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

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9218

Bartle, J. March 26, 2014

Michele E. Lee ("Ms. Lee" 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

(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 October, 2010, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Stephen Raskin, M.D. Based on an echocardiogram dated March 25, 2010,[3] Dr. Raskin attested in Part II of claimant's Green Form that Ms. Lee suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s)

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2. (...continued)
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.

3. Because claimant's March 25, 2010 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated November 23, 1998 to establish her eligibility to receive Matrix Benefits.

following the use of Pondimin® and/or Redux™.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits.[5]

Dr. Raskin also attested in claimant's Green Form that Ms. Lee suffered from 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). As the Trust does not contest Ms. Lee's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In April, 2011, the Trust forwarded the claim for review by Waleed Irani, M.D., F.A.C.C., one of its auditing cardiologists.[6] In audit, Dr. Irani concluded that there was a reasonable medical basis for Dr. Raskin's finding that Ms. Lee had mitral annular calcification.

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4. Dr. Raskin also attested that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class III symptoms. These conditions are not at issue in this claim.

5. 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).

6. Ms. Lee's claim originally was audited in December, 2010, but was subjected to re-audit pursuant to Court Approved Procedure No. 11.

Based on the auditing cardiologist's finding, the Trust issued a post-audit determination that Ms. Lee was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant argued that the audit and her Green Form "are all mistaken" as to the presence of mitral annular calcification because the "best evidence" is the surgeon's operative report, which does not mention mitral annular calcification. Claimant also contended that the fact that the initial auditing cardiologist did not find mitral annular calcification on her November 23, 1998 echocardiogram provides additional support for the assertion that she did not have mitral annular calcification.

In addition, claimant submitted a letter from Dr. Raskin in which he stated, in relevant part, that the March 25, 2010 "echocardiogram suggests that the slightly more prominent mitral annular echoreflectance without echo shadowing is most likely explained by the acoustic proportion of fibrosis and the exaggerating effect of tissue harmonic imaging and *not to annular calcification*." (Emphasis in original.) Accordingly, Dr. Raskin stated, "The previously reported finding of [mitral

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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 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. Lee's claim.

annular calcification] as noted in the 3/25/10 pre-operative Green Form is incorrect and should be amended."[8]

Claimant also submitted a declaration of Kamal Khabbaz, M.D., the surgeon who performed her mitral valve surgery. Dr. Khabbaz stated, in penitent part:

> My operative report 4/5/10 for Ms. Lee carefully described the procedure conducted on Ms. Lee, a mitral valve replacement with a 27-mm St. Jude Medical Epic tissue valve.
>
> Whenever I perform a mitral valve replacement, I carefully study and always describe in my operative report the presence of any mitral annular calcification because its presence is very significant to such surgery. The presence of mitral annular calcification requires the area to be debrided to successfully accept a prosthetic valve.
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> In the case of Michele Lee, my operative report reveals no mitral annular calcification and, as a result, she did not have mitral annular calcification. If she had had mitral annular calcification, I would have had to debride her valve prior to replacing it and no such debridement is reflected in the operative report and no such debridement occurred. Again, that is because she did not have mitral annular calcification.

Although not required to do so, the Trust forwarded the claim to Dr. Irani for a second review. Dr. Irani submitted a declaration in which he again concluded that, consistent with Dr. Raskin's initial Green Form representation, claimant had mitral annular calcification and Dr. Raskin's later assertion

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8. In addition, claimant included "a new superseding Green Form Submission," signed by Dr. Raskin, wherein he stated that Ms. Lee did not suffer from mitral annular calcification.

that claimant did not have mitral annular calcification lacked a reasonable medical basis. Specifically, Dr. Irani stated, in pertinent part, that:

