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

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9000

Bartle, J. January 31, 2013

Joyce Davis ("Ms. Davis" 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

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To seek Matrix Benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is 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, claimant's attorney must complete Part III if claimant is represented.

In November, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Milton D. Concannon, M.D. Based on an echocardiogram dated December 14, 2002, Dr. Concannon attested in Part II of claimant's Green Form that Ms. Davis suffered from moderate 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 $207,947.[3]

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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.

3. 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
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In the report of claimant's echocardiogram, Dr. Concannon stated, "There is moderate (26%) 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.

In March, 2004, the Trust forwarded the claim for review by Qahtan Malki, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Malki concluded that there was no reasonable medical basis for Dr. Concannon's finding that claimant had moderate mitral regurgitation. Dr. Malki explained:

> The LA is clearly enlarged. One of the measurements is 27 cm2, the [other] one from the apical 2 chambers is 21cm2. It is hard to see the atrium borders from this view. The [mitral regurgitant] jet was overmeasured from [one] of the views. The other jets are probably little oversized but close enough. I do not see any turbulent jet with the [mitral regurgitation], which makes me think it is not as severe. [I] think the [mitral regurgitation] is mild but close to 20%. Maybe 18%. Better quality study may show more [mitral regurgitation].

Based on Dr. Malki's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination

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five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II mitral valve claim, the only issue is claimant's level of mitral regurgitation.

denying this claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[4] In contest, claimant argued that Dr. Malki should have declared the echo was not susceptible to evaluation pursuant to Rule 7 of PTO No. 2807 or deferred to the finding of the attesting physician since he could not determine with certainty whether the regurgitation was mild or moderate and because he indicated a "better quality study may show more [mitral regurgitation]." Further, claimant stated that she "contest[ed] all findings contrary to Dr. Concannon's findings, and maintains that the claimant to [sic] has moderate mitral valve regurgitation which qualifies as a matrix claim."

The Trust then issued a final post-audit determination again denying the claim. 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, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On August 2, 2006, we issued an Order to show cause and referred the matter to the

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4. 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 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 this claim.

Special Master for further proceedings. See PTO No. 6455 (Aug. 2, 2006).

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 23, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[5] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, 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 Report are now before the court for final determination. See id. 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 had moderate mitral regurgitation. See id. Rule 24. Ultimately if we determine that there is no reasonable medical

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5. 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. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, 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 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 is 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 reasserts many of the arguments raised during contest, namely, that Dr. Malki should have declared that he could not evaluate the December 2002 echocardiogram or should have deferred to Dr. Concannon's interpretation because Dr. Malki was unable to determine with certainty whether claimant had mild or moderate mitral regurgitation. In addition, she argues that Dr. Concannon's interpretation is entitled to more weight than Dr. Malki because Dr. Concannon's involvement in "Phen-Fen" is limited.

In response, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because she did not rebut the auditing cardiologist's findings that the left atrium was "overmeasured" and that there was no turbulent jet with the mitral regurgitation. In addition, the Trust contends that the RJA was measured early in systole consistent with backflow and included non-regurgitant flow. The Trust also asserts that Dr. Malki specifically found that claimant's echocardiogram was evaluable.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante stated that:

> In this study, the mitral valve was structurally normal with thin leaflets that moved normally. There was no evidence of mitral valve prolapse nor mitral annular calcification. In the parasternal long-axis view, a thin central jet of mitral regurgitation was noted. Mitral regurgitation was also noted in the apical four chamber and two chamber views. Visually, the degree of mitral regurgitation appeared to be mild in these views. I digitized those representative cardiac cycles in which the mitral regurgitation appeared most impressive in the apical four chamber and apical two chamber views. I then digitally traced and calculated the RJA and LAA. The LAA was 27.3 cm2 in the apical four chamber view. The largest RJA/LAA ratio in the apical four chamber view was less than 11%. In the apical two chamber view, the accurate LAA was 21.0 cm2. The accurate RJA was 2.0 cm2. Therefore, the RJA/LAA ratio in the apical two chamber view was less than 10%. Most of the RJA/LAA ratios were less than 8% during this study qualifying for mild mitral regurgitation. There was no RJA/lAA ratio that came close to approaching 20%.
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> I reviewed the measurements made by the sonographer on the tape ... The sonographer measured two RJA's in the apical four chamber view. These measurements were 4.27 cm2 and 4.99 cm2. The measurement of 4.27 cm2 included a great deal of low velocity and non-mitral regurgitant flow and was completely inaccurate. The sonographer's RJA measurement of 4.99 cm2 in the apical four chamber view was a measurement of backflow and not mitral regurgitation. The sonographer also measured an RJA of 5.69 cm2 in the apical two chamber view. This was an

> inaccurate measurement of backflow and not mitral regurgitation. The representative RJA in the apical four chamber view was 2.9 cm2 and the representative RJA measurement in the apical two chamber view is 2.0 cm2. The Attesting Physician used the sonographer's inaccurate RJA measurement of 5.69 cm2 in determining that the RJA/lAA ratio was 26%.

In response to the Technical Advisor Report, claimant reasserts her arguments regarding the auditing cardiologist's alleged uncertainty that she raised in contest. Claimant also argues that Dr. Vigilante's reading of the December 14, 2002 echocardiogram was "grossly different from the other two doctors" and thus should be "totally disregarded."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest Dr. Malki's and Dr. Vigilante's specific findings. In particular, Dr. Malki determined that claimant's mitral regurgitant jet area was "overmeasured" in at least one view.[6] In addition, Dr. Vigilante determined that the sonographer's measurements included low velocity and non-mitral regurgitant flow. Mere disagreement with the auditing cardiologist and Technical Advisor without identification of specific errors by them is insufficient to meet a claimant's burden of proof.

We also disagree with claimant's assertion that Dr. Concannon's interpretation should be given greater weight.

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6. For this reason as well, we disagree with Ms. Davis that Dr. Malki was obligated to find the echocardiogram of attestation was uninterpretable.

We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. 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 to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26. As previously noted, Dr. Malki determined in audit that Dr. Concannon's finding of moderate mitral regurgitation was based on overtracing the amount of claimant's mitral regurgitation, and Dr. Vigilante determined that the sonographer's measurements were inaccurate because they included backflow and not mitral regurgitation. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable

medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Davis for Matrix Benefits.