

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

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9217

Bartle, J.

March 15, 2014

The Estate of Lois Goldblatt ("Estate"), a representative claimant 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 the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").³

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

2. Neil D. Goldblatt ("Mr. Goldblatt"), the spouse of Lois Goldblatt ("Ms. Goldblatt"), 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 Diet Drug (continued...)

To seek Matrix Benefits, a representative claimant⁴ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In July, 2011, Mr. Goldblatt, the personal representative of the Estate, submitted a completed Green Form to the Trust signed by the attesting physician, Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. Based on an echocardiogram

3. (...continued)

Recipients 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 the Diet Drug Recipient'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 representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they 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 representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators, or other legal representatives, heirs, or beneficiaries. See Settlement Agreement § II.B.

dated November 3, 2002, Dr. Dlabal attested in Part II of the Estate's Green Form that Ms. Goldblatt suffered from moderate mitral regurgitation, had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™, and had ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise. Dr. Dlabal also attested that Ms. Goldblatt died as a result of a condition caused by VHD or valvular repair/replacement surgery.⁵ Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits in the amount of \$972,751.⁶

Dr. Dlabal also attested that Ms. Goldblatt did not suffer from 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). As the Trust does not contest the

5. Dr. Dlabal also attested that Ms. Goldblatt suffered from a reduced ejection fraction in the range of 30% to 34% and New York Heart Association Functional Class III symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a representative claimant is entitled to Level V benefits if the Diet Drug Recipient:
(1) suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records," and also had underlying medical conditions sufficient to satisfy the requirements of a Level I or Level II Matrix Claim, Settlement Agreement § IV.B.2.c.(5)(c); Seventh Amendment § I.30.e., or (2) qualified for Level III benefits and suffered from ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise, Settlement Agreement § IV.B.2.c.(5)(d).

Estate's entitlement to Level V benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.

In September, 2011, 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 concluded that there was no reasonable medical basis for Dr. Dlabal's finding that Ms. Goldblatt did not have mitral annular calcification. In support of this conclusion, Dr. Irani explained, "Mild posterior [mitral annular calcification] on [the November 3, 2003] study. Severe [mitral annular calcification] on 4/2002 study and all subsequent studies."

Based on the auditing cardiologist's finding that Ms. Goldblatt had mitral annular calcification, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁷ In contest, the Estate argued that there was a reasonable medical basis for finding that Ms. Goldblatt did not have mitral annular calcification on the April 11, 2002 and November 3, 2002 echocardiograms. In support,

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 Estate's claim.

the Estate submitted declarations from Leon J. Frazin, M.D., F.A.C.C., and Michael E. Staab, M.D., F.A.C.C., wherein they stated that they reviewed Ms. Goldblatt's April 11, 2002, November 3, 2002, October 4, 2010, and January 12, 2011 echocardiograms and determined that there was no mitral annular calcification present on Ms. Goldblatt's April 11, 2002 and November 3, 2002 echocardiograms.⁸ In addition, Dr. Frazin noted that mitral annular calcification was not the cause of Ms. Goldblatt's mitral regurgitation.

The Estate also argued that its claim should not be reduced because the Settlement Agreement required that the presence of a reduction factor such as mitral annular calcification must be diagnosed between the commencement of Diet Drug use and the end of the Screening Period.⁹ In support, the Estate submitted a declaration from Manoj R. Muttreja, M.D., who stated, in pertinent part:

3. [Mitral annular calcification] is sometimes a cause of mitral regurgitation When the mitral valve annulus becomes thick and rigid due to the presence of [mitral annular calcification], these conditions might interfere with valve

8. Although they reviewed Ms. Goldblatt's October 4, 2010 and January 12, 2011 echocardiograms, neither Dr. Frazin nor Dr. Staab opined as to the presence or absence of mitral annular calcification on these echocardiograms.

9. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

closure, thus causing low levels of [mitral regurgitation].

4. However, if [mitral annular calcification] was not present at the time of the patient's diagnosis of moderate [mitral regurgitation], then [mitral annular calcification] could not possibly cause this condition.

5. Therefore, if a patient had moderate [mitral regurgitation], any later finding of [mitral annular calcification] would be an incidental finding, and it would have no bearing on the patient's actual medical or clinical condition.

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 again concluded that there was no reasonable medical basis for Dr. Dlabal's finding that Ms. Goldblatt did not have mitral annular calcification. Specifically, Dr. Irani stated, in pertinent part:

9. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant did not have mitral annular calcification. I reviewed the [echocardiograms] dated 4/11/02, 11/3/02, 10/4/10 and 1/12/11. Mitral annular calcification is seen on all of these studies.

10. Mitral annular calcification is present on the 11/3/02 echocardiogram of attestation. This was a much better study than any of the others, with lower gain settings. Mitral annular calcification is evident on this study, including at frames time stamped:
3:54.22, 4:01.22, 9:42.01.

