

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.

April 12, 2007

Teresa Telschow ("Ms. Telschow" 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 Wyeth¹ ("Settlement Agreement").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. August Telschow, Ms. Telschow's spouse, has also submitted a claim for derivative 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 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. 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, has a reasonable medical basis.

In January 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Thomas

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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.

Davidson, M.D. Based on an echocardiogram dated July 18, 2001, Dr. Davidson attested in Part II of Ms. Telschow's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and pulmonary hypertension secondary to moderate mitral regurgitation. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$492,142.⁴

In the report of claimant's echocardiogram, David A. Rawling, M.D., F.A.C.C., the reviewing cardiologist, stated that claimant had "moderately severe" mitral regurgitation. 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. Rawling also stated that claimant had "[m]oderate left atrial ... enlargement." 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). Lastly, Dr. Rawling estimated claimant's peak pulmonary artery pressure as 47 mm Hg

4. 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).

by Doppler evaluation. Under the Settlement Agreement, pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic artery pressure >40 mm Hg measured by cardiac catheterization or >45 mm Hg measured by Doppler echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See id.

In April 2003, the Trust forwarded the claim at issue to Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Davidson's finding that claimant had moderate mitral regurgitation. According to Dr. Irani, "only mild MR [was] present." In addition, Dr. Irani concluded that there was no reasonable medical basis for finding an abnormal left atrial dimension. Dr. Irani was not asked to review whether claimant had pulmonary hypertension secondary to moderate or greater mitral regurgitation.⁵

Thereafter, the Trust issued a post-audit determination denying Ms. Telschow's claim.⁶ Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant

5. It should be noted that Dr. Irani confirmed that claimant had pulmonary hypertension. Therefore, if claimant establishes that she was diagnosed with moderate mitral regurgitation, her pulmonary hypertension would qualify as a complicating factor as it would be secondary to moderate mitral regurgitation.

6. Based on findings in audit, the Trust issues a post-audit determination regarding whether a claimant is entitled to Matrix Benefits. 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.

contested this adverse determination.⁷ In contest, claimant submitted, among other things, declarations from two cardiologists, Jack Schwade, M.D. and Jose Rivera, M.D. In the first declaration, Dr. Schwade stated, in pertinent part, that claimant's RJA/LAA ratio was 38% and her left atrial antero-posterior systolic dimension in the parasternal long-axis view was 4.5 cm.⁸ In the second declaration, Dr. Rivera stated, in pertinent part, that claimant's RJA/LAA ratio was 25% and her left atrial antero-posterior systolic dimension in the parasternal long-axis view was 4.2 cm. These declarations support findings of moderate mitral regurgitation and an abnormal left atrial dimension.

Based on claimant's contest, the Trust submitted her claim to Dr. Irani for a second review. Dr. Irani confirmed his previous conclusions that there was no reasonable medical basis for Dr. Davidson's finding of moderate mitral regurgitation or an abnormal left atrial dimension. Specifically, Dr. Irani stated that:

In real time, Claimant's level of mitral regurgitation is clearly mild. Claimant's

7. 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. Telschow's claim.

8. Dr. Schwade attached two still frames from claimant's echocardiogram in support of his findings.

Attesting Cardiologist inflated the regurgitant jet area ("RJA") to left atrial area ("LAA") ratio by grossly overtracing the RJA. Claimant's Attesting Cardiologist relied upon planimetry that overtraced the regurgitant jet to include substantial pulmonary venous inflow. Claimant's true RJA/LAA ratio is less than 10%.

I measured Claimant's left atrial dimension in the parasternal long-axis view in 2D mode and concluded that it measures 3.93 cm.

Thereafter, the Trust issued a final post-audit determination, again denying Ms. Telschow's claim.⁹ 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, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Telschow's claim should be paid. On January 29, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3228 (Jan. 29, 2004).

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

9. In its denial letter, the Trust asserted that claimant violated the Audit Rules by submitting more than one expert report. Specifically, the Trust argued that claimant was limited to one verified statement from an expert under Audit Rule 18(b), which provides that a claimant may contest a determination by submitting "certain materials ... to the Trust" and that such materials "may include a verified statement of a medical expert." We disagree. Contrary to the Trust's position, there is no express limitation on the number of verified expert opinions that may be submitted by a claimant and we decline to impose one.

