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

MEMORANDUM AND PRETRIAL ORDER NO. _____

Bartle, C.J. May 25, 2007

Mary Schrodi[1] ("Ms. Schrodi" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.[2] 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").[3]

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1. Claimant is Pro Se.

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

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 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 2000, claimant submitted a completed Green Form to the Trust signed by her attesting physician Howard S. Lite, M.D., F.A.C.C., F.A.S.E. Based on an echocardiogram performed on November 3, 1999, Dr. Lite attested in Part II of the Green Form that claimant suffered from moderate mitral regurgitation, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction in the range of 40% to 49%, and aortic stenosis. Dr. Lite also attested that claimant did not have any level of aortic regurgitation and that

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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.

she had surgery to repair or replace the aortic valve after the use of Pondimin® and/or Redux™.[4]

In reviewing the claim at issue, the Trust considered claimant's Matrix A-1, Level III claim for surgery to replace her aortic valve as well as whether she was entitled to Matrix A-1, Level II benefits because her Green Form facially set forth a claim for damage to her mitral valve. Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered to be eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.1.a.; see also id. § I.22.

Eligible claimants are entitled to Level III benefits for aortic valve surgery if the following definition is met:

> (3) Matrix Level III is left sided valvular heart disease requiring surgery or conditions of equal severity, and is defined as:
>
> (a) Surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.

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4. A handwritten note in the Green Form indicates that claimant had only "trivial" aortic regurgitation. In a report of claimant's echocardiogram, Dr. Lite stated that "[a]ortic insufficiency was present but appeared trivial," "[m]itral insufficiency was present and appeared probably moderate," and the left atrium was mildly dilated.

Settlement Agreement § IV.B.2.c.(3)(a); see also Green Form, App. at 19. Thus, a claimant must have left sided valvular heart disease and undergo surgery to repair or replace the aortic valve after the ingestion of diet drugs.

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). 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 id. § I.22. 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. A left ventricular end-systolic dimension is considered to be abnormal if the dimension is greater than or equal to 45 mm by M-mode or a 2-D echocardiogram. See id. 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.

In September 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 the attesting physician's finding that claimant

had moderate mitral regurgitation, stating that claimant had only "mild MR."[5] Dr. Irani was not asked to review the findings of an abnormal left atrial dimension, abnormal left ventricular end-systolic dimension or reduced ejection fraction.[6]

Based on Dr. Irani's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Schrodi's claim. Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant disputed 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, Audit Policies and Procedures § VI.[7] The Trust

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5. Dr. Irani also concluded that claimant had mitral annular calcification, which is a reduction factor under the Settlement Agreement. See Settlement Agreement § IV.B.2.d.(2)(c)(ii)(d). Given the resolution of the issue of claimant's level of mitral regurgitation as discussed infra, the presence of mitral annular calcification is irrelevant to the resolution of this claim.

6. As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension and a reduced ejection fraction, each of which is a condition needed to qualify for a Level II claim, the only issue is whether claimant has moderate mitral regurgitation.

7. 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. Schrodi's claim.

then applied to the court for issuance of an Order to show cause why Ms. Schrodi's claim should be paid. On February 6, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2736 (Feb. 6, 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 April 10, 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, James F. Burke, M.D., 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.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical

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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.

basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. More specifically, Dr. Burke explained that only 7 seconds of color flow Doppler in the apical four chamber view was available in real time and he measured claimant's RJA/LAA ratio in this view as 2%, 6.6% and 12.4%. Dr. Burke also noted that "[e]xcessive gain is used for the color flow imaging" and the measurements of the beat used in calculating the 12.4% RJA/LAA ratio were "an aberration compared to the other beats recorded, but still falls well within the range of mild regurgitation."

In response to the Technical Advisor's Report, claimant submitted a letter from Dr. Lite, in which he reaffirmed his view that claimant had moderate mitral regurgitation. Therein, Dr. Lite stated that:

> [I]n the parasternal long-axis view, there is a somewhat eccentric anteriorly directed large jet of mitral insufficiency seen for two beats which very clearly wraps around to the posterior aspect of the left atrium and this jet very clearly occupies greater than 50 percent of the left atrial surface area in this view. Since this jet is directed somewhat anteriorly, it would be very difficult to clearly see in the apical four-chamber view; however, at 3:07 into the recording, a jet is clearly seen extending the length of the left atrium that although is "broken," would clearly occupy 20 percent of the surface area. In addition, subsequent pulsed wave Doppler clearly shows mitral regurgitation signals that proceed to the posterior aspect of the left atrium and there is definite pulmonary vein systolic flow reversal which is commonly seen in severe mitral insufficiency. I graded her mitral

> insufficiency as moderate instead of severe due to suboptimal signals on apical four-chamber views; however, on the basis of the above statements, her mitral regurgitation may well have been much worse. There should certainly be no argument that her mitral insufficiency is at least moderate.

