

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 IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, C.J.

August 31, 2010

Lorilee A. Gill ("Ms. Gill" 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. Rick A. Gill, Ms. Gill's spouse, and Paige D. Gill, Ms. Gill's child, also have submitted derivative claims 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

(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 December, 2003, claimant submitted an amended Green Form to the Trust signed by her attesting physician, Pierre P. Leimgruber, M.D.⁴ Based on an echocardiogram dated January 16, 2002, Dr. Leimgruber attested in Part II of Ms. Gill's Green Form that she suffered from moderate mitral

3. (...continued)
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.

4. Claimant originally submitted a Green Form to the Trust signed by Lorne E. Goldman, M.D. Based on the echocardiogram dated January 16, 2002, Dr. Goldman attested in Part II of Ms. Gill's Green Form that claimant suffered from moderate mitral regurgitation, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms.

regurgitation and a reduced ejection fraction in the range of 50% to 60%.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$556,216.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, Darren C. Hollenbaugh, M.D., F.A.C.C., stated that claimant had moderate mitral regurgitation, which he measured at 35%. 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.

In February, 2004, the Trust forwarded the claim for review by Issam A. Mikati, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Mikati concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Mikati explained that "this is not moderate

5. Dr. Leimgruber also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition, however, is not at issue in this claim.

6. 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 does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

[mitral regurgitation. Left atrial] area is 20 cm2[.] The [mitral regurgitant] jet area is at most 1.9 cm2[.] That is clearly in mild range[.] No tracing on [the] tape[.]"

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Gill's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted a declaration from Robert N. Notske, M.D., F.A.C.C., F.A.C.P. Dr. Notske is no stranger to this litigation. According to the Trust, he has signed in excess of 42 Green Forms on behalf of claimants seeking Matrix Benefits. In his declaration, Dr. Notske stated:

I have reviewed the 16 January 2002 echocardiogram multiple times and observed that there are multiple "normal" views demonstrating moderate regurgitation of greater than 20% of RJA/LAA without need of any specific measurements to document it numerically. The Attesting Cardiologist, Dr. Hollenbaugh, and I are in agreement that Lorilee Gill has moderate Mitral Regurgitation within the provisions of the settlement agreement. It is demonstrated on echocardiogram.

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. Gill's claim.

Ms. Gill also submitted a letter from Dr. Hollenbaugh, who confirmed his original finding that claimant had moderate mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Ms. Gill's 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 Ms. Gill's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5238 (May 20, 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 August 5, 2005, and claimant submitted a sur-reply on January 24, 2006. Under the Audit Rules it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and

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. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, 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.

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, 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 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 her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's 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).

In support of her claim, claimant argues that there is a reasonable medical basis for her claim because four cardiologists, including "three highly qualified Cardiologists, who worked at the clinic recommended by the Trust for the

Screening Program,"⁹ all determined that claimant had moderate mitral regurgitation.

In response, the Trust argues that claimant has failed to establish a reasonable medical basis for her claim because she did not rebut the specific measurements of Dr. Mikati. The Trust also contends that the additional letter from Dr. Hollenbaugh and the declaration of Dr. Notske do not establish a reasonable medical basis for Ms. Gill's claim because they do not provide any support for their conclusions. Finally, the Trust asserts that Dr. Hollenbaugh's letter is improper because it was not verified in accordance with the Audit Rules.

In her sur-reply, claimant submitted a declaration by Dr. Hollenbaugh wherein he restated his conclusion that Ms. Gill had moderate mitral regurgitation.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Gill had moderate mitral regurgitation. Specifically, Dr. Burke observed that:

Upon my review of the tape, my overall assessment of the mitral regurgitation is trace to mild.

Using representative beats in the apical four chamber view, I calculated RJA/LAA ratios consistent to 5%. This represents mild mitral regurgitation.

9. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

Using representative beats in the apical two chamber view, I calculated RJA/LAA ratios to range from 1 to 10%, with an average of 6%. This represents mild mitral regurgitation.

Using representative beats in the apical three chamber view, I calculated RJA/LAA ratios to range from 3% to 16%, with an average of 9%. This represents mild mitral regurgitation.

* * *

In conclusion, even taking into account inter-reader variability, I believe there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a., which states that Claimant suffers from moderate mitral regurgitation.

In response to the Technical Advisor Report, claimant argues that three separate cardiologists, including cardiologists who participated in the Trust's Screening Program, determined that Ms. Gill had moderate mitral regurgitation, and therefore "they likely used the 'most common approach' to interpret the severity of the mitral regurgitation." According to claimant, the Technical Advisor's opinion does not discount the reasonable medical basis established by claimant's attesting physician and her additional experts because rather than "address Feigenbaum or the 'most common approach,'" the Technical Advisor based his conclusion on the use of "representative beats," which Feigenbaum does not reference.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest the finding of the auditing cardiologist. Specifically, claimant does not

challenge Dr. Mikati's determination that "this is not moderate [mitral regurgitation]," and that claimant's RJA of 1.9 cm² and LAA of 20 cm² are "clearly in [the] mild range." Claimant never identified any particular error in Dr. Mikati's measurements. Mere disagreement with the auditing cardiologist without identifying and substantiating any specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

Moreover, we disagree with claimant's argument that Dr. Burke did not apply the appropriate standard in evaluating Ms. Gill's echocardiogram. Specifically, Dr. Burke concluded, using representative beats, that claimant's echocardiogram demonstrated RJA/LAA ratios of 5% in the apical four chamber view, 1% to 10% in the apical two chamber view, and 3% to 16% in the apical three chamber view. As previously stated, moderate mitral regurgitation is defined as an RJA/LAA ratio in the range of 20% to 40%, which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although claimant objects to Dr. Burke's use of "representative beats" to evaluate the level of mitral regurgitation, we have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram." PTO

No. 6997 at 11. "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." Id.

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of her claim was conducted by a cardiologist who participated in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Settlement Agreement, § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to

seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. See, e.g., PTO No. 2662 at 13. As nothing in the Settlement Agreement supports the conclusion that a cardiologist's participation in the Screening Program entitles his or her opinion to more weight, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Gill's claim for Matrix Benefits and the related derivative claims submitted by her spouse and child.

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PRETRIAL ORDER NO.

AND NOW, this 31st day of August, 2010, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is AFFIRMED and that the Matrix A, Level II claims submitted by claimant Lorilee A. Gill, her spouse, Rick A. Gill, and her child, Paige D. Gill, are DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.