

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
)
Plaintiffs,)
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION,)
)
Defendant.)

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

December 20, 2006

Larue Taylor ("Ms. Taylor" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement with Wyeth, Inc.¹ ("Settlement Agreement") 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. Rodney Taylor, Ms. Taylor's child, has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices
(continued...)

To apply for 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 February 2002, claimant submitted a completed Green Form to the Trust. Based on an echocardiogram dated December 12, 2001, claimant's physician, Thomas Davidson, M.D., attested in Part II of her Green Form that she suffered from moderate mitral regurgitation, moderate aortic regurgitation, and an enlarged left atrial dimension. In the report of claimant's echocardiogram, Charles F. Dahl, M.D., F.A.C.C., F.A.C.P., stated

3.(...continued)

(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 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.

that claimant had: (1) "[m]ildly thickened aortic valve with moderate aortic insufficiency"; (2) "[m]inimally thickened mitral valve with moderate mitral regurgitation"; and (3) "left atrial enlargement."⁴ If accepted, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$195,953.00.

In September 2002, the Trust advised claimant that her claim was selected for audit. In response, claimant submitted a letter from Dr. Davidson stating that claimant's left atrium was measured at 4.15 cm in the parasternal view. Claimant also submitted a report prepared by Amjad Iqbal, M.D., in which he stated that claimant's "[l]eft atrium is mildly enlarged, with a short-axis measurement of 4.2 cm and AP dimensions of 5.7 cm."

In October 2002, the Trust forwarded the claim at issue to Waleed Irani, M.D., one of its auditing cardiologists, for review. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Davidson's finding that claimant had an abnormal left atrial dimension because her "LA measurement in m-mode overestimated - LA size by 2D 3.5 - m-mode 3.9 AP4CH measurement severely overestimated."⁵

4. The echocardiogram report also indicates that it was prepared for the law firm of Abbott & Walker, P.C.

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 did not contest the attesting physician's finding of moderate mitral regurgitation, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's left atrial
(continued...)

Thereafter, the Trust issued a post-audit determination denying claimant's claim.⁶ 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.⁷ The Trust then applied to the court for issuance of an Order to show cause why claimant's claim should be paid. On October 1, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3046 (Oct. 1, 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 November 7, 2003. The Trust submitted a reply on November 26, 2003. Under the Audit Policies and Procedures it is within the Special Master's discretion to

5.(...continued)
dimension.

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

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. 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 2807 (Mar. 26, 2003).

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. The Special Master assigned a 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. Audit Policies and Procedures § VI.O.

As noted above, 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 has 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.

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 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. 863 F.2d at 158 (use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper).

During the show cause process, claimant submitted a Declaration prepared by Jack Schwade, M.D., to which he attached a still frame allegedly showing an enlarged left atrial dimension. She argues that the reasonable medical basis standard incorporates the concept of inter-reader variability. In her view, this accounts for any differences in measurements between her attesting physician and the Trust's auditing cardiologist. Claimant further argues that the auditing cardiologist failed to comply with the Audit Policies and Procedures because he did not provide an "underlying explanation for the opinion on the attestation form." Finally, claimant maintains that her due process rights were violated.

The Technical Advisor, Dr. Vigilante, concluded that there was no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. Claimant responded to the report of the Technical Advisor by arguing that he merely substituted his own opinion for that of the attesting physician and failed to discuss adequately "reasonable medical basis" and inter-reader variability.⁹

9. In response to the Technical Advisor's Report, claimant argues, for the first time, that Level II trained cardiologists have a different view of valvular heart disease than Level III trained cardiologists. Claimant asserts that the attesting physician is only Level II trained and, therefore, should be held to a different standard than the auditing cardiologist and Technical Advisor. The reasonable medical basis in the Settlement Agreement does not specify that such standard must be tailored to the level of a cardiologist's training. Thus, claimant's argument is without merit.

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 echocardiogram does not support the conclusions reflected in Part II of the Green Form. The Technical Advisor reviewed claimant's December 12, 2001 echocardiogram. Based on this review, the Technical Advisor explained that:

I reviewed the echocardiogram in question dated December 12, 2001. This was of excellent quality. . . . The left atrial size was normal. In multiple systolic frames, the left atrial antero-posterior systolic dimension was 3.5 cm. Multiple measurements of the left atrial supero-inferior dimension in systole was 5.0 cm. The parasternal long axis left atrial measurement noted on the echocardiogram tape on M-mode is incorrect as this was a tangential measurement. In the apical four-chamber view on the tape, there is a measurement of 5.6 cm of systolic left atrial dimension. However, the first point is actually too apically positioned towards the left ventricle.

The Technical Advisor further concluded that no abnormal left atrial dimension was measured and the left atrium could not "be reasonably read as being enlarged even taking into consideration inter-reader variability."

We reject claimant's argument that inter-reader variability accounts for the discrepancy between the measurements of the auditing cardiologist and the attesting physician. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard. The Technical Advisor took it

into account in concluding that claimant's echocardiogram demonstrates a normal left atrial size.

We also reject claimant's assertions that the auditing cardiologist and Technical Advisor failed to provide the bases underlying their conclusions. Dr. Irani specifically stated that the attesting physician's measurements were overestimated. Likewise, the Technical Advisor pointed out specific deficiencies in the measurements of claimant's left atrial dimension. Claimant has not rebutted the conclusions that the measurements relied upon by the attesting physician were incorrect. Accordingly, claimant has failed to establish a reasonable medical basis for Dr. Davidson's statements in claimant's Green Form regarding her left atrial dimension.

Finally, claimant's argument that her "due process" rights have been violated is equally meritless. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See, e.g., Audit Policies and Procedures § IV.D. The audit and show cause process, as approved by this court, comply with due process requirements, as claimant has had notice and an opportunity to present her evidence in support of her claim.

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 finding that she had an abnormal left atrial dimension. Therefore, we affirm the Trust's

denial of her claim for Matrix Benefits and the related derivative claim submitted by her child.

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AND NOW, on this 20th day of December, 2006, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the post-audit determination by the AHP Settlement Trust is AFFIRMED and the Level II Matrix claims submitted by claimant Larue Taylor and her child, Rodney Taylor, are DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.