

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.

September 7th, 2010

Charlene A. Todd ("Ms. Todd" 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. Jeffrey A. Todd, Ms. Todd'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
(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 November, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Bassem Mikhail, M.D. Based on an echocardiogram dated March 6, 2002, Dr. Mikhail attested in Part II of Ms. Todd's Green Form that she suffered from moderate mitral regurgitation,⁴ an abnormal left atrial dimension, and a reduced ejection fraction in the range of

3. (...continued)
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. In August, 2002, claimant submitted a Green Form based on the same March 6, 2002 echocardiogram and signed by Azam Ansari, M.D. In the August, 2002 Green Form, Dr. Ansari attested that claimant had mild mitral regurgitation.

50% to 60%.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$522,266.⁶

In the report of claimant's echocardiogram, Dr. Ansari, the reviewing cardiologist, stated that claimant had "mild mitral regurgitation, which occupied 19% of the left atrial volume." 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. Ansari further stated that claimant's "left atrium is mildly enlarged at 42 mm." 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). Finally, Dr. Ansari estimated claimant's ejection fraction as "60-65%." An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id.

5. Dr. Mikhail also attested that claimant suffered from New York Heart Association Functional Class I 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).

In June, 2006, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for Dr. Mikhail's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Oliner explained that: "[t]here is mild [mitral regurgitation] with an RJA/LAA of 10-15%. The freeze frame RJA's include non-[mitral regurgitant] low velocity signal. The measured LAA freeze frame underestimates LAA due to foreshortening." Dr. Oliner also found that there was no reasonable medical basis for finding that claimant had an abnormal left atrial dimension because: "[t]he [left atrium] appears visually normal in size," which he measured as 3.4 cm in the parasternal long-axis view and 4.8 cm in the apical four chamber view. Finally, Dr. Oliner found that there was no reasonable medical basis for the attesting physician's finding regarding claimant's ejection fraction because "[ejection fraction] is >60%," which he specifically found to be 65%.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Todd's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷

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
(continued...)

In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant further contended that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."⁸ Claimant also submitted that the Trust did not properly apply the "reasonable medical basis" standard established in the Settlement Agreement as the auditing cardiologist simply substituted his own opinion for that of the attesting physician.⁹ In addition, claimant asserted that, as to her left atrial dimension, the auditing cardiologist's determination is inconsistent with the finding on her echocardiogram report, which was performed in the Trust's Screening Program.¹⁰ Finally, as to her ejection

7. (...continued)

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. Todd's claim.

8. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, addressed Ms. Todd's echocardiogram.

9. In contest, claimant also asserted that, in another claim, Dr. John Dent, a Trust expert, purportedly had concluded that Dr. Oliner wrongfully denied a claim. We will not consider references to determinations made in other, unrelated show cause claims in determining whether claimant has established a reasonable medical basis to support her claim.

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

fraction, claimant argued that "it is highly unlikely for a 5% difference of opinion to have 'no reasonable medical basis.'"¹¹

The Trust then issued a final post-audit determination again denying Ms. Todd's claim. Claimant disputed 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.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Todd's claim should be paid. On December 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6812 (Dec. 28, 2006).

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 March 20, 2007, and claimant submitted a sur-reply on April 16, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a

11. Claimant also contended that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence of any "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how these filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are 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 answers, 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, Ms. Todd reasserts the arguments that she made in contest. Claimant also contends that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation and, as such, "[n]either diagnosis is correct or incorrect; both fall within the realm of having a 'reasonable medical basis.'"¹² As to her left atrial dimension, claimant relies on her Green Form answer. Finally, as to her ejection fraction, claimant asserts that the attesting physician's finding should be accepted because

12. Claimant also relies on Dr. Ansari's measurement of her mitral regurgitation as 19%. Nothing in the Settlement Agreement, however, allows a claimant to recover Matrix Benefits where the claimant relies on a measurement that is close to the specific requirements of the Settlement Agreement. As we previously have concluded, "a claimant with mitral regurgitation at 19.9% RJA/LAA, a level just below moderate, is ineligible for benefits." PTO No. 2640 at 8 n.5 (Nov. 14, 2002).

it "falls well within established inter-reader variability of 10%."¹³

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. The Trust also argues that claimant failed to establish a reasonable medical basis for her claim because she did not rebut any of Dr. Oliner's specific findings. Moreover, the Trust asserts that the deficiencies identified by Dr. Oliner constitute impermissible conduct. Finally, the Trust contends that claimant cannot rely on "a single frame that is not representative of [claimant's] degree of mitral regurgitation" to establish that she was diagnosed as having moderate mitral regurgitation.