Master. The Trust submitted a reply on April 7, 2004. Claimant submitted a Sur-Reply on April 22, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ 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.

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 findings that she had moderate mitral regurgitation and an abnormal left atrial dimension. See id. at 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 confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. at Rule 38(a). If, on the other hand, we determine that there was a reasonable medical

10. 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. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. at Rule 38(b).

In support of her claim, Ms. Telschow argues, among other things, that there is a reasonable medical basis for her claim because four doctors concluded that she had moderate mitral regurgitation and an abnormal left atrial dimension.¹¹ The Trust responded principally by relying on the determination of its auditing cardiologist.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's findings of moderate mitral regurgitation and an abnormal left atrial dimension. Specifically, Dr. Vigilante found that:

I reviewed the echocardiogram of July 18, 2001 in detail. This was a good quality study with the standard views demonstrated on the tape. This study demonstrates a

11. Claimant also argues that: (1) the phrase "reasonable medical basis" is a fluid term, which incorporates inter-reader variability; (2) the auditing cardiologist's attestation form, worksheet and certification do not comply with the Audit Rules; (3) the auditing cardiologist's opinion is inadmissible because it fails to explain the lack of a reasonable medical basis; and (4) the Trust's conduct amounts to a violation of claimant's due process rights. The Trust responds that: (1) claimant's characterization of the reasonable medical basis standard is incorrect; (2) the auditing cardiologist followed the Audit Rules and completed the attestation form properly, which incorporates the requirements of the Settlement Agreement and the Audit Rules; (3) claimant's inter-reader variability argument does not refute the auditing cardiologist's conclusions; and (4) claimant's due process argument must fail because the Audit Rules provide adequate notice and an opportunity to be heard.

moderately thickened anterior mitral leaflet that opens and closes adequately. There is mild thickening of the posterior mitral leaflet with some restriction of leaflet excursion. There is an eccentric mitral regurgitation jet that travels posterolaterally within the left atrium. This jet is noted on the parasternal long axis view, apical four-chamber view, and apical two-chamber view. On both the apical four and two-chamber views, it is clearly noted that the RJA/LAA ratio is above 25%. The left ventricle size and contractility is completely normal with a left ventricular ejection fraction above 60%. The left atrium is dilated measured 4.2 cm in the antero-posterior systolic dimension in the parasternal long axis view as well as 5.7 cm in the supero-inferior systolic dimension in the apical four-chamber view. The aortic valve is normal. The left ventricular size contractility is normal. There is mild tricuspid regurgitation and Doppler evaluation of this does demonstrate mild pulmonary hypertension with a pulmonary artery systolic pressure calculated at 48 mmHg.

Dr. Vigilante further stated that he disagreed with Dr. Irani's assessment that "substantial pulmonary venous in-flow was included in the assessment of the mitral regurgitant jet" and that claimant's regurgitant jet "is a very eccentric jet noted on three views"

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, Dr. Davidson, found that claimant had moderate mitral regurgitation and an abnormal left atrial dimension.¹² Although the Trust contested

12. Although unnecessary for resolution of this claim, as noted
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the attesting physician's conclusions Dr. Vigilante confirmed these findings.¹³ Specifically, Dr. Vigilante stated that "there is a reasonable medical basis for the Attesting Physician's answer[s] ... that Claimant suffers from moderate mitral regurgitation" and "an abnormal left atrial dimension."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Further, 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 id. at § IV.B.2.c.(2)(b). Here, Dr. Vigilante found that moderate mitral regurgitation was visible in the apical four chamber view, and he measured claimant's left atrial dimension as 5.7 cm in the apical four chamber view and 4.2 cm in the parasternal long axis view. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim. We, therefore, need not address claimant's remaining arguments.

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above, claimant also submitted declarations of two additional cardiologists who similarly concluded that claimant had moderate mitral regurgitation and an abnormal left atrial dimension.

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

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. We will reverse the Trust's denial of the claims submitted by Ms. Telschow and her spouse for Matrix Benefits.

