

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.

November 9, 2007

Carrie Norman ("Ms. Norman" 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. Charity G. Norman, Ms. Norman's child, also has 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 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 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, Elliot D. Agin, M.D. Based on an echocardiogram dated August 28, 2000,⁴ Dr. Agin attested in Part II of Ms. Norman's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral

3.(...continued)

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. In the Green Form, Dr. Agin listed the date of claimant's echocardiogram as August 30, 2000. The echocardiogram report in the Show Cause Record, however, reflects a date of August 28, 2000. We need not resolve this discrepancy as neither the Trust nor claimant asserts that there are different echocardiograms at issue in this claim.

regurgitation, an abnormal left atrial dimension and a reduced ejection fraction in the range of 30% to 34%. Based on such findings, claimant would be entitled to Matrix B-1,⁵ Level II benefits in the amount of \$104,453.

In the report of claimant's echocardiogram, John Prather, M.D., the reviewing cardiologist, stated that there was "[m]ild mitral regurgitation." Dr. Prather, however, 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. Prather also concluded that claimant had "[m]oderate pulmonary hypertension with a PA pressure of 57mmHg." Under the Settlement Agreement, pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic artery pressure >40 mm Hg measured by cardiac catheterization or >45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See id. § IV.B.2.c.(2)(b). Dr. Prather further noted that claimant's left atrium measured 3.39 cm. The Settlement Agreement, however,

5. Claimant ingested diet drugs for less than sixty-one days. Thus, if eligible for benefits, claimant only would be entitled to payment based on Matrix B-1. See Settlement Agreement § IV.B.2.d.(2)(b). Claimant concedes that her claim is on Matrix B-1.

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. Finally, Dr. Prather estimated claimant's ejection fraction as 21%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. Id. In a handwritten note in the Green Form, Dr. Agin stated the following:

I have reviewed the 8/30/2000 videotape, Moderate MR is present. LA enlargement 5.5 cm supero inferior dimension. LVEF aprox. 30% ... Pulm. areterial hypertension (57 mmHg).

In March 2006, the Trust forwarded the claim for review by one of its auditing cardiologists. Pursuant to Court Approved Procedure No. 11 ("CAP 11"), approved by this court in Pretrial Order ("PTO") No. 6100 (Mar. 31, 2006), the Consensus Expert Panel ("CEP") reviewed the results of claimant's audit and recommended that her claim be re-audited.⁶ According to the CEP,

6. Under CAP 11, the CEP, which consists of three experts designated by the Trust, Wyeth and Class Counsel, "assist[s] the Trust in the administration of Claims" and "develop[s] and implement[s] such quality assurance measures as it believes are appropriate to provide a reasonable degree of assurance that the Audits conducted by the Auditing Cardiologists fairly and accurately distinguish between those Claims that are payable and those in which there is no reasonable medical basis for the claim." CAP 11 at ¶¶ 3, 8. In addition, "[i]f the CEP determines that the result(s) of the review of a Claim or a group of Claims in Audit depart from accepted standards of practice in applying the medical criteria of the Settlement Agreement (and
(continued...)

"Claimant appears to meet criteria for moderate MR by Singh criteria."⁷

Thereafter, in June 2006, the Trust forwarded the claim for re-audit by Irmina Gradus-Pizlo, M.D., one of its auditing cardiologists. In re-audit, Dr. Gradus-Pizlo also concluded that there was no reasonable medical basis for Dr. Agin's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Dr. Gradus-Pizlo, however, concurred with the attesting physician's finding of an abnormal left atrial dimension and a reduced ejection fraction.⁸

Based on Dr. Gradus-Pizlo's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Norman's claim. Pursuant to the Rules for the Audit

6.(...continued)

any applicable Pre-Trial Orders)," and have also "determined that an Audit result on a Claim or group of Claims for Matrix Compensation Benefits is not reliable," the Trust may require the re-audit of a claim. Id. at ¶ 9(c).

7. As required by CAP 11, the original audit results, as well as the results of the re-audit, are part of the Show Cause Record. In the prior audit, the auditing cardiologist found that claimant had mild mitral regurgitation.

8. 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 did not contest the attesting physician's finding of an abnormal left atrial dimension and a reduced ejection fraction, each of which is one of the conditions needed to qualify for a Level II mitral valve claim, the only issue is claimant's level of mitral regurgitation.

of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁹ In contest, claimant submitted five (5) still frames from claimant's echocardiogram, which purportedly demonstrated moderate mitral regurgitation.

The Trust then issued a final post-audit determination again denying Ms. Norman's claim. In its final post-audit determination, however, the Trust conceded the following:

The Trust believes that, notwithstanding the inappropriate measurements of your mitral regurgitation by your Attesting Physician, your true level of mitral regurgitation may approach moderate.¹⁰

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. Norman's claim should be paid. On January 22, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6873 (Jan. 22, 2007).

9. 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 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. Norman's claim.

10. This statement by the Trust is similar to the conclusion of the CEP that: "Claimant appears to meet criteria for moderate MR by Singh criteria."

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 13, 2007. The Show Cause Record is now before the court for final determination. See Audit 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 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).

In support of her claim, claimant reasserts the arguments raised during the contest phase of the audit process. In response, the Trust argues that claimant failed to establish a reasonable medical basis for her claim.

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 moderate mitral

regurgitation. Similarly, the CEP appointed by the court pursuant to PTO No. 6100 concluded that: "Claimant appears to meet criteria for moderate MR by Singh criteria."¹¹ Although in re-audit the Trust's auditing cardiologist concluded that claimant had mild mitral regurgitation, in its final post-audit determination, the Trust nevertheless conceded that claimant's "true level of mitral regurgitation may approach moderate."¹² Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.¹³

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 B-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Norman for Matrix Benefits and the related derivative claim submitted by her child.

11. Under CAP 11, a claim may not be re-audited twice. See CAP 11 at ¶ 9(c). Accordingly, notwithstanding the Trust's concession, claimant's claim could not be re-audited again.

12. The Trust never explains why, given the conclusion of the CEP and its own concession in the final post-audit determination, it nevertheless still concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Although the Trust asserts that a Technical Advisor should review claimant's echocardiogram, given the finding of the CEP and the concession of the Trust, review by a Technical Advisor is unnecessary.

13. Accordingly, we need not address claimant's arguments in support of her claim.