> 10. Based on my review, I find that there is no reasonable medical basis for Dr. Raskin's representation, at Question D.9 of the Green Form signed on June 1, 2011, that Claimant did not have mitral annular calcification. At Contest, I reviewed the March 25, 2010 echocardiogram several times. Mitral annular calcification ("MAC") is certainly present and it is unreasonable to say it is not. MAC is present in the parasternal long axis view, apical 4 chamber and apical 2 chamber. This is not merely increased echoreflectance. There is additionally calcification present in the aortic annulus and ascending aorta. The presence of MAC in multiple views lends support to its presence.
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> 11. Dr. Khabbaz did not note mitral annular calcification at the time of Claimant's April 5, 2010 surgery, as he states in his Declaration submitted at Contest. However, MAC was not severe on the March 25, 2010 [echocardiogram]. Such mild mitral annular calcification would likely not be noted by a surgeon upon visual inspection, and would not affect the surgeon's approach to the surgery.

The Trust then issued a final post-audit determination, again determining that Ms. Lee was entitled only to Matrix B-1, Level III benefits. 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. Lee's claim should be paid. On November 29, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8711 (Nov. 29, 2011).

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 24, 2012, and claimant submitted a sur-reply on June 27, 2012. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] 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.

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 she did not have mitral

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9. 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.

annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the 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 the 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. Lee reasserts the arguments made in contest. Specifically, claimant argues that the statement of Dr. Khabbaz that he did not see mitral annular calcification during claimant's mitral valve surgery "should trump any alleged interpretation of grainy [echocardiogram] images" because claimants are permitted to rely on surgical examinations to support a claim for Matrix Benefits and such direct medical examinations are the "best evidence" and the "gold standard" for determining whether mitral annular calcification is present. In addition, claimant submitted another letter from Dr. Raskin dated September 6, 2011, which stated, in pertinent part:

> Michele Lee's 4/02/10 cardiac angiogram revealed no occlusive or severe coronary atherosclerosis. Dr. Khabbaz's operative note and his subsequent written report confirmed by both visual and palpable examination the absence of mitral annular calcification. The failure to document [mitral annular calcification] by intra-operative [transesophageal echocardiogram], and my critical review of Michele Lee's 3/25/2010 echocardiogram supports the

> observation that [mitral annular calcification] is not present.

According to claimant, Dr. Raskin's letter explains "why any [echocardiogram] suggestions of the possibility of [mitral annular calcification] are wrong and also contradicted by the absence of significant coronary artery disease."

In response, the Trust argues that claimant's submissions do not rebut Dr. Irani's specific finding of mitral annular calcification based on his review of Ms. Lee's March 25, 2010 echocardiogram. The Trust also argued that claimant's surgeon may not have noted mitral annular calcification at the time of claimant's mitral valve surgery because it was not severe and, in any event, echocardiographic evidence may be used to determine the presence of mitral annular calcification. Finally, the Trust also identified specific loops on claimant's March 25, 2010 echocardiogram where it maintained mitral annular calcification was evident.

The Technical Advisor, Dr. Vigilante, reviewed claimant's March 25, 2010 echocardiogram and concluded that there was no reasonable medical basis for finding that Ms. Lee did not have mitral annular calcification. Specifically, Dr. Vigilante stated, in pertinent part, that:

> Visually, the mitral valve was markedly abnormal. There was significant thickening of the mitral leaflets with restriction of posterior leaflet excursion and poor coaptation. In addition, there was significantly thickened and increased reflectance of echoes in the posterior annulus classic for mitral annular

> calcification. There was obvious calcification of the posterior mitral annulus noted on loops 1, 2, 3, 7, 8, 15, 34, 38, 40, and 50. This was seen in the parasternal long-axis, parasternal short-axis, and apical two chamber views. This was not visualized adequately in the apical four chamber view since the posterior annulus is not visualized in this view.

Dr. Vigilante also reviewed claimant's April 2, 2010 and April 5, 2010 echocardiograms and concluded that they demonstrated "classic" mitral annular calcification.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor ignored the best evidence as to the presence of mitral annular calcification, namely, the statement of claimant's surgeon, Dr. Khabbaz. Claimant again maintains that the statement of her surgeon alone should entitle her to Matrix A-1 benefits and contends that Dr. Vigilante is not qualified to evaluate Dr. Khabbaz's conclusions because Dr. Vigilante is not a Board-Certified cardiothoracic surgeon.

