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. August 27, 2007

Yolanda Garcia ("Ms. Garcia" 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]

---

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

2. Melissa S. Nava, Ms. Garcia's daughter, 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

(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 February 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Thomas S. Davidson, M.D. Based on an echocardiogram dated May 4, 2001, Dr. Davidson attested in Part II of Ms. Garcia's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Dr. Davidson also attested that claimant did not have a rheumatic heart valve or mitral annular calcification

---

3(...continued)
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 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.

("MAC").[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $551,721.

In the report of claimant's echocardiogram, David A. Rawling, M.D., F.A.C.C., stated that: "[t]here is moderate to moderately severe regurgitation" and noted "3-4+ [mitral regurgitation]."[5] 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. Davidson also measured claimant's left atrial dimension as 4.4 cm. 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).

In October 2002, the Trust advised claimant that her claim was selected for audit by Wyeth and further advised claimant that Wyeth's audit designations included the level of mitral regurgitation and whether a rheumatic heart valve was

---

4. Under the Settlement Agreement, the presence of either a rheumatic heart valve or MAC requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)(ii)(d).

5. The clinical history on claimant's echocardiogram report is noted as "Phen-fen echo." The echocardiogram report also indicates that it was prepared for Abbott & Walker.

present.[6] In response, claimant submitted a letter from Dr. Davidson wherein he stated that:

> Today, I reviewed the cardiac echocardiogram. I found the mitral regurgitation area to be 6.23. The left atrial area was 25.4. The percentage was 24.5 and is consistent with moderate mitral regurgitation. She did not have rheumatic mitral stenosis.

Claimant also submitted an "Echocardiographic Overview" prepared by Amjad Iqbal, M.D. According to the Trust, as of May 31, 2003 Dr. Iqbal signed at least 66 Green Forms on behalf of claimants seeking Matrix Benefits. In his "Echocardiographic Overview," Dr. Iqbal stated that:

> The review of the echocardiographic study confirms the presence of moderate degree of mitral regurgitation. The regurgitant jet area to left atrial area ratio is greater than 20%, but less than 40%.
>
> The anterior and the posterior leaflets of the mitral valve are thickened, but no doming or commissural fusion is present. There is no echocardiographic evidence for rheumatic heart disease involvement of the mitral valve present.[7]

---

6. 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; 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.

7. Ms. Garcia also submitted a report by Richard L. Callihan, M.D., F.A.C.C., based on an echocardiogram dated November 6, 2002. Ms. Garcia's Green Form, however, was based on an echocardiogram dated May 4, 2001. Thus, the May 4, 2001 echocardiogram is the only echocardiogram at issue in these

(continued...)

In December 2002, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Davidson's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only "mild" mitral regurgitation, which he measured as 17.99%. Dr. Irani further found that the "area reported is overestimated outside the borders of the color jet."[8] Finally, in conducting his review, Dr. Irani also concluded that claimant had MAC "with restricted views of posterior leaflets," and there was no reasonable medical basis for the attesting physician to find no MAC.[9]

Based on Dr. Irani's diagnoses, the Trust issued a post-audit determination denying Ms. Garcia's claim. Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"),

---

7(...continued)
proceedings.

8. Dr. Irani found that there was a reasonable medical basis for the attesting physician's finding that claimant did not have a rheumatic heart valve.

9. 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 abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issues are claimant's level of mitral regurgitation and the presence of MAC.

claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See id. § VI.E.7; PTO No. 2457 (May 31, 2002), Audit Policies and Procedures § VI.[10] The Trust then applied to the court for issuance of an Order to show cause why Ms. Garcia's claim should be paid. On April 30, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2839 (Apr. 30, 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 July 28, 2003. Claimant filed a Sur-Reply on January 6, 2005. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor[11] to review claims after the Trust

---

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

11. 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 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

(continued...)

