IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	MDL NO. 1203
THIS DOCUMENT RELATES TO: SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8398

February 9, 2010

Bartle, C.J.

Donna Glach ("Ms. Glach" 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"). 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").[2]

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

2. 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 Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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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 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, claimant's attorney must complete Part III if claimant is represented.

In April 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Bradley M. Leonard, M.D. Based on an echocardiogram dated January 19, 2002, Dr. Leonard attested in Part II of Ms. Glach's Green Form that she suffered from moderate mitral regurgitation, moderate aortic regurgitation,[3] pulmonary hypertension secondary to moderate or greater mitral regurgitation, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would

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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.

3. As Ms. Glach's claim does not present any of the complicating factors 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).

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. Leonard stated: "Doppler echocardiography demonstrates ... moderate 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. Leonard also found "[t]here is evidence for pulmonary hypertension with a calculated pulmonary artery systolic pressure of 46 mmHg." Pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic pulmonary 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. at § IV.B.2.c.(2)(b)i). Finally, Dr. Leonard observed that "[t]he left ventricular ejection fraction is 56% with normal chamber dimensions." An ejection fraction is considered reduced

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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). Pulmonary hypertension secondary to moderate or greater mitral regurgitation and a reduced ejection fraction are two of the complicating factors, one of which would be needed to qualify for a Level II claim.

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).

In October 2002, the Trust notified claimant that her claim had been selected for audit and, in December 2002, the Trust forwarded the claim for review by Nancy V. Strahan, M.D., one of its auditing cardiologists.[5] In audit, Dr. Strahan concluded that there was no reasonable medical basis for Dr. Leonard's finding that claimant had moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, or a reduced ejection fraction. In support of these conclusions, Dr. Strahan explained that:

> To my eye, there was only trace mitral regurgitation. Again, I saw only trace aortic regurgitation. I calculated an RVSP [right ventricular systolic pressure] of only 34 mmHg using a peak velocity across TV [tricuspid velocity] of 2.4 mm/sec. I believe the physician read the question wrong and just checked off the box corresponding to her current E.F. [ejection fraction] - In any event it was normal (E.F.).[6]

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5. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. and VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit claimant's levels of mitral and aortic regurgitation, pulmonary artery systolic pressure, and ejection fraction. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

6. In the Auditing Cardiologist Worksheet, Dr. Strahan indicated (continued...)

Based on the auditing cardiologist's diagnoses, the Trust issued a post-audit determination denying Ms. Glach's claim. Pursuant to the Audit Policies and Procedures, claimant disputed this adverse 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. 2457, Audit Policies and Procedures § IV.C.[7] The Trust then applied to the court for issuance of an Order to show cause why Ms. Glach's claim should be paid. On November 2, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4099 (Nov. 2, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Although represented by counsel, claimant did not serve a response upon the Special Master. The Show Cause Record is now before the court for final determination. See Audit Policies and Procedures § VI.O.

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that claimant's ejection fraction was in the range of 50% to 60%. In her Attestation of Auditing Cardiologist and in her Certification, however, Dr. Strahan concluded that the claimant's ejection fraction was normal and, accordingly, there was no reasonable medical basis for the attesting physician's finding that claimant had a reduced ejection fraction.

7. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Glach's claim.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and a reduced ejection fraction. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

A claimant seeking Matrix Benefits must provide an echocardiogram that meets specific and defined criteria. See Settlement Agreement § VI.C.1. An attesting physician's opinion cannot have a reasonable medical basis if the underlying echocardiogram does not support the conclusions reflected in Part II of the Green Form. The Trust's auditing cardiologist determined that the echocardiogram at issue demonstrated mild mitral regurgitation, no pulmonary hypertension secondary to moderate or greater mitral regurgitation, and a normal ejection fraction. Despite the opportunity to do so, claimant made no attempt to refute the conclusions of the auditing cardiologist that there was no reasonable medical basis to support the attesting physician's findings at issue. Under these

circumstances, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Glach's claim for Matrix Benefits.