

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. ) CIVIL ACTION NO. 99-20593  
v. ) 2:16 MD 1203  
AMERICAN HOME PRODUCTS )  
CORPORATION )

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

January 26, 2007

Sondra Nace ("Ms. Nace" 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"). 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>2</sup>

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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. and 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  
(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 March 2002, claimant submitted a Green Form to the Trust. Based on an echocardiogram dated November 29, 2001, claimant's physician, Elliot D. Agin, M.D., attested in Part II of her Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension. In the report for claimant's echocardiogram, Roger W. Evans, M.D., F.A.C.P., F.A.C.C., stated that claimant had "[m]oderately [sic] mitral regurgitation due to mitral valve prolapse" and that her "left atrium is slightly increased in size 4.1 cm." If accepted,

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2.(...continued)

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.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$449,381.00.<sup>3</sup>

Under the Settlement Agreement, a claimant is entitled to Level II Matrix 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 abnormal left atrial dimension is one of the complicating factors needed to qualify for a Level II claim. 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 id. § I.22. 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 December 2002, the Trust forwarded the claim at issue to one of its auditing cardiologists, Keith B. Churchwell, M.D., for review. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Agin's finding that

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3. In Part I of her Green Form, claimant requested benefits on Matrix B-1. Part II of claimant's Green Form, however, does not indicate the presence of any reduction factors, which would require payment on Matrix B-1. As discussed infra, resolution of the issue of which Matrix would apply to the claim is unnecessary because claimant does not have the requisite level of regurgitation and one of the five complicating factors delineated in the Settlement Agreement for her claim to be compensable.

claimant had moderate mitral regurgitation because her echocardiogram demonstrated only "trivial" mitral regurgitation.<sup>4</sup> Dr. Churchwell also concluded that there was no reasonable medical basis for Dr. Agin's finding that claimant had an abnormal left atrial dimension. According to Dr. Churchwell, claimant's left atrial size was 3.7 cm in the parasternal long-axis view and 4.5 cm in the apical four chamber view.

Thereafter, the Trust issued a post-audit determination denying Ms. Nace's claim.<sup>5</sup> Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("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; Pretrial Order ("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. Nace's claim should be paid. On April 30, 2003, we

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4. Dr. Churchwell noted that claimant's echocardiogram contained "[e]xtremely difficult & limited views."

5. Based on findings in audit, the Trust issues a post-audit determination regarding whether or not a claimant is entitled to Matrix Benefits.

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. See 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. See PTO No. 2807 (Mar. 26, 2003). By letter dated October 21, 2002, claimant was notified that her claim was selected for audit. Thus, the Audit Policies and Procedures govern her claim.

issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2839 (Apr. 30, 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 on June 4, 2003. The Trust submitted a reply on June 26, 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 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 two 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

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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 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. See id. (use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper).

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 that are 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.

During the show cause process, claimant submitted four color still frames from her November 29, 2001 echocardiogram videotape, referred to as Frames 1, 2, 3, and 4. Claimant argues that the still frames demonstrate that she had moderate mitral regurgitation and an enlarged left atrial dimension.<sup>8</sup> Specifically, she argues that: (1) Frames 1 and 2 show Regurgitant Jet Area/Left Atrial Area ("RJA/LAA") ratios of 42% and 31% respectively; and (2) Frames 3 and 4 evidence an abnormal left atrial dimension measured at 5.44 cm and 4.05 cm, respectively.

A claimant seeking Matrix Benefits must provide an echocardiogram that meets specific and defined criteria. See Settlement Agreement § VI.C.1. An attesting physician's opinion cannot have a reasonable medical basis if the underlying

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8. Although claimant represents that the still frames attached to her response were taken from her November 29, 2001 echocardiogram, we note that she did not provide a certification from a cardiologist to authenticate such still frames.

echocardiogram does not support the conclusions reflected in Part II of the Green Form. We reject claimant's argument that the still frames from her echocardiogram demonstrate a reasonable medical basis for her attesting physician's findings that she has moderate mitral regurgitation and an abnormal left atrial dimension.

The Settlement Agreement specifies criteria for conducting echocardiograms. Settlement Agreement § VI.C.1.b. An echocardiogram is performed by using sound waves to create a moving image of the heart. The cardiologist performing the echocardiogram will create videotaped images of multiple loops<sup>9</sup> and still frames of the claimant's heart. Still frames are created when the cardiologist periodically freezes the moving image to measure the claimants regurgitant jet. We have previously stated that although still frames are necessary to determine a claimant's level of mitral regurgitation, they are not sufficient alone. "Only 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. 2640 at 9.

The Technical Advisor, Dr. Vigilante, concluded that there was no reasonable medical basis for the attesting

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9. Loops show a complete cardiac cycle. A cardiac cycle has two phases: (1) diastole, where the heart fills with blood, and (2) systole, the emptying of the heart.

physician's findings of moderate mitral regurgitation and an abnormal left atrial dimension. With respect to the level of regurgitation, he concluded that:

[c]olor flow is only performed in the parasternal view and apical four-chamber view for evaluation of mitral regurgitation. There is an incorrect gain setting with color flow artifact seen within the ventricular and atrial myocardium. On the parasternal long axis view, only trace mitral regurgitation can be seen. In the apical four-chamber view, there is only mild mitral regurgitation with the RJA/LAA area of less than 10%. The two still frames of mitral regurgitation provided by the Claimant's attorneys were found on this tape. These still frames are not representative of the mitral regurgitation jet and actually represent artifact. This was seen only in a split second and clearly is not noted during the rest of systole. This is "back flow" artifact. The true regurgitant jet can easily be seen within a couple of frames after this artifact. Once again, this true regurgitant jet is quite small and clearly mild.

Dr. Vigilante also determined that claimant's left atrial dimension was normal and that:

[t]his was measured as 3.5 cm in diameter in the antero-posterior systolic dimension in the parasternal long axis view including at the time that frame # 4 was generated by the Claimant's attorneys. In addition, left atrial size was measured at 5.1 cm in diameter in the supero-inferior systolic dimension in the apical four-chamber view including at that time that frame # 3 was generated. Right-sided cardiac structures were not well seen due to technical limitations.

Although permitted, claimant did not refute or respond to the specific issues identified in Dr. Vigilante's Report.

Particularly, claimant did not respond to his observations that an incorrect gain setting was used in performing claimant's echocardiogram, and that the still frames presented by claimant actually represent "back flow" artifact as opposed to true regurgitation. Finally, claimant did not authenticate the still frames she relies upon in challenging the conclusions of the Trust's auditing cardiologist.

Based on our review of the Show Cause Record, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for her claim. Therefore, we affirm the Trust's denial of her claim for Matrix Benefits.

