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. June 28, 2007

Gwendolyn Byrd ("Ms. Byrd" 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. Jesse Byrd, Ms. Byrd'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

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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.[4]

In March 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Linda Crouse, M.D. Based on an echocardiogram dated January 26, 2002, Dr. Crouse attested in Part II of Ms. Byrd's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and an ejection fraction in the range of 30% to 34%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $497,928.

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contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. and 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. Claimant is Pro Se.

In the report of claimant's echocardiogram,[5] Dr. Crouse stated: "Moderate MR 5.41/18.92-29%." 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. Crouse also measured claimant's left atrium to be 6.60 cm in the apical four chamber view. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Finally, Dr. Crouse measured claimant's ejection fraction as 30%, which meets the definition for a reduced ejection fraction under the Settlement Agreement. See id.

In October 2002, the Trust forwarded the claim for review by Ioannis Panidis, M.D., one of its auditing cardiologists. In audit, Dr. Panidis concluded that there was no reasonable medical basis for Dr. Crouse's finding that claimant

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5. The report states that the echocardiogram was performed on January 26, 2002. According to the echocardiogram report, the report was printed on February 5, 2002. The date of the echocardiogram referenced by the auditing cardiologist, however, is February 3, 2002. Claimant does not dispute that the auditing cardiologist reviewed the correct echocardiogram. In any event, as only one echocardiogram was submitted by claimant in support of her claim, it is unnecessary to determine the actual date of the echocardiogram.

had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Panidis also found that "[h]igh gain settings on color Doppler study resulted in overestimation of mitral regurgitant jet area measurement." Dr. Panidis did not contest the findings that claimant's left atrial dimension was enlarged and that claimant had a reduced ejection fraction.[6]

Based on Dr. Panidis' diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Byrd's claim. 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.[7] The Trust then applied to the court for issuance of an

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6. 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 Trust did not contest the attesting physician's finding of an enlarged left atrial dimension or a reduced ejection fraction, each of which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of regurgitation.

7. 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

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Order to show cause why Ms. Byrd's claim should be paid. On February 20, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2756 (Feb. 20, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Despite an opportunity to do so, claimant did not submit a response to the Trust's statement of the case and supporting documentation. See Audit Policies and Procedures § VI.E.

The sole 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 had moderate mitral regurgitation. See id. at § 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 confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. at § 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.

After reviewing the entire Show Cause Record, we conclude that there was no reasonable medical basis for the

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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 Policies and Procedures contained in PTO No. 2457 apply to Ms. Byrd's claim.

attesting physician's diagnosis that claimant had moderate mitral regurgitation. First, and of crucial importance, claimant chose not to respond to the Trust's statement of the case and supporting documentation. In support of her claim, Ms. Byrd rests only on Dr. Crouse's check-the-box diagnosis on her Green Form.[8] Claimant did not dispute or respond to the determination of Dr. Panidis that she had mild mitral regurgitation and that "[h]igh gain settings on color Doppler study resulted in overestimation of mitral regurgitant jet area measurement." Although she bears the burden of proof in show cause, claimant failed to present any arguments or factual evidence to establish that Dr. Panidis' findings were erroneous. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

Moreover, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing

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8. Part II of the Green Form, to be completed by a claimant's physician, consists of approximately 45 "yes/no" and two multiple choice questions. Claimant also attached Dr. Crouse's echocardiogram report.

to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Panidis found, and claimant does not dispute, that Dr. Crouse relied on inaccurate echocardiogram settings that overestimated claimant's level of mitral regurgitation. Such an unacceptable practice by claimant's physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

Claimant has failed to prove that there is a reasonable medical basis to conclude that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of her claim for Matrix benefits and the related derivative claim submitted by her spouse.

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PRETRIAL ORDER NO._____

AND NOW, on this 28th day of June, 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 the Level II Matrix claims submitted by claimant, Gwendolyn Byrd, and her spouse, Jesse Byrd, are DENIED.

BY THE COURT:

/s/ Harvey Bartle III
C.J.