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

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J. July 24, 2007

Nora Gioia ("Ms. Gioia" 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]

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

2. Michael Gioia, Ms. Gioia'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. 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 December 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Wendy Post, M.D. Based on an echocardiogram dated March 21, 2001, Dr. Post attested in Part II of Ms. Gioia's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction between 50% and 60%. Dr. Post also attested that claimant's echocardiogram did not reveal the presence of mitral valve prolapse, which is a reduction factor that would require the payment of benefits on Matrix B-1.

(...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.

In the report of claimant's echocardiogram, Julia Y. Wen, M.D., F.A.C.C., stated that claimant's "mitral valve leaflets are slightly thickened with mild systolic prolapse into the left atrium." Mitral valve prolapse is defined in the Settlement Agreement as a condition where:

> (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

Settlement Agreement § I.39. Under the Settlement Agreement, mitral valve prolapse requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii). Therefore, the only issue is whether payment should be made on Matrix A-1 or Matrix B-1 due to the finding of mitral valve prolapse. If paid on Matrix A-1, claimant would be entitled to $551,721.[4]

In May 2002, the Trust forwarded the claim for review by Waleed Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Post's finding that claimant did not have mitral valve prolapse. Dr. Irani concluded that: "[t]here appears to be mitral valve prolapse. Image quality make [sic] precise

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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 id. § IV.B.2.c.(2)(b). The Trust does not contest claimant's entitlement to Level II benefits.

measurement of amount of prolapse difficult; however, it appears to be 2 mm."[5]

Based on Dr. Irani's diagnosis of mitral valve prolapse, the Trust issued a post-audit determination that Ms. Gioia was entitled only to Matrix B-1, Level II benefits. Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant contested 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; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Audit Policies and Procedures § VI.[6] The Trust then applied to the court for issuance of an Order to show cause why Ms. Gioia's claim should be paid on Matrix A-1. On December 9, 2002, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2672 (Dec. 9, 2002).

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5. In his initial attestation, Dr. Irani, in a handwritten explanation, states that the mitral valve prolapse "appears to be > 2 mm." Dr. Irani's final certification, however, does not indicate that the mitral valve prolapse is greater than 2 mm. We need not resolve this inconsistency. As discussed infra, the auditing cardiologist did not make the findings necessary under the Settlement Agreement to reduce the payment of Ms. Gioia's Matrix Benefits.

6. 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. Gioia's claim.

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 February 24, 2003. Claimant submitted a sur-reply on March 7, 2003. The Show Cause Record is now before the court for final determination. See Audit Policies and Procedures § VI.O.

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 does not have mitral valve prolapse as that condition is defined in the Settlement Agreement. See id. § VI.D. 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. § VI.Q. 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 id.

In support of her claim, Ms. Gioia submitted the affidavits of two additional cardiologists, Julia Wen, M.D., and Mark M. Applefeld, M.D. Consistent with the findings of claimant's attesting physician, both doctors opined that claimant did not have mitral valve prolapse. More specifically, Dr. Wen opined that there is a reasonable medical basis for concluding that claimant "does not have mitral valve prolapse" and that "the

parasternal long-axis view on this echocardiogram does not reveal mitral valve prolapse greater than 2mm." Moreover, Dr. Applefeld opined that "it is a reasonable medical conclusion that the parasternal long-axis view on this echocardiogram does not reveal mitral valve prolapse." Claimant also argues that the auditing cardiologist's conclusion was "vague and inconclusive" and his statement that "[i]mage quality make [sic] precise measurement of amount of prolapse difficult; however, it appears to be 2 mm" is an insufficient basis for denying her claim for Matrix A-1 benefits.

In response, the Trust argues that claimant is improperly attempting to shift the burden to the Trust to show that the auditing cardiologist's conclusion was rendered "with the same degree of medical certainty as that required in a medical malpractice action." According to the Trust, the "proper focus" is on the auditing cardiologist's "final conclusion and on Claimant's burden of proof to refute that conclusion. In Ms. Gioia's case the decisive conclusion is that she has mitral valve prolapse and that no reasonable medical basis exists to substantiate Ms. Gioia's claim on the A-1 Matrix."

In sur-reply, claimant disputes the Trust's characterization of the standard to be applied in determining her claim and argues that the appropriate standard is whether "there was a reasonable medical basis for the opinion of the certifying cardiologist ... that Ms. Gioia does not have mitral valve prolapse, as defined in the Settlement Agreement." Claimant also

argues, inter alia, that three Board Certified cardiologists have concluded that there is a reasonable medical basis for finding that claimant does not have mitral valve prolapse greater than 2 millimeters above the atrial-ventricular border during systole, and greater than 5 millimeters leaflet thickening during diastole and that "the Trust has failed to submit any definitive evidence to the contrary."

The Settlement Agreement requires that a claim for benefits be reduced to Matrix B-1 if certain medical conditions are present. See Settlement Agreement § IV.B.2.d. In claimant's case, her mitral valve claim must be reduced to Matrix B-1 if she has mitral valve prolapse, as that condition is defined in the Settlement Agreement. See id. § I.39; see also id. § IV.B.2.d.(2)(c)(ii)(b). As noted above, mitral valve prolapse is defined as follows:

> "Mitral Valve Prolapse" refers to a condition where (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

Id. § I.39.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her attesting physician's finding that she did not have mitral valve

prolapse.[7] Unlike other reduction factors (e.g. mitral annular calcification), the Settlement Agreement sets forth specific measurements regarding whether the presence of mitral valve prolapse requires the payment of reduced benefits on Matrix B-1. In support of its position that claimant should be paid reduced Matrix Benefits, the Trust solely relies on its auditing cardiologist's conclusion. However, Dr. Irani merely states that: "[t]here appears to be mitral valve prolapse" and "it appears to be 2mm." He further qualified his conclusion by explaining that measurement of claimant's mitral valve prolapse was "difficult."

Additionally, to reduce the payment of a mitral valve claim based on a finding of mitral valve prolapse, the Settlement Agreement explicitly requires that the parasternal long axis view show a displacement of one or both mitral leaflets greater than 2 millimeters above the atrial-ventricular border during systole, and greater than 5 millimeters leaflet thickening during diastole. The auditing cardiologist did not reach these two conclusions. Indeed, the auditing cardiologist merely concluded that there "appears" to be mitral valve prolapse of 2 millimeters and did not separately determine the level of mitral valve prolapse during both systole and diastole. Given the opinions of

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7. The Trust argues that claimant must "demonstrate that she does not experience mitral valve prolapse" to receive benefits. This is incorrect. The standard is whether there is a reasonable medical basis for finding that claimant does not have mitral valve prolapse as that condition is defined in the Settlement Agreement.

claimant's cardiologists, and the auditing cardiologist's failure to state that mitral valve prolapse is present and exceeds the required 2 millimeters in systole and 5 millimeters in diastole, the Trust's determination that there is no reasonable medical basis for finding that claimant does not have mitral valve prolapse is erroneous.

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 thus, is entitled to Matrix A-1, Level II benefits. We will, therefore, reverse the post-audit determination by the Trust and order that claimant and her spouse be paid in accordance with the Settlement Agreement.

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PRETRIAL ORDER NO._____

AND NOW, on this 24th day of July, 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 claimants Nora Gioia and her spouse, Michael Gioia, are entitled to Matrix A, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805.

BY THE COURT:

/s/ Harvey Bartle III
C.J.