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.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9090

Bartle, J. June 19, 2013

Linda A. Shelton ("Ms. Shelton" 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"). 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").[2]

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

2. 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 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

(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.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered to be eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.[3] See Settlement Agreement §§ IV.B.1.a. & I.22.

In April, 2007, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Mohamad S.

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2. (...continued)
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.

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

Martini, M.D. Based on an echocardiogram dated June 23, 2006,[4] Dr. Martini attested in Part II of Ms. Shelton's Green Form that claimant suffered from mild aortic regurgitation, congenital aortic valve abnormalities, and aortic stenosis with an aortic valve area < 1.0 square centimeters by the Continuity Equation and that she had surgery to repair or replace the aortic and/or mitral valve(s) following use of Pondimin® and/or Redux™.[5] Based on such findings, claimant would be entitled to Matrix B-1,[6] Level III benefits in the amount of $150,888.[7]

In November, 2008, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for finding that

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4. Because claimant's June 23, 2006 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated December 23, 2002 to establish her eligibility to Matrix Benefits.

5. Dr. Martini also attested that claimant suffered from mild mitral regurgitation, a reduced ejection fraction in the range of 50% to 60%, and either New York Heart Association Functional Class I or II symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement the presence of congenital aortic valve abnormalities or aortic stenosis requires the payment of reduced Matrix Benefits. See Settlement Agreement §§ IV.B.2.d.(2)(c)i)a) & e).

7. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Ms. Shelton has met these requirements, the only issue is whether she is eligible for benefits.

claimant's December 23, 2002 echocardiogram demonstrated mild aortic regurgitation. Specifically, Dr. Gillespie determined, "Trace aortic regurgitation noted. The Nyquist limit was set at 43 cm/s which was too low. [Aortic regurgitation] was trace at this setting."[8]

Based on Dr. Gillespie's finding that claimant did not have at least mild aortic regurgitation, the Trust issued a post-audit determination denying Ms. Shelton's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[9] In contest, claimant submitted the reports of four echocardiograms performed on November 16, 1998; November 10, 1999; April 30, 2002; and January 2, 2003; each of which claimant noted indicated that she suffered from mild aortic regurgitation. Claimant contended these reports provided a reasonable medical basis for finding that her December 23, 2002 echocardiogram

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8. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is less than ten percent (10%) of the left ventricular outflow tract height ("LVOTH")."

9. 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. Shelton's claim.

demonstrated mild aortic regurgitation. Claimant also noted that two of these four echocardiograms were performed by physicians who participated in the Trust's Screening Program.

The Trust then issued a final post-audit determination, again denying Ms. Shelton'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. Shelton's claim should be paid. On April 22, 2009, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8155 (Apr. 22, 2009).

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 June 12, 2009, and claimant submitted a sur-reply on July 6, 2009. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See

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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.

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.

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 finding that claimant's December 23, 2002 echocardiogram demonstrated mild aortic regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for such finding, 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 such finding, 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. Shelton reasserts the arguments she raised in contest. In addition, she contends that the auditing cardiologist and the Trust erred because neither considered her additional echocardiograms performed before the end of the Screening Period.

In response, the Trust argues that Dr. Gillespie properly applied the reasonable medical basis standard. In addition, the Trust asserts that the claimant did not submit any

materials that rebut Dr. Gillespie's findings at audit that the December 23, 2002 echocardiogram demonstrated trace aortic regurgitation or that the Nyquist setting was improperly low. Finally, the Trust contends that the additional echocardiograms claimant submitted do not rebut Dr. Gillespie's findings at audit.