After reviewing the entire show cause record, we find claimant's arguments are without merit. As noted previously, the Settlement Agreement provides that the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). The auditing cardiologist and the Technical Advisor each reviewed claimant's medical records, including her March 25, 2010; April 2, 2010; and April 5, 2010 echocardiograms, and concluded that there was no reasonable medical basis for finding that claimant did not have mitral annular calcification. In particular, Dr. Irani stated

that mitral annular calcification "is certainly present" in multiple views on claimant's March 25, 2010 echocardiogram. Similarly, Dr. Vigilante concluded that "the echocardiograms of March 25, 2010, April 2, 2010, and April 5, 2010, all show classic mitral annular calcification limited to the posterior annulus."[10]

We disagree with claimant that the statements of Dr. Raskin and the declaration of Dr. Khabbaz establish a reasonable medical basis for finding that Ms. Lee did not have mitral annular calcification at the time of her surgery.[11] As an initial matter, Dr. Khabbaz states that Ms. Lee did not have mitral annular calcification because he did not note it in his operative report and he "always describe[s] in [his] operative report the presence of any mitral annular calcification because its presence is very significant to such surgery." However, Dr. Irani considered Dr. Khabbaz's declaration and explained that "[s]uch mild mitral annular calcification would likely not be noted by a surgeon upon visual inspection, and would not affect

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10. Despite claimant's argument, the Technical Advisor did not ignore the declaration of Dr. Khabbaz. To the contrary, the Technical Advisor's Report specifically notes Dr. Khabbaz's declaration and that it was reviewed. We also reject claimant's assertion that only a Board-Certified cardiothoracic surgeon is competent to evaluate Dr. Khabbaz's statements with respect to whether claimant has mitral annular calcification.

11. As the issue is whether Ms. Lee had mitral annular calcification at any time prior to her surgery, it is irrelevant that the initial auditing cardiologist did not find mitral annular calcification on claimant's November 23, 1998 echocardiogram.

the surgeon's approach to the surgery." Although claimant submitted a supplemental statement from Dr. Raskin following Dr. Irani's second review, neither he nor Dr. Khabbaz addressed this finding. Moreover, Dr. Khabbaz did not state that he has an independent recollection of Ms. Lee's mitral valve, and he did not state in her operative report that she did not have mitral annular calcification.

This is particularly true in light of the express findings of the auditing cardiologist and Technical Advisor. Notably, Dr. Khabbaz did not express any opinion as to the presence of mitral annular calcification on any of Ms. Lee's echocardiograms. Further, Dr. Raskin only stated that he was mistaken as to the presence of mitral annular calcification on claimant's March 25, 2010 echocardiogram. Significantly, Dr. Raskin expressed no opinion as to mitral annular calcification on claimant's April 5, 2010 echocardiogram and, as to claimant's April 2, 2010 echocardiogram, only stated that it "revealed no occlusive or severe coronary atherosclerosis." Under the Settlement Agreement, however, <u>any</u> presence of mitral annular calcification requires that a mitral valve claim be reduced to the B Matrix. <u>See, e.g.</u>, Mem. in Supp. of PTO No. 8421 at 8 (Mar. 10, 2010): "Unlike some of the other factors that reduce a claim to Matrix B-1, any presence of [mitral

annular calcification], regardless of the amount, places the claim on Matrix B-1."[12]

For the foregoing reasons, we conclude that there is no reasonable medical basis for finding that claimant did not have mitral annular calcification prior to her surgery. Therefore, we will affirm the Trust's denial of Ms. Lee's claim for Matrix A-1 benefits.

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12. We also reject claimant's assertion that "the absence of significant coronary artery disease ... related to [mitral annular calcification]" supports a finding that claimant does not have mitral annular calcification. There is no requirement under the Settlement Agreement that a claimant's mitral annular calcification must be "related" to significant coronary disease.