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 29, 2007

Kristi Carrigan ("Ms. Carrigan" 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 J. Carrigan, Ms. Carrigan'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.

In July 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician Irvin F. Goldenberg, M.D. Based on an echocardiogram dated October 10, 1997, Dr. Goldenberg attested in Part II of Ms. Carrigan's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $551,721.

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.

In the report of claimant's echocardiogram, Marianne Serkland, M.D., stated claimant had "[m]ild mitral insufficiency." Dr. Serkland 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. The report did not indicate claimant's level of ejection fraction. 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 October 2001, the Trust forwarded the claim for review by Ernest Madu, M.D., one of its auditing cardiologists.[4] In audit, Dr. Madu concluded that there was no reasonable medical basis for Dr. Goldenberg's finding that claimant had a reduced ejection fraction because claimant's echocardiogram demonstrated an ejection fraction greater than 60%.[5]

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4. Under the Settlement Agreement, Wyeth and the Trust could each designate for audit a certain number of claims for Matrix Benefits and identify the condition(s) to be reviewed during the audit. See Settlement Agreement § VI.F; Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. In Pretrial Order ("PTO") No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

5. Dr. Madu was not asked to review claimant's level of mitral

(continued...)

Based on Dr. Madu's diagnosis of a normal ejection fraction, the Trust issued a post-audit determination denying Ms. Carrigan's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and submitted additional medical information. See Settlement Agreement § VI.E.7; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Audit Policies and Procedures § VI. Claimant submitted an affidavit from Dr. Goldenberg and several still frames from her echocardiogram, which purportedly demonstrated a reduced ejection fraction. Dr. Goldenberg again concluded that claimant had a reduced ejection fraction, stating that:

> I quantitatively determined the left ventricular ejection fraction ... I photographed the relevant cardiac structures at appropriate times during the cardiac cycle ... All assessments were made and confirmed on multiple cardiac beats so that the conclusions reached would accurately depict the chamber dysfunction present in the echocardiogram ... the patient's ejection fraction was between 50-60% ... Using apical two chamber views on three consecutive beats ... I was able to calculate left ventricular

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regurgitation in audit. In its Reply, the Trust concedes that the mitral valve question was not "posed in audit and that finding is not the basis for this proceeding."

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 moderate mitral regurgitation, the only issue is claimant's level of ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim.

> diastolic and systolic volumes as well as the left ventricular ejection fraction ... resulting [in an] ejection fraction of 52% ... 58% ... [and] 56%; each of the three quantified ejection fraction percentages range between 50%-60% ... Calculations made from the apical four chamber view ... revealed ... ejection fraction[s] of 56% ... 55% ... [and] 57%.

Based on claimant's submissions, the Trust forwarded the claim to an additional auditing cardiologist, Keith Churchwell, M.D., for a second review.[6] In audit, Dr. Churchwell concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Dr. Churchwell estimated claimant's ejection fraction to be "›65%, by observation. Simpson's rule used to evaluate EF in the study underestimates the EF I think because of the difficulty in identifying endocardial borders in the apical four chamber and 2 chamber views."[7]

Thereafter, the Trust issued a final post-audit determination, again denying Ms. Carrigan's claim. Pursuant to the 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; PTO No. 2457, Audit Policies and

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6. Throughout the Show Cause Record, the parties refer to Dr. Churchwell as the auditing cardiologist. Additionally, in its Reply, the Trust stated that Dr. Madu's findings are not at issue in this proceeding because his audit was completed prior to the receipt of claimant's additional submissions.

7. Dr. Churchwell was also not asked to review claimant's level of mitral regurgitation.

Procedures § VI. The Trust then applied to the court for issuance of an Order to show cause why Ms. Carrigan's claim should be paid. On March 10, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2777 (Mar. 10, 2003).

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 June 9, 2003. Claimant submitted a sur-reply on June 25, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned Technical Advisor, Sandra V. Abramson, 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. § VI.O.

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8. 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 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 a reduced ejection fraction. 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 confirm 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 for the answer, 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. Carrigan argues, among other things, that the standard of review in audit is for the auditing cardiologist to determine whether there is a reasonable medical basis for the attesting physician's findings and not to render a "second opinion." Claimant further argues that "Dr. Goldenberg's estimated ejection fraction in the range of '50%-60%' satisfies the Settlement Agreement's 'modest' burden of medical reasonableness." Claimant also contends that there is a reasonable medical basis for Dr. Goldenberg's finding of a reduced ejection fraction based on the concept of "interobserver variability."

In response, the Trust argues that Dr. Churchwell determined that the attesting physician underestimated claimant's ejection fraction, and thus, there was no reasonable medical

basis for finding a reduced ejection fraction. The Trust contends that Dr. Churchwell's conclusion was based on a two step analysis where he first assessed claimant's ejection fraction and then determined whether there was a reasonable medical basis for the attesting physician's finding in light of this assessment. The Trust notes that, although Dr. Madu's findings are not at issue in this proceeding, both Drs. Churchwell and Madu undertook this analysis and reached the same conclusion.

In a sur-reply, claimant argues that the auditing cardiologist failed to provide an underlying explanation for his conclusion that there is no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Claimant also reiterates her arguments that there is a reasonable medical basis for her claim based on the concept of "interobserver variability."

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Specifically, Dr. Abramson found that "my visual estimate is that this Claimant has an ejection fraction between 55%-60%. I measured two ejection fractions using the Simpson's Method of Disks and calculated the ejection fractions to be 59% and 60%."

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 reviewed

claimant's echocardiogram and found that claimant had a reduced ejection fraction in the range of 50% to 60%. Although the Trust contested the attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's finding of a reduced ejection fraction.[9] Specifically, Dr. Abramson concluded that "there is a reasonable medical basis to interpret the ejection fraction of [claimant] as 50%-60%."

As stated above, 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). Here, Dr. Abramson found that claimant's ejection fraction was in the range of 50% to 60%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.[10]

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 is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claims submitted by Ms. Carrigan and her spouse for Matrix Benefits.

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9. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor's Report. See Audit Policies and Procedures § VI.N.

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

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PRETRIAL ORDER NO. _____

AND NOW, on this 29th day of June, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the post-audit determination of the AHP Settlement Trust is REVERSED and that the Level II claims submitted by claimants Kristi Carrigan and her spouse, Michael J. Carrigan, are GRANTED. The Trust shall promptly pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805, and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III
C.J.