

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 IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8631

Bartle, C.J. April 1, 2011

Rebecca Thompson ("Ms. Thompson" 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

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 (continued...)

To seek Matrix Benefits, a claimant must first 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 August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam Ansari, M.D., F.A.C.C. Dr. Ansari is no stranger to this litigation. According to the Trust, he has signed in excess of 163 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated March 13, 2002, Dr. Ansari attested in Part II of Ms. Thompson's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in

2. (...continued)

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 drug.

the range of 50% to 60%.³ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$545,310.⁴

In the report of claimant's echocardiogram, Dr. Ansari stated that claimant had "moderate mitral regurgitation, which occupied 20% of the left atrial volume." 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. Ansari also measured claimant's left atrial dimension as 3.6 cm in the parasternal long-axis view and stated that "[t]here is biatrial enlargement" in the apical four chamber view. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than

3. Dr. Ansari also attested that claimant suffered from moderate aortic regurgitation. As Ms. Thompson's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

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). Claimant has conceded that she does not have a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim. Claimant, however, contends that Dr. Ansari inadvertently checked "No" in responding to the Green Form question regarding whether she had an enlarged left atrial dimension, which is one of the other complicating factors needed to qualify for a Level II claim.

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, 2003, the Trust forwarded the claim for review by Alan J. Bier, M.D., one of its auditing cardiologists. In audit, Dr. Bier concluded that there was no reasonable medical basis for Dr. Ansari's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Bier explained that:

Only slight [mitral regurgitation] was seen in all projections. Traced jet area includes both low velocities of normal flow and sub-threshold velocities. Despite that, the area they report is only 20%, borderline even with this major overestimate of jet size.

Dr. Bier also measured claimant's left atrial dimension as 4.0 cm in the parasternal long-axis view and 4.9 cm in the apical four chamber view. Both measurements are within the range of normal under the Settlement Agreement.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Thompson's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant submitted a

5. 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 (continued...)

supplemental opinion from Dr. Ansari, who confirmed his findings of moderate mitral regurgitation and left atrial enlargement and attached still frames from claimant's echocardiogram, which purportedly demonstrated these conditions. Claimant also asserted that: (1) the auditing cardiologist only visually assessed her level of mitral regurgitation as opposed to taking actual measurements; (2) the Green Form does not have the same answer choices as the Auditor's Report; and (3) the Trust failed to specify the auditing cardiologist's credentials in connection with its denial.⁶

The Trust then issued a final post-audit determination, again denying Ms. Thompson's 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 Ms. Thompson's claim should be paid. On November 10, 2004, we issued an Order to show cause and referred

5. (...continued)
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 Ms. Thompson's claims.

6. The Trust provided claimant with Dr. Bier's credentials with its final post-audit determination. In contest, claimant also had argued that the auditing cardiologist failed to declare under penalty of perjury that the information contained in the Report of the Auditing Cardiologist was correct to the best of his knowledge. Dr. Bier signed an Attestation Form dated November 2, 2003 and a Certification dated October 26, 2004 averring that his findings were true and correct.

the matter to the Special Master for further proceedings. See PTO No. 4135 (Nov. 10, 2004).

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 8, 2005, and claimant submitted a sur-reply on June 30, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ 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, 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 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 finding that she had moderate mitral regurgitation and an abnormal left atrial dimension. See id.

7. 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.

Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are 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 answers, 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, Ms. Thompson reasserts the arguments she made in contest. Claimant also argues that: (1) the auditing cardiologist "selectively downgraded" her level of mitral regurgitation from moderate to mild; (2) the Trust cannot modify the definition of mitral regurgitation by referencing "low velocity" flow or "sub-threshold velocities"; and (3) the auditing cardiologist's findings are unverifiable. Claimant further criticizes the Trust's administration of claims and argues that the audit process is unfair to claimants.

In response, the Trust disputes that the auditing cardiologist selectively downgraded claimant's level of mitral regurgitation. Instead, the Trust explains that the auditing cardiologist concluded that there was no reasonable medical basis to find moderate mitral regurgitation because the attesting physician relied on "planimetry that was significantly overtraced." The Trust also asserts that claimant cannot establish a claim for Matrix Benefits because she failed to demonstrate the existence of a complicating factor. The Trust

further contends that the auditing cardiologist complied with the Settlement Agreement in assessing claimant's level of mitral regurgitation. Finally, the Trust argues that the additional possible responses regarding the level of a claimant's mitral regurgitation included in the Report of the Auditing Cardiologist have no effect on the outcome of claims and that claimant's criticisms of the Trust's administration of claims are beyond the scope of the show cause proceedings.

