

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.

November 9, 2007

Nina N. Nailor ("Ms. Nailor" 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.

2. Initially, claimant did not submit any derivative claims. By a subsequent letter, claimant sought to submit derivative claims for benefits on behalf of Charles Nailor, Sr., Ms. Nailor's spouse, and Charles Nailor, Jr. and Shondra Steib, Ms. Nailor's children.

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

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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 October 2003, claimant submitted a completed Green Form signed by her attesting physician, Paul E. Nathan, M.D.⁴ Dr. Nathan attested in Part II of claimant's Green Form that

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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 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. Claimant's Show Cause Record also contains a partially completed Green Form submitted in August 2003 and attested to by Kevin Kilpatrick, M.D. Dr. Kilpatrick's partial attestation was resubmitted by claimant with the Green Form submitted in October 2003.

claimant had surgery to repair or replace the aortic valve.⁵ In July 2005, claimant also submitted a Green Form Part II Clarification executed by Dr. Nathan in which he also attested that claimant had valvular repair or replacement surgery and required a second surgery through the sternum within 18 months of the initial surgery due to prosthetic valve malfunction, poor fit or complications reasonably related to the initial surgery. See Settlement Agreement § IV.B.2.c.(4)(g). Based on such findings, claimant would be entitled to additional Matrix A-1, Level IV benefits in the amount of \$347,121.⁶

5. Dr. Nathan also attested that claimant suffered from arrhythmias, a reduced ejection fraction in the range of 50% to 60% and a persistent noncognitive state caused by a complication of valvular heart disease. In response to a deficiency notice from the Trust, Dr. Nathan attested that claimant had an abnormal left atrial dimension and an abnormal left ventricular end-systolic dimension greater than or equal to 45 mm by M-mode or 2-D echocardiogram. Claimant's Show Cause Record contains an additional Part II of claimant's Green Form, signed in April 2005 by Dr. Nathan, in which Dr. Nathan attested that claimant had moderate aortic regurgitation, aortic sclerosis, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension greater than or equal to 45 mm by M-mode or 2-D echocardiogram, a reduced ejection fraction in the range of 40% to 49%, and severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valves where such surgery was not performed. In a subsequent Clarification, however, Dr. Nathan attested that claimant did not have aortic sclerosis or severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valves where such surgery was not performed. None of these conditions, however, is at issue in this claim.

6. In December 2005, claimant was paid Matrix Benefits at Matrix A-1, Level III in the amount of \$772,285. According to the Trust, if entitled to Matrix A-1, Level IV benefits, claimant
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By letter dated September 29, 2005, the Trust advised claimant that it had determined that claimant was entitled to Matrix A-1, Level III benefits.⁷ The Trust advised claimant that her Level IV claim was being sent to audit to determine whether claimant had a second surgery through the sternum within 18 months of claimant's initial surgery. As stated by the Trust, in pertinent part, in its September 29, 2005 letter:

Note that Part II of the GREEN Form which you submitted to the Trust asserts conditions in support of Matrix Compensation Benefits at Level [IV]. Wyeth has concurrently designated your claim as a Medical Disagreement (for Audit) as follows: Green Form Question at issue: J - SECOND SURGERY WITHIN 18 MONTHS: Based on operative note dated 12/13/01. NOTE: Second surgery did not require re-opening of the median sternotomy as required by the Settlement.

(emphasis added).

In September 2005, the Trust forwarded the claim for review by Nancy V. Strahan, M.D., one of its auditing cardiologists.⁸ In audit, Dr. Strahan concluded that there was

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would be entitled to Matrix Benefits in the amount of \$1,119,406. The amount at issue, therefore, is the difference between the Level III Matrix Benefits already paid and the amount of Level IV Matrix Benefits.

7. Under the Settlement Agreement, a claimant is entitled to Level III benefits if the claimant had: "[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).

8. Pursuant to Pretrial Order ("PTO") No. 3882, all Level III, Level IV and Level V Matrix claims are subject to the Parallel
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no reasonable medical basis for the attesting physician's finding that claimant had a second surgery through the sternum within 18 months of the initial surgery because, according to the auditing cardiologist: "The pt. had a subxiphoid drainage of a pericardial effusion. There was no evidence of reoperation thru [sic] the sternum."⁹

Based on Dr. Strahan's diagnosis, the Trust issued a post-audit determination denying Ms. Nailor's claim for Level IV benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.¹⁰ In contest, claimant submitted a verified statement from Dr. Nathan, which stated, in relevant part, the following:

I am a Board-Certified Cardiologist with a level 2 training in echocardiography. I have reviewed all of the applicable medical

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Processing Procedures ("¶") for Matrix claims asserting high-level medical conditions. As Wyeth did not agree that claimant had a Matrix A-1, Level IV claim, pursuant to the ¶, claimant's claim was audited by the Trust.

