

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2:15MD1203
-----	:	
SHEILA BROWN, ET AL.	:	
v.	:	
AMERICAN HOME PRODUCTS CORPORATION	:	CIVIL ACTION NO.
-----	:	99-20593
Appellant: REDACTED	:	REPORT AND AWARD
Arbitration No.: REDACTED	:	OF ARBITRATOR
Claim No.: REDACTED	:	

**FINDINGS OF FACT**

1. On [DATE], Claimant [APPELLANT] submitted a GREEN FORM requesting Matrix Compensation Benefits. [APPELLANT] claimed a Matrix A/Level IV Benefit of \$1,034,158.

2. Part II of his/her GREEN FORM was attested to by [DOCTOR A], a Board-Certified Cardiologist. GREEN FORM at 9 (attested to by [DOCTOR A] on [DATE]). In the GREEN FORM, [DOCTOR A] provided a "yes" answer to Question D(8), which asks, in pertinent part, whether the claimant has "acute myocardial infarction associated with acute mitral regurgitation." Id. at 9. [DOCTOR A] qualified his answer, however, by placing a handwritten note next to Question D(8), stating: "Murmur appeared in setting of acute MI [myocardial infarction]. Relationship to MI [myocardial infarction] not known [with] certainty." Id.

3. On or about **[DATE]**, the AHP Settlement Trust ("Trust") issued its Tentative Determination Letter awarding **[APPELLANT]** a Matrix B/Level III gross Benefit of \$145,548.00. The Tentative Determination Letter did not state the basis for the Trust's determination.

4. In a letter responding to this determination, **[APPELLANT]** stated his/her disagreement and argued that he/she was entitled to a Matrix A Benefit. **[APPELLANT]** also asked the Trust to state its basis for placing him/her on Matrix B. In response, the Trust explained that:

In order to make that determination, the parties drafted a series of questions including Questions C(3)(A)(2) and D(8). Your claim form indicates "yes" answers to both those questions which reflects pre-existing Moderate Mitral Valve Regurgitation. Under the terms of the approved Settlement Agreement that the Trust is required to implement, that factual situation requires the Trust to place your claim on the "B" matrix.

**[DATE]** letter from **[TRUST PERSONNEL]**, Claims Administration, to **[APPELLANT]** and **[COUNSEL FOR APPELLANT]** Esquire (the "**[TRUST PERSONNEL]** Letter").

5. While the Tentative Determination Letter did not identify the basis for placing **[APPELLANT]** on Matrix B, and the **[TRUST PERSONNEL]** Letter states incorrectly that a "preexisting Moderate Mitral Valve Regurgitation" condition required placement of **[APPELLANT]** on Matrix B, the actual basis for the determination can be assumed. I find that the Trust determined that **[APPELLANT]** was entitled to a Matrix B Benefit because the affirmative answer to Question D(8) on the GREEN FORM indicated that **[APPELLANT' S]**

myocardial infarction predated his/her moderate mitral valve regurgitation, and that indication of such regurgitation was not established until after the myocardial infarction.

6. I find, furthermore, that the erroneous explanation in the **[TRUST PERSONNEL]** Letter of the rationale for the Tentative Determination did not materially disadvantage **[APPELLANT]** in challenging the Tentative Determination or, later, in appealing the Final Determination. While the explanation in the **[TRUST PERSONNEL]** Letter may have been confusing to him/her, **[APPELLANT]** immediately responded by submitting correspondence and medical records supporting his/her claimed entitlement to Matrix A compensation. **[DATE]** letter from **[COUNSEL FOR APPELLANT]** to **[TRUST PERSONNEL]**.

7. In this letter, **[APPELLANT]** explained that after ingesting the diet drugs, and prior to suffering his/her myocardial infarction, he/she developed symptoms "showing possibilities of value [sic] damage and PPH." Id. **[APPELLANT]** further explained that **[DOCTOR A]** qualified his affirmative answer to question D(8) because "the association between the regurgitation, at its increased level, and the heart attack will never be known to a certainty." Id. **[APPELLANT]** thus argued that his/her medical history demonstrated his/her eligibility for a Matrix A Benefit. Id.