The Technical Advisor, Dr. Vigilante, reviewed claimant's December 23, 2002 echocardiogram and concluded that there was no reasonable medical basis for finding that it demonstrated at least mild aortic regurgitation. Specifically, Dr. Vigilante observed, in pertinent part, that:

> .... Visually, only trace aortic regurgitation was noted in the parasternal long-axis view. The aortic regurgitant jet could be also viewed in the apical long-axis view. In this view, trace to mild aortic regurgitation was suggested. I digitized those cardiac cycles in the parasternal long axis view in which the aortic regurgitant jet was best visualized. I then measured the JH and LVOTH with electronic calipers. I determined that the largest representative JH was 0.2 cm. I determined that the LVOTH was 2.4 cm. Therefore, the largest representative JH/LVOTH ratio was less than 9%. This ratio did not reach 10% in any cardiac cycle. Therefore, only trace aortic regurgitation could be diagnosed in the parasternal long-axis view on this study. A couple of the cardiac cycles showed no evidence of aortic regurgitation at all. There was no sonographer measurement of the JH on this study. The sonographer did measure an LVOTH of 2.17 cm. This measurement was inaccurately small as the distal point of the measurement did not reach the posterior aspect of the left ventricular outflow tract.

> .... An echocardiographer could not reasonably conclude that mild aortic regurgitation was present when making quantitative measurements of the aortic regurgitant jet in the parasternal long-axis view ... even taking into account inter-reader variability.[11]

In response to the Technical Advisor Report, claimant argues "that the Technical Advisor chose to substitute his independent analysis of the pertinent echocardiographic studies rather than to consider whether under the entire record the Attesting Physician's findings were medically reasonable." In addition, Ms. Shelton asserts that Dr. Vigilante failed to consider the findings of mild aortic regurgitation noted in the reports of her November 16, 1998 and November 10, 1999 echocardiograms. Finally, claimant contends that there is a reasonable medical basis for finding mild aortic regurgitation on her December 23, 2002 echocardiogram because Dr. Vigilante's measurements are "very close" to the 10% threshold.

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 and Technical Advisor that there is no reasonable medical basis for finding that her December 23, 2002 echocardiogram demonstrates mild aortic regurgitation. Dr. Gillespie and Dr. Vigilante each determined that claimant's

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11. Dr. Vigilante also reviewed the only other study in claimant's record performed before the close of the Screening Period, a study dated April 30, 2002, and concluded that it also demonstrated only trace aortic regurgitation.

December 23, 2002 echocardiogram demonstrated only trace aortic regurgitation. Rather than respond to that specific finding, claimant submitted the echocardiogram reports of four other echocardiograms. These echocardiogram reports, however, do not provide an explanation for finding that claimant's December 23, 2002 echocardiogram demonstrated mild aortic regurgitation.[12] Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying specific errors by them is insufficient to meet a claimant's burden of proof.

We also disagree with claimant's interpretation of the reasonable medical basis standard. 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. For example, 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

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12. Claimant indicated in a letter dated May 27, 2008 that "[t]he echocardiogram that [she] wish[es] [the Trust] to use is of 12-23-02." Contrary to her contention, it is the reasonableness of finding mild aortic regurgitation on the basis of this echocardiogram that is at issue in these proceedings.

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 Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Dr. Vigilante observed, and claimant did not dispute, that the sonographer-measured LVOTH "was inaccurately small as the distal point of the measurement did not reach the posterior aspect of the left ventricular outflow tract."[13] Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis of mild aortic regurgitation. To conclude otherwise would allow claimants who do not have mild or greater aortic regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had mild aortic regurgitation 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, a finding of mild aortic regurgitation cannot be medically reasonable where the auditing cardiologist and the Technical Advisor concluded, and claimant

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13. For this reason as well, we reject claimant's argument that Dr. Vigilante simply substituted his opinion for that of the reviewing cardiologist.

did not adequately dispute, that Ms. Shelton's December 23, 2002 echocardiogram demonstrated at most trace aortic regurgitation. Adopting claimant's argument regarding inter-reader variability would allow a claimant who did not have the requisite level of regurgitation to recover benefits and would render meaningless this critical provision of the Settlement Agreement.[14]

Finally, to the extent claimant argues that there is a reasonable medical basis for finding mild aortic regurgitation simply because a physician who participated in the Trust's Screening Program also found mild aortic regurgitation on a different echocardiogram, such argument is misplaced. 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.

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14. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "An echocardiographer could not reasonably conclude that mild aortic regurgitation was present when making quantitative measurements of the aortic regurgitant jet in the parasternal long-axis view in these studies even taking into account inter-reader variability."

See 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 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 mandates 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.

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 mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Ms. Shelton's claim for Matrix B-1, Level III benefits.