

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
_____))
THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.)
v.) CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

May 29, 2007

Andrea Buchanan ("Ms. Buchanan" 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 Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with
(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 August 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician Malcolm P. Taylor, M.D. Dr. Taylor is no stranger to this litigation. According to the Trust, as of November 2004, he has signed in excess of 1,130 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated June 22, 2001, Dr. Taylor attested in Part II of Ms. Buchanan's Green Form that she suffered from moderate mitral regurgitation, moderate aortic regurgitation, and an ejection fraction in the range of 50% and

2(...continued)

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.

60%.³ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$524,135.

In the report of claimant's echocardiogram, Dr. Taylor stated that there was "[m]itral regurgitation with RJA/LAA ratio of 29%." 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. Taylor also stated that claimant had an ejection fraction of 60%, which meets the definition of a reduced ejection fraction under the Settlement Agreement. See id. § IV.B.2.c.(2)(b).

In November 2001, 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. Taylor's finding that claimant had moderate mitral regurgitation. Dr. Irani determined that claimant's mitral regurgitation was "trace-mild" with an RJA/LAA ratio of less than 20%. The Settlement Agreement provides that claimants who exhibit only mild, trace or physiologic mitral regurgitation, that is, those who exhibit an RJA/LAA ratio of

3. Ms. Buchanan's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve. Thus, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

less than 20%, are ineligible for Level II Matrix Benefits. See Settlement Agreement § IV.B.2.c.(2).

Dr. Irani also indicated on the Attestation of Auditing Cardiologist form that there was a reasonable medical basis for the attesting physician's finding of an ejection fraction in the range of 50% and 60%.⁴ Dr. Irani stated that: "EF⁵ estimate 65% - EF in normal range, which is adequately expressed [with] 50 - 60% choice."⁶

Based on Dr. Irani's diagnosis of trace to mild mitral regurgitation and a normal ejection fraction, the Trust issued a post-audit determination denying Ms. Buchanan's claim. Claimant disputed this adverse determination and submitted additional medical information in support of her claim. In particular, claimant submitted an April 30, 2002 letter from Dr. Taylor, in which he stated that:

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). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim.

5. "EF" refers to ejection fraction.

6. According to the Trust: "[a]n anomaly of the Green Form is that at Question F.8. no choice of an ejection fraction range higher than 50% - 60% is given, notwithstanding the fact that normal ejection fractions can be well above 60%." The Trust, therefore, argues that Dr. Irani's estimate of an ejection fraction of 65% indicates that claimant's ejection fraction is "well beyond the range for a claim based on moderate mitral regurgitation" and that the finding of an ejection fraction between 50% and 60% was not medically reasonable.

[a]s requested, I have once again reviewed the echocardiogram on Ms. Andrea Buchanan which was done on June 22, 2001 I have retraced the RJA/LAA calculations and the patient has a ratio of 26 percent which is still positive for moderate mitral regurgitation based on the AHP settlement agreement. The color flow doppler study also shows evidence of moderate mitral regurgitation.

After thorough review of the echocardiogram, there is no doubt that this patient has Fen-Phen induced aortic and mitral valve disease. Both the aortic and mitral valve regurgitation are moderate based on the nationwide class action settlement agreement using the SING [sic] criteria.

Upon receipt of the additional medical information, the Trust determined that claimant's submission was cumulative of materials previously submitted with her claim and that such submission was contrary to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures").⁷ Therefore, the Trust refused to consider the materials or forward the claim to an auditing cardiologist for a second review and issued a final post-audit determination letter again denying Ms. Buchanan's claim.

Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim

7. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in Pretrial Order ("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. Buchanan's 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. The Trust then applied to the court for issuance of an Order to show cause why Ms. Buchanan's claim should be paid. On September 10, 2002, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2595 (Sept. 10, 2002).

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 January 3, 2003. Under the Audit Policies and Procedures it is within the Special Master's discretion to appoint a Technical Advisor⁸ 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, 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

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. See id.

Show Cause 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 has moderate mitral regurgitation. See Audit Policies and Procedures § 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, 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. Buchanan submitted a verified expert opinion from Dr. Taylor, along with his curriculum vitae. In his verified expert opinion, Dr. Taylor stated, in pertinent part, that:

Based upon sonographic images and measurements produced by a cardiac sonographer working under my supervision, I found Ms. Buchanan to have mitral regurgitation with an RJA/LAA ratio of 29%.

* * *

On April 30, 2002, I reviewed Ms. Buchanan's June 22, 2001 echocardiogram tape per her attorney's request. At that time I recalculated the RJA/LAA ratio and found it to be 26% under my understanding of the national diet drug settlement agreement, this

still constitutes FDA Positive mitral valve regurgitation.

At this time, I concur with my findings of April 30, 2002 and I remain of the opinion that the RJA/LAA ratio shown on the June 22, 2001 echocardiogram is greater than 20% and is, more specifically, approximately 26%.

Nov. 26, 2002 Affidavit of Dr. Taylor ¶¶ 3-6 (attached as Exhibit 1 to Claimant's Show Cause Response). Dr. Taylor also stated that, in evaluating claimant's echocardiogram, he "calculated [claimant's] left-atrial supero-inferior systolic dimension and found the left atrial length to be 5.55 cm." Id. ¶ 7.

