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 AND PRETRIAL ORDER NO.

Bartle, C.J. August 24, 2007

Gloria Thedell ("Ms. Thedell" 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]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Alex K. Thedell, Ms. Thedell's son, has also 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

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be 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, Part III is to be completed by the claimant's attorney if he or she is represented.

In April 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Thomas S. Davidson, M.D., F.A.C.C. Based on an echocardiogram dated December 6, 2001, Dr. Davidson attested in Part II of Ms. Thedell's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and an ejection fraction in the range of 50% to 60%. Based on such findings,

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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.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of $492,142.[4]

In the report of claimant's echocardiogram, Dr. Davidson stated that "[m]oderate mitral regurgitation was noted, with the jet filling 25% of the left atrial area." 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. Davidson also stated that claimant had "[l]eft atrial enlargement" and measured her left atrial dimension as 4.3 cm in the parasternal long axis view. 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).

In July 2003, the Trust forwarded the claim for review by Rohit Parmar, M.D., one of its auditing cardiologists. In audit, Dr. Parmar concluded that there was no reasonable medical

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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). Claimant ultimately concedes that she has a normal ejection fraction. Thus, the only remaining issue is whether claimant has moderate mitral regurgitation and an abnormal left atrial dimension, which is one of the complicating factors needed for a Level II claim.

basis for Dr. Davidson's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. According to Dr. Parmar, "[t]he MRA calculated by the tech is over-estimated. It is a still frame. The tech should have showed real time MR. By real time echo the MR, by my estimation is mild." Dr. Parmar also determined that there was no reasonable medical basis for Dr. Davidson's finding of an abnormal left atrial dimension because "[t]he tech measured the [supero-inferior systolic] dimension at an oblique. The measurement is 5.2 cm at most."

Based on Dr. Parmar's diagnoses, the Trust issued a post-audit determination denying Ms. Thedell's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant submitted, among other things, expert reports from Jack L. Schwade, M.D., and Amjad Iqbal, M.D. Both Drs. Schwade and Iqbal confirmed Dr. Davidson's findings of moderate mitral regurgitation and an abnormal left atrial dimension. Specifically, Dr. Iqbal measured claimant's RJA/LAA ratio as 25% and her left atrial dimension as 4.3 cm in the parasternal long axis view. Dr. Schwade visually estimated claimant's mitral

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5. 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. Thedell's claim.

regurgitation to be "close to 30%" and measured claimant's left atrial dimension as 5.6 cm in the apical four chamber view. Dr. Schwade also included two still frames, which purportedly demonstrated moderate mitral regurgitation and left atrial enlargement. Claimant asserted that the expert reports of Drs. Schwade and Iqbal provide a reasonable medical basis for her attesting physician's findings.[6]

The Trust then issued a final post-audit determination, again denying Ms. Thedell'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 (Mar. 26, 2003), Audit Rule 18(c). The Trust applied to the court for issuance of an Order to show cause why Ms. Thedell's claim should be paid. On January 29, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3228 (Jan. 29, 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 April 7, 2004. Claimant submitted a Sur-Reply on April 22, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a

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6. In contest, claimant also submitted an excerpt from previous testimony of Richard Dent, M.D. Claimant, however, did not explain how this testimony was relevant to her claim.

Technical Advisor[7] 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 Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.

As noted above, 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 findings that she had moderate mitral regurgitation and an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must confirm 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 was 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).

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7. 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 technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, 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. See id.

In support of her claim, Ms. Thedell argues that "reasonable medical basis" is a fluid term, which incorporates inter-reader variability and allows for variations and disagreements between physicians. Claimant also argues that: (1) the auditing cardiologist's attestation form, worksheet and certification are incomplete and, thus, do not comply with the Audit Rules; (2) the auditing cardiologist's opinion is inadmissible ipse dixit[8] because it fails to explain the lack of a reasonable medical basis; and (3) the Trust's conduct amounts to a violation of her due process rights because she is being wrongfully deprived of Matrix Benefits without the opportunity to be heard in a meaningful manner.