In her sur-reply, claimant reiterates most of her arguments and asserts that she had contested Dr. Oliner's conclusions regarding her left atrial dimension and ejection fraction. Claimant also argues that: (1) the Trust failed to acknowledge that her attesting physician concurred with Dr. Ansari's original diagnoses that claimant had an abnormal left atrial dimension and a reduced ejection fraction; and

13. Claimant further argues that Dr. Mikhail's assertions on her Green Form should be accepted because he and his partner have declined to attest to Matrix level conditions where they have found moderate and severe regurgitation. Claimant also asserts that Dr. Oliner's determination should be disregarded because, in another show cause claim, one of the court's Technical Advisors found a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation even though Dr. Oliner's conclusion was that the particular claimant only had mild mitral regurgitation. As the issue before us is whether Dr. Mikhail's findings as to Ms. Todd have a reasonable medical basis, these arguments are not relevant to the resolution of this claim.

(2) the attesting physician's finding that claimant's RJA/LAA ratio was 20% was close to Dr. Ansari's conclusion that claimant's RJA/LAA ratio was 19%.

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 Dr. Oliner's diagnoses of mild mitral regurgitation, a normal left atrial dimension, and a normal ejection fraction. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Todd rests only on Dr. Mikhail's check-the-box diagnoses on her Green Form and the echocardiogram report prepared by Dr. Ansari for the claim at issue. She does not adequately refute or respond to Dr. Oliner's findings that the "freeze frame RJA's include non-[mitral regurgitant] low velocity signal," and the "measured LAA freeze frame underestimates [the] LAA due to foreshortening." Claimant never identified any particular error in Dr. Oliner's measurements or conclusions. Mere disagreement with the auditing cardiologist without identifying 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.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the

Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Oliner determined in audit, and Ms. Todd does not adequately dispute, that the attesting physician's findings of moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction were unreasonable. Specifically, Dr. Oliner measured claimant's RJA/LAA ratio to be 10-15%. With respect to her left atrial dimension and ejection fraction, Dr. Oliner determined that Ms. Todd's left atrium appeared visually normal in size measuring 3.4 cm in the parasternal long-axis view and 4.8 cm in the apical four chamber view and her ejection fraction was 65%. Contrary to claimant's argument, Dr. Oliner properly applied the reasonable medical basis standard established under the Settlement Agreement.

Moreover, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include:

- (1) failing to review multiple loops and still frames;
- (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram;
- (3) failing to examine the regurgitant jet throughout a portion of systole;
- (4) over-manipulating echocardiogram settings;
- (5) setting a low Nyquist limit;
- (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation;
- (7) failing to take a claimant's medical history; and

(8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26. Here, Dr. Oliner determined in audit, and Ms. Todd does not adequately dispute, that her attesting physician incorrectly included low velocity flow as mitral regurgitation and improperly measured claimant's left atrial area, resulting in an erroneous diagnosis of moderate mitral regurgitation. Such unacceptable practices by the attesting physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.¹⁴

Additionally, for 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.¹⁵ 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. Moreover, we have stated previously that "[o]nly after reviewing

14. For this reason as well, we find that this is not merely conflicting "subjective" diagnoses between the attesting physician and the auditing cardiologist. Nor has Dr. Oliner merely substituted his opinion for that of the attesting physician. Instead, Dr. Oliner found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation based on clearly identified deficiencies in the attesting physician's conclusion.

15. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on an isolated instance of what appears to be the requisite level of regurgitation to meet this definition.

multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate regurgitation has been achieved." PTO No. 6897 (Jan. 26, 2007) (quoting PTO No. 2640 at 9). To the extent that claimant purports to rely on a single frame to establish that she has moderate mitral regurgitation, her claim must fail.

We also reject claimant's suggestion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of the claim for Matrix Benefits was conducted 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 an eligible class member is entitled to receive based on an echocardiogram performed in 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.

Id. § 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 receiving 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 for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

Finally, we reject claimant's inter-reader variability argument concerning Dr. Oliner's conclusion as to her ejection fraction. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of a reduced ejection fraction in the range of 50% to 60% cannot be medically reasonable where the auditing cardiologist concluded that claimant's ejection fraction exceeded 60%. To conclude otherwise would allow a claimant, for purposes of a mitral valve claim, to assert the presence of a reduced ejection fraction even where the ejection fraction was as

high as 70%. This result would render meaningless the standards established in the Settlement Agreement.

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, an abnormal left atrial dimension, and a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Todd's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

