

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.

November 6, 2007

Marilyn Turner ("Ms. Turner" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,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. Donald Turner, Ms. Turner'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 presence of other medical conditions that also may have caused or
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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 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, Stephen A. Bloom, M.D. Based on an echocardiogram dated August 12, 1997, Dr. Bloom attested in Part II of Ms. Turner's Green Form that claimant had surgery to replace the mitral valve after use of Pondimin® and/or Redux™.⁴ Based on such findings, if accepted,

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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. Bloom also attested that claimant had surgery to replace the aortic valve after use of Pondimin® and/or Redux™ and suffered from severe mitral and aortic regurgitation, pulmonary hypertension secondary to severe aortic regurgitation, pulmonary
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claimant would be entitled to Matrix A-1, Level III benefits⁵ in the amount of \$696,987.⁶

Dr. Bloom also attested that claimant did not have mitral annular calcification ("MAC"). Under the Settlement Agreement, the presence of MAC requires the payment of reduced Matrix Benefits for mitral valve claims. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

In August 2004, the Trust forwarded the claim at issue to Kevin Wei, M.D., one of its auditing cardiologists. In audit, Dr. Wei concluded that there was no reasonable medical basis for Dr. Bloom's finding regarding the presence of MAC.⁷ Specifically, Dr. Wei concluded that claimant had MAC because her echocardiogram revealed MAC "at the posterior annulus in the

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hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% and 60%.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if the claimant had "[s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

6. In her Green Form, Ms. Turner requested Matrix A-1, Level II benefits. After conducting a review of claimant's Green Form and supporting materials, the Trust determined that claimant alleged conditions consistent with a Matrix A-1, Level III claim, for surgery to replace the aortic and mitral valves.

7. Dr. Wei also found that there was no reasonable medical basis for Dr. Bloom's findings regarding claimant's level of mitral regurgitation (finding moderate not severe), claimant's ejection fraction (finding it in excess of 60%), and claimant's aortic regurgitation (finding it not evaluable). These findings, however, are irrelevant for resolution of this claim.

PLAX⁸ view."⁹ Dr. Wei, however, concluded that there was a reasonable medical basis to find that claimant had surgery to replace both her mitral and aortic valves.

Based on Dr. Wei's diagnosis that claimant had MAC, the Trust issued a post-audit determination finding that Ms. Turner was entitled only to Matrix B-1, Level III benefits for her mitral valve surgery claim.¹⁰ Pursuant to the Rules for the

8. "PLAX" refers to the parasternal long-axis view.

9. Typically, auditing cardiologists complete three documents: (1) the Attestation of Auditing Cardiologist ("Attestation"); (2) the Report of Auditing Cardiologist Opinions Concerning Green Form Questions At Issue ("Report"); and (3) the Certification of Auditing Cardiologist ("Certification"). The Attestation and Report are completed contemporaneously with the auditing cardiologist's review of the echocardiogram and related materials and provide a detailed account of the auditing cardiologist's conclusions. The Certification is completed later in time and contains a general statement of the auditing cardiologist's findings. In the present case, Dr. Wei resigned from the Trust before completing the Certification. However, Dr. Wei's conclusions at audit are reflected in the Attestation and Report.

10. Based on Dr. Wei's finding that claimant's level of aortic regurgitation was not evaluable, the Trust also determined that Ms. Turner was not entitled to any benefits for her aortic valve surgery claim. A finding of at least mild aortic regurgitation is necessary for claimant to establish her eligibility for Matrix Benefits based on damages to her aortic valve. See Settlement Agreement § IV.B.1.a.; Pretrial Order ("PTO") No. 3192 at 3 (Jan. 7, 2004). Although not necessary for resolution of this claim, we also find that claimant met her burden in proving that she had at least mild aortic regurgitation. Specifically, we reject the Trust's argument that claimant could not rely on an October 1, 1997 transesophageal echocardiogram ("TEE") because it purportedly was intraoperative rather than post operative. Contrary to the Trust's assertion, the TEE report states that the purpose of the TEE was to: "Assess mitral valve and aortic valve and need for replacement and/or repair." The ultimate conclusion of the TEE, moreover, was that claimant had "[m]oderate to severe
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Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.¹¹

