

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION))))))	MDL NO. 1203
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THIS DOCUMENT RELATES TO:)))	
SHEILA BROWN, et al.)))	CIVIL ACTION NO. 99-20593
v.)))	
AMERICAN HOME PRODUCTS CORPORATION)))	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9132

Bartle, J.

August 16, 2013

John V. Davis ("Mr. Davis" 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"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. 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 Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is 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, claimant's attorney must complete Part III if claimant is represented.

In July, 2010, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Manoj R. Muttreja, M.D. Based on an echocardiogram dated April 21, 2003,³ Dr. Muttreja attested in Part II of claimant's Green Form that Mr. Davis suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Based on such findings, claimant

2. (...continued)
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.

3. Because claimant's April 21, 2003 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated June 14, 2002 to establish his eligibility for Matrix Benefits.

would be entitled to Matrix A-1, Level V benefits in the amount of \$1,059,643.⁴

In the report of claimant's April 21, 2003 echocardiogram, the reviewing cardiologist, James W. Smith, M.D., stated, "The mitral valve shows calcification of the mitral annulus with mild systolic anterior motion of the anterior leaflet." In addition, in the report of claimant's June 14, 2002 echocardiogram, the reviewing cardiologist, David Liang, M.D., stated, "There is mild mitral annular calcification." Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Dr. Muttreja, however, attested in claimant's Green Form that Mr. Davis did not suffer from mitral annular calcification.

In September, 2010, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Irani determined that there was no reasonable medical basis for the attesting physician's representation that claimant had moderate mitral regurgitation based on claimant's April 21, 2003 echocardiogram. Specifically,

4. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level II benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.C.(5)(d). A claimant qualifies for 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 id. § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the factors needed to qualify for Level II benefits.

Dr. Irani explained, "Only mild [mitral regurgitation] seen on study with ratio of approximately 10-15%." Dr. Irani also concluded that there was a reasonable medical basis for the Green Form representation⁵ that claimant did have mitral annular calcification based on claimant's June 14, 2002 echocardiogram because "mild posterior [mitral annular calcification] [was] present."⁶

Based on Dr. Irani's finding that claimant's April 21, 2003 echocardiogram demonstrated only mild mitral regurgitation, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, Mr. Davis argued that the auditing cardiologist should have determined whether claimant's

5. As noted, Dr. Muttreja did not attest that claimant suffered from mitral annular calcification.

6. In addition, Dr. Irani found that claimant's June 14, 2002 echocardiogram demonstrated moderate mitral regurgitation and agreed with Dr. Muttreja's representation that claimant suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise because "[patient] had [ventricular tachycardia] which deteriorated to [ventricular fibrillation] requiring defibrillation in the [emergency room]."

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 the claim of Mr. Davis.

June 14, 2002 echocardiogram demonstrated an abnormal left atrial dimension. According to claimant, he may rely on his June 14, 2002 echocardiogram to satisfy the Matrix Level II prerequisite to his claim for Matrix Level V benefits based on ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise, irrespective of the results of the audit of his April 21, 2003 echocardiogram. Claimant also contended that the auditing cardiologist's finding of mitral annular calcification was not supported by the evidence.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review.

Dr. Irani submitted a declaration in which he concluded that there was no reasonable medical basis for finding that Mr. Davis did not have mitral annular calcification. In particular, Dr. Irani explained:

11. At Contest, I was also asked to determine whether mitral annular calcification is present on the April 21, 2003 echocardiogram of attestation, the June 14, 2002 eligibility echocardiogram, and echocardiogram studies dated November 30, 2001, May 28, 2002, and September 20, 2002.
12. Upon review of the April 21, 2003 echocardiogram study at Contest, I observed posterior mitral annular calcification that is mild, but present, in the PLAX images. There is no reasonable medical basis to conclude that mitral annular calcification is *not* present on this study.

13. Mitral annular calcification is also present on the June 14, 2002 echocardiogram study, as I noted at audit. There is no reasonable medical basis to conclude that mitral annular calcification is not present on this study.

Dr. Irani also reviewed claimant's June 14, 2002 echocardiogram and determined that, in addition to moderate mitral regurgitation, "it would not be unreasonable to conclude that left atrial enlargement is present on that study."

The Trust then issued a final post-audit determination, again denying the claim. 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 his claim should be paid. On April 13, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8634 (Apr. 13, 2011).

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 14, 2011, and claimant submitted a sur-reply on August 2, 2011. Under the Audit Rules, 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 Rule 30. The Special Master assigned a 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 Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for his claim. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Davis argues that he is entitled to Level V Matrix Benefits because the Trust concedes both that his June 14, 2002 echocardiogram qualified him for

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. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Level II benefits and that he suffered from ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise on December 9, 2004. According to Mr. Davis, whether his April 21, 2003 echocardiogram qualifies him for Level II benefits is irrelevant because the plain language of the Settlement Agreement only requires that he qualify for benefits at Matrix Level II at the time he suffers ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Claimant contends this interpretation is consistent with our decisions in PTO Nos. 3193 and 8595 and Section VI.C.1.d. of the Settlement Agreement, which provides:

A claimant who qualifies for a particular Matrix payment, by virtue of a properly interpreted Echocardiogram showing the required levels of regurgitation and/or complicating factors, after exposure to fenfluramine and/or dexfenfluramine, shall not be disqualified from receiving that Matrix payment in the event that a subsequent Echocardiogram shows that the required levels of regurgitation and/or complicating factors are no longer present.

Claimant also asserts that the only relevant echocardiogram for determining whether claimant has mitral annular calcification is his June 14, 2002 echocardiogram and that there is a reasonable medical basis for Dr. Muttreja's representation that Mr. Davis did not have mitral annular calcification based on that echocardiogram.

