

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.

June 29, 2007

Alma Mitchell ("Ms. Mitchell" 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. Steven Mitchell, Ms. Mitchell'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 March 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Charles F. Dahl, M.D. Based on an echocardiogram dated December 14, 2001, Dr. Dahl attested in Part II of Ms. Mitchell's Green Form that she suffered from moderate mitral regurgitation, moderate aortic regurgitation,⁴ and an abnormal left atrial dimension. Based on

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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. Ms. Mitchell's claim does not present any of the complicating factors necessary to receive Matrix Benefits for an aortic valve claim. Thus, claimant's level of aortic regurgitation is not
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such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$449,381.

In the report of claimant's echocardiogram, Dr. Dahl stated that "[m]oderate mitral regurgitation was noted, with the jet filling 30% of the left atrial area." 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. Dahl also measured claimant's left atrial supero-inferior systolic dimension as 5.4 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).

In November 2002 the Trust advised claimant that Wyeth had selected her claim for audit. Claimant was further advised that the audit would focus on whether her left atrium was enlarged.⁵ In response, claimant submitted a letter from Stephen

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relevant to this claim. See Settlement Agreement
§ IV.B.2.c.(2)(a).

5. 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
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Raskin, M.D., who reviewed claimant's December 4, 2001 echocardiogram and stated that claimant's "left atrium is enlarged based on the superior-inferior dimension of 5.4 cm."

In February 2003, the Trust forwarded the claim for review by Donna Zwas, M.D., one of its auditing cardiologists. In audit, Dr. Zwas measured claimant's left atrial superior-inferior dimension as 5.0 cm and concluded that there was no reasonable medical basis for Dr. Dahl's finding that claimant had an abnormal left atrial dimension. Dr. Zwas further found that "[t]he measurement on the tape includes the pulmonary vein and is overmeasured."⁶

Based on Dr. Zwas' diagnosis of a normal left atrial dimension, the Trust issued a post-audit determination denying Ms. Mitchell's claim. Pursuant to the 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

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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.

6. 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 moderate mitral regurgitation, the only issue is whether claimant suffers from an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim.

Agreement § VI.E.7; PTO No. 2457 (May 31, 2002), Audit Policies and Procedures § VI.⁷ The Trust then applied to the court for issuance of an Order to show cause why Ms. Mitchell's claim should be paid. On June 30, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2910 (June 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. The Trust submitted a reply on August 19, 2003. Claimant submitted a sur-reply on September 5, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁸ 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.

7. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. 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. Mitchell's claim.

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.

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 to 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 an abnormal left atrial dimension. 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 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 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. Mitchell submitted: (1) testimony from Richard L. Weiss, M.D., who found that claimant had an enlarged left atrium, which he measured as 5.38 cm; (2) a letter from Dr. Dahl, confirming his finding that claimant's left atrium is enlarged, and disputing the auditing cardiologist's claim that his measurement included claimant's pulmonary vein;⁹ (3) a study conducted by Dr. Dahl, which purportedly demonstrates

9. Dr. Dahl stated that he measured "to the true inferior wall of the left atrium."

his impartiality; and (4) a letter from Dr. Raskin, which claimant had submitted previously to the Trust. Claimant also argues that the auditing cardiologist failed to apply the reasonable medical basis standard and, instead, substituted her conclusion with that of the attesting physician. Claimant further contends that her experts are more qualified than the auditing cardiologist, and, therefore, there is a reasonable medical basis for their finding of an abnormal left atrial dimension.

In response, the Trust submitted Ms. Mitchell's claim to Dr. Zwas for a second review. Dr. Zwas confirmed her previous conclusion that there was no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension because the "measurement of 5.38 ... is performed at an oblique angle and does include a portion of the take-off of the pulmonary vein." The Trust argues that the attesting physician's finding is "beyond the bounds of medical reason" because he relied on a measurement that improperly included the pulmonary vein. Finally, the Trust argues that claimant cannot meet her burden of proof simply by proffering opinions from additional physicians.¹⁰

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).

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In a sur-reply, claimant disputes the auditing cardiologist's finding that Dr. Dahl's measurement was "taken at the takeoff of the pulmonary vein" from an "oblique angle." In support, claimant submitted a verified supplemental opinion from Dr. Dahl who stated that:

The superior inferior measurement is not taken at the takeoff of the pulmonary vein. This measurement is in fact taken about 1 cm lateral to the pulmonary vein and is taken at the posterior wall of the left atrium. The measurement is minimally oblique (5 degrees at most). Using a ruler, a measurement taken by myself using a strict anterior posterior view measures 5.4 cm.

Claimant also asserts that the opinions of Drs. Raskin and Weiss support the conclusion of the attesting physician, and, thus, there is a reasonable medical basis for her claim.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. In particular, Dr. Abramson stated that:

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Finally, the Trust contends that the opinions of Drs. Weiss and Raskin should be excluded because they are not verified. We disagree. While the Audit Policies and Procedures allow for the submission of verified expert opinions, it does not preclude the submission of expert opinions that are not verified. See Audit Policies and Procedures § VI.F.(3). A claimant may submit "any evidence that refutes the Auditing Cardiologist's finding that no reasonable medical basis exists to support a material representation made in connection with the Audit Question(s)." Id. In any event, in her sur-reply, claimant submitted verifications from both Drs. Weiss and Raskin.

I also measured the left atrial dimension in the supero-inferior axis in the apical-4-chamber view at 5.3 cm, 5.3 cm and 5.4 cm. I did not include the pulmonary veins in my measurement Collectively, all of these measurements could reasonably be read as demonstrating that the Claimant has an abnormal left atrial dimension.

In response to the Technical Advisor Report, claimant argues that, as the Technical Advisor confirmed the finding of her experts that she has an abnormal left atrial dimension, she has met her burden of proof and is entitled to Matrix Benefits. Claimant also notes that the Technical Advisor found left atrium enlargement while avoiding the pulmonary vein in her measurements.

After reviewing the entire Show Cause Record before us, 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 an enlarged left atrium.¹¹ Although the Trust contested the attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's finding of an abnormal left atrial dimension.¹² Specifically, Dr. Abramson concluded that claimant's left atrium

11. Although unnecessary for resolution of this claim, as noted above, claimant also submitted reports of two additional cardiologists who similarly concluded that claimant had an abnormal left atrial dimension.

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

was "in the upper limits of normal, and it could reasonably be read as mildly dilated."

As stated above, a left atrial dimension is abnormal where a left atrial supero-inferior systolic dimension is greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension is greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b). Here, Dr. Abramson determined that claimant's left atrium was greater than 5.3 cm in the apical four chamber view. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her attesting physician's finding that she had an abnormal left atrial dimension.¹³

For the foregoing reasons, 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 Trust's denial of the claims submitted by Ms. Mitchell and her spouse for Matrix Benefits.

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

