

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.)
) CIVIL ACTION NO. 99-20593
v.)
))
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

February 26, 2007

Diane Broadbent ("Ms. Broadbent" 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. Brittany Maudsley, claimant's daughter, 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

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 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 not recover benefits if the attesting physician's reading of the echocardiogram, and thus his or her accompanying Green Form answers, have no reasonable medical basis.

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 other 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 June 2002, claimant submitted a completed Green Form to the Trust signed Richard L. Callihan, M.D. Based on an echocardiogram dated June 16, 2001, Dr. Callihan attested, in pertinent part, that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of 518,044.00.⁴

In the report of claimant's echocardiogram, Dr. Callihan stated that claimant had "moderate (2+) 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.

In September 2003, the Trust forwarded the claim for review by Benjamin Citrin, M.D., one of its auditing cardiologists. In audit, Dr. Citrin reviewed claimant's June 16, 2001 echocardiogram and concluded that there was no reasonable medical basis for Dr. Callihan's finding that claimant had

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if 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 an enlarged left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

moderate mitral regurgitation. Dr. Citrin concluded that claimant's "MR is trace to mild with RJA/LAA is [sic] 10-15%. I do not appreciate a significant regurgitant jet into the LA."

Thereafter, the Trust issued a post-audit determination denying Ms. Broadbent's claim.⁵ Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"),⁶ claimant contested this adverse determination.⁷ In contest, claimant submitted a verified transcript of sworn testimony from a second cardiologist, Dr. Sheldon Litwin.⁸ Dr. Litwin testified that:

[a]nd so I'll go ahead and get that on this clip. So here's a still frame image of the mitral regurgitation, and here is where I have traced that. There is a small area of drop out here in the middle, but I believe this actually is a part of the MR jet which I have measured at 6.06 centimeters squared . . . I'm going to go ahead and play this in real time to show that there is a significant turbulent

5. Based on findings in audit, the Trust issues a post-audit determination regarding whether or not a claim is entitled to Matrix Benefits.

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 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. Broadbent's claim.

7. 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.

8. Claimant also submitted a DVD of the testimony of Dr. Litwin, and a verified statement.

jet which emanates from the tips of the mitral leaflets and corresponds to what I believe is this area. The left atrial area . . . is significantly enlarged an [sic] was measured at 27 square centimeters. I would consider that to be moderate or moderate/severe left atrial enlargement. Even with that, the calculated MR to left atrial area came out to 22%.

The Trust reviewed claimant's contest materials and issued a final post-audit determination, again denying Ms. Broadbent'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. Broadbent's claim should be paid. On April 26, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3473 (Apr. 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 October 8, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and

9. 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

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 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 moderate mitral regurgitation. See Audit 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 Audit 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 Audit Rule 38(b).

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 opposition positions" is proper. See id.

In her show cause submissions, Ms. Broadbent relies on the materials she submitted to the Trust to contest its final determination.¹⁰

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 moderate mitral regurgitation. Specifically, the Technical Advisor concluded that:

I reviewed the Claimant's echocardiogram in detail. The date of the study was actually documented as June 13, 2001 on the tape. The left atrium is dilated measuring 4.3 cm in the antero-posterior systolic dimension and 5.8 cm in the super-inferior systolic dimension. In the apical four chamber view, there is the appearance of a left atrial mass that is somewhat pedunculated attached to the mid portion of the inter-atrial septum measuring 2 cm in its longest diameter. This is possibly consistent with left atrial myxoma but needs further evaluation. The mitral leaflet is somewhat thickened. There is clear restriction of posterior leaflet excursion seen both on the parasternal long axis and apical four chamber views. Moderate mitral regurgitation is suggested on the parasternal long axis view with a central jet. The mitral regurgitation jet was most impressively noted

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. While the Audit Rules allow claimants to submit verified expert opinions in support of their claims, they do not require Rule 26(a)(2) disclosures. See Audit Rule 18(b). Discovery relating to claims is prohibited by the Audit Rules. See Audit Rule 41. Thus, requiring Rule 26(a)(2) disclosures would serve no purpose.

in the apical two chamber view. This measures 5.8 cm squared in a couple of cardiac cycles. The left atrial area was measured at 23.6 cm squared and RJA/LAA ratio was calculated at 24.5%. Also, the RJA/LAA ratio was calculated at 21% when the mitral regurgitation jet was measured in the apical four chamber view. Therefore, all three standard views (parasternal long axis, apical four chamber, and apical two chamber) demonstrate moderate mitral regurgitation.

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 reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation. Although the Trust challenged the attesting physician's conclusion, Dr. Vigilante confirmed the attesting physician's finding of moderate mitral regurgitation.¹¹

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Vigilante found that moderate mitral regurgitation was visible in the apical four chamber view. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical

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

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. Broadbent and her daughter for Matrix Benefits.

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.)
) CIVIL ACTION NO. 99-20593
v.)
))
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

PRETRIAL ORDER NO.

AND NOW, on this 26th day of February, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that the Level II claims submitted by claimants Diane Broadbent and her daughter, Brittany Maudsley, are GRANTED. The Trust shall pay such benefits in accordance with the terms of the Settlement Agreement and Pretrial Order No. 2805, and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III
C.J.