

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

Karen DeWitt ("Ms. DeWitt" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> 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").<sup>3</sup>

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

2. Gabriel L. DeWitt, Ms. DeWitt'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 for compensation purposes based upon the severity of their

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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 April 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Michael Liston, M.D. Dr. Liston is no stranger to this litigation. According to the Trust, he signed 156 Green Forms on the same day that he signed claimant's form. As we have previously noted, in total he has signed more than 1,600 Green Forms on behalf of claimants seeking Matrix Benefits. See PTO No. 6339 at 3 (May 25, 2006). Based on an echocardiogram dated December 15,

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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.

2001, Dr. Liston attested in Part II of claimant'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 \$580,759.<sup>4</sup>

In the report of claimant's echocardiogram, Dr. Liston stated that claimant had "moderate mitral insufficiency with the regurgitant jet measuring 25% of total left atrial dimension." 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. Liston also stated that claimant had mild left atrial enlargement and measured her left atrium as 5.4 cm in the apical four chamber view and 4.2 cm in the parasternal long axis view. 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. at § IV.B.2.c.(2)(b).

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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).

In December 2002, the Trust forwarded the claim for review by Keith B. Churchwell, M.D., F.A.C.C., one of its auditing cardiologists.<sup>5</sup> In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Liston's finding that claimant had moderate mitral regurgitation because "[t]here is trivial (physiologic) mitral regurgitation present."<sup>6</sup> Dr. Churchwell further found that "[o]verestimation of the few pixels of mitral regurgitant jet area is seen on the tape." Dr. Churchwell also concluded that there was no reasonable medical basis for Dr. Liston's finding of an abnormal left atrial dimension because her left atrium measured approximately 3.8 cm<sup>7</sup> in the parasternal long axis view and "size overestimation seen with measurement."

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5. In October 2002, the Trust notified claimant that Wyeth had selected her claim for audit. 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; Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("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.

6. Physiologic regurgitation is defined as "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or  $\leq$  5% RJA/LAA." AHP Settlement Trust Auditing Cardiologist Worksheet, 3.

7. On the AHP Settlement Trust Auditing Cardiologist Worksheet, Dr. Churchwell notes that he measured claimant's left atrium as 3.9 cm in the parasternal long axis view.

Based on Dr. Churchwell's diagnosis, the Trust issued a post-audit determination denying Ms. DeWitt's 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 Agreement § VI.E.7; PTO No. 2457, Audit Policies and Procedures § VI.<sup>8</sup> The Trust then applied to the court for issuance of an Order to show cause why Ms. DeWitt's 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. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor<sup>9</sup> to review claims after

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8. 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. DeWitt's claim.

9. 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  
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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 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 an abnormal left 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, 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. DeWitt submitted a "Limited Fen-Phen Echocardiogram Study" and certification prepared by Robert Rosenthal, M.D., regarding claimant's

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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.

December 15, 2001 echocardiogram.<sup>10</sup> Dr. Rosenthal is also no stranger to this litigation.<sup>11</sup> In his study, Dr. Rosenthal found that claimant had moderate mitral regurgitation and an abnormal left atrial dimension. More specifically, Dr. Rosenthal stated that:

The degree of mitral regurgitation is 20% with the maximal jet of 4.41 cm<sup>2</sup> documented at 15:55:26 recording time. This is an appropriately blue colored Doppler jet emanating from the mitral valve in systole .... The jet is confirmed by CW Doppler. Furthermore, the sonographer has specifically documented the presence and the extent of the mitral regurgitation using pulsed Doppler which confirms that the color jets are real and extend more than ½ the length of the left atrium.

. . .

An appropriately drawn left atrial parasternal dimension of 4.19 cm is clearly documented on the tape conforming to the guidelines of Feigenbaum ...

Claimant also argues that the auditing cardiologist's conclusions should be given no weight because he did not provide any explanation or detail to support his findings. Claimant further contends 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

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

11. The Trust submitted an affidavit, dated June 18, 2003, stating that Dr. Rosenthal had attested to 48 Green Forms as of May 31, 2003.

medical perspective." Finally, claimant 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.

