

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.

August 29, 2007

Louise Noris ("Ms. Noris" 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

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 serious VHD who took the drugs for 61 days or longer and who did
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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. 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 he or she is represented.

In March 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Warren J. Manning, M.D. Based on an echocardiogram dated April 23, 1997, Dr. Manning attested in Part II of Ms. Noris's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 40% and 49%.³ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$467,536.

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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. Dr. Manning also attested that Ms. Noris had mild aortic regurgitation. As Ms. Noris's claim does not present any of the conditions 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).

In the report of claimant's echocardiogram, P. Douglas, M.D., the reviewing cardiologist, stated that claimant suffered from "moderate mitral regurgitation" but 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. Douglas also estimated claimant's ejection fraction as 40%. 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).

In April 2003, the Trust forwarded the claim for review by Michael Rihner, M.D., one of its auditing cardiologists. In audit, Dr. Rihner concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Rihner, however, found that claimant had a reduced ejection fraction in the range of 40% and 49%.⁴

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). As the auditing cardiologist concurred with the attesting physician's finding of a reduced ejection fraction, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

Based on Dr. Rihner's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Noris's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ She submitted a letter from Dr. Manning, in which he reiterated his previous finding of moderate mitral regurgitation. She also argued that Dr. Manning, as her cardiologist since 1993, was more aware of her medical condition than the auditing cardiologist.

The Trust then issued a final post-audit determination, again denying Ms. Noris'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 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Noris's claim should be paid. On April 14, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3431 (Apr. 14, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

5. 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. Noris's claim.

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 21, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁶ 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 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's Report are now before the court for final determination. Id. 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 of 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

6. 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 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 opposite positions" is proper. Id.

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, Ms. Noris submitted a second letter from Dr. Manning. Therein, Dr. Manning stated that:

I have again reviewed the original copy of the 4/23/97 echocardiographic study of Ms. Noris and find there is moderate mitral regurgitation utilizing the 20-40% regurgitant jet area/left atrial area criterion.

Dr. Manning further identified several frames on Ms. Noris's echocardiogram tape that, according to him, confirmed the severity of her mitral regurgitation.

Claimant also argues that her attesting physician's knowledge of her medical history and prior echocardiogram provide a reasonable medical basis for his finding of moderate mitral regurgitation. Claimant further contends that the auditing cardiologist's opinion lacks a reasonable medical basis because his report did not specify "the actual readings of the echocardiogram" or the medical records upon which he relied.

In response, the Trust counters that claimant's argument regarding the lack of actual readings is without merit because "eyeballing" is permissible under PTO No. 2640. According to the Trust, the attesting physician's supplemental opinion does not provide any further support for his Green Form representation and is insufficient to satisfy claimant's burden of showing a reasonable medical basis for her claim.

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, Dr. Vigilante concluded that:

There was an obvious jet of mitral regurgitation traveling posteriorly along the left atrium in the parasternal long axis view. The mitral regurgitation jet was best seen in the apical four chamber view. Overall, the degree of mitral regurgitation was moderate. It should be noted, however, that the Claimant was in atrial fibrillation during the performance of this study and the severity of mitral regurgitation tended to change from beat to beat at least partly related to her arrhythmia. However, several representative frames were digitized and the RJA and LAA were determined. Several cardiac cycles demonstrated that the RJA/LAA ratios were between 20 and 30%. A moderate degree of mitral regurgitation was also noted in the apical two chamber view with two cardiac cycles demonstrating RJA/LAA ratios of between 20% and 25%. The echocardiogram frames referenced by Dr. Manning in his letter of October 31, 2003 were reviewed in detail. Indeed, the apical four chamber and apical two chamber frames which he referenced did 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, Dr. Manning, reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation. Although the Trust contested the attesting physician's conclusion, Dr. Vigilante confirmed this

finding.⁷ Specifically, Dr. Vigilante concluded that claimant had moderate mitral regurgitation and that "[s]everal cardiac cycles [in the apical four chamber view] demonstrated that the RJA/LAA ratios were between 20 and 30%" and that there were "two cardiac cycles [in the apical two chamber view] demonstrating RJA/LAA ratios of between 20% and 25%."

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 measured claimant's level of mitral regurgitation in the apical views and determined that her RJA/LAA ratio was 20% or greater. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.⁸

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Noris for Matrix Benefits.

7. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

8. Accordingly, we need not address claimant's remaining arguments.

