

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 )  
CORPORATION ) 2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

May 18, 2007

Vicky Simmons ("Ms. Simmons" 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, Inc. was known as American Home Products Corporation.

2. Gregory Simmons, Ms. Simmons' 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 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. 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 May 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Michael J. Liston, M.D., F.A.C.C. Dr. Liston is no stranger to this litigation. According to the Trust, on the same day on which he signed Ms. Simmons' Green Form, Dr. Liston also signed 188 Green Forms on behalf of claimants seeking Matrix Benefits. 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 February 7, 2002, Dr. Liston attested in Part II of Ms. Simmons'

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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.

Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$497,928.

In the report of claimant's echocardiogram, Dr. Liston stated that: "Doppler interrogation of the mitral valve reveals moderate mitral insufficiency with the regurgitant jet measuring 27% 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 noted that claimant had "[m]ild left atrial enlargement," which he measured as 5.8 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). Finally, Dr. Liston measured claimant's ejection fraction as 60%, which meets the definition of a reduced ejection fraction for a mitral valve claim under the Settlement Agreement. See id.

In December 2002, the Trust forwarded the claim for review by Ernest C. Madu, M.D., one of its auditing

cardiologists.<sup>4</sup> In audit, Dr. Madu concluded that there was no reasonable medical basis for Dr. Liston's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In his worksheet, Dr. Madu noted that there was an "[i]nappropriate Nyquist limit and color gain setting." Dr. Madu also concluded that there was no reasonable medical basis for Dr. Liston's finding of a reduced ejection fraction. Dr. Madu, however, was not asked to review Dr. Liston's finding of an abnormal left atrial dimension.<sup>5</sup>

Based on Dr. Madu's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Simmons' claim. Pursuant to the Audit Policies and

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4. In November 2002, the Trust notified Ms. Simmons that her claim was selected for audit by Wyeth and further advised claimant that Wyeth's audit designation focused on whether she had moderate mitral regurgitation and a reduced ejection fraction. In response, claimant stated that she 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 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.

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

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.<sup>6</sup> The Trust then applied to the court for issuance of an Order to show cause why Ms. Simmons' claim should be paid. On May 19, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2861 (May 19, 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 July 11, 2003. Claimant submitted a Sur-Reply on July 24, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor<sup>7</sup> to review claims after the Trust and

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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. Simmons' claim.

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  
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claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special 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 her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she 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 her claim, Ms. Simmons submitted a "Limited Fen-Phen Echocardiogram Study" and an expert opinion by

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outstanding experts who take opposite positions" is proper. Id.

Robert Rosenthal, M.D.<sup>8</sup> Dr. Rosenthal also is no stranger to this litigation.<sup>9</sup> In his opinion, Dr. Rosenthal stated that:

The degree of mitral regurgitation is 27% with the maximal regurgitant jet of 4.59 cm<sup>2</sup> documented at 18:40:49 recording time. This is an appropriately colored blue Doppler jet emanating from the mitral valve in systole. 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 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. The auditing cardiologist may be expressing his or her qualitative opinion of the degree of mitral regurgitation; however, the Settlement documents specify a scientific and quantitative degree of mitral regurgitation, a degree which is clearly substantiated by the echocardiogram.

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 maximal regurgitant jet, documented at

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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. The Trust submitted an affidavit, signed July 11, 2003, stating that Dr. Rosenthal had attested to 550 Green Forms as of May 31, 2003.

frame 18:40:49, supports a reasonable medical basis for her 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, non-representative still frame, which is not permitted under the Settlement Agreement. The Trust also disputes claimant's characterization of the reasonable medical basis standard and argues that a claim cannot be supported by a reasonable medical basis where the attesting physician relied on an inappropriate Nyquist limit and color gain settings. The Trust further contends that Dr. Madu complied with the Settlement Agreement in the manner in which he reviewed claimant's echocardiogram. Lastly, the Trust argues that claimant cannot meet her burden of proof simply by proffering an opinion from an additional cardiologist.<sup>10</sup> In a Sur-Reply, claimant argues that the submission of the expert report from Dr.

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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).

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>11</sup>

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 her echocardiogram demonstrated only mild mitral regurgitation. Specifically, Dr. Abramson stated:

In reviewing the transthoracic echocardiogram, my visual estimate is that there is only mild mitral regurgitation. I chose not to measure this jet because it is not even close to being moderate. Most cardiac cycles show no mitral regurgitation. There is no reasonable medical basis for a physician to interpret this minimal amount of regurgitation as moderate mitral regurgitation. Also, the Nyquist limit is set at 51 cm/sec which will increase the appearance of the mitral regurgitation more than a Nyquist limit set at 60 to 70 cm/sec. In addition, the color gain settings are set too high which will increase the appearance of the mitral regurgitation. The tracing that the sonographer measured on the tape includes mostly dark blue which is not part of the regurgitant jet and is present because of the incorrect settings.

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In summary, it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate. There is no reasonable medical

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11. 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 consideration of signing Green Forms on behalf of claimants is unnecessary for the resolution of this claim, we need not address this issue.

basis for the Attesting Physician's claim that this patient has moderate 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 either the auditing cardiologist or Technical Advisor.<sup>12</sup> Claimant does not address Dr. Madu's conclusions that claimant's attesting physician relied upon an "[i]nappropriate Nyquist limit and color gain setting."<sup>13</sup> Nor does claimant challenge Dr. Abramson's specific findings that claimant had only mild mitral regurgitation and that "[m]ost cardiac cycles show no mitral regurgitation." Claimant also does not refute Dr. Abramson's finding that the Nyquist setting was too low and that the attesting physician improperly overtraced the regurgitant mitral jet. 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

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

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

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 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) over-manipulating echocardiogram settings; (2) setting a low Nyquist limit; and (3) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 22, 26 (Nov. 14, 2002); see also PTO No. 6280 at 9-10 (May 19, 2006). Here, Drs. Madu and Abramson determined, and claimant does not dispute, that claimant's attesting physician relied upon an inappropriate Nyquist limit and overtraced the mitral regurgitant jet. Such unacceptable practices by claimant's physicians 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 settings and measurements underlying the findings of the attesting physician

We also reject claimant's assertion that she may recover Matrix Benefits by the use of a single maximum regurgitant jet to establish her level of mitral regurgitation. In support, claimant proffered the certification of Dr. Rosenthal, who concluded, based on a single measurement of "the maximal regurgitant jet," that claimant had moderate mitral regurgitation. We do not accept this position. See PTO No. 6997 (Feb. 26, 2007). 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.<sup>14</sup> 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.

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

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14. 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.

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 "maximal regurgitant jet" offered in support of her claim is representative of her level of mitral regurgitation, claimant has failed to establish a reasonable medical basis for her claim.

Finally, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Moderate or greater 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; see also PTO No. 6280 at 7-9.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis to conclude that she had moderate mitral regurgitation and a reduced ejection fraction. Therefore, we will affirm the Trust's denial of both Ms. Simmons' claim for

Matrix Benefits and the related derivative claim submitted by her husband.

