Claims placed into audit on or before December 1, 2002 are
(continued...)

In contest, claimant did not assert that there was a reasonable medical basis for the attesting physician's representations that she suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation or an abnormal left atrial dimension. Instead, she argued that Dr. Arazoza's finding of a reduced ejection fraction in the range of 50% to 60% entitled her to Level II Matrix Benefits. Claimant also noted that despite his Green Form representation, Dr. Banks actually agreed with Dr. Arazoza because he stated in the echocardiogram report that "[g]lobal biventricular systolic function is normal with a visually estimated left ventricular ejection fraction of 0.50. Of note, left ventricular ejection fraction may underestimate the degree of systolic dysfunction and the presence of significant mitral regurgitation." Moreover, claimant argues that Audit Rule 5 applies to claims involving intentional misrepresentation, not claims "where the auditing cardiologist makes an affirmative finding that the attesting cardiologist did not make, but where reasonable medical minds may disagree."

The Trust then issued a final post-audit determination again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show

7. (...continued)
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 the claim of Ms. Holmes.

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 the 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. 5240 (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 November 17, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ 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, 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 Report are now before the court for final determination. See id. Rule 35.

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 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.

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 finding that she had at least one complicating factor necessary to receive Level II Matrix Benefits. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for this claim, 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 this claim, 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. Holmes reasserts the arguments that she made in contest; namely, that she is entitled to Matrix Benefits because the auditing cardiologist found a reduced ejection fraction, which is consistent with the attesting physician's finding in the original echocardiogram report. Claimant also includes a letter from Victor E. Mejia, M.D., F.A.C.P., F.A.C.C., her treating physician, who stated that he "found that her echocardiogram dating April 26, 2002 clearly indicated an ejection fraction at or close to 50%, or less." Dr. Mejia also explained that "[d]ue to the complexity of the 'Green Form,'" Dr. Banks "mistakenly" indicated that claimant did not have a reduced ejection fraction. As in contest, claimant did not attempt to establish a reasonable medical basis for the attesting physician's representations that Ms. Holmes suffered

from pulmonary hypertension secondary to moderate or greater mitral regurgitation or an abnormal left atrial dimension. Moreover, in his letter, Dr. Mejia states: "In regards to the other findings from the echocardiogram I agree with the auditor."

In response, the Trust argues that claimant has not challenged, and has therefore conceded, Dr. Arazoza's conclusions that there is no reasonable medical basis for the attesting physician's findings of pulmonary hypertension secondary to moderate or greater mitral regurgitation or an abnormal left atrial dimension. The Trust further asserts that although Dr. Arazoza found claimant had an ejection fraction less than or equal to 60%, Ms. Holmes may not use this finding to establish entitlement to Matrix Benefits because Dr. Arazoza determined that there was a reasonable medical basis for the Green Form representation that claimant did not have a reduced ejection fraction. The Trust also contends that, despite claimant's argument to the contrary, Audit Rule 5 does apply and requires the auditing cardiologist to determine whether there is a reasonable medical basis for the attesting physician's Green Form representation when there is a dispute between the auditing cardiologist and attesting physician. Finally, the Trust questions why claimant produced correspondence from Dr. Mejia rather than Dr. Banks to explain that the attesting physician made a mistake while completing the Green Form.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no

reasonable medical basis for the attesting physician's findings of pulmonary hypertension secondary to moderate or greater mitral regurgitation and an abnormal left atrial dimension.

Specifically, Dr. Vigilante stated that:

The left atrium was normal in size. I measured the left atrium to be 3.5 cm in the antero-posterior dimension and 4.7 cm in the supero-inferior dimension. There was no view in which the left atrium was dilated.... Mild tricuspid regurgitation was found. I determined the tricuspid regurgitation velocity to be no more than 2.5 meters per second in reviewing multiple cardiac cycles. Therefore, the calculated pulmonary systolic pressure was 35 mmHg.

Dr. Vigilante also determined that there was a reasonable medical basis for the attesting physician's finding that claimant did not have a reduced ejection fraction. Specifically, Dr. Vigilante found that:

The left ventricle was normal in size and not dilated. There was excellent contractility of all walls. There was excellent endocardial definition of the left ventricle. I digitized several cardiac cycles in the apical four chamber and apical two chamber views in which there was excellent endocardial definition and the left ventricle was not off axis. The apex could be well seen in these views. I then measured the left ventricular areas at end diastole and end systole and calculated the left ventricular ejection fraction via Simpson's Rule. The calculated volumes at end diastole and end systole were normal. The left ventricular ejection fraction was between 62 and 65% in several cardiac cycles in which the left ventricular end diastolic and left ventricular end systolic volumes could be accurately calculated. I never found the left ventricular ejection fraction to be 60% or less in any appropriately measured cardiac cycle. I disagree with the statement of

Dr. Banks in his echocardiogram report of April 26, 2002. That is, the left ventricular systolic function was not low normal with a visually estimated left ventricular ejection fraction of 50%. Indeed, the left ventricular ejection fraction was greater than 60%. I also disagree with Dr. Arazoza. The ejection fraction was not 50%-60%.

* * *

An echocardiographer could not reasonably conclude that an ejection fraction of 50%-60% was present on this study when appropriate measurements are made even taking into account inter-reader variability.

In response to the Technical Advisor Report, claimant argues that her claim is supported by the findings of Dr. Banks, Dr. Mejia, and Dr. Arazoza. Ms. Holmes also notes that "Dr. Vigilante indicates less than moderate regurgitation."⁹

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not refute the determinations of the auditing cardiologist and the Technical Advisor that there was no reasonable medical basis for the attesting physician's findings of pulmonary hypertension secondary to moderate or greater mitral regurgitation and an abnormal left atrial dimension. Notably, Dr. Mejia, claimant's treating physician, stated that "[i]n regards to the other findings from the echocardiogram I agree with the auditor." On this basis alone, claimant has failed to

9. To the contrary, Dr. Vigilante specifically found that "[t]he apical two and apical four chamber views demonstrated moderate mitral regurgitation with the RJA/LAA ratio of between 20 and 25%."

meet her burden in proving that there is a reasonable medical basis for the attesting physician's representations that Ms. Holmes suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation and an abnormal left atrial dimension.

We also disagree with claimant that she is entitled to Matrix Benefits based on a reduced ejection fraction. Initially, Dr. Banks did not represent that claimant suffered from a reduced ejection fraction. Although Ms. Holmes relies on Dr. Arazoza's finding that claimant's ejection fraction was visually estimated to be in the range of 50% to 60%, she ignores that he also concluded that there was a reasonable medical basis for her attesting physician's representation that she did not have a reduced ejection fraction. Moreover, the Technical Advisor reviewed claimant's echocardiogram and determined that "there is no reasonable medical basis for finding that the Claimant has an ejection fraction in the range of 50%-60%," because claimant had an ejection fraction of 62% to 65%.

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 pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, or a reduced ejection fraction. Therefore, we affirm the Trust's denial of her claim for Matrix Benefits and the related derivative claim submitted by her spouse.

