

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.)
))
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM AND PRETRIAL ORDER NO. _____

Bartle, C.J.

February 26, 2007

Kathryn W. Killorin¹ ("Ms. Killorin" or "claimant") is a class member seeking benefits from the AHP Settlement Trust ("Trust"), which was established under the Diet Drug Nationwide Class Action Settlement Agreement with Wyeth² ("Settlement Agreement").³ 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").⁴

1. Claimant is Pro Se.

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

3. George P. Killorin, Ms. Killorin's spouse, also submitted a derivative claim for benefits.

4. 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
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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. To obtain Matrix Benefits, a claimant must establish that there is a reasonable medical basis for his or her claim under the criteria set forth in the Settlement Agreement. Accordingly, a claimant may recover benefits if the attesting physician's reading of the echocardiogram, and thus his or her accompanying Green Form answers, have a reasonable medical basis.

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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 other 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.

In January 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician Alan S. Gertler, M.D. Based on an echocardiogram dated December 10, 2002, Dr. Gertler attested in Part II of Ms. Killorin's Green Form that she suffered from severe mitral regurgitation, mild aortic regurgitation,⁵ and an ejection fraction in the range of 50% to 60%.⁶ Under the definition set forth in the Settlement Agreement, severe mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 40% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. An ejection fraction is considered reduced if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b).

Dr. Gertler 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. Based on such findings, claimant would be

5. Ms. Killorin's level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2).

6. Underneath Dr. Gertler's signature on the Green Form, there is a handwritten note explaining that Dr. Gertler had scheduled claimant for open heart surgery in February 2003 and that "all hospital reports, examination records, cardiac catheterization reports, surgery reports shall be forwarded to the AHP Settlement Trust during mid March of 2003." It is unclear who wrote this note.

entitled to Level II benefits.⁷ The only issue before us is whether such payment should be made on Matrix A-1 or Matrix B-1 due to the finding of MAC.⁸ If paid on Matrix A-1, Level II, claimant would be entitled to \$449,381.

In December 2003, the Trust forwarded the claim for review by Stuart G. Tauberg, M.D., one of its auditing cardiologists. In audit, Dr. Tauberg concluded that there was no reasonable medical basis for Dr. Gertler's finding that claimant did not have MAC. Based on Dr. Tauberg's diagnosis of MAC, the Trust issued a post-audit determination stating that Ms. Killorin was entitled only to Matrix B-1, Level II benefits.⁹ Pursuant to

7. In her Green Form, Ms. Killorin asserted a claim for Level V benefits. Upon review of Ms. Killorin's Green Form and supporting documents, the Trust determined that she set forth a claim for Level II benefits. In response, Ms. Killorin retracted her claim for Level V benefits and asserted that she was entitled to "[M]atrix A-1 at level II or III." See infra. Although Ms. Killorin stated that she had "open heart surgery" in February 2003, her claim is based on her Green Form, which only sets forth a claim for Level II benefits. Further, the medical documentation provided by Ms. Killorin does not indicate that this surgery was for valve repair or replacement as required for Level III benefits. Thus, we agree with the Trust that Ms. Killorin qualifies for Level II benefits.

8. 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). The Trust has conceded that claimant had severe mitral regurgitation and a reduced ejection fraction, one of the complicating factors needed for a Level II claim.

9. Based on findings in audit, the Trust issues a post-audit
(continued...)

the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"),¹⁰ claimant contested this adverse determination.¹¹

In contest, claimant submitted a February 11, 2004 letter from Dr. Gertler. Therein, Dr. Gertler stated that:

Ms. Killorin's previous echocardiograms were reviewed to determine if there is any evidence for [MAC]. Dr. Pohoy Fan re-interpreted the study that was performed on 12/10/02. It was Dr. Fan's impression that there was no evidence to suggest [MAC].

Claimant also re-submitted her December 10, 2002 echocardiogram report, which included an addendum containing Dr. Fan's findings. Dr. Fan stated that: "[n]o echocardiographic evidence of [MAC] was noted."¹²

The Trust then issued a final post-audit determination, again determining that Ms. Killorin was entitled only to Matrix

9(...continued)

determination regarding whether a claimant is entitled to Matrix Benefits.