In response, the Trust argues that the attesting physician's finding of moderate mitral regurgitation was based on a still frame and that, when viewed in "real time," claimant had only mild mitral regurgitation. The Trust also asserts that the attesting physician improperly measured claimant's left atrial dimension on an oblique and that the auditing cardiologist measured her left atrial supero-inferior systolic dimension as "5.2 cm at most." The Trust further disputes that claimant has been deprived of her due process rights, as claimant has had notice and an opportunity to be heard.[9]

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8. Ipse dixit is Latin for "he himself said it." It stands for the proposition that something is asserted but not proved. Black's Law Dictionary 833 (7th Ed. 1999).

9. The Trust also argues that, under Rule 26(a)(2) of the (continued...)

In her Sur-Reply, claimant denies the Trust's contention that her attesting physician's finding of moderate mitral regurgitation was based on a single still frame. Rather, claimant argues that the attesting physician's opinion was based on his review of the entire echocardiogram and the still frame was presented only for evidentiary and demonstrative purposes. Claimant also contends that the Trust has shown merely a disagreement of opinion and has failed to address inter-reader variability.

Dr. Abramson, the Technical Advisor, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson stated that:

> I measured the mitral regurgitant jet and the left atrial area (in the same frame)in five representative cardiac cycles .... These ratios are 18%, 14%, 25%, 25%, and 17%. Two of these measurements fall in the moderate range of a RJA/LAA between 20% and 40%. I therefore concluded that this echocardiogram could reasonably be interpreted as moderate mitral regurgitation.

9(...continued)
Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. While the Audit Rules allow claimants to submit verified expert opinions in support of their claims, they do not require Rule 26(a)(2) disclosures. See Audit Rule 18(b). Discovery relating to claims is prohibited by the Audit Rules. See Audit Rule 41. Thus, requiring Rule 26(a)(2) disclosures would serve no purpose.

Dr. Abramson also concluded that there was a reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension. According to Dr. Abramson:

> I measured the left atrial diameter in the parasternal long axis view at 4.2 cm, 4.2 cm and 4.2 cm .... The parasternal-long axis view measurements meet the criteria for being abnormal. I agree that the sonographer measured the left atrial dimensions obliquely, but even when measured correctly, I found the left atrium to be enlarged.

Claimant submitted a response to the Technical Advisor's Report wherein she concurs with the Technical Advisor's findings of moderate mitral regurgitation and an abnormal left atrial dimension. She also argues that, based on the Technical Advisor's determinations, there is a reasonable medical basis for her claim.

After reviewing the entire show cause record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician reviewed claimant's echocardiogram and found moderate mitral regurgitation and an abnormal left atrial dimension.[10] Although the Trust contested the attesting physician's conclusion, Dr. Abramson confirmed the attesting physician's findings.[11] Specifically, Dr. Abramson determined that "there is a reasonable medical basis

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10. Although unnecessary for resolution of this claim, as noted above, claimant also submitted reports of two additional cardiologists who similarly concluded that claimant had moderate mitral regurgitation and an abnormal left atrial dimension.

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

for the Attesting Physician's claim stating that this Claimant has both moderate mitral regurgitation and a dilated left atrium."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Further, a left atrial dimension is abnormal where a left atrial supero-inferior systolic dimension is greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension is greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Here, Dr. Abramson found that moderate mitral regurgitation was visible in the apical four chamber view, and she measured claimant's left atrial dimension as 4.2 cm in the parasternal long axis view. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.[12]

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claims submitted by Ms. Thedell and her son for Matrix Benefits.

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12. Accordingly, we need not address claimant's remaining arguments.

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PRETRIAL ORDER NO._____

AND NOW, on this 24th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimants Gloria Thedell and her son, Alex K. Thedell, are entitled to Matrix A-1, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805 and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III
C.J.