

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)
CORPORATION) 2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

July 24, 2007

Claudia Doyle ("Ms. Doyle" 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. Anthony Doyle, Ms. Doyle'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 contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

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.

In May 2000, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D. Based on an echocardiogram dated November 12, 1997, Dr. Evans attested in Part II of Ms. Doyle's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, arrhythmias or atrial fibrillation associated with left atrial enlargement, a reduced ejection fraction between 50% and 60%, and had surgery to repair or replace the mitral valve. Dr. Evans also attested that claimant's echocardiogram did not reveal the presence of mitral valve prolapse, which is a

3(...continued)

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.

reduction factor that would require the payment of benefits on Matrix B-1.

In the report of claimant's echocardiogram, Randolph Cohen, M.D., the reviewing cardiologist, stated that claimant's "mitral valve demonstrated prolapse of the posterior leaflet of the mitral valve." In the Green Form, however, Dr. Evans stated that claimant was "negative for prolapse by Dr. Kelly Pathologist." Mitral valve prolapse is defined in the Settlement Agreement as a condition where:

- (a) the echocardiogram video tape or disk includes the parasternal long axis view and
- (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

Settlement Agreement § I.39. Under the Settlement Agreement, mitral valve prolapse requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii). Therefore, the only issue is whether payment should be made on Matrix A-1 or Matrix B-1 due to the finding of mitral valve prolapse. If paid on Matrix A-1, claimant would be entitled to \$733,670.⁴

In June 2001, Waleed Irani, M.D., one of the Trust's auditing cardiologists, audited Ms. Doyle's claim. In audit, Dr. Irani concluded that there was no reasonable medical basis for

4. Under the Settlement Agreement, a claimant generally is entitled to Level III benefits if the claimant had surgery to repair or replace the mitral valve following the use of Pondimin® and/or Redux™. See id. § IV.B.2.c.(3)(a). The Trust did not contest that claimant qualified for a Level III claim.

Dr. Evans' finding that claimant did not have mitral valve prolapse. In his certification, Dr. Irani stated that: "[t]here is clear evidence of posterior mitral valve prolapse with anteroseptally directed jet of mitral regurgitation." In Part II of the Auditing Cardiologist Worksheet, Dr. Irani further stated that claimant "did appear to have MV prolapse of 2 mm of posterior mitral leaflet. This is in agreement with the original echo report. Unclear whether reviewing cardiologist felt <2mm prolapse was present."

Based on Dr. Irani's diagnosis of mitral valve prolapse, the Trust issued a post-audit determination that Ms. Doyle was entitled only to Matrix B-1, Level III benefits. 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 (May 31, 2002), Audit Policies and Procedures § VI.⁵ The Trust then applied to the court for issuance of an Order to show cause why

5. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in 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 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Doyle's claim.

Ms. Doyle's claim should be paid on Matrix A-1.⁶ On July 11, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5418 (Jul. 11, 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 October 4, 2005. The Show Cause Record is now before the court for final determination. See Audit Policies and Procedures § 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 did not have mitral valve prolapse as defined by the Settlement Agreement. See id. § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form 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, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

6. Although Ms. Doyle contested the Trust's post-audit determination in September 2001, the Trust did not submit its Application until May 2005 because, according to the Trust, "[r]espondent's dispute was misdirected within the Trust and came to the attention of Trust personnel in May, 2005."

In support of her claim, claimant submitted a report from Karen L. Kelly, M.D., and a report from Dr. Evans. In her report, Dr. Kelly stated that: "the histologic findings of Ms. Doyle's surgically resected mitral valve are, more likely than not, due to diet drug effect." In his report, Dr. Evans concluded that claimant did not have mitral valve prolapse.

In response, the Trust argues that there is no reasonable medical basis for Dr. Evan's finding that claimant did not have mitral valve prolapse because Dr. Irani reviewed claimant's November 12, 1997 echocardiogram and found "clear evidence" that claimant has mitral valve prolapse. The Trust also argues that claimant's reliance on Dr. Kelly's report is misplaced as Dr. Kelly based her findings on her histologic study of slides of claimant's surgically resected mitral valve tissue, and not on claimant's November 12, 1997 echocardiogram. Further, the Trust argues that the report of claimant's echocardiogram of November 12, 1997 specifically states that "mitral valve demonstrated prolapse of the posterior leaflet of the mitral valve." Finally, the Trust contends that a December 1, 1997 "Operative Report" for claimant's mitral valve replacement surgery states that: "[t]he [mitral] valve was found to be markedly insufficient with some prolapse of both anterior and posterior leaflets, primarily the posterior leaflet." The Trust argues that claimant's echocardiogram report and Operative Report establish that she has mitral valve prolapse.

