

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

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

October 10, 2007

Voyce Ann Lansdell ("Ms. Lansdell" 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

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

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
(continued...)

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 in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In May 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall E. Little, M.D., F.A.C.C. Based on an echocardiogram dated July 15, 1997, Dr. Little attested in Part II of Ms. Lansdell's Green Form that, among other things, claimant had surgery to repair the mitral valve after use of Pondimin® and/or Redux™ and that she suffered from severe mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension and a reduced ejection fraction in

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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.

the range of 50%-60%.³ Dr. Little also attested that claimant did not have a rheumatic mitral valve. If accepted, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$719,285.⁴

In September 2003, the Trust forwarded the claim for review by Keith Churchwell, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Little's finding that claimant did not have a rheumatic mitral valve. In his Certification, Dr. Churchwell concluded, in relevant part, that:

Echo evidence of rheumatic involvement of the mitral valve is present on the 2D study (doming of the anterior leaflet with thickened leaflets and chords). Pathologic evaluation of chordae tendinae from surgical removal reveals thickened chords with post

3. Dr. Little also attested that Ms. Lansdell had moderate aortic regurgitation. As Ms. Lansdell's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.b.2.c.(2)(a).

4. In her Green Form, Ms. Lansdell requested Matrix A-1, Level IV benefits. After conducting a review of claimant's Green Form and supporting materials, the Trust determined that claimant's alleged condition is consistent with a Matrix A-1, Level III claim for surgery to repair the mitral valve. Under the Settlement Agreement, a claimant is entitled to Level III benefits if the claimant had: "Surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a). Claimant never contested the Trust's determination that she is entitled to Level III benefits rather than Level IV.

inflammatory changes again c/w rheumatic involvement.⁵

Under the Settlement Agreement, evidence of a rheumatic mitral valve is defined as "doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion." See id. §IV.B.2.d.(2)(c)ii)e).

Under the Settlement Agreement, the absence of a finding of no rheumatic mitral valve requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). The Trust does not contest that claimant is entitled to Level IV Matrix Benefits. Rather, the Trust challenges claimant's right to payment on Matrix A-1 instead of a payment on Matrix B-1.

Based on Dr. Churchwell's diagnosis that claimant had a rheumatic mitral valve, the Trust issued a post-audit determination that Ms. Lansdell 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.⁶ In contest, claimant submitted: a

5. Dr. Churchwell also concluded that there was no reasonable medical basis for Dr. Little's finding that claimant had moderate aortic regurgitation. This conclusion, however, is irrelevant for resolution of this claim.

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 Ms.

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letter from Dr. Little; a letter from Dr. Lyman Mitchell, Ms. Lansdell's family physician; and a notarized letter from Ms. Lansdell's mother.

In his letter, Dr. Little stated, in relevant part:

[Ms. Lansdell] did have evidence suggestive of rheumatic valvular heart disease in that her echocardiogram did reveal doming of the anterior leaflet of the mitral valve. Also, the operative findings noted by Dr. Stinson were felt to be most consistent with rheumatic valvular heart disease. However, the final pathology report of the mitral valve revealed post inflammatory scarring. In my opinion this is a nonspecific finding.

Accordingly, in Dr. Little's opinion, claimant's "diet drug therapy certainly played a significant role in her severe valvular heart disease which led to her requiring mitral valve repair in July of 1997."

In his letter, Dr. Mitchell stated that Ms. Lansdell had been a patient for twenty (20) years and, during that time, there had not been any "history of rheumatic fever [or] rheumatic valvular disease." In her letter, Ms. Lansdell's mother stated that claimant never experienced any symptoms consistent with rheumatic disease nor had any physician diagnosed any condition of claimant as rheumatic disease. Based on her contest materials, claimant argued that she should prevail because the submitted letters established a reasonable medical basis for the

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Lansdell's claim.

attesting physician's finding that claimant did not have a rheumatic mitral valve.

The Trust then issued a final post-audit determination, again determining that Ms. Lansdell 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 thereafter applied to the court for issuance of an Order to show cause why Ms. Lansdell's claim should be paid at Matrix A-1, Level III. On June 16, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3618 (June 16, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant served a response upon the Special Master. The Trust submitted a reply on August 13, 2004. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

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 did not have a rheumatic mitral valve. See id. Rule 24. Ultimately, if we determine that there was 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 was 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, claimant relies on the letters she submitted in contest to establish that there is a reasonable medical basis for the attesting physician's representation that claimant did not have a rheumatic mitral valve. In response, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because both the auditing cardiologist and the attesting physician agreed that claimant's echocardiogram revealed evidence of a rheumatic mitral valve. The Trust also argued that claimant could not rely on the pathology report to support her claim because the report failed to determine that there was no evidence of rheumatic valve disease. Finally, the Trust asserts that the statements by claimant's family physician and mother that there is no history of claimant having rheumatic fever or rheumatic valvular disease does not establish a reasonable medical basis for claimant's claim, given the evidence of a rheumatic mitral valve on claimant's echocardiogram.

After reviewing the entire Show Cause Record, we find claimant's arguments without merit. First, the Settlement Agreement specifically provides, in pertinent part, that a claimant will receive reduced Matrix Benefits if the

echocardiogram reveals evidence of a specific medical condition, including a rheumatic mitral valve:

M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease.

Settlement Agreement § IV.B.2.d.(2)(c)ii)e) (emphasis added).

Here, claimant does not contest the auditing cardiologist's determination that claimant's echocardiogram revealed evidence of a rheumatic mitral valve. Further, the operative report for claimant's mitral valve repair surgery also specifically noted a rheumatic mitral valve. The operative report for claimant's mitral valve surgery states, in relevant part, that:

Valve analysis confirmed prolapse of the entire A2 segment of the anterior leaflet with some involvement of the A3 segment. The posterior leaflet appeared to be normal. There were numerous, markedly thickened secondary cordal structures to the anterior leaflet as well as mild thickening of the anterior leaflet and mild commissural fusion of the posteromedial commissure. All the above suggest a rheumatic etiology for the incompetence.

Indeed, claimant's own attesting physician also reached the same conclusion. Specifically, in his letter, Dr. Little states, in relevant part, that:

Cardiac surgery was consulted and she underwent mitral valve repair by Dr. Stinson. She did have evidence suggestive of rheumatic valvular heart disease in that her echocardiogram did reveal doming of the anterior leaflet of the mitral valve. Also,

the operative findings noted by Dr. Stinson were felt to be most consistent with rheumatic valvular heart disease.

To meet her burden, claimant attempts to rely on the pathology report from her surgery asserting that, because the pathology report does not state that claimant had a rheumatic mitral valve, there is a reasonable medical basis for the attesting physician's conclusion that claimant did not have a rheumatic mitral valve. Claimant's attempted reliance on the pathology report, however, is misplaced.

Under the Settlement Agreement, if there is echocardiographic evidence of a rheumatic mitral valve, a claim will be reduced to the B-1 Matrix, except where a Board-Certified Pathologist examines the mitral valve tissue and determines that there is no evidence of rheumatic valve disease. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Claimant's own attesting physician concedes that "the operative findings noted by Dr. Stinson were felt to be most consistent with rheumatic valvular heart disease," although he ultimately opined that it was "nonspecific." Claimant asserts that a "nonspecific finding" supports her claim, however the exact opposite is true. Namely, only a specific finding by a Board-Certified Pathologist that the mitral valve tissue does not reveal evidence of rheumatic valve disease will allow a claimant to avoid application of the reduction factor at issue.⁷

7. Claimant's attempted reliance on the opinion of Dr. Little
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Similarly, claimant's reliance on letters from her family physician and her mother is also misplaced because nothing in the Settlement Agreement provides that evidence of the reduction factor of a rheumatic mitral valve or a claimant's echocardiogram may be disregarded based on a claimant's assertion that he or she never was diagnosed or treated for rheumatic fever or rheumatic valvular disease. We previously rejected a similar argument in PTO No. 3472 (Apr. 26, 2004), where a claimant failed to establish a reasonable basis for her attesting physician's finding that she did not have a rheumatic mitral valve. See generally PTO No. 3472 at 4-7. Further, as noted above, the only means to rebut the review of an echocardiogram is the specific determination of a Board-Certified Pathologist as set forth in the Settlement Agreement. As claimant has not provided the required determination from a Board-Certified Pathologist, claimant is only entitled to Matrix B-1 benefits.

Finally, claimant's assertion that she is entitled to Matrix A-1 benefits because, as opined by her attesting physician, "diet drug therapy certainly played a significant role in her severe valvular heart disease" is erroneous. Causation is not at issue in resolving claims for Matrix Benefits. Rather,

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as to the meaning of the pathology report also is erroneous because, as reflected above, the Settlement Agreement mandates that a Board-Certified Pathologist provide the required determination. As nothing in the record reflects that Dr. Little is a Board-Certified Pathologist, on this basis as well, claimant's argument fails.

claimants are required to show that they meet, or in the case of the presence of reduction factors, do not meet, the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred

* * *

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

In re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., Memorandum and PTO No. 1415, No. CIV. A. 99-20593, 2000 WL 1222042 at *22, *43 (E.D. Pa. Aug. 28, 2000). As the Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if claimant's echocardiogram reveals evidence of a rheumatic mitral valve and a Board-Certified Pathologist has not provided a contrary determination after examination of the mitral valve tissue, the court must apply the Settlement Agreement as written. Accordingly, claimant's assertion that the cause of her mitral valve repair was the ingestion of diet drugs is irrelevant to the issue before the court. As claimant does not contest that her echocardiogram

revealed evidence of a rheumatic mitral valve, and a Board-Certified Pathologist has not provided a contrary determination, the Settlement Agreement mandates that Ms. Lansdell's claim be reduced to Matrix B-1.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she did not have a rheumatic mitral valve. Therefore, we will affirm the Trust's denial of Ms. Lansdell's claim for Matrix A-1 benefits.

