

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. 8414

Bartle, C.J.

March 9, 2010

Judith Brassfield ("Ms. Brassfield" 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

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

2. John Brassfield, Ms. Brassfield's former spouse, also submitted a derivative claim for benefits. The Trust, however, determined, and claimant did not contest, that he is not an eligible derivative claimant under the Settlement Agreement.

support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

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 May, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, James E. Lies, M.D., F.A.C.C. Based on an echocardiogram dated June 11, 2001, Dr. Lies attested in Part II of Ms. Brassfield's Green Form that claimant suffered from severe mitral regurgitation and had

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 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.

valvular repair or replacement surgery and required 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.⁴ Dr. Lies also attested that claimant did not have mitral annular calcification ("MAC").⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level IV benefits in the amount of \$971,033.⁶

In the report of claimant's June 11, 2001 echocardiogram, Dr. Lies noted that: "[t]here is thickening of

4. Dr. Lies also attested that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation, arrhythmias, a reduced ejection fraction in the range of 40% to 49%, and New York Heart Association Functional Class II symptoms. These conditions, however, are not relevant to Ms. Brassfield's claim.

5. Although Dr. Lies initially checked "Yes" on claimant's Green Form in response to the question regarding MAC, it is crossed out, the "No" box is checked, and the word "insignificant" appears in the margin. In July, 2003, claimant submitted a second Part II of her Green Form in which Dr. Lies circled "No" and initialed and dated the change. Claimant later submitted a verified statement by Dr. Lies dated January 27, 2004 wherein he explained that he initially checked "Yes" because he misinterpreted the question as referring to calcification in the aortic wall, and he wrote "insignificant" in the margin to indicate the presence of mild calcification in the ascending aortic wall. After realizing the question referred to MAC, he crossed out the check in the "Yes" box and instead checked the "No" box.

6. Under the Settlement Agreement, a claimant is entitled to Level IV benefits if he or she 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. See Settlement Agreement § IV.B.2.c.(4)(g).

the mitral leaflets." He also stated that: "[t]here is thickening of the mitral annulus."

In November, 2003, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for the attesting physician's representation that claimant had valvular repair or replacement surgery and required 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.⁷ Specifically, Dr. Irani noted that the "[s]urgeons [sic] op report clearly states valve functions appropriately no thrombosis present." Dr. Irani also found that there was no reasonable medical basis for the attesting physician's representation that claimant did not have MAC.⁸

Based on Dr. Irani's findings, the Trust issued a post-audit determination denying Ms. Brassfield's claim for Matrix A-1, Level IV benefits but finding her eligible for Matrix B-1, Level III benefits.⁹ Pursuant to the Rules for the Audit of

7. Dr. Irani, however, concluded that there was a reasonable medical basis for the attesting physician's representation that claimant suffered from severe mitral regurgitation and had surgery to repair or replace her mitral valve.

8. Under the Settlement Agreement, the presence of MAC requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)b).

9. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from left sided valvular
(continued...)

Matrix Compensation Claims in Audit ("Audit Rules"), claimant contested this adverse determination.¹⁰ In contest, claimant argued that the attesting physician's representation that claimant underwent a second surgery through the sternum within eighteen months of her initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery is supported by the medical records submitted in support of Ms. Brassfield's claim. Specifically, claimant noted, among other things, that the operative report for her second surgery states that "one [prosthetic] mitral valve leaflet did not demonstrate full excursion. As a result, she is taken to the operating room for mitral valve replacement"

Claimant also submitted that there is a reasonable medical basis for the attesting physician's representation that Ms. Brassfield did not have MAC. In support, claimant argues that: (1) the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue must be rejected because Dr. Irani failed to provide an underlying explanation for his

9. (...continued)
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).

