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
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	)	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9209

Bartle, J. March 20, 2014

Janice I. Oaks (a/k/a Janice I. Phillips) ("Ms. Oaks" 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. In 2009, Pfizer, Inc. acquired Wyeth.

2. Jamie W. Oaks, claimant'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

(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 September, 2011, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Based on an echocardiogram dated May 21, 2009,[4] Dr. Evans attested in Part II of claimant's Green Form that Ms. Oaks suffered from moderate mitral regurgitation and a reduced ejection fraction in the range

---

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. Because claimant's May 21 2009 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated June 27, 2002 to establish her eligibility to receive Matrix Benefits.

of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $588,156.[5]

In the report of claimant's May 21, 2009 echocardiogram, the reviewing cardiologist, Stacy D. Brewington, M.D., stated that claimant's "ejection fraction [was] greater than 60%." 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 Settlement Agreement § IV.B.2.c.(2)(b)iv).

In March, 2012, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Parmar concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Dr. Parmar explained:

> In my review of the echocardiograms the ejection fraction is over 60%. In the specific echocardiogram dated 5/21/09, the ejection fraction is greater than 60%, in my opinion. The echocardiogram report states "the ejection fraction is greater than 60%." I concur.[6]

---

5. 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). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim. Although the Trust contests claimant's level of mitral regurgitation, we need not resolve this dispute given our determination as to claimant's ejection fraction.

6. Dr. Parmar also found that there was no reasonable medical (continued...)

Based on the auditing cardiologist's finding that claimant did not have a reduced ejection fraction, 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, claimant submitted affidavits of Dr. Evans and Gregory R. Boxberger, M.D., F.A.C.C. In his affidavit, Dr. Evans stated, in relevant part:

> The Trust auditor found that the ejection fraction shown in the subject echocardiogram was greater than 60%. I disagree with this interpretation by the Trust auditor. I calculate the ejection fraction to be between 55% and 60%. It is not greater than 60%.

In his affidavit, Dr. Boxberger stated, in relevant part:

> The Trust auditor found that the ejection fraction in the subject echocardiogram was greater than 60%. I disagree with this interpretation by the Trust auditor. I calculate the ejection fraction to be 58% according to the Teichholz method. It

---

6. (...continued)
basis for the attesting physician's finding that Ms. Oaks did not have 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). Given our disposition with respect to claimant's ejection fraction, we need not address this issue.

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 this claim.

> certainly is not greater than 60%. **My opinion is consistent with the calculations of the echocardiogram technologist who performed the echocardiogram and calculated the ejection fraction to be 58.5% according to the Teichholz method**.

(Emphasis in original.)

Claimant argued, therefore, that there was a reasonable medical basis for her claim because these cardiologists independently agreed that she had a reduced ejection fraction. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between [his] **personal opinion** ... and the 'reasonable medical basis' standard."

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Parmar submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Oaks had a reduced ejection fraction. Dr. Parmar stated, in relevant part:

> I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had an ejection fraction of 50-60%. At Contest, I reviewed the May 21, 2009 Echocardiogram of Attestation and confirmed that the ejection fraction was greater than 60%. There is no reasonable medical basis to conclude otherwise.

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 November 8, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8959 (Nov. 8, 2012).

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 February 14, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] 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, Gary J. Vigilante, 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 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.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she suffered from a reduced ejection fraction. 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. Oaks repeats the arguments she made in contest, namely, that the opinions of Dr. Evans and Dr. Boxberger provide a reasonable medical basis for the finding of a reduced ejection fraction. In addition, claimant contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and that of the auditing cardiologist, Dr. Parmar. According to claimant, there is an "absolute" inter-reader variability of 18% when evaluating an ejection fraction using Simpson's Rule, 16% when using the wall motion index, and 19% when using subjective visual assessment. Thus, Ms. Oaks contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that an ejection fraction is as high as 79%, a finding

of an ejection fraction of 60% by an attesting physician is medically reasonable.

In response, the Trust argues that the opinions of claimant's physicians do not establish a reasonable medical basis for her claim. The Trust also contends that inter-reader variability does not establish a reasonable medical basis for this claim because Dr. Parmar specifically determined that there was no reasonable medical basis for the attesting physician's finding.

The Technical Advisor, Dr. Vigilante, reviewed claimant's May 21, 2009 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Oaks had a reduced ejection fraction. Specifically, Dr. Vigilante determined, in pertinent part:

> .... I determined the left ventricular end diastolic and end systolic areas by planimetering with electronic calipers in both the apical four and two chamber views. I determined the ejection fraction by Simpson's Method. The left ventricular ejection fraction was 69%. This ejection fraction never came close to approaching 60%. This study was diagnostic of an ejection fraction of greater than 60%. This finding correlates with the finding of Dr. Brewington who noted that the ejection fraction was greater than 60% on the official echocardiogram report. I reviewed the sonographer's calculation of the ejection fraction of 58.5% via the Teichholz's Method. This calculation, performed on the parasternal long-axis view, was inaccurate as the measurement was taken in an off-axis rather than perpendicular line. The correct ejection fraction was 69%.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. Ms. Oaks does not rebut Dr. Parmar's determination that, consistent with the echocardiogram report for claimant's May 21, 2009 echocardiogram, claimant's ejection fraction was greater than 60%.[9] Nor does claimant challenge Dr. Vigilante's conclusion that claimant's ejection fraction "never came close to approaching 60%" and that the sonographer's calculation of claimant's ejection fraction, noted by both Dr. Evans and Dr. Boxberger, "was inaccurate as the measurement was taken in an off-axis rather than perpendicular line." Neither claimant nor her experts identified any particular error in the conclusions of the auditing cardiologist and Technical Advisor.[10] Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.[11]

Moreover, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the

---

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

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

11. Thus, we reject claimant's argument that the opinions of her physicians provide a reasonable medical basis for her claim.

attesting physician's representation that Ms. Oaks had a reduced ejection fraction is misplaced. 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 opinion cannot be medically reasonable where the claimant does not adequately refute the auditing cardiologist's determination that she had an ejection fraction greater than 60% and the Technical Advisor concluded that claimant's ejection fraction was 69%. Adopting claimant's argument that inter-reader variability expands the range of a reduced ejection fraction by as much as ±19% would allow a claimant to recover benefits with an ejection fraction as high as 79%. 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 a reduced ejection fraction. Therefore, we affirm the Trust's denial of the claim of Ms. Oaks for Matrix Benefits and the related derivative claim submitted by her spouse.

---

12. Moreover, the Technical Advisor specifically took into account the concept of inter-reader variability as reflected in his statement that, "An echocardiographer could not reasonably conclude that an ejection fraction was in the range of 50-60% when taking appropriate quantitative measurements even taking into account the issue of inter-reader variability."