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, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and 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 issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and that claimant did not have MAC. See id. § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answers in claimant's Green Form that are 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 answers, 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. Garcia submitted verified opinions of Drs. Davidson and Iqbal, who both confirmed their previous findings that claimant had moderate mitral regurgitation. Claimant argues that she has established a

---

11(...continued)
Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. See id.

reasonable medical basis for her claim through these submissions. According to claimant, "reasonable medical basis" is a fluid term, which incorporates inter-reader variability and allows for variations and disagreements between physicians.[12] Claimant also maintains, inter alia, that: (1) the auditing cardiologist's opinion is inadmissible ipse dixit[13] because it fails to explain the lack of a reasonable medical basis; and (2) the Trust's conduct amounts to a violation of her due process rights because she is being deprived of Matrix Benefits without the opportunity to be heard in a meaningful manner.[14]

The Trust counters, inter alia, that claimant "improperly attempts to shift the burden of proof in the Show Cause proceedings to the Trust." The Trust also contends that the auditing cardiologist properly found no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because he overestimated claimant's regurgitant jet. Additionally, the Trust asserts that claimant's inter-reader variability argument does not refute the auditing cardiologist's conclusions and that the Audit Policies and

---

12. In support, claimant submitted a partial transcript of testimony from John Dent, M.D., the Trust's expert during the September 3-4, 2002 hearings, which ultimately resulted in the court's issuance of PTO No. 2640 (Nov. 14, 2002).

13. Ipse dixit is Latin for "he himself said it." It stands for the proposition that something is asserted but not proved. Black's Law Dictionary 833 (7th Ed. 1999).

14. In her response, claimant does not address or respond to the auditing cardiologist's finding that she has MAC.

Procedures provide claimant with adequate notice and an opportunity to be heard.[15] Finally, the Trust argues that, even if claimant could meet her burden of proving moderate mitral regurgitation, her claim would only be payable on Matrix B-1 because of the presence of MAC.

In a Sur-Reply, claimant identified several frames from her echocardiogram that purportedly demonstrate moderate mitral regurgitation. Claimant argues that, based on the detailed evidence presented, there is a reasonable medical basis for her claim.[16]

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In particular, Dr. Vigilante found that:

> Moderate mitral regurgitation was found with a central jet traveling towards the posterior aspect of the left atrium. I measured the

---

15. In its show cause submissions, the Trust 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. While the Audit Policies and Procedures allow claimants to submit verified expert opinions in support of their claims, they do not require Rule 26(a)(2) disclosures. See Audit Policies and Procedures § VI.F. Discovery relating to claims is prohibited by the Audit Policies and Procedures. See id. § VII.A. Thus, requiring Rule 26(a)(2) disclosures would serve no purpose.

16. In her sur-reply, claimant did not address the Trust's finding of MAC.

> RJA and LAA in four cardiac cycles. These cycles were representative of the actual degree of mitral regurgitation. The RJA/LAA ratios were well over 20% in all four of these cardiac cycles.

Dr. Vigilante, however, concluded that there was no reasonable medical basis for the attesting physician's finding of no MAC. Specifically, Dr. Vigilante stated:

> There were significant abnormalities of the mitral apparatus. The posterior mitral leaflet was significantly thickened with very poor motion. There was partial calcification of the mid portion and tip of the posterior leaflet. The anterior leaflet was more mobile but also thickened. There was doming of the anterior leaflet with the body of this leaflet opening more than the tip of the leaflet consistent with partial comissural fusion. There was [MAC] noted both of the medial and posterolateral areas of the annulus. Both of these areas had significantly increased reflectance of ultrasound found in [MAC]. The [MAC] was also characterized by increased echogenicity and thickness of the medial and posterolateral portions of the mitral annulus. There was thickening of the mitral subvalvular apparatus. These mitral valve findings were classic for rheumatic mitral valvular disease in the absence of significant mitral stenosis.
>
> * * *
>
> [MAC] is clearly noted on the echocardiographic study of May 4, 2001. This is due to the presence of rheumatic mitral valvular disease with co-existent partial commissural fusion and doming of the anterior mitral leaflet as well as significant thickness and calcification of the two mitral leaflets as well as increased thickness of the subvalvular apparatus.

