

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 16, 2007

Terry Justis ("Mr. Justis" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.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 his claim for Matrix Compensation Benefits ("Matrix Benefits").³

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

2. Sandra Justis, Mr. Justis' 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

(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 January 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Michael S. Mancina, M.D.⁴ Based on an echocardiogram dated November 11, 2001, Dr. Mancina attested in Part II of Mr. Justis' Green Form

3(...continued)

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 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.

4. As we previously found, Dr. Mancina is no stranger to this litigation. See Pretrial Order ("PTO") No. 6280 (May 19, 2006) (finding that Dr. Mancina signed in excess of 20 Green Forms on the same day on behalf of claimants seeking Matrix Benefits).

that he 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 \$473,032.

In the report of claimant's echocardiogram, Dr. Mancina stated that "[t]here is moderate mitral valve regurgitation with 30% of the left atrium occupied by regurgitant flow during systole." 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. Mancina also stated that claimant had "mild left atrial enlargement at 4.6 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 November 2002, the Trust forwarded the claim for review by Michael Rihner, M.D., one of its auditing cardiologists.⁵ In audit, Dr. Rihner concluded that there was no

5. In October 2002, the Trust notified Mr. Justis that his claim was selected for audit by Wyeth and further advised claimant that Wyeth's audit designation focused on whether he had moderate mitral regurgitation. In response, claimant stated that he would not submit any further medical information prior to the audit. Under the Settlement Agreement, Wyeth could designate for audit a certain number of claims for Matrix Benefits and identify the
(continued...)

reasonable medical basis for Dr. Mancina's finding that claimant had moderate mitral regurgitation because his echocardiogram demonstrated only mild mitral regurgitation. Dr. Rihner determined that: "[t]he mitral regurgitation is not well demonstrated. The mitral regurgitant jet is mild. The one frame the sonographer traced does appear mild to moderate but the majority of the mitral regurgitant jets are clearly mild." Dr. Rihner, however, was not asked to review Dr. Mancina's finding of an abnormal left atrial dimension.⁶

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

5(...continued)
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. 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.

6. 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 conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

Agreement § VI.E.7; PTO No. 2457, Audit Policies and Procedures § VI.⁷ The Trust then applied to the court for issuance of an Order to show cause why Mr. Justis' claim should be paid. On April 8, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2826 (Apr. 8, 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 19, 2003. Claimant submitted a Sur-Reply on July 7, 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

7. 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 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 Mr. Justis' claim.

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. Id.

Master assigned Technical Advisor, Sandra V. Abramson, 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 issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he 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 his claim, Mr. Justis submitted a "Limited Fen-Phen Echocardiogram Study" and an expert opinion from Robert Rosenthal, M.D.⁹ Dr. Rosenthal is no stranger to this litigation.¹⁰ In his opinion, Dr. Rosenthal stated that:

9. We note that Dr. Rosenthal's "Limited Fen-Phen Echocardiogram Study" includes a disclaimer stating that: "[i]nterpretation of this study by the above named physician does not constitute a Doctor/Patient relationship."

10. The Trust submitted an affidavit, signed June 18, 2003, stating that Dr. Rosenthal had attested to 48 Green Forms as of
(continued...)

The degree of mitral regurgitation is $\geq 20\%$ with the greatest documented jet of mitral regurgitation filling 30% of the left atrial area. The auditing cardiologist's report does not contest the presence of mitral regurgitation. His/her report states "The MR jet is mild. The one frame the sonographer traced does appear *mild to moderate* (my italics) but the majority of the MR jets are clearly mild." However, the Settlement documents (Green Form, page 22) specify maximum regurgitant jet area as a valid indicator of the severity of mitral regurgitation. Hence, even by the admission of the auditing cardiologist, there is a reasonable basis for the Claimant physician's assertion of moderate mitral regurgitation.

Claimant also argues that: (1) the auditing cardiologist's conclusions should be given no weight because he did not provide any explanation or detail to support his findings; (2) the phrase "reasonable medical basis" means that an attesting physician's conclusions must be accepted unless the Trust proves they were "irrational or senseless from any medical perspective"; (3) Dr. Rosenthal's finding of moderate mitral regurgitation based on the maximum regurgitant jet supports a reasonable medical basis for his claim; and (4) under the Settlement Agreement, the auditing cardiologist was required to provide a specific measurement as to the level of regurgitation.

In response, the Trust argues that claimant's reviewing cardiologist, Dr. Rosenthal, based his findings of moderate mitral regurgitation on a single, maximum, non-representative regurgitant jet, which is not permitted under the Settlement

10(...continued)
May 31, 2003.

