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. August 21, 2007

Diane Barlow ("Ms. Barlow" 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. Reed Barlow, Ms. Barlow'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 May 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Charles F. Dahl, M.D. Based on an echocardiogram dated March 20, 2002, Dr. Dahl attested in Part II of Ms. Barlow's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $473,032.

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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, Dr. Dahl stated that claimant had "[m]oderate mitral regurgitation," but 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. Dr. Dahl also found that "[m]oderate tricuspid regurgitation was noted, with a peak velocity of 3.0 m/sec, suggesting mild to moderate pulmonary hypertension." Under the Settlement Agreement, pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic pulmonary artery pressure >40 mm Hg measured by cardiac catheterization or >45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See id. § IV.B.2.c.(2)(b)i). Finally, Dr. Dahl measured claimant's left atrium as 5.4 cm in the supero-inferior dimension and as 4.2 cm in the antero-posterior dimension. 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.

In October 2002, the Trust notified Ms. Barlow that her claim had been selected for audit. Under the Settlement

Agreement, Wyeth could 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; Pretrial Order ("PTO") No. 2457 (May 31, 2002). Here, Wyeth identified only claimant's level of mitral regurgitation and her left atrial dimension as the conditions to be audited. Wyeth did not designate for audit claimant's pulmonary hypertension. In 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.

In response, claimant submitted an expert report from Stephen Raskin, M.D., and a supplemental report by Dr. Dahl. In the report, Dr. Raskin stated that he reviewed claimant's March 20, 2002 echocardiogram and determined that "[m]y calculations confirm a ratio exceeding 20 percent indicating moderate mitral regurgitation." In the supplemental report, Dr. Dahl confirmed his finding of moderate mitral regurgitation. Dr. Dahl further explained that "[m]ost of the regurgitant flow is in the first half of systole, but overall it still occupies 25% of the left atrial area."

In December 2002, the Trust forwarded the claim for review by Susan Mayer, M.D., one of its auditing cardiologists. In audit, Dr. Mayer concluded that there was no reasonable

medical basis for Dr. Dahl's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Mayer also found that there was no reasonable medical basis for Dr. Dahl's finding that claimant had an abnormal left atrial dimension. Although Dr. Mayer was not asked to review claimant's pulmonary hypertension in audit, she measured claimant's pulmonary artery pressure as 46.0 mm Hg.[4]

Based on Dr. Mayer's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Barlow'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 Procedures § VI.[5] The Trust then applied to the court for issuance of an

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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 Settlement Agreement § IV.B.2.c.(2)(b). One of the complicating factors needed to qualify for a Level II claim is pulmonary hypertension secondary to moderate or greater mitral regurgitation. It should be noted that Dr. Mayer's measurements confirm that claimant had pulmonary hypertension. Therefore, if claimant establishes that she was diagnosed with moderate mitral regurgitation, her pulmonary hypertension would qualify as a complicating factor as it would be secondary to moderate mitral regurgitation. Thus, the only issue is claimant's level of mitral regurgitation.

5. 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

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Order to show cause why Ms. Barlow's claim should be paid. On April 15, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2834 (Apr. 15, 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 13, 2003. Claimant submitted a sur-reply on June 20, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor[6] 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

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December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). By letter dated October 4, 2002, claimant was notified that her claim was selected for audit. There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Barlow's claim.

6. 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.

Record and Technical Advisor's Report are now before the court for final determination. Id. § 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 had moderate mitral regurgitation. 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 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. Barlow submitted a transcript and videotaped expert opinion of Richard L. Weiss, M.D.[7] In his report, Dr. Weiss stated:

> This mitral regurgitation jet extends nearly to the posterior dome of the left atrium and its area is greater than 20 percent of the left atrial area, consistent with moderate mitral regurgitation.[8]

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7. Claimant also resubmitted the expert report of Dr. Raskin and supplemental report of Dr. Dahl that she previously provided to the Trust in response to the audit notification.

8. Dr. Weiss also found that claimant had moderate pulmonary hypertension. In particular, he stated that: "[h]ere is a jet that's greater than 3 meters per second coming out to a pulmonary artery pressure assuming a right atrial pressure of 10 of 47 millimeters of mercury consistent with moderate pulmonary

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Claimant argues that the opinions of Drs. Dahl, Raskin, and Weiss provide a reasonable medical basis for her claim. She also argues that the auditing cardiologist "substituted her judgment for that of the attesting physician rather than to apply the 'reasonable medical basis' standard that is required by the Audit Procedures."

In response, the Trust argues that the auditing cardiologist determined that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated mild mitral regurgitation. The Trust also argues that, by stating that "most of the regurgitant flow is in the first half of systole," Dr. Dahl concedes that he based his finding of moderate mitral regurgitation on a non-representative regurgitant jet. Finally, the Trust argues that claimant cannot establish a reasonable medical basis for her claim simply by proffering additional opinions.[9]

In a sur-reply, claimant maintains that the opinions of Drs. Dahl, Raskin, and Weiss are valuable because of their weight, and not their number. Claimant also contends that her

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hypertension."

9. The Trust also argues that under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Policies and Procedures. See PTO No. 6997 (Feb. 26, 2007).

physicians based their findings of moderate mitral regurgitation on regurgitant jets that were representative of her level of mitral regurgitation.

The Technical Advisor, Dr. Abramson, reviewed claimant's March 20, 2002 echocardiogram and found that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Dr. Abramson explained that:

> I measured the RJA/LAA ratios in the apical-4-chamber view as described by Singh, et al in the Green [F]orm. I measured the mitral regurgitant jet on 3 different beats .... These average out to 24.3%. This meets the definition of moderate mitral regurgitation as stated in the Green Form ....[10]

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation. Claimant's attesting physician, Dr. Dahl, reviewed claimant's echocardiogram and determined that claimant had moderate mitral regurgitation, which he measured as 25%.[11] Although the Trust challenged the attesting physician's finding, Dr. Abramson confirmed that claimant suffers from moderate mitral

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10. In response to the Technical Advisor Report, claimant noted that she has submitted a supplemental claim to the Trust based on her echocardiogram dated December 6, 2002. Claimant's supplemental claim is not before us, and, therefore, it is not at issue in these show cause proceedings.

11. Although unnecessary for resolution of this claim, as noted above, claimant also submitted expert reports of two additional cardiologists who similarly concluded that claimant had moderate mitral regurgitation.

regurgitation.[12] Specifically, Dr. Abramson concluded that "there is a reasonable medical basis for the Attesting Physician's claim that this patient has moderate mitral regurgitation based on the RJA/LAA ratios of 24.3%."

As stated above, 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. Here, Dr. Abramson found that moderate mitral regurgitation was present in the apical-four chamber view. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation.[13]

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. Barlow and her husband for Matrix Benefits.

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

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

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PRETRIAL ORDER NO._____

AND NOW, on this 21st day of August, 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, Diane Barlow, and her husband, Reed Barlow, are GRANTED. The Trust shall 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.