

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 21, 2007

Geraldine Glidewell ("Ms. Glidewell" 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 her claim for Matrix Compensation Benefits ("Matrix Benefits").³

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

2. Bobby Glidewell, Ms. Glidewell's 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
(continued...)

To seek Matrix Benefits, a claimant must 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 in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In December 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician Michael S. Mancina, M.D., F.A.C.C. In Pretrial Order ("PTO") No. 6280 (May 19, 2006), the Court found that "Dr. Mancina is no stranger to this litigation." There, we noted that in one day Dr. Mancina signed twenty Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated September 8, 2001,

3(...continued)

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 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.

Dr. Mancina attested in Part II of Ms. Glidewell's Green Form that she 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 26% 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 measured claimant's left atrium at 3.46 cm and there is an additional measurement of 5.62 cm in parentheses on the echocardiogram report. 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.⁴ See id. § IV.B.2.c.(2)(b).

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). An enlarged left atrial dimension is one of the complicating factors needed to qualify for a Level II claim.

In November 2002, the Trust forwarded the claim at issue to Ernest C. Madu, M.D., one of its auditing cardiologists. In audit, Dr. Madu concluded that there was no reasonable medical basis for Dr. Mancina's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only "mild" mitral regurgitation.⁵ Dr. Madu also determined that there was no reasonable medical basis for Dr. Mancina's finding of an enlarged left atrial dimension because claimant's "LA antero-posterior systolic dimension is 3.5 cm and supero-infero [sic] systolic dimension is 5.0 cm."

Thereafter, the Trust issued a post-audit determination denying Ms. Glidewell's claim. Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant disputed this adverse 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. 2457, Audit Policies and Procedures § VI.⁶ The Trust then applied to the court for issuance of an Order to show cause why Ms.

5. In his worksheet, Dr. Madu noted that claimant's echocardiogram was a "[t]echnically very difficult and suboptimal study with marginal instrument settings and doppler evaluations."

6. 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 Ms. Glidewell's claim.

Glidewell's claim should be paid. On June 10, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2884 (June 10, 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 May 2, 2006. Under the Audit Policies and Procedures, 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 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 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 findings that she had moderate mitral regurgitation and an abnormal left

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. 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.

atrial dimension. 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 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, 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. Glidewell submitted a "Limited Fen-Phen Echocardiogram Study" prepared by Robert Rosenthal, M.D., along with Dr. Rosenthal's curriculum vitae.⁸ In his study, Dr. Rosenthal quantified claimant's RJA/LAA ratio as 20% and measured claimant's left atrial dimension as 3.5 cm in the parasternal long-axis view and 5.5 cm in the apical four chamber view.

Claimant submitted a certification prepared by Dr. Rosenthal. In his certification, Dr. Rosenthal stated that:

The degree of mitral regurgitation is >20% with the echocardiographer documenting multiple jets which satisfy this criterion. As per Green Form appendix end notes #3 and #5, the maximal regurgitant jet is expressed as a percentage of the left atrial area. The jet is confirmed by CW⁹ Doppler. Furthermore, the sonographer has specifically documented the presence and extent of the

8. 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."

9. "CW" stands for continuous wave.

mitral regurgitation using pulsed Doppler which confirms that the color jets are real and extend more than ½ the length of the left atrium. The auditing cardiologist may be expressing his or her qualitative opinion on the degree of mitral regurgitation; however, the Settlement Agreement documents specify a scientific and quantitative degree of mitral regurgitation, a degree which is clearly substantiated by the echocardiogram.

The auditing cardiologist contests the presence of left atrial enlargement. The left atrium is elongated and enlarged on apical views and re-measurement with calipers from the hinge point of the leaflets to the posterior wall using approved guidelines (Green Form, page 27) yields a measurement of 5.5 cm.

Claimant also argues that 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" and that an opinion lacks a reasonable medical basis only when it is "so slanted" that it exists outside the "present state of science." Claimant further argues that the auditing cardiologist did not follow the Settlement Agreement because he visually estimated her level of mitral regurgitation as opposed to taking actual measurements, which, in her view, are required by the Settlement Agreement. Finally, claimant maintains that that the auditing cardiologist failed to indicate that he measured her left atrial dimension properly by using calipers.

In response to claimant's show cause submissions, the Trust had Dr. Madu review claimant's echocardiogram for a second time. In a supplemental declaration, Dr. Madu confirmed his

previous conclusion that there was no reasonable medical basis for finding moderate mitral regurgitation and an abnormal left atrial dimension. Dr. Madu stated that:

In connection with my review, I again viewed the entire echocardiogram tape provided by Claimant, which confirmed the following:

(a) Ms. Glidewell's echo documents only very mild mitral regurgitation, with absolutely no reasonable basis for the assertion of moderate mitral regurgitation. The left atrium also was normal measuring between 3.4 and 3.6 cm in the antero-posterior view and about 5.0 cm in the superior-inferior [sic] dimension.

(b) The study quality was poor with an unacceptably low Nyquist limit of 42 cm/sec (for most of the study) and technical inaccuracy in measurement. The planimetered "mitral regurgitant" jet was indeed a non-regurgitant jet occurring in end-diastole. Mitral regurgitation jets occur during the systolic phase of the cardiac cycle.

(c) I agree with the statement in the Claimant's response that ". . . . if time is taken to measure the jet and atrium that an accurate assessment of regurgitation can be made." However, the jet measured must be the accurate jet, the planimetry of the atrium must be properly and accurately done and the instrument settings (Nyquist limit, gain setting etc[.]), must be within an acceptable range. Measuring a diastolic jet would not qualify. The true regurgitant jet area (RJA) in this case was in all views significantly less than the Trust agreement of 20% of the left atrial area (LAA) and would not qualify as moderate mitral regurgitation.

The Trust also disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust argues that the manner in which Dr. Madu evaluated claimant's level of regurgitation complied with the Settlement Agreement and

claimant cannot meet her burden of proof simply by proffering an opinion from an additional cardiologist.¹⁰

The Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., concluded that there was no reasonable medical basis for the attesting physician's findings of moderate mitral regurgitation and an abnormal left atrial dimension. As explained by the Technical Advisor:

Only trace mitral regurgitation was seen in the parasternal long axis view. Only mild mitral regurgitation was seen in the apical four chamber and apical two chamber views. The high velocity mitral regurgitation jet was only slightly above the coaptation point of the mitral leaflets in systole. The RJA/LAA was less than 15%.

* * *

At the end of the tape, several still frames of the supposed mitral regurgitation jet and left atrial size were provided. The mitral regurgitation jet area was inaccurately measured and included non-mitral regurgitant flow.

* * *

[I]naccurate measurements of the RJA [were] made. Non-mitral regurgitant jet flow was included in this determination. The RJA/LAA ratio was much less than 20%.

10. 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).

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. Vigilante.¹¹ Nor does claimant challenge Dr. Vigilante's specific finding that the attesting physician relied on inaccurate tracings. In addition, claimant does not refute Dr. Vigilante's conclusion that "[i]t would not be possible for a reasonable echocardiographer to conclude that any more significant mitral regurgitation than mild was present on this echocardiogram." On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's definition of reasonable medical basis. Claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962), 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. We are not persuaded that these circumstances are even remotely analogous to the present case.

Instead, we are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and

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

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 example, 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 echocardiograms; (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, 22, 26.

Here, the auditing cardiologist determined, and Ms. Glidewell does not dispute, that a review of claimant's echocardiogram revealed that the study had "an unacceptably low" Nyquist limit and the planimetered jet was a non-regurgitant jet measured at "end-diastole." Mitral regurgitation must be measured during systole. The Technical Advisor also concluded, and Ms. Glidewell does not contest, that claimant's RJA was inaccurately measured and included non-regurgitant flow. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

Further, 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).

While claimant relies on the Settlement Agreement's use of the word "measured" in the definition of "FDA Positive", its meaning must be considered in the context of the phrase "by an echocardiographic examination," which immediately follows it. See Settlement Agreement § I.22. In its entirety, the phrase placed at issue by claimant is "measured by an echocardiographic examination." See id. The plain meaning of this phrase does not require actual measurements for assessing the level of mitral regurgitation. To the contrary, claimant's level of regurgitation must be determined based on an echocardiogram, as opposed to other diagnostic techniques. 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.

Nor are we persuaded by Dr. Rosenthal's certification that Ms. Glidewell's claim is medically reasonable. As stated by Dr. Rosenthal, his opinion is based on one maximal jet, which he believes is confirmed by continuous wave Doppler. For a reasonable medical basis to exist, a claimant must demonstrate that his or her regurgitation is representative of the level of regurgitation seen on an echocardiogram.¹² 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. Additionally, it is improper to rely on continuous wave Doppler to support a finding of regurgitation. As we stated in PTO No. 2640, "[n]owhere does the Green Form authorize the use of continuous wave Doppler to establish the severity or duration of mitral regurgitation." PTO No. 2640 at 18.

Finally, we find that there is no reasonable medical basis for the attesting physician's finding of an abnormal left

12. 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.

atrial dimension. The Technical Advisor determined that claimant's left atrial dimension was normal measuring 3.4 cm in the parasternal long axis view and 5.1 cm in the apical four chamber view. Claimant did not respond to these findings.

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 and an enlarged left atrial dimension. Therefore, we will affirm the Trust's denial of her claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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AND NOW, on this 21st 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 claims submitted by claimant Geraldine Glidewell and her spouse, Bobby Glidewell, are DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.