In response to the Technical Advisor Report, claimant argues, inter alia, that: (1) the Technical Advisor merely

diagnosed claimant with MAC and "swapped his diagnosis for the Attesting Physician's"; (2) the Technical Advisor failed to address whether the presence of doming is within the predicted range of inter-reader variability; and (3) the Technical Advisor's opinion is ipse dixit expert testimony because there was insufficient rationale for the diagnosis of doming.

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. Although the Trust challenged the attesting physician's conclusions, Dr. Vigilante confirmed that claimant suffers from moderate mitral regurgitation.[17] Specifically, Dr. Vigilante concluded that "[c]laimant does suffer from moderate mitral regurgitation with a RJA/LAA found to be between 20% and 40% on the echocardiographic study of May 4, 2001."

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. Vigilante found that moderate mitral regurgitation was visible in "four cardiac cycles." Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation.

---

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

We, however, find that there is no reasonable medical basis for the attesting physician's finding that claimant does not have MAC. We disagree with claimant that the opinions of Drs. Irani and Vigilante are unsupported. Dr. Irani concluded that claimant had MAC "with restricted views of posterior leaflets." Likewise, Dr. Vigilante provided a detailed explanation in support of his conclusion that "[i]t would be impossible for a reasonable echocardiographer to conclude that [MAC] was not present on this study." The specific deficiencies identified by Drs. Irani and Vigilante negate claimant's assertion that their respective conclusions constitute ipse dixit.[18]

Further, claimant's reliance on the concept of inter-reader variability to dispute Dr. Vigilante's detailed conclusion that there was no reasonable medical basis for the attesting physician to find no MAC is misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard. See PTO No. 6824. In this instance, the attesting physician's representation cannot have a reasonable medical basis where the Technical Advisor concluded that claimant

---

18. Moreover, as we previously stated in PTO No. 6824, "[c]ourt-appointed Technical Advisors are not experts subject to the Federal Rules of Evidence .... 'Throughout its text, Fed. R. Evid. 706 refers not to 'experts' generally, but to a more exclusive class: 'expert witnesses.' Because the plain language of the Civil Rule is the most reliable indicator of its meaning, we are constrained to conclude that the grasp of Rule 706 is confined to court-appointed expert witnesses; the rule does not embrace advisors or consultants.'" PTO No. 6824 (Dec. 29, 2006) (quoting Reilly, 863 F.2d at 155) (citation omitted).

had MAC. Moreover, unlike some of the other factors that reduce a claim to Matrix B-1, any presence of MAC, regardless of the amount, places the claim on Matrix B-1. See Settlement Agreement, § IV.B.2.d.(2)(c)(ii)(d); Cf. § IV.B.2.d.(2)(c)(i)(d) ("Aortic root dilatation > 5.0 cm"). We cannot ignore Dr. Vigilante's clear findings, which identify precisely where claimant's MAC is observed on her May 4, 2001 echocardiogram. To do otherwise would jeopardize the future allocation of funds for meritorious claims.

Finally, claimant's argument that her "due process" rights have been violated is meritless. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Policies and Procedures § VI.D. The audit and show cause process, as approved by this court, comply with due process requirements, as claimant has had notice and an opportunity to present her evidence in support of her claim.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for finding that had moderate mitral regurgitation. We conclude, however, that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she does not have MAC. Therefore, we will affirm in part and reverse in part the Trust's denial of the claims submitted by Ms. Garcia and her daughter for Matrix A-1, Level II benefits, and find that Ms. Garcia and her daughter are consequently entitled to Matrix B-1, Level II benefits.

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

PRETRIAL ORDER NO.

AND NOW, on this 27th 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 AFFIRMED in part and REVERSED in part and that the Matrix A-1, Level II Matrix claims submitted by claimant Yolanda Garcia, and her daughter Melissa S. Nava, are DENIED. Claimant Yolanda Garcia, and her daughter Melissa S. Nava, are entitled only to Matrix B-1, Level II benefits. 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.