The Settlement Agreement requires that a claim for benefits be reduced to Matrix B-1 if certain medical conditions are present. See Settlement Agreement § IV.B.2.d. In claimant's case, her mitral valve claim must be reduced to Matrix B-1 if she has mitral valve prolapse, as that condition is defined in the Settlement Agreement. See id. § I.39; see also id. § IV.B.2.d.(2)(c)(ii)(b). As noted above, mitral valve prolapse is defined as follows:

"Mitral Valve Prolapse" refers to a condition where (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

Id. § I.39.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her attesting physician's finding that she did not have mitral valve prolapse. Unlike other reduction factors (e.g. mitral annular calcification), the Settlement Agreement sets forth a specific measurement regarding whether the presence of mitral valve prolapse requires payment of reduced benefits on Matrix B-1. In support of its position that claimant should be paid reduced Matrix Benefits, the Trust relies on Dr. Irani's conclusion. This determination, however, is not persuasive. In the AHP Settlement Trust Echocardiogram Report, Dr. Irani merely referenced "posterior leaflet prolapse [with] anteroseptally

directed jet of MR" and, in Part II of the Auditing Cardiologist Worksheet, he stated that: "videotape quality was poor but [patient] did appear to have [mitral valve] prolapse of 2 mm of posterior mitral leaflet. This is in agreement with the original echo report. Unclear whether reviewing cardiologist felt <2 mm prolapse was present."⁷

To reduce the payment of a mitral valve claim based on a finding of mitral valve prolapse, the Settlement Agreement explicitly requires that the parasternal long axis view show a displacement of one or both mitral leaflets greater than 2 millimeters above the atrial-ventricular border during systole, and greater than 5 millimeters leaflet thickening during diastole. The auditing cardiologist did not reach these two conclusions. Indeed, Dr. Irani merely concluded that there "appears" to be mitral valve prolapse of 2 millimeters. The Settlement Agreement, however, requires a displacement of greater than 2 millimeters. The auditing cardiologist also did not separately determine the level of mitral valve prolapse during both systole and diastole.

In support of its denial, the Trust also relies on the report of claimant's November 12, 1997 echocardiogram and the December 1, 1997 "Operative Report" for claimant's mitral valve replacement surgery. These medical records, however, do not support the Trust's denial because neither record reflects the

7. In a later Attestation and Certification prepared by Dr. Irani and dated July 22, 2005, this statement does not appear.

necessary mitral valve prolapse measurement required to reduce a claim for Matrix Benefits to Matrix B-1.

Finally, unaddressed by the Trust is a contemporaneous medical record that supports the attesting physician's conclusion that claimant did not have mitral valve prolapse as defined by the Settlement Agreement. On November 25, 1997, claimant underwent a coronary angiography to evaluate her mitral regurgitation. The report of that procedure, signed by Randolph D. Cohen, M.D., stated that claimant did not have mitral valve prolapse.⁸

Under these circumstances, claimant has established a reasonable medical basis for her claim because the Trust's auditing cardiologist failed to find that claimant's echocardiogram revealed the presence of mitral valve prolapse as defined in the Settlement Agreement. The auditing cardiologist did not state that mitral valve prolapse is present and exceeds the required 2 millimeters in systole and 5 millimeters in diastole. Moreover, the existing records contained in the Show Cause Record support the answer to the Green Form question at

8. The Trust also does not address Dr. Evans' statement, both in the Green Form and by subsequent letter, that his Green Form answer was based on the separate report of Dr. Kelly. While the Trust challenges the conclusions of both Drs. Kelly and Evans, Dr. Irani concluded his audit prior to the submission of the reports of these two physicians. Thus, the reports apparently were not considered by the Trust's auditing cardiologist. As a result, the conclusions set forth in the reports of Drs. Kelly and Evans were not rebutted by the Trust.

issue. The Trust's determination that there is no reasonable medical basis for the claimant's answer, therefore, is erroneous.

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 thus, she is entitled to Matrix A-1, Level III benefits. We will, therefore, reverse the post-audit determination by the Trust and order that claimant and her spouse be paid in accordance with the Settlement Agreement.

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AND NOW, on this 24th day of July, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the post-audit determination of the AHP Settlement Trust is REVERSED and that claimants Claudia Doyle and her spouse, Anthony Doyle, are entitled to Matrix A, Level III benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805.

BY THE COURT:

/s/ Harvey Bartle III

C.J.