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 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. Brassfield's claim.

findings; (2) the echocardiogram does not show MAC; and (3) no other medical records reveal MAC. Claimant also submitted a verified statement of Dr. Lies, wherein he stated that:

Some thickening of both the mitral leaflets and the mitral annulus was observed, but without evidence of [MAC]. The only calcification evident on the echocardiogram was mild degree of calcification of the ascending aortic wall. This calcification, of course, was far distant from and had no relation to the mitral annulus, which did not show any of the features of [MAC].

(emphasis in original). In addition, claimant submitted verified statements by Stephen Raskin, M.D., F.A.C.C., and Elyse Foster, M.D. In his report, Dr. Raskin stated that he reviewed claimant's echocardiogram and found no evidence of MAC. He noted that "[m]ild increased echogenicity is seen near the mitral-aortic intervalvular fibrosa and should not be mistaken for [MAC]."

In her report, Dr. Foster stated that she reviewed claimant's echocardiogram and explained that:

The appearance of MAC in an echocardiogram is characteristic and easily identified. In the short axis view, MAC will typically appear as a C-shaped image between the papillary muscles which can vary in its severity and extent. In the long axis view, it appears as a bright reflection usually along the posterior atrioventricular groove.

She concluded that "[a]fter careful examination of the images recorded from both short axis and long axis views, I would not make a diagnosis of [MAC]."

In response, the Trust submitted Ms. Brassfield's claim to Dr. Irani for a second review. Based on this review, Dr. Irani concluded that there was a reasonable medical basis for the attesting physician's representation that claimant had a second surgery through the sternum within eighteen months of her initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery. Dr. Irani, however, confirmed his previous conclusion that there was no reasonable medical basis for the attesting physician's finding that claimant did not have MAC.

The Trust then issued a final post-audit determination, again denying Ms. Brassfield's claim for Matrix A-1, Level IV benefits, but finding her eligible for Matrix B-1, 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. Brassfield's claim should be paid. 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 then served a response upon the Special Master. The Trust submitted a reply on August 19, 2004.

Claimant submitted a sur-reply on September 3, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹¹ 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, James F. Burke, M.D., 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 in proving that there is a reasonable medical basis for the attesting physician's finding that she did not have MAC. See id. Rule 24. Ultimately, if we determine that there is 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 is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the

11. 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. 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. Id.

claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Brassfield reasserts the arguments she made in contest. In addition, claimant argues that the operative report provides a reasonable medical basis for the representation by Dr. Lies that Ms. Brassfield did not have MAC because "[s]ince the surgery involved the excision of the mitral valve (which is directly attached to the mitral annulus), it is clearly reasonable to expect that any presence of an important condition like MAC would have been noticed and recorded."

In response, the Trust argues that the echocardiogram report provides support for Dr. Irani's finding of MAC because it states that "[t]here is thickening of the mitral leaflets. There is thickening of the mitral annulus." The Trust also argues that absence of a finding of MAC in claimant's operative report is expected because the mitral annulus would not have been visible during the surgery because the surgeon decided to leave the posterior leaflet in place. Finally, the Trust argues that Dr. Irani satisfied the requirements of the Audit Rules because he observed MAC and "noted the same in his answers."

In her sur-reply, claimant argues that the presence of thickening of the leaflets is not evidence of MAC. In support, claimant relies on the expert opinion of Dr. Raskin, who explains that "[m]ild increased echogenicity is seen near the mitral-aortic intervalvular fibrosa and should not be mistaken for [MAC]." Claimant also submits a second supplemental statement of

Dr. Lies, wherein Dr. Lies reaffirms his finding that claimant did not have MAC and states that:

Some thickening of both the mitral leaflets and the mitral annulus was observed, but without evidence of [MAC]. These findings were not suggestive of [MAC]. [MAC] appears in an echocardiogram as a significant opaque formation in the annulus - not as diffuse thickening. My findings were inconsistent with the condition of [MAC].