9. As the Trust concedes that claimant underwent surgery to replace the aortic valve, the only issue is whether there is a reasonable medical basis for the attesting physician's attestation that claimant had a second surgery through the sternum within 18 months of the initial surgery.

10. 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. Nailor's claim.

records of Mrs. Nina Nailor which were submitted to the AHP Settlement Trust in connection with her claim (Claim No. 183/00 8253977).

In my expert opinion the operative report of Dr. Rigby, dated 12/13/01, clearly states Mrs. Nailor required a second surgery through her sternum as a result of complications from her initial surgery. The report states that "the lower end of the sternotomy incision was reopened and the xiphoid process excised."

The xiphoid process is the lower end of the sternum and the December 13, 2001, surgery was performed through the lower end of the sternum.

Claimant also asserted that the operative report for her second surgery, which states that "[t]he lower end of the sternotomy incision was reopened and the xiphoid process excised," supports her Level IV claim because it "clearly describes surgery performed through the lower end of the sternum."

The Trust then issued a final post-audit determination, again denying Ms. Nailor's claim for Level IV 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. Nailor's claim should be paid. On March 20, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6077 (Mar. 20, 2006).

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 July 14, 2006. Claimant submitted a sur-reply on September 6, 2006. The Show Cause Record is now before the court for final determination. 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 the attesting physician's finding that claimant had a second surgery through the sternum within 18 months of her initial surgery. 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, Ms. Nailor argues that the operative report and the verified statement from her attesting physician establish that claimant had a second surgery through the sternum within 18 months of her initial surgery as required by the Settlement Agreement for the recovery of Level IV Matrix Benefits. In response, the Trust asserts that claimant's

argument is inconsistent with the requirements of the Settlement Agreement.¹¹

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Under the Settlement Agreement, a claimant is entitled to Level IV Matrix Benefits for the following:

- (g) The individual has had valvular repair or replacement surgery and requires a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery.

Settlement Agreement § IV.B.2.c.(4)(g).

As reflected on claimant's operative report for her aortic valve replacement surgery, claimant underwent a sternotomy. The basic definition of a sternotomy is a "surgical incision through the sternum." Merriam Webster's Medical Desk Dictionary (1996) at 769. Equally important, claimant's second surgery, as reflected in the operative report, consisted of, in relevant part, the following: "The lower end of the sternotomy incision was reopened and the xiphoid process excised." The basic definition of the xiphoid process is "the smallest and lowest division of the sternum." Id. at 880. Thus, contrary to the Trust's argument, claimant's operative report reflects that

11. In a sur-reply, claimant argues that, contrary to the Trust's assertion, there is no requirement that claimant establish that the second surgery required a "reopening" of claimant's sternum.

claimant had a second surgery through the sternum within 18 months of her initial surgery as required under the plain language of the Settlement Agreement.¹²

In asserting that claimant was required to establish that there was a "reoperation" through the sternum, the Trust is mistakenly relying on a separate provision of the Settlement Agreement, which also allows a claimant to receive Level IV benefits for the following:

- (f) The individual has had valvular repair or replacement surgery and suffers from post operative endocarditis, mediastinitis or sternal osteomyelitis, any of which requires reopening the median sternotomy for treatment, or a post-operative serious infection defined as HIV or Hepatitis C within six months of surgery as a result of blood transfusion associated with the heart valve surgery.

Settlement Agreement § IV.B.2.c.(4)(f). As the Settlement Agreement does not contain a similar requirement in Section (g) of the Level IV definition of a "reopening" of a specific portion of the sternum (the median sternotomy), the court will not impose such a requirement. The Settlement Agreement clearly reflects a distinct set of circumstances, which entitles claimant to Level IV benefits based simply on a second surgery "through the sternum."¹³

12. The Trust does not dispute that a second surgery was required due to complications from the initial aortic valve replacement surgery.

13. Although the Trust, in its initial determination letter,
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For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for finding that claimant had a second surgery through the sternum within 18 months of her initial surgery. Therefore, we will reverse the Trust's denial of Ms. Nailor's claim for Level IV Matrix Benefits.¹⁴

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noted that Wyeth designated claimant's claim for audit to determine whether claimant had a condition, which required a "re-opening of the median sternotomy," this assertion is misplaced as Section (g) of the Settlement Agreement's Level IV definition does not require reopening of the median sternotomy but simply "surgery through the sternum."

14. The Show Cause Record does not indicate whether any derivative claimants received payment in connection with Ms. Nailor's prior receipt of Level III Matrix Benefits. With respect to claimant's Level IV claim, the Trust shall determine whether there are any derivative claimants also entitled to Level IV benefits.