There are two issues presented for resolution of this claim. First, we must determine whether claimant is entitled to Level III Matrix Benefits. Second, we must determine 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 and thus is entitled to Level II Matrix Benefits. 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, claimant argues that her ingestion of Diet Drugs caused her aortic valve replacement surgery and her attesting physician, Dr. Lite, is one of the "top cardiologist's [sic] in St. Louis . . . ." In response, the Trust argues that claimant failed to meet her burden of proof because she did not submit any additional evidence in support of her claims. With respect to claimant's Level III claim, the Trust further explains that claimant's aortic valve replacement

surgery was due to aortic stenosis, which is not a compensable valvular condition under the Settlement Agreement. The Trust also argues that only aortic valve surgery that occurs after the ingestion of Diet Drugs and the onset of moderate or severe aortic regurgitation is compensable. As Dr. Lite attested in the Green Form that claimant had no aortic regurgitation, the Trust argues that claimant is not entitled to Level III benefits for her aortic valve replacement surgery. After reviewing the entire Show Cause Record, we find that claimant is not entitled to either Level III benefits for surgery to replace her aortic valve or Level II benefits for damage to her mitral valve.

As to claimant's Level III claim, claimant's medical condition appears to meet the definition of a Level III claim as the Trust does not contest that: (1) claimant's aortic valve required surgery; or (2) claimant had surgery to replace her aortic valve following the use of Pondimin® and/or Redux™. As we previously explained in PTO No. 3192, meeting the definition of Level III alone is insufficient to qualify for Matrix Benefits. Rather, a claimant also must satisfy the eligibility requirements set forth in Section IV.B.1.a. of the Settlement Agreement. See PTO No. 3192 at 3. If a claimant is deemed eligible under the Settlement Agreement, he or she may receive Matrix Benefits only for matrix-level conditions resulting from the valve or valves for which eligibility was satisfied. See Settlement Agreement §§ IV.B.2.h and IV.B.2.i. Thus, claimant was required to establish

her eligibility to seek Matrix Benefits for surgery on her aortic valve by demonstrating at least mild aortic regurgitation.

In claimant's Green Form, Dr. Lite attested that claimant did not have mild, moderate or severe aortic regurgitation and, in a handwritten notation in the Green Form, stated that claimant only had "trivial AR." Accordingly, consistent with the terms of the Settlement Agreement, claimant does not meet the threshold eligibility requirement for seeking Matrix Benefits and her Level III claim based on surgery to replace her aortic valve must be denied.

With regard to the Level II claim, claimant has not met her burden in establishing a reasonable medical basis for Dr. Lite's finding that she had moderate mitral regurgitation. The Technical Advisor, Dr. Burke, concluded that the level of mitral regurgitation shown on claimant's echocardiogram clearly fell within the definition of mild mitral regurgitation. Dr. Burke determined that excessive gain was used for the color flow imaging on claimant's echocardiogram and, at best, claimant's RJA/LAA ratio in the apical four chamber view was 12.4%.

While claimant submitted a letter from Dr. Lite in response to the Technical Advisor's Report, we disagree that such letter supports the conclusion that there is a reasonable medical basis for Ms. Schrodi's Level II claim. In the letter, Dr. Lite fails to address the Technical Advisor's findings. In particular, Dr. Lite does not rebut the Technical Advisor's observation that excessive gain was used for the color flow

imaging on claimant's echocardiogram. A "reasonable medical basis" does not exist for any conclusion of a cardiologist that is based on over-manipulated echocardiogram settings that result in an inflated level of regurgitation. See PTO No. 2640 at 11 (Nov. 14, 2002) (finding that conduct "beyond the bounds of medical reason" can include over-manipulating echocardiogram settings).

Additionally, Dr. Lite bases his finding of moderate mitral regurgitation, at least in part, on two beats in the parasternal long-axis view. As defined in the Settlement Agreement, 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. Dr. Lite, however, neither states that the apical view on claimant's echocardiogram is not evaluable nor contests the Technical Advisor's conclusion that claimant's RJA/LAA ratio in the apical four chamber view is consistent with mild mitral regurgitation. Thus, under these circumstances, claimant cannot meet her burden in proving a reasonable medical basis for her claim based on Dr. Lite's opinion that moderate mitral regurgitation is depicted in the parasternal long-axis view.

Finally, Dr. Lite appears to opine that one "broken" jet in the apical four-chamber view occupies "20 percent of the surface area." Other than this ambiguous statement, Dr. Lite has failed to quantify claimant's level of mitral regurgitation as required by the Settlement Agreement. See Settlement Agreement

§ IV.B.2.c.(2)(b). Moreover, we previously have stated that "'[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.'" PTO No. 6897 (Jan. 26, 2007) (quoting PTO No. 2640 at 9). Therefore, we find that Dr. Lite's opinion that one "broken" jet in the apical view demonstrates an RJA/LAA ratio of 20% is inadequate.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for either her Level II or Level III claim. Therefore, we will affirm the Trust's denial of Ms. Schrodi's claims for Matrix Benefits.

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PRETRIAL ORDER NO.

AND NOW, on this 25th day of May, 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 AFFIRMED and the Level II and Level III claims submitted by claimant Mary Schrodi are DENIED.

BY THE COURT:

/s/ Harvey Bartle III
C.J.