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

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J. October 10, 2007

Emily Reed ("Ms. Reed" 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 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 July 2003, Ms. Reed submitted a completed Green Form to the Trust signed by her attesting physician, Peter B. Frechie, M.D. Based on an echocardiogram dated December 15, 2000, Dr. Frechie attested in Part II of claimant's Green Form that, among other things, claimant had severe mitral regurgitation, a reduced ejection fraction in the range of 50% to 60% and surgery to replace the mitral valve after use of Pondimin® and/or Redux™. Dr. Frechie also attested that claimant did not have a rheumatic mitral valve. If accepted, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $719,285.[3]

2(...continued)
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. Under the Settlement Agreement, a claimant is entitled to
(continued...)

In October 2003, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for Dr. Frechie's finding that claimant did not have a rheumatic mitral valve. In his Certification, Dr. Oliner noted that:

> The Attesting Physician did not recognize the abnormality so there was no reasonable medical basis. The echocardiographic features of the mitral valve were characteristic of rheumatic mitral disease.

Under the Settlement Agreement, the absence of a finding of no rheumatic mitral valve requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). The Trust does not contest that claimant is entitled to Level III Matrix Benefits. Rather, the Trust challenges claimant's right to a payment on Matrix A-1 instead of a payment on Matrix B-1.

Based on Dr. Oliner's diagnosis that claimant had a rheumatic valve, the Trust issued a post-audit determination that claimant 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.[4]

3(...continued)
Level III benefits if the claimant had: "Surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement IV.B.2.c.(3)(a).

4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition (continued...)

In contest, claimant provided the Surgical Pathology Report performed by Yongling Bian, M.D. and argued that she should prevail because Dr. Bian, a Board-Certified Pathologist, examined Ms. Reed's mitral valve tissue and did not indicate on the Surgical Pathology Report that she had rheumatic heart disease.

The Trust then issued a final post-audit determination, again determining that claimant 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 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On August 9, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3817 (Aug. 9, 2004).

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 October 8, 2004. The

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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. Reed's claim.

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 did not have a rheumatic mitral valve. 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 argues that Matrix A-1, Level III benefits should be paid because Dr. Bian, a Board-Certified Pathologist, examined claimant's mitral valve tissue and did not state in the Surgical Pathology Report that such examination revealed evidence of rheumatic valve disease. In response, the Trust argues that claimant cannot rely on the pathology report to meet her burden in establishing a reasonable medical basis for her claim because the report failed to determine that there was no evidence of rheumatic valve disease.

After reviewing the entire Show Cause Record, we find claimant's arguments without merit. First, the Settlement

Agreement specifically provides, in pertinent part, that a claimant will receive reduced Matrix Benefits if there is:

> M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), <u>except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease</u>.

Settlement Agreement § IV.B.2.d.(2)(c)ii)e) (emphasis added). Here, claimant does not contest the auditing cardiologist's determination that her echocardiogram revealed evidence of a rheumatic mitral valve.

Second, to meet her burden, claimant relies solely on the pathology report from her surgery asserting that the absence of a finding of rheumatic valve disease on the report is a sufficient "determination" by a Board-Certified Pathologist that claimant did not have a rheumatic mitral valve. Claimant's attempted reliance on the pathology report, however, is misplaced.

We must apply the Settlement Agreement as written. Claimant correctly notes that, under the Settlement Agreement, a claim will not be reduced to the B-1 Matrix where a Board-Certified Pathologist examines the mitral valve tissue <u>and</u> determines that there is no evidence of rheumatic valve disease. <u>See</u> Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Claimant has not provided the necessary determination from a Board-Certified Pathologist as required by the Settlement Agreement. Indeed,

claimant concedes that the pathology report does not include a specific finding as to the presence or absence of rheumatic mitral valve disease. Although claimant essentially asserts that the lack of a finding or determination in the pathology report supports her claim, the exact opposite is true; namely, only an affirmative determination by a Board-Certified Pathologist that the mitral valve tissue does not reveal evidence of rheumatic valve disease will allow a claimant to avoid application of the reduction factor at issue.

Contrary to claimant's argument, the absence of a notation in a surgical pathology report as to rheumatic valve disease is insufficient to satisfy her burden under the Settlement Agreement. The Settlement Agreement specifically states that echocardiographic evidence will not control the application of the reduction factor of a rheumatic mitral valve only where the Board-Certified Pathologist has "determined that there was no evidence of rheumatic valve disease." Settlement Agreement § IV.B.2.d.(2)(c)ii)e). The mere absence of a notation as to the condition of a rheumatic mitral valve does not constitute the affirmative determination required by the Settlement Agreement. As claimant does not contest that her echocardiogram revealed evidence of a rheumatic mitral valve, and a Board-Certified Pathologist has not provided a contrary determination, the Settlement Agreement mandates that Ms. Reed's claim be reduced to Matrix B-1.

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 did not have a rheumatic mitral valve. Therefore, we will affirm the Trust's denial of Ms. Reed's claim for Matrix A-1 benefits.

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PRETRIAL ORDER NO.

AND NOW, on this 10th day of October, 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 AFFIRMED and that the A-1, Level IV Matrix claim submitted by claimant Emily Reed is DENIED. Claimant Emily Reed is entitled only to Matrix B-1, Level III benefits.

BY THE COURT:

/s/ Harvey Bartle III
C.J.