In support of her mitral valve surgery claim, claimant provided a Pathology Report, which set forth the results of the examination of claimant's mitral valve tissue. The report stated that "sectioning reveals no distinct calcification" and "[t]here is no evidence of calcification[.]" Based on the medical records provided, claimant asserted that she was entitled to Matrix A-1, Level III benefits.¹²

The Trust then issued a final post-audit determination, again determining that Ms. Turner was entitled only to Matrix B-1, Level III benefits.¹³ Claimant disputed this final

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aortic insufficiency" and, as a result, the "recommendation" was "[a]ortic valve replacement with mitral valve repair." On this basis alone, claimant is entitled to Matrix A-1, Level III benefits for her aortic valve surgery claim.

11. 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 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. Turner's claim.

12. In the background section of its final post-audit determination, the Trust states that it also denied Ms. Turner's claim for Matrix A-1, Level II benefits, based on Dr. Wei's conclusions. Claimant did not raise in the show cause proceedings any aspect of the Trust's denial of her claim for Level II Matrix Benefits. The only issue, therefore, is claimant's request for Matrix A-1, Level III benefits.

13. With its determination, the Trust submitted the claim to Keith B. Churchwell, M.D. for a second review because Dr. Wei had
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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, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Turner's claim should be paid. On October 26, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5811 (Oct. 26, 2005).

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 February 27, 2006. Claimant filed a sur-reply on March 24, 2006. The Show Cause Record is now before the court for final determination. See Audit 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 did not have MAC. See id. Rule 24. 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. Rule 38(a). If, on the

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resigned as an auditing cardiologist. Dr. Churchwell, however, did not address whether claimant had MAC.

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. Turner asserts that her medical records, the reports of her physicians and the echocardiograms submitted establish a reasonable medical basis for her claim. In response, the Trust argues that claimant is entitled to reduced benefits for her mitral valve surgery due to the reduction factor of MAC.

After reviewing the entire Show Cause Record, we find that claimant is entitled to Matrix A-1 benefits. We reject the Trust's assertion that claimant is not entitled to Matrix A-1 benefits for her mitral valve surgery claim.¹⁴ The Settlement Agreement provides that a claimant will receive reduced Matrix Benefits based on the presence of MAC. See Settlement Agreement § IV.B.2.d.(2)(c) ii)d). In the present case, Ms. Turner supported her attesting physician's determination that she did not have MAC with a Pathology Report, which specifically notes that, after an examination of claimant's mitral valve tissue, "[t]here is no evidence of calcification."

In its show cause submissions, the Trust asserts that "the absence of a notation regarding the presence of mitral

14. The Trust does not contest that claimant has established a claim for Level III benefits for her mitral valve surgery claim. The only issue, therefore, is whether the claim is to be paid on the A-1 or B-1 Matrix.

annular calcification in Respondent's post-surgery pathology report is expected, because the pathologist was only provided with a 'remnant' of the mitral valve leaflet-not the mitral annulus, where mitral annular calcification would be observed."¹⁵ Significantly, however, this statement by the Trust is neither supported by any certification from a Trust auditing cardiologist, nor any provision of the Settlement Agreement. As the Trust has not provided any support for this assertion, the court finds that claimant has met her burden in establishing a reasonable medical basis for her attesting physician's conclusion that she does not have MAC.¹⁶

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for finding that she did not have mitral annular calcification. Therefore, we will reverse the Trust's denial of Ms. Turner's claim for Matrix A-1 benefits and the related derivative claim submitted by her spouse.

15. The Trust also made this assertion in its Final Post-Audit Determination Letter.

16. We also note that the Trust did not have Dr. Churchwell address the issue of MAC. As previously noted, the Trust's first auditing cardiologist, Dr. Wei, resigned. Accordingly, the Trust relies solely on Dr. Churchwell. Although the Trust asserts that MAC is an issue, the Trust never provided any attestation or certification from Dr. Churchwell on that issue. On this basis as well, we conclude that claimant is entitled to Matrix A-1 benefits for her mitral valve surgery claim.