Claimant further argues that Dr. Taylor is a veteran cardiologist who "repeatedly re-evaluated" her echocardiogram and determined that she had moderate mitral regurgitation and that the presence of a reduced ejection fraction, which is one of the complicating factors for a Level II claim, was confirmed by Dr. Irani. In the alternative, claimant argues that she qualifies for Level II benefits because Dr. Taylor concluded that she had an abnormal left atrial dimension. Finally, claimant argues that Dr. Irani did not follow the Settlement Agreement because he visually estimated her level of mitral regurgitation as opposed to making a "still-frame two-dimensional calculation" of her RJA/LAA ratio, which, in her view, is required by the Settlement Agreement.

In response to claimant's show cause submissions, the Trust submitted a December 19, 2002 letter from Dr. Irani regarding the manner in which a claimant's severity of mitral

regurgitation is determined in audit. In this letter, Dr. Irani stated that:

[u]pon receipt of a tape, review of the entire study is made with a visual estimation of the RJA/LAA ratio. Differences in findings between the stated RJA/LAA ratio on the Green form and my estimate are often due to perceived overestimation of the RJA or underestimation of the LAA.

Overestimated RJAs are frequently due to high gain settings, low Nyquist limits, or documented tracing of the jet outside the bounds of the color signal. Underestimated LAA may be due to foreshortening of the LA, or measurement of the area in the incorrect phase of the cardiac cycle. These are factors that the court's Technical Advisor will need to consider in reviewing the above claims.

Dec. 19, 2002 Letter from Dr. Irani (attached as Exhibit A to the Trust's Show Cause Reply).⁹ It appears that the Trust is relying on this general letter to argue that Dr. Taylor's finding of moderate mitral regurgitation was based on an overestimation of her RJA or an underestimation of her LAA.

The Trust also disputes claimant's assertion that a "still-frame two-dimensional calculation" is required by the Settlement Agreement and that a claimant's level of mitral regurgitation cannot be assessed visually. The Trust further argues that claimant is precluded from alleging in this show cause proceeding that she suffers from an abnormal left atrial

9. Dr. Irani's letter is addressed to Jules S. Henshell, Esquire of the Trust and concerns Ms. Buchanan and one other claimant. The letter, however, does not address any findings specifically related to Ms. Buchanan's claim.

dimension because this condition was not reported in Part II of her Green Form and, therefore, was not subject to audit.

The Technical Advisor, Dr. Vigilante, concluded that there was a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction in the range of 50% and 60%. Dr. Vigilante, however, also determined that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Dr. Vigilante reviewed claimant's June 22, 2001 echocardiogram and stated in his Report that:

Only trace mitral regurgitation was seen in the parasternal long axis view. Both the apical four chamber and apical two chamber views demonstrated only mild mitral regurgitation with a RJA/LAA of less than 15%. This low ratio was noted on all evaluable cardiac cycles. At 12:18:51 on the tape, a non-representative still frame was noted of the supposed mitral regurgitation jet and left atrial area that were traced by the sonographer. This jet could not be found in real-time evaluation of the tape. In addition, the traced RJA is inaccurate encompassing a good deal of low velocity non-mitral regurgitant flow. An accurate RJA/LAA ratio could not be obtained on this still frame.

After reviewing the entire Show Cause Record, we find that claimant's arguments regarding her level of mitral regurgitation are without merit. First, we are not persuaded by Dr. Taylor's Affidavit that Ms. Buchanan's claim is medically reasonable. The auditing cardiologist determined that a review of claimant's echocardiogram revealed that claimant only had trace to mild mitral regurgitation. The Technical Advisor

concluded that claimant had, at best, mild mitral regurgitation and that on the echocardiogram tape he observed a non-representative still frame, which could not be located in real-time, that showed an inaccurately traced RJA. Claimant did not respond to the Technical Advisor's findings.

Second, 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 9-15, 21-22, 26. Here, the Technical Advisor determined, and Ms. Buchanan does not dispute, that the RJA tracing depicted in the non-representative still frame on claimant's echocardiogram was inaccurate, that such RJA tracing included "a good deal of low velocity non-mitral regurgitant flow" and that an accurate RJA/LAA "could not be obtained" from the still frame. This unacceptable still frame cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

Third, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Moderate mitral regurgitation is defined as "20%-40% RJA/LAA," which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). 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 to determine the amount of a claimant's regurgitation. As we explained in PTO No. 2640, "[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15 (Nov. 14, 2002).

Finally, we need not address whether claimant was diagnosed with a reduced ejection fraction in the range of 50% and 60% or an abnormal left atrial dimension. Without establishing the existence of moderate mitral regurgitation, claimant cannot meet the criteria delineated in the Settlement Agreement for Level II benefits.

For the foregoing reasons, we conclude that claimant has not met her burden in 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 Ms. Buchanan's claim for Matrix Benefits.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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)	MDL NO. 1203
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v.)	
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AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203

PRETRIAL ORDER NO.

AND NOW, on this 29th 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 Matrix claim submitted by claimant Andrea Buchanan is DENIED.

BY THE COURT:

/s/ Harvey Bartle III
C.J.