10. 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. Killorin's claim.

11. A claimant may submit contest materials to challenge a post-audit determination. After considering any contest materials, the Trust then issues a final post-audit determination.

12. Claimant also submitted a January 9, 2004 echocardiogram report, which included an addendum by Chiara Liguori, M.D. Dr. Liguori found "[n]o evidence of [MAC]."

B-1, Level II benefits. Claimant disputed this final post-audit 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). In her letter of dispute, claimant clarified that she was not contesting the Trust's determination that her claim was not eligible for Matrix A-1, Level V benefits, but rather, she was disputing the Trust's finding of MAC.

Claimant also submitted a July 30, 2004 letter from Dr. Gertler wherein he stated that "[Navin C. Nanda, M.D.] interpreted Ms. Killorin's transthoracic echocardiogram from 12/10/02 and it was his impression after reviewing the videotape that there was absolutely no evidence of significant [MAC]." In addition, Ms. Killorin re-submitted her December 10, 2002 echocardiogram report, which included an addendum containing Dr. Nanda's findings. Dr. Nanda stated that: "I have reviewed the video tape and do not find any evidence of significant [MAC]."

The Trust then applied to the court for issuance of an Order to show cause why Ms. Killorin's claim should be paid. On February 1, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4427 (Feb. 1, 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 July 6, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹³ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. 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. at Rule 35.

In support of her claim, Ms. Killorin argues, among other things, that there is a reasonable medical basis for her claim because three doctors have concluded that she did not have MAC. She further argues that the auditing cardiologist's findings were not supported by a reasonable medical basis because he failed to provide any measurements of MAC. Ms. Killorin also contends that she does not have MAC because the physician who performed her open-heart surgery in February 2003, Albert D.

12. 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 a 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. See id.

Pacifico, M.D., stated that claimant did not have any complications with her mitral valve.¹⁴

In response, the Trust relies principally on the determination of its auditing cardiologist. The Trust also argues that, under the Settlement Agreement, the amount of MAC is not pertinent to the dispute because the presence of any MAC places the claim on Matrix B-1. Additionally, the Trust asserts that claimant cannot meet her burden of proof simply by proffering opinions from additional cardiologists.

The Technical Advisor, Dr. Vigilante, concluded that there was a reasonable medical basis for the attesting physician's finding of no MAC. As explained by Dr. Vigilante:

[MAC] was not present. [MAC] is characterized by increased echogenicity and reflectance of ultrasound especially in the posterolateral and medial portions of the mitral annulus. This was not found on the echocardiogram of December 10, 2002. There was no increased echogenicity in the annular area. There was thickening and mild calcification of the aortic leaflets but this calcification did not travel down into the mitral annular area. There was asymmetric septal hypertrophy with the interventricular septum much thicker than the posterior wall. There was a subvalvular gradient that increased to about 100 mmHg during valsalva. . . . [T]his echocardiogram demonstrated classic hypertrophic obstructive cardiomyopathy with mitral regurgitation secondary to this process. However, no mitral annular calcification was present. There was

13. Ms. Killorin did not submit any medical records from Dr. Pacifico.

thickening and mild calcification of the aortic leaflets only.

Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report. See Audit Rule 34. Claimant's attesting physician, Dr. Gertler, reviewed claimant's December 10, 2002 echocardiogram tape and determined that there was no MAC and the Technical Advisor confirmed this finding.¹⁵ Specifically, Dr. Vigilante stated that "it would be impossible for a reasonable echocardiographer to conclude that this study demonstrated [MAC]." Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.

Based on our review of the entire Show Cause Record, we conclude that claimant has met her burden in proving 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 final post-audit determination by the Trust and order that claimant and her spouse be paid in accordance with the Settlement Agreement.

15. Although unnecessary for resolution of this claim, as noted above, claimant also submitted reports of two additional cardiologists who similarly concluded that claimant did not have MAC.

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AND NOW, on this 26th day of February, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimants Kathryn W. Killorin and her spouse, George P. Killorin, are entitled to Matrix A-1, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805 and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III

C.J.