In addition, claimant argues that: (1) the Trust's assertion that the mitral annulus was not seen during claimant's surgery is unsupported by the record and refuted by the supplemental declaration of Dr. Lies submitted in support of her sur-reply; (2) the Trust's explanation for Dr. Irani's failure to comply with Audit Rule 7(c) is unacceptable; and (3) the Trust's request that this matter be referred to a Technical Advisor deprives her of the procedural protections of the Audit Rules.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding that Ms. Brassfield did not have MAC. Specifically, Dr. Burke found that:

Based on my review of the transthoracic echocardiogram dated June 11, 2001 from Judith Brassfield, there is not a reasonable medical basis for the physician completing the Green Form to state that this patient does not have [MAC].

Upon my review of the tape, [MAC] was clearly evident in multiple views

[MAC] is indeed a C-shaped morphology predominantly between the papillary muscles. This is precisely where the echo-density is noted on this study. The echo-density is not

limited to the mitral-aortic intervalvular fibrosa. This echo-density is clearly also evident in the posterior and posterolateral area of the mitral annulus in these multiple views. Moreover, the echo-density is most compatible with [MAC] and not merely thickening of the annulus.

In summary, there is no reasonable medical basis for the Attesting Physician's claim that Judith Brassfield does not have [MAC].

In response to the Technical Advisor Report, claimant argues that the Technical Advisor applies a narrow and literal conception of MAC, which is inconsistent with the language and intent of the Settlement Agreement. Specifically, claimant argues that the MAC referred to in the Settlement Agreement and Green Form should be interpreted to refer to the pathological condition known as MAC rather than the mere presence of any calcification in the mitral annulus, which claimant asserts is found "in the vast majority of Americans over the age of 50." In addition, claimant reasserts her arguments that: (1) the Trust's refusal to provide Dr. Irani's explanation for his conclusion that she had MAC deprives her of the opportunity to contest meaningfully the Trust's denial of her claim for Matrix A-1 benefits; and (2) the record establishes a reasonable medical basis for the representation by Dr. Lies that claimant did not have MAC.

After reviewing the Show Cause Record, we find that claimant's arguments are without merit. First, we reject Ms. Brassfield's argument that MAC under the Settlement Agreement is the "recognized pathological condition . . . , which occurs when

calcium deposits progressively build up and coalesce to form a thick, rigid ring encircling the annulus and rendering it so stiff and unpliable that the movement of the leaves of the valve becomes impaired, resulting in valvular regurgitation." The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits if the echocardiogram reveals evidence of specific medical conditions, including MAC. Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Moreover, the Settlement Agreement does not qualify MAC with the term "pathological." Therefore, claimant's argument is contrary to the plain language of the Settlement Agreement.

In addition, although claimant relies upon the attesting physician's opinion that her MAC was insignificant, the amount of MAC is not pertinent to the dispute. Unlike some of the other conditions that reduce a claim to Matrix B-1, any presence of MAC, regardless of the amount, places the claim on Matrix B-1. Compare Settlement Agreement § IV.B.2.d.(2)(c)ii)d) with Settlement Agreement § IV.B.2.d.(2)(c)i)d) ("Aortic root dilatation > 5.0 cm").

Moreover, we disagree with claimant that the verified statements of Dr. Raskin and Dr. Foster provide a reasonable medical basis for her attesting physician's finding that she did not have MAC. Dr. Burke reviewed claimant's echocardiogram and concluded that MAC was evidenced in multiple views.¹²

12. We reject claimant's argument that absence of a reference in (continued...)

Specifically, Dr. Burke concluded that "[MAC] is indeed a C-shaped morphology predominantly between the papillary muscles. This is precisely where the echo-density is noted on this study." We cannot ignore the Technical Advisor's specific findings, which identify precisely where claimant's MAC is observed on her June 11, 2001 echocardiogram.¹³

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 does not have MAC. Therefore, we will affirm the Trust's denial of Ms. Brassfield's claim for Matrix A-1 benefits.

12. (...continued)
the operative report and other medical records provides a reasonable medical basis for the attesting physician's representation that Ms. Brassfield did not have MAC.

13. For this reason as well, we reject claimant's argument that she should be paid on Matrix A-1 because the Trust did not comply with Audit Rule 7(c).