

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.

8956

Bartle, J.

November 6, 2012

Deborah Estes ("Ms. Estes" 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. Robert M. Estes and Bonnie M. Estes, claimant's children, 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 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 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, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gregory R. Boxberger, M.D., F.A.C.C. Based on an echocardiogram dated September 24, 2001, Dr. Boxberger attested in Part II of claimant's Green Form that Ms. Estes suffered from moderate mitral regurgitation, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, and a reduced ejection fraction of less than 30%. Based on such findings,

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.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$545,310.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Lynda O. Tirao, M.D., stated that claimant had mild mitral regurgitation. Dr. Tirao, however, did not specify a percentage as to claimant's level of mitral regurgitation.⁵ 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 September, 2003, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.S.E., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Estes had moderate mitral

4. 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 findings of an abnormal left atrial dimension or a reduced ejection fraction, each of 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.

5. Claimant also submitted an echocardiogram report prepared by Dr. Boxberger in July, 2002 based on her September 24, 2001 echocardiogram. In this report, Dr. Boxberger stated that claimant had "moderate mitral regurgitation, based on RJA to LAA radio [sic] of .2."

regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Gillespie explained that the "RJA/LAA was not 20% or greater in any of the views evaluated. The parasternal jet was less than 10% and the apicals less than 15%."

Based on the auditing cardiologist's finding that claimant had 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.⁶ In contest, claimant submitted affidavits from Dr. Boxberger, Roger W. Evans, M.D., F.A.C.P., F.A.C.C.,⁷ and G. Whitney Reader, M.D., F.A.C.P., F.A.C.C. In his affidavit, Dr. Boxberger confirmed his previous finding that claimant had moderate mitral regurgitation with an RJA/LAA of 20%. Dr. Evans stated that "[t]he echocardiogram tape in question shows 'moderate' mitral valve regurgitation with an RJA/LAA ratio of 22%." Dr. Reader also concluded that claimant's echocardiogram showed moderate mitral

6. 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 this claim.

7. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed in excess of 322 Green Forms on behalf of claimants seeking Matrix Benefits. See PTO No. 8412 (Mar. 9, 2010).

regurgitation, and found "an RJA/LAA ratio of at least 20%." Claimant argued, therefore, that she had established a reasonable medical basis for her claim because three Board-Certified Cardiologists independently agreed that she had moderate mitral regurgitation. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.)

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Gillespie submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Estes had moderate mitral regurgitation. Specifically, Dr. Gillespie stated:

In connection with my review, I found that Claimant's echocardiogram tape is of such poor quality that it was not possible to planimeter the tape. It is clear from a visual observation of the tape, however, that Claimant's [RJA/LAA] ratio is 10% - 15%, and clearly no more than 15%. Moreover, I observed that the echocardiogram report prepared in connection with the echocardiogram that is the basis of Claimant's claim indicates that Claimant has only mild mitral regurgitation.

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 the claim should be paid. On March 26, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3380 (Mar. 26, 2004).

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 November 3, 2004, and claimant submitted a sur-reply on November 19, 2004. 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.

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 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.

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, Ms. Estes repeats the arguments she made in contest; namely, that the opinions of Dr. Boxberger, Dr. Evans, and Dr. Reader provide a reasonable medical basis for the finding of moderate mitral regurgitation. Claimant also contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and the auditing cardiologist, Dr. Gillespie. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Estes contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that the opinions of Dr. Evans and Dr. Reader do not establish a reasonable medical basis for the claim of Ms. Estes because they are all based on the "same erroneous interpretation of [claimant's] echocardiogram as Dr. Boxberger's finding and are in direct conflict with the findings of the report prepared contemporaneously with [claimant's] echocardiogram." The Trust also contends that inter-reader variability does not establish a reasonable medical basis for the claim because Dr. Gillespie specifically determined that there was no reasonable medical basis for Dr. Boxberger's findings.⁹

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

In reviewing the transthoracic echocardiogram, my visual estimate is that there is only mild mitral regurgitation. I chose not to measure this jet because it is not even close to being moderate. The quality of this echocardiogram is fair, but it is clear that there is only mild mitral regurgitation. There is merely a central jet which is only seen in the apical-4-chamber

9. The Trust also argues that claimant's additional expert reports should be disregarded because Ms. Estes did not disclose their compensation or submit a list of previous cases in which they have served. We disagree. As we previously have held, requiring disclosures pursuant to Rule 26(a)(2) of the Federal Rules of Civil Procedure would serve no purpose given the prohibition on discovery contained in the Audit Rules. See, e.g., PTO No. 6996 at 7 n.10 (Feb. 26, 2007).

view. The [claimant] is tachycardic which causes artifact that may have been misread as mitral regurgitation. The color gains are also inappropriately increased which may also account for color flashing which may have been misread as mitral regurgitation.

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. She does not rebut the auditing cardiologist's determination that the "RJA/LAA was not 20% or greater in any of the views evaluated."¹⁰ Nor does she challenge Dr. Abramson's conclusion that "there is only mild mitral regurgitation. There is merely a central jet which is only seen in the apical-4-chamber view."¹¹ Although Ms. Estes submitted the affidavits of several cardiologists, neither claimant nor her experts identified any particular errors in the conclusions of the auditing cardiologist or the Technical Advisor. They also did not provide an explanation for the reviewing cardiologist's determination that claimant's echocardiogram demonstrated only mild mitral regurgitation. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific error by them is insufficient to meet a claimant's burden of proof.

10. For this reason as well, we reject claimant's argument that the auditing cardiologist substituted his personal opinion for the diagnosis of the attesting physician.

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

Moreover, we disagree with claimant that the opinions of her physicians establish a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those 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. 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 (Nov. 14, 2002). Here, Dr. Abramson determined that claimant was tachycardic and that the color gain settings were inappropriately increased, resulting in, respectively, artifact and color flashing, which may have been misread by claimant's attesting physician and expert cardiologists as mitral regurgitation. Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Estes had moderate mitral regurgitation is misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be reasonable where the Technical Advisor concluded that claimant had only mild mitral regurgitation and the auditing cardiologist determined that claimant's echocardiogram demonstrated RJA/LAA ratios of less than 15% in the apical views and 10% in the parasternal views. Adopting claimant's argument that inter-reader variability would expand the range of moderate mitral regurgitation by $\pm 15\%$ would allow a claimant to recover benefits with an RJA/LAA as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.¹²

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

12. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in her statement that "it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate. There is no reasonable medical basis for the Attesting Physician's claim that this Claimant has moderate mitral regurgitation, even taking into account inter-reader variability."

the claim of Ms. Estes for Matrix Benefits and the related derivative claims submitted by her children.