

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 3, 2010

Helen Goodman ("Ms. Goodman" 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. Austin A. Goodman, Ms. Goodman'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
(continued...)

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 October, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Van H. De Bruyn, M.D., F.A.C.C. Based on an echocardiogram dated June 1, 2000, Dr. De Bruyn attested in Part II of Ms. Goodman's Green Form that she suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valves following the use of Pondimin® and/or Redux™.⁴ Based on such

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. De Bruyn also attested that claimant suffered from mild aortic regurgitation, aortic sclerosis, an abnormal left atrial
(continued...)

findings, claimant would be entitled to Matrix A-1, Level III⁵ benefits.⁶

Dr. De Bruyn also attested in claimant's Green Form that Ms. Goodman did not suffer from mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest Ms. Goodman's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In June, 2004, the Trust forwarded the claim for review by Kevin S. Wei, M.D., one of its auditing cardiologists.⁷ In audit, Dr. Wei concluded that there was no reasonable medical

4. (...continued)
dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions, however, are not at issue in this claim.

5. In Part I of her Green Form, Ms. Goodman requested Matrix Benefits at Level IV. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not dispute, that Ms. Goodman alleged conditions consistent only with a claim for Level III benefits.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

7. Following his evaluation of claimant's echocardiogram, Dr. Wei resigned from the program in light of a conflict of interest. Claimant did not elect to have her claim re-audited.

basis for Dr. De Bruyn's finding that claimant did not have mitral annular calcification. In support of this conclusion, Dr. Wei explained that "[m]itral annular calcification involving the posterior mitral annulus [is] seen on [the parasternal long-axis] view."

Based on the auditing cardiologist's finding that claimant had mitral annular calcification, the Trust issued a post-audit determination that Ms. Goodman was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant submitted a statement from C.D. Williams, M.D., the surgeon who performed claimant's mitral valve surgery, in which he stated that "[a]s my operation note states - no calcification seen."

The Trust then issued a final post-audit determination, again determining that Ms. Goodman was entitled only to Matrix B-1, Level III benefits. 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

8. 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. Goodman's claim.

show cause why Ms. Goodman's 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. 5244 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant did not submit a response to the Trust's statement of the case, thereby relying only on the materials submitted during the contest phase of the audit process. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ 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.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a

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 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.

reasonable medical basis for the attesting physician's finding that she did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is 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 is 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).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Goodman did not have mitral annular calcification. Specifically, Dr. Vigilante determined that:

There was mild but definite calcification of a portion of the mitral annulus. In particular, the posterolateral annulus had several bright echodensities and increased refractoriness classic for mitral annular calcification. In addition, the anteromedial annulus also had mitral annular calcification with increased echodensities. The mitral annulus was thickened.

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, claimant does not adequately refute Dr. Wei's conclusion that mitral annular calcification was present in the parasternal long-axis view of her echocardiogram. Instead, she submitted a statement from Dr. Williams that his operative notes did not reflect that there

was calcification. Dr. Williams, however, did not opine as to whether claimant's echocardiogram demonstrated mitral annular calcification.

Moreover, claimant does not contest Dr. Vigilante's observation that "the echocardiogram of June 1, 2000 demonstrated classic echocardiographic features of mitral annular calcification" and that "[a]n echocardiographer could not reasonably conclude that mitral annular calcification was not present on this echocardiogram even taking into consideration the issue of inter-reader variability." Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

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 did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of Ms. Goodman's claim for Matrix A benefits and the related derivative claim submitted by her spouse.