11. Mitral annular calcification is also present on the 4/11/02 study. This is a lower quality study with high gain settings, which can make all structures look brighter. This certainly may have led me to say the [mitral annular calcification] was more severe on this study than on others, it was nonetheless present.
12. Mitral annular calcification is also present on the 10/4/10 and 1/12/11 studies.
13. Accordingly, I affirm my findings at audit, that there is no reasonable medical basis for a finding that Claimant did not have mitral annular calcification.

The Trust then issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate 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 the Estate's claim should be paid. On March 21, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8856 (Mar. 21, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on August 21, 2012, and the Estate submitted a sur-reply on November 7, 2013. Under

the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. 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 the Estate 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 the Estate has met its burden of proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Goldblatt did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, 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 answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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 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.

In support of its claim, the Estate reasserts the arguments made in contest. The Estate also argues that it has sufficiently identified the specific errors by the auditing cardiologist in finding the presence of mitral annular calcification. The Estate contends, therefore, that it established a reasonable medical basis for the attesting physician's finding that Ms. Goldblatt did not have mitral annular calcification. In addition, the Estate submitted a declaration from the attesting physician, Dr. Dlabal, who stated, in pertinent part:

2. I re-reviewed the echocardiogram disc dated 11/03/02.

3. There is no [mitral annular calcification] on ANY of the [parasternal long-axis] views, nor on the [parasternal short-axis] views, the primary views in which one would expect to see [mitral annular calcification] if present.

4. There is no [mitral annular calcification] at 3:54:22. NONE.

5. There is a "fleck" of increased density on the posterior-lateral aspect of the mitral valve annulus, in the [apical four chamber] view at 4:01:22. This however, correlates with an increase in transducer gain, to image at depth. This increase in gain also creates artifact of the same density in the [left atrium], through the [left atrium] wall, and even outside the cardiac silhouette. Clearly the [mitral valve] annular density, as well as the other densities, are artifactual in nature, and do not represent calcium deposition. Further, as noted above, the [mitral valve] annular density is not seen on other views, thus confirming the artifactual nature of the finding in the [apical four chamber] view.

6. Ibid, as above for 9:42:01.

Finally, the Estate asserts that the Settlement Agreement and the Seventh Amendment to the Settlement Agreement "guarantee Matrix Level III, IV and V payments on the current Matrix if Class Members' conditions progressed to more severe events, including valve surgery."

In response, the Trust reasserts that the Estate has not established a reasonable medical basis for finding that Ms. Goldblatt did not have mitral annular calcification. In addition, the Trust points out that we previously have rejected the argument that the Trust may not rely on echocardiograms conducted after the Screening Period to find the presence of a reduction factor.

In its sur-reply, the Estate argues that the Trust misstates the standard for determining a reasonable medical basis. According to the Estate, "the use of this term in the Settlement Agreement suggests deference to the attesting physician's opinion" and that "[t]he role of the auditing cardiologist is not to 'second guess' the attesting cardiologist."¹¹

11. The Estate also argues that the Trust's Reply was untimely and should be disallowed by the court. To the contrary, the Trust timely submitted its Reply to the Estate's response. In any event, as we previously discussed in PTO No. 6339, "we are unwilling to order payment on an uncompensable claim solely based on an 'out of time' argument without, at a minimum, some showing of prejudice." Mem. in Supp. of PTO No. 6339, at 13 n.10 (May 25, 2006).

The Technical Advisor, Dr. Vigilante, reviewed Ms. Goldblatt's echocardiograms and concluded that there was no reasonable medical basis for finding that Ms. Goldblatt did not have mitral annular calcification based on her October 4, 2010 and January 12, 2011 echocardiograms. Dr. Vigilante stated, in pertinent part:

I reviewed the DVD of the Claimant's October 4, 2010 echocardiogram....

I reviewed the mitral apparatus which demonstrated classic and severe calcification of the posterolateral mitral annulus. This was manifested by significantly increased echoes and refractoriness of these echoes in the posterolateral area of the mitral annulus. Classic significant mitral annular calcification was seen in loops 1 and 2 in the parasternal long-axis view, loop 18 in the parasternal short-axis view, loop 30 in the apical four chamber view, and loop 61 in the apical two chamber view. The mitral leaflets were thickened and there was obvious systolic anterior motion of the mitral valve....

....

I reviewed the Claimant's echocardiogram of January 12, 2011.... There was significantly increased echoes and refractoriness of the echoes in the posterolateral mitral annulus best seen in loops 1 and 8. This study was classic for significant mitral annular calcification. There was thickening of the mitral leaflets with systolic anterior motion of the mitral valve....¹²

12. Dr. Vigilante also concluded that there was a reasonable medical basis for finding that Ms. Goldblatt's April 11, 2002 and November 3, 2002 echocardiograms did not demonstrate mitral annular calcification. Given our disposition, this determination is not relevant.