8. To further clarify the D(8) response, **[APPELLANT]** also submitted to the Trust a **[DATE]** letter from **[DOCTOR B]**, his/her cardiothoracic surgeon. In the letter, **[DOCTOR B]** stated:

[I]n the circumstance of acute myocardial infarction, mitral regurgitation is usually the consequence of

chordal infarction with indicated normal valve structure and only ring dilatation, this suggests that his/her mitral regurgitation had been present prior to his/her myocardial infarction.

[DATE] letter from [DOCTOR B] to [COUNSEL FOR APPELLANT] (emphasis added). According to [APPELLANT], [DOCTOR B'S] letter confirmed that his/her mitral valve regurgitation predated his/her myocardial infarction and that "no objectively definable condition existed independent from diet drug use to cause the Claimant to be removed from Matrix A." [DATE] letter from [COUNSEL FOR APPELLANT] to [TRUST PERSONNEL]. [APPELLANT] argued that the new information essentially changed [DOCTOR A'S] answer to D(8) from a "yes" to a "no."

9. On [DATE], the Trust issued its Final Determination Letter. The Trust awarded [APPELLANT] a gross Matrix Benefit of \$206,831.00, consistent with a Matrix B/Level IV Benefit, an increase from the Level III Benefit awarded in the Tentative Determination Letter. After receipt of the Final Determination Letter, [APPELLANT] submitted a new GREEN FORM (Supplemental GREEN FORM). This form was attested to by [DOCTOR B] on [DATE] and expressly changed the answer to Question D(8) from a "yes" to a "no." Supplemental GREEN FORM at 9.

10. Upon receipt of the Supplemental GREEN FORM, the Trust advised [APPELLANT] that it had no authority to consider information submitted after the Final Determination Letter was issued. [DATE] letter from [TRUST PERSONNEL] to [COUNSEL FOR APPELLANT]. On [DATES], the Trust also stated that it would not object to an arbitrator's consideration of information submitted after the issuance of the Final Determination Letter. [DATES] letters from [TRUST PERSONNEL] to [COUNSEL FOR APPELLANT].

11. On, **[DATE]** a Notice of Appeal of Determination of Trustees and/or Claims Administrator(s) ("Appeal") was filed by **[APPELLANT]**. The Court, on **[DATE]**, referred **[APPELLANT'S]** Appeal to the Chair of this Arbitration Panel.

12. In conjunction with his/her appeal, **[APPELLANT]** filed a Petition to Submit New Evidence Into Arbitration. **[DATE]** Petition by **[APPELLANT]** ("Petition"). In the Petition, **[APPELLANT]** contended that it was necessary to submit his/her Supplemental GREEN FORM as new evidence to clarify the ambiguity created by **[DOCTOR A'S]** answer to Question D(8) and his corresponding handwritten notes in the original GREEN FORM.

13. After reviewing the Petition, the Chair of the Arbitration Panel stayed the arbitration proceeding and directed that **[APPELLANT'S]** Supplemental GREEN FORM be submitted to the Trust's Claims Administrator for an evaluation of whether an amended Final Determination should be issued or whether the new evidence had no impact on the final Benefits determination. Chair Arbitration Decision No. **REDACTED** Regarding **[APPELLANT'S]** Petition to Submit New Evidence Into Arbitration (**[DATE]**) at 19. The Supplemental GREEN FORM thus became part of the record considered by the Trust and, eventually, part of the arbitration record. The Chair stated, however, that:

I note, however, that the Trust is not required to accept blindly **[APPELLANT'S]** Supplemental Green Form answers. The Settlement Agreement expressly provides that if the Trust determines "any inconsistency in the information provided in a Claim Form, [the Trust] shall review the Medical Information relating to such Claim to determine if the Medical Information resolves such inconsistency."