In her sur-reply, claimant argues that while the auditing cardiologist's findings are not substantiated by any independent evidence, the attesting physician's findings are based on computerized assessments and still frames, which, according to claimant, provide a reasonable medical basis for her claim. Claimant again contends that the Trust is attempting to modify the definition of mitral regurgitation.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's findings that claimant had moderate mitral regurgitation and an abnormal left atrial dimension. Dr. Abramson measured claimant's mitral regurgitant jet in four representative cardiac cycles and obtained ratios of "13%, 14%, 14%, and 14%, all of which are considerably less than 20%, which is consistent with mild mitral regurgitation." Dr. Abramson also determined that the tracings made by the sonographer and the tracings submitted by Dr. Ansari

do not depict mitral regurgitation. Specifically, Dr. Abramson found that:

The one tracing performed by the sonographer includes color flow areas unrelated to the mitral regurgitation. At meter number 41:09:16 the RJA traced by the sonographer was measured at 4.48cm². I remeasured the same jet at 2.56cm². The tracings that were submitted in Exhibit II (Dr. Ansari) do not show the regurgitant jet area and left atrial area tracings in the same cardiac cycle. Also, low velocity flow is included in his tracing of the mitral regurgitant jet.

Dr. Abramson also concluded that claimant's left atrial dimension was "within normal limits and could not reasonably be read as abnormal." In addition, she found that "[t]he measurements in the apical view on the tape include pulmonary veins."

In response to the Technical Advisor Report, claimant argues that Dr. Abramson's conclusions are unsubstantiated. Claimant also contends that, by referencing low velocity flow, Dr. Bier and Dr. Abramson have attempted to rewrite the Settlement Agreement definition of mitral regurgitation. Additionally, claimant dismisses Dr. Abramson's finding that she had a normal left atrial dimension as a "non-verifiable assertion without an exhibit." Finally, claimant argues that there is a reasonable medical basis for her claim based on the verifiable documentation that was provided by Dr. Ansari.⁸

8. Claimant additionally contends that Dr. Abramson lacks the necessary credentials to be a Technical Advisor as set forth in Audit Rule 32. We disagree. We appointed Dr. Abramson to assist the court in reviewing certain claims in the show cause process after finding that she possessed the requisite skills and

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After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that the auditing cardiologist's findings lack verifiable evidence and that Dr. Abramson did not substantiate her findings. To the contrary, the auditing cardiologist identified specific deficiencies with Dr. Ansari's measurements; namely, that he traced jet areas that included "both low velocities of normal flow and sub-threshold velocities."⁹ Similarly, Dr. Abramson concluded that Dr. Ansari relied upon non-representative regurgitant jets, improperly considered low velocity flow in his measurements, and included claimant's pulmonary vein in measuring claimant's left atrium. On these bases alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.¹⁰

We also disagree with claimant that low velocity flow is considered mitral regurgitation. 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

8. (...continued)
expertise. See PTO No. 3212 (Jan. 14, 2002).

9. The auditing cardiologist, therefore, did not selectively downgrade claimant's level of mitral regurgitation from moderate to mild.

10. For these reasons as well, the still frames submitted by claimant are insufficient to establish a reasonable medical basis for her claim.

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 (Nov. 14, 2002). Here, both Dr. Bier and Dr. Abramson concluded that Dr. Ansari improperly included low velocity flow in his measurements of claimant's mitral regurgitation. Dr. Abramson also found that Dr. Ansari inflated claimant's left atrial dimension by improperly including pulmonary veins in his measurements. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnoses and Green Form answers.

Moreover, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See id. at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant

qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.¹¹

Finally, we disagree with claimant's assertion that the Trust's audit system is unfair to claimants. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Rule 24. The audit and show cause process, as approved by this court, provide claimant with notice and an opportunity to present her evidence in support of her claim.¹² Claimant has not provided any evidence that the audit of her claim was not done in an objective manner. We, therefore, reject claimant's challenge to the audit process.

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 and an abnormal left atrial dimension. Therefore, we will affirm the Trust's denial of Ms. Thompson's claim for Matrix Benefits.

11. Claimant's argument also fails because the Technical Advisor, although not required to, measured her level of mitral regurgitation, which further establishes that claimant is not entitled to Matrix Benefits.

12. We reject claimant's argument that there are inconsistencies between the possible answers on the Green Form and the Auditor's Report. Although the Auditor's Report includes additional selections for the level of mitral regurgitation and ejection fraction, these choices have no bearing on whether a claimant is eligible for Matrix Benefits.