After reviewing the entire show cause record, we find the Estate's arguments are without merit. 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 and the Technical Advisor reviewed Ms. Goldblatt's October 4, 2010 and January 12, 2011 echocardiograms and concluded that there was no reasonable medical basis for Dr. Dlabal's representation that Ms. Goldblatt did not have mitral annular calcification. In particular, Dr. Vigilante concluded that these two echocardiograms demonstrated "classic" mitral annular calcification.¹³ In addition, the report of Ms. Goldblatt's October 4, 2010 echocardiogram notes, "Mitral valve is thickened."¹⁴

Significantly, none of the Estate's physicians disputes that Ms. Goldblatt's October 4, 2010, January 12, 2011, and January 13, 2011 echocardiograms show the presence of mitral annular calcification.¹⁵ Instead, the Estate only argues that

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

14. The report of an echocardiogram performed on December 3, 2010 also states, "Mitral annular calcium."

15. Although Dr. Frazin and Dr. Staab reviewed Ms. Goldblatt's October 4, 2010 and January 12, 2011 echocardiograms, the only opinion they offered with respect to mitral annular calcification was as to the April 11, 2002 and November 3, 2002 echocardiograms. The Estate's other physicians, Dr. Muttreja and Dr. Dlabal, also rendered no opinions as to the October 4, 2010 and January 12, 2011 echocardiograms.

these later echocardiograms should be disregarded because, according to claimant, the reduction factors set forth in the Settlement Agreement, such as mitral annular calcification, have a temporal limitation. We have rejected this argument, ruling that "[t]o avoid receiving reduced Matrix Benefits, claimant must demonstrate, at a minimum, that she did not suffer from a reduction factor at the time she suffered from the conditions supporting her supplemental claim." See Mem. in Supp. of PTO No. 8822, at 9 (Feb. 22, 2012), aff'd, In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 525 F. App'x 140 (3d Cir. 2013); see also Mem. in Supp. of PTO No. 8743, at 2-7 (Dec. 27, 2011).

We also reject the Estate's argument that it is entitled to Matrix A-1 benefits because Ms. Goldblatt's mitral regurgitation was not caused by mitral annular calcification. Causation is not at issue in resolving claims for Matrix Benefits. Rather, representative claimants are required to show that Diet Drug Recipients meet the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If representative claimants are not required to demonstrate causation, the converse also is true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the medical condition at issue. The Settlement Agreement unequivocally requires a claim for damage to the mitral valve to be reduced to Matrix B-1 if the Diet Drug Recipient had mitral annular calcification. We must apply the Settlement Agreement as written. Accordingly, the Estate's assertion as to the cause of Ms. Goldblatt's mitral valve regurgitation is irrelevant to the issue before the court.

Finally, we do not agree that the Estate is entitled to Matrix A-1, Level V benefits under the Seventh Amendment. As an initial matter, the Seventh Amendment specifically states, "The determinations and actions of the Trust on any aspect of a claim for Cash/Medical Services Benefits of a Category One Class Member or Category Two Class Member, or on any claim for the Matrix Election Payment, shall have no preclusive or precedential effect of any kind on the Trust in the administration ... of claims for Seventh Amendment Matrix Compensation Benefits." Seventh Amendment § IX.E. The Seventh Amendment further provides that:

For each Category One Class Member or Category Two Class Member found to be eligible for Seventh Amendment Matrix

Compensation Benefits, the Trust shall calculate as a Net Matrix Amount, a sum equal to the gross amount payable to the Diet Drug Recipient or Representative Claimant and their associated Derivative Claimants, if any, on the applicable Matrix under section IV.B.2 of the Settlement Agreement

Id. § IX.A.2. (emphasis added).¹⁶ Section IV.B.2.d. sets forth "[t]he circumstances which determine whether Matrix A-1 or Matrix B-1 is applicable" Settlement Agreement § IV.B.2.d. As the Estate does not dispute that Ms. Goldblatt had mitral annular calcification prior to her January 12, 2011 mitral valve surgery, the Settlement Agreement requires that the Estate's Level V claim be reduced to the B Matrix.

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there is a reasonable medical basis for finding that Ms. Goldblatt did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix A benefits and the related derivative claim submitted by Ms. Goldblatt's spouse.

16. Under the Seventh Amendment, Seventh Amendment Matrix Compensation Benefits means "those Matrix Compensation Benefits which may be paid or claimed for High Matrix Level Qualifying Factors to or by Category One Class Members or Category Two Class Members in accordance with the terms of the Seventh Amendment." Seventh Amendment § I.64. The Estate is a Category Two Class Member and its claim for Level V Matrix Benefits is a claim for Seventh Amendment Matrix Compensation Benefits.