In response, the Trust argues that there is no reasonable medical basis for Ms. DeWitt's claim because the auditing cardiologist determined that the attesting physician overtraced the regurgitant jet area and overestimated the size of the left atrial area. The Trust also argues that the auditing cardiologist complied with the Settlement Agreement in the manner in which he reviewed claimant's echocardiogram. The Trust further asserts that claimant cannot meet her burden simply by proffering additional opinions. Finally, the Trust contends that claimant's additional expert, Dr. Rosenthal, improperly referred to the use of continuous wave Doppler, whereas the Settlement Agreement and Green Form allow only the use of color flow Doppler to measure mitral regurgitation.<sup>12</sup> In a Sur-Reply, claimant argues that the submission of the expert report from Dr.

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12. 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 Drs. Liston and Rosenthal. See supra.

Rosenthal is not merely cumulative, but substantiates the findings of her attesting physician.<sup>13</sup>

The Technical Advisor, Dr. Vigilante, reviewed claimant's December 15, 2001 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

Specifically, Dr. Vigilante stated that:

Only very mild mitral regurgitation was noted with the RJA/LAA less than 10% in spite of the fact that excessive color flow gain was noted with color artifact seen within the myocardium. At 17:31:06 recording time of the tape, a non-representative still frame of supposed mitral regurgitation jet was seen. However, when played in "real-time" only very mild mitral regurgitation was noted. Towards the end of the tape, the sonographer made several measurements of the mitral regurgitation jet. These were completely inaccurate and clearly overtraced non-regurgitant jet flow.

Dr. Vigilante also concluded that there was no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. Dr. Vigilante determined that claimant's left atrial dimension was normal in both the parasternal long axis view and the apical four chamber view. Dr. Vigilante further found that "the traced left atrial area was

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

also inaccurate. The posterior region of the left atrium was not included in the tracing."

After reviewing the entire Show Cause Record before us, we find claimant's arguments without merit. First, and of crucial importance, claimant does not contest the analysis provided by either the auditing cardiologist or Technical Advisor.<sup>14</sup> Claimant does not address Dr. Churchwell's conclusions that claimant's attesting physician overestimated her level of mitral regurgitation and left atrial dimension.<sup>15</sup> Nor does claimant challenge Dr. Vigilante's specific findings that claimant's "RJA/LAA is less than 10%" and that claimant's "left atrium is normal in size measured both in the parasternal long axis and apical four chamber views." Claimant also 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 . . . [or that an] abnormal left atrial size was present on the Claimant's echocardiogram of December 15, 2001." On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

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

15. Dr. Churchwell's specific findings also negate claimant's argument that his ultimate conclusions should be disregarded because of an alleged lack of explanation or detail.

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 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 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 (Nov. 14, 2003). Here, Drs. Vigilante and Churchwell determined, and claimant does not dispute, that claimant's physicians overtraced non-regurgitant jet flow, overestimated the level of claimant's mitral regurgitation, and improperly measured her left atrial dimension. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer. Moreover, 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, claimant has failed to address the improper measurements underlying the findings of the attesting physician.<sup>16</sup>

Finally, 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

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16. We also find that claimant's additional expert, Dr. Rosenthal, improperly relied on continuous wave Doppler in examining claimant's echocardiogram. As we explained previously, "the Settlement Agreement and Green Form refer to the use of color flow Doppler to measure the existence and severity of mitral regurgitation. Neither authorizes the use of continuous wave Doppler in measuring the severity of mitral regurgitation." See PTO No. 2640, 10, n. 7.

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."

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." The plain meaning of this phrase does not require actual measurements for assessing the level of mitral regurgitation. To the contrary, it means that a 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.

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 abnormal left atrial dimension. Therefore, we affirm the Trust's denial of Ms. DeWitt's claim for Matrix Benefits and the related derivative claim submitted by her husband.

