

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.

August 23, 2007

Phyllis L. Schaffer ("Ms. Schaffer" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<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. Charles M. Schaffer, Ms. Schaffer'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 medical conditions, their ages when they are diagnosed, and the

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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 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician Robert N. Notske, M.D., F.A.C.C. Based on an echocardiogram dated November 1, 2002, Dr. Notske attested in Part II of Ms. Schaffer's 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%.<sup>4</sup> Based on such

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3(...continued)

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. Dr. Notske also attested that Ms. Schaffer had mild aortic  
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findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025.

In the report of claimant's echocardiogram, R. Alan Wales, M.D., F.A.C.C., the reviewing cardiologist, stated that claimant had "[m]ild to moderate mitral regurgitation," which he measured as "20-23%." 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. Wales also stated that claimant had "[l]eft atrial enlargement" with a supero-inferior systolic dimension of 5.7 cm and an antero-posterior systolic dimension of 4.3 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. Finally, Dr. Wales estimated claimant's ejection fraction as "at least 65%." An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b).

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4(...continued)  
regurgitation. As Ms. Schaffer's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

In July 2005, the Trust forwarded the claim for review by Dai-Trang Elizabeth Le, M.D., one of its auditing cardiologists. In audit, Dr. Le concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In particular, Dr. Le stated that: "[r]epeat measurement RJA/LAA: 3.15/18.0 = 17.5%." Dr. Le, however, found that there was a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension.<sup>5</sup>

Thereafter, the Trust issued a post-audit determination denying Ms. Schaffer's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In support, claimant submitted supplemental declarations by Drs. Notske and Wales

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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 concedes that claimant had 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.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Schaffer's claim.

dated October 19, 2005 and September 23, 2005, respectively. In his declaration, Dr. Notske stated that:

The only cardiologist who has reviewed the November 1, 2002 echocardiogram and found an RJA/LAA of less than 20% is the auditing cardiologist. In reviewing the echocardiogram, I note that there are two separate still frames with the regurgitant jet and the left atrium planimetered. The first still frame demonstrates more of a regurgitant jet than the second still frame. Presumably, the auditing cardiologist chose the second still frame for her measurements. Feigenbaum states that "[t]o meet the criteria for measuring the regurgitant area, one probably should take the maximum turbulent flow area." Feigenbaum, *Echocardiography*, at 253 (5<sup>th</sup> ed.). In this instance, the first still frame should be chosen for measurement. That first still frame clearly demonstrates a regurgitant jet of over 20% [RJA/LAA].

Likewise, in his declaration, Dr. Wales confirmed his original findings that claimant had moderate mitral regurgitation with an RJA/LAA ratio of "20-23%." Claimant argued that the declarations of Drs. Notske and Wales presented a reasonable medical basis for her claim.

Claimant also argued that: (1) the findings of Dr. Wales should be credited because he was a Screening Program cardiologist;<sup>7</sup> (2) unlike the auditing cardiologist, Drs. Notske and Wales complied with the standards set forth in the Weyman and Feigenbaum texts; and (3) the auditing cardiologist failed to

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7. The Screening Program was established under the Settlement Agreement. See Settlement Agreement § IV.A.1.

specify how Drs. Notske and Wales violated the Weyman and Feigenbaum texts.

The Trust then issued a final post-audit determination, again denying Ms. Schaffer's claim. Claimant disputed this final 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. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Schaffer's claim should be paid. On January 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

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 9, 2006, and claimant submitted a sur-reply on June 29, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>8</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See

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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.

Audit Rule 30. 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. Rule 35.

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. Rule 24. 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. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Schaffer reasserts her previous arguments. See supra pp. 4-5. Claimant also argues that Drs. Notske and Wales complied with PTO No. 2640, which provides "that the interpreter of the echocardiogram must be observing a true regurgitant jet, not artifacts, phantom jets or backflow." Further, claimant argues that the auditing cardiologist did not suggest that claimant's physicians violated PTO No. 2640 by interpreting artifacts, phantom jets or backflow as regurgitation, but questioned the severity of the regurgitant

jet. Finally, claimant submits that Dr. Notske's measurement of the first still frame complied with the Settlement Agreement because he measured the "maximum turbulent flow area."

In response, the Trust counters that Dr. Wales' participation in the Screening Program does not automatically establish a reasonable medical basis for Ms. Schaffer's claim. The Trust also argues that the supplemental declarations of Drs. Notske and Wales do not establish a reasonable medical basis for Ms. Schaffer's claim because Drs. Notske and Wales merely reaffirmed their original findings. Further, the Trust contends that Drs. Notske and Wales improperly included low velocity flows in their measurement of the mitral regurgitant jet. In addition, the Trust maintains that Dr. Notske does not identify a sustained, representative high velocity jet representing moderate mitral regurgitation that appears in multiple loops and multiple consecutive frames.

In a sur-reply, claimant argues that the Trust failed to cite a legitimate basis to ignore Dr. Wales' finding of moderate mitral regurgitation. Claimant also asserts that PTO No. 2640 is not inconsistent with Feigenbaum and does not stand for the proposition that "surrounding lower flow spray" should not be included in measuring mitral regurgitation in transthoracic echocardiograms. Finally, claimant argues that Drs. Notske and Wales did not engage in any conduct that was "beyond the bounds of medical reason."

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram. After review, Dr. Abramson concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Dr. Abramson explained, in relevant part, that:

To confirm my visual evaluation, I measured the mitral regurgitant jet and the left atrial area in the same frame in five representative cardiac cycles. Based on these measurements, I calculated RJA/LAA ratios which were equal to or slightly less than 20%, which confirmed my visual estimate.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation.<sup>9</sup> Although the Trust contested the attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's finding.<sup>10</sup> Specifically, Dr. Abramson concluded, in relevant part, that: "it would be possible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate. There is a reasonable medical basis for the [a]ttesting [p]hysician's [finding]." Under the

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9. Although unnecessary for resolution of this claim, as noted above, claimant also submitted a supplemental declaration of Dr. Wales who similarly concluded claimant had moderate mitral regurgitation.

10. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report. See Audit Rule 34.

circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.<sup>11</sup>

For the foregoing reasons, we conclude that claimant has met her burden of demonstrating that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Schaffer and her spouse for Matrix Benefits.

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11. Accordingly, we need not address claimant's remaining arguments.