In response, the Trust argues that Mr. Davis cannot meet the requirements for Matrix Level V benefits because he did

not concurrently qualify for Matrix Level II benefits and suffer ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise. The Trust maintains that his April 21, 2003 echocardiogram, the echocardiogram performed immediately preceding his episode of ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise, does not demonstrate Matrix Level II qualifying conditions. The Trust further asserts that Section VI.C.1.d. does not change this result because that section pertains only to whether a claimant qualifies for certain Matrix Benefits, not the presence or absence of the medical conditions giving rise to the particular claim. Finally, the Trust argues that Mr. Davis did not establish a reasonable medical basis for Dr. Muttreja's representation that claimant did not have mitral annular calcification.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiograms and concluded that there was no reasonable medical basis for Dr. Muttreja's representation that Mr. Davis did not have mitral annular calcification. Specifically, Dr. Abramson noted that each of claimant's echocardiograms, dated November 30, 2001, May 28, 2002, June 14, 2002, September 20, 2002, and April 21, 2003, demonstrated mild mitral annular calcification.

Mr. Davis submitted a response to the Technical Advisor Report but did not address Dr. Abramson's findings with respect to mitral annular calcification.⁹

After reviewing the entire Show Cause Record, we find that claimant is entitled to Matrix B-1, Level V benefits. Under the Settlement Agreement, a claimant is entitled to Level V Matrix Benefits if the following definition is met:

- (d) The individual otherwise qualifies for payment at Matrix Level II, III, or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

Settlement Agreement § IV.B.2.c.(5)(d).

In the present case, the Trust does not contest that Mr. Davis qualified for Level II Matrix Benefits based on his June 14, 2002 echocardiogram or that Mr. Davis suffered from ventricular fibrillation or sustained tachycardia which resulted in hemodynamic compromise on December 9, 2004. The Trust, however, argues that Mr. Davis cannot meet the requirements for Matrix Level V benefits as set forth in PTO No. 3193 because his

9. Claimant also included with his response to the Technical Advisor Report a supplemental declaration of Dr. Muttreja. Pursuant to Audit Rule 34, the Special Master advised Mr. Davis that Dr. Muttreja's supplemental declaration could not become part of the Show Cause Record. Thereafter, claimant filed a motion to have this additional report included in the Show Cause Record. As we previously have stated, pursuant to Audit Rule 34, there is no procedure by which a supplemental declaration such as Dr. Muttreja's can become part of the Show Cause Record. See Mem. in Supp. of PTO No. 9041, at 9-10 n.11 (Apr. 5, 2013). In any event, given our disposition, Dr. Muttreja's supplemental declaration is irrelevant to resolution of this claim. Accordingly, we will deny the motion as moot.

April 21, 2003 echocardiogram does not demonstrate that he qualifies for payment at Matrix Level II, III, or IV.

In PTO No. 3193, we rejected a claim for Matrix Level V benefits because claimant's episode of "ventricular fibrillation occurred and ended before the existence of factors qualifying her for Matrix Level II payments." Mem. in Supp. of. PTO No. 3193, at 4 (Jan. 7, 2004). In PTO No. 8595, we found that claimant demonstrated it was entitled to Level V benefits where the Diet Drug Recipient qualified for Level II Matrix Benefits based on an echocardiogram performed in March, 2002 but did not suffer an episode of ventricular fibrillation or ventricular tachycardia which resulted in sustained hemodynamic compromise until August, 2003. Mem. in Supp. of PTO No. 8595, at 2-3, 12-15 (Feb. 3, 2011).

As did the Diet Drug Recipient in PTO No. 8595, Mr. Davis qualified for Matrix Level II benefits based on an echocardiogram performed prior to his episode of ventricular fibrillation. Specifically, Mr. Davis qualifies for Level II benefits based on his June 14, 2002 echocardiogram and he subsequently suffered an episode of ventricular fibrillation on December 9, 2004. The fact that claimant's April 21, 2003 echocardiogram does not qualify him for Level II benefits is thus irrelevant. Accordingly, he has satisfied the criteria for Level V benefits.

We must, however, still determine whether claimant should be paid on Matrix A-1 or Matrix B-1. As noted previously,

the Settlement Agreement provides that the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)(ii)d). The auditing cardiologist reviewed claimant's medical records, including his echocardiograms, and concluded that there was a reasonable medical basis for representing that claimant had mitral annular calcification. Although claimant responded that Dr. Irani did not consider claimant's June 14, 2002 echocardiogram, Dr. Irani submitted a supplemental declaration wherein he confirmed that claimant's June 14, 2002 echocardiogram in fact demonstrated mitral annular calcification.¹⁰ In addition, Dr. Abramson reviewed claimant's medical records, including claimant's numerous echocardiograms, and concluded that each one demonstrated mitral annular calcification. Despite submitting a response to the Technical Advisor Report, claimant did not dispute Dr. Abramson's finding in this regard. Thus, claimant has not established a reasonable medical basis for Dr. Muttreja's representation that claimant did not have mitral annular calcification.

For the foregoing reasons, we conclude that claimant has met his burden of proving that he is entitled to Level V benefits but has not met his burden of proving that he is

10. In any event, we reject claimant's contention that his June 14, 2002 echocardiogram is the "relevant echocardiogram" for purposes of determining whether the reduction factor of mitral annular calcification applies. See Mem. in Supp. of PTO No. 8822, at 9-11 (Feb. 22, 2012), aff'd, No. 12-3138, 2013 WL 216619, at *2-3 (May 21, 2013).

entitled to Matrix A-1 benefits. Therefore, we will affirm the Trust's denial of the claim of Mr. Davis for Matrix A-1, Level V benefits but will reverse the Trust's denial of the claim of Mr. Davis for Matrix B-1, Level V benefits.