Agreement. The Trust also disputes claimant's characterization of the reasonable medical basis standard. The Trust further argues that Dr. Rihner complied with the Settlement Agreement in the manner in which he reviewed claimant's echocardiogram. Lastly, the Trust asserts that claimant cannot meet his burden of proof simply by proffering an opinion from an additional cardiologist.¹¹ In a Sur-Reply, claimant maintains that the submission of the expert report from Dr. Rosenthal is not merely cumulative but substantiates the findings of his attesting physician.¹²

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because his echocardiogram demonstrated only mild mitral regurgitation. Specifically, Dr. Abramson stated:

11. 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).

In addition, the Trust submitted evidence regarding the number of Green Forms signed by Dr. Rosenthal. See supra.

12. In his Sur-Reply, claimant also disputed that Drs. Mancina and Rosenthal derive a financial benefit from providing favorable opinions to claimants. As claimant's physicians' alleged financial motivations in consideration of signing Green Forms on behalf of claimants is unnecessary for the resolution of this claim, we need not address this issue.

In reviewing the transthoracic echocardiogram, my visual estimate is that there is only mild mitral regurgitation. In the two views where the sonographer used color flow imaging, the parasternal long axis and the apical-4-chamber, most of the cardiac cycles show only mild mitral regurgitation. The freeze frame of the mitral regurgitant jet that the sonographer chose to measure is the largest area of the entire study and is not representative of the MR area of the remainder of the study. In addition to my visual estimate, I measured the mitral regurgitant jet in four different cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are 1.54 cm²/19.89 cm², 1.85 cm²/20.04 cm², 1.93 cm²/20.54 cm², and 1.47 cm²/19.51 cm². These ratios are 7.7%, 9.2%, 9.4%, and 7.5%, all of which are considerably less than 20% which is consistent with mild mitral regurgitation. Many of the cardiac cycles demonstrated no mitral regurgitation.

In summary, it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate. There is no reasonable medical basis for the Attesting Physician's claim that this patient has moderate mitral regurgitation. This patient has only mild mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments all without merit. First, and of crucial importance, claimant does not contest the analysis provided by Dr. Abramson that claimant had only mild mitral regurgitation and that "[m]any of the cardiac cycles demonstrated no mitral regurgitation." Claimant also does not refute Dr. Abramson's finding that "it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate." On this basis alone, claimant has

failed to meet his burden of demonstrating that there is a reasonable medical basis for his claim.

We further reject claimant's assertion that he may recover Matrix Benefits by the use of a single maximum regurgitant jet to establish his level of mitral regurgitation. In support, claimant proffered the certification of Dr. Rosenthal, who concluded, based on a single measurement of "the maximum regurgitant jet," that claimant had moderate mitral regurgitation. We do not accept this position. See PTO No. 6997. While one of the endnotes in the Green Form refers to obtaining the regurgitant jet area from a "maximum or average [of] three planes," this does not mean that a claim is compensable based only on the maximum or average regurgitant jet measured. For a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram.¹³ To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

13. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

Moreover, we have previously stated that "[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.'" PTO No. 6897 (Jan. 26, 2007) (quoting PTO No. 2640 at 9). As claimant has not established that the "maximum regurgitant jet" offered in support of his claim is representative of his level of mitral regurgitation, he has failed to establish a reasonable medical basis for his claim. This is especially true where, as here, the Auditing Cardiologist noted that "[t]he one frame the sonographer traced does appear mild to moderate but the majority of the mitral regurgitant jets are clearly mild."¹⁴ Dr. Abramson confirmed this finding, stating that "[t]he freeze frame of the mitral regurgitant jet that the sonographer chose to measure is the largest area of the entire study and is not representative of the MR area of the remainder of the study." On this basis as well, claimant has not met his burden in establishing a reasonable medical basis for his claim.¹⁵

14. Dr. Rihner's specific findings also negate claimant's argument that his ultimate conclusion should be disregarded because of an alleged lack of explanation of detail.

15. Similarly, a claimant cannot establish a reasonable medical basis for his or her claim simply by supplying additional cardiologist opinions. This is especially true where, as here, the additional cardiologist improperly based his finding on a maximum regurgitant jet.

Furthermore, 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); See also PTO No. 6280 at 7-9 (May 19, 2006).

Finally, we also disagree with claimant's definition of reasonable medical basis. Without any discussion, claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962) and Black's Law Dictionary, 1538 (6th ed. 1990), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court addressed the situation where a court would appoint an impartial expert witness to be presented to the jury. See Gallagher, 31 F.R.D. at 38. Claimant also relies on the definition of "unreasonable" in Black's. The word "unreasonable" does not always mean "irrational," as claimant would have us believe. It can also be defined as "not guided by reason."

We are not persuaded that either Gallagher or Black's supports claimant's position. Instead, we are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. 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.

For the foregoing reasons, we conclude that claimant has not met his burden in proving that there is a reasonable medical basis to conclude that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of both Mr. Justis' claim for Matrix Benefits and the related derivative claim submitted by his wife.