[DATE] Chair Arbitration Decision No. REDACTED, at 19.

14. On [DATE], the Trust concluded that its evaluation of the Supplemental GREEN FORM did not change its Final Determination, and thus confirmed its prior decision awarding [APPELLANT] Benefits under Matrix B, Level IV.

15. On [DATE], and according to Rule 8 of the Rules Governing Arbitration Process, [APPELLANT] submitted an Amended Statement of the Case setting forth the rationale of the appeal.

16. During the Arbitration hearing, reference was made to additional attestations from doctors proffered by [APPELLANT]. I further learned during the hearing that the Chair had ruled the information was duplicative, and therefore, not allowed.

#### **ANALYSIS**

1. The issue in this Appeal is whether the Trust's decision to award Benefits under Matrix B rather than Matrix A is clearly erroneous within the meaning of Rule 5 of the Rules Governing Arbitration Process (Arbitration Rules).

2. The Matrix compensation structure of the Nationwide Class Action Settlement Agreement ("Agreement") provides higher levels of benefits to claimants whose valvular conditions are coincident solely with diet drug ingestion, and not with other causative or contributory conditions, such as a myocardial infarction. This policy does not require a claimant to prove that diet drug ingestion "caused" a valvular condition. It merely reduces the claimant's level of compensation if a specified type of condition is present.

3. Claimants with specified pre-existing or contributory conditions are thus compensated under Matrix B, rather than Matrix A. The Trust determined that **[APPELLANT]** should be compensated under Matrix B because he/she had the condition of "acute myocardial infarction associated with acute mitral [valve] regurgitation" (Agreement, Section IV.B.2.d(2)(c)(ii)(c)), and that the record did not support a finding that his/her moderate mitral valve regurgitation (which made him/her eligible for Matrix Benefits) existed before his/her myocardial infarction.

4. In evaluating the record, the Trust considered two GREEN FORMS, the original GREEN FORM signed by **[DOCTOR A]**, and the Supplemental GREEN FORM signed by **[DOCTOR B]**. The two GREEN FORMS contain contradictory answers to question D(8); an affirmative answer on the original GREEN FORM, a negative answer on the Supplemental GREEN FORM.

5. The GREEN FORMS were not only contradictory, but ambiguous. The original GREEN FORM contained a handwritten note apparently to the effect that the relationship of the "murmur" (apparently a reference to regurgitation) "to MI [myocardial infarction] not known [with] certainty." Whatever this note may mean, it does not transform the "yes" answer into a "no" answer. I find that the combination of the "yes" answer and the note, and hence the original GREEN FORM, are ambiguous.

6. Similarly, the Supplemental GREEN FORM is ambiguous, despite the fact that it answers Question D(8) negatively and contains no handwritten notes. It is ambiguous because it must be read in connection with **[DOCTOR B'S]** letter of **[DATE]**, which was entered into evidence by **[APPELLANT]**. In that letter **[DOCTOR B]** indicated that because "your husband's/wife's [sic] operation was

performed as an emergency, I never dictated a consultation. My only documentation of the encounter is my operative note."

**[DOCTOR B]** hence acknowledges a limited basis for his opinion. He goes on to caution that in the operative note "I make no statement regarding the presence or absence or duration of your husband's/wife's [sic] mitral regurgitation. For that reason, [sic] anything I could state would be at best hearsay and nothing I could in any fashion document." **[DOCTOR B]** does not seem to be using the term "hearsay" in the technical legal sense, but when the term is regarded in the context of the rest of the sentence, it does indicate that he is offering much less than a definitive medical opinion. This tentativeness affects the weight of his next statements, in which he states that "in the circumstance of acute myocardial infarction, mitral regurgitation is usually the consequence of chordal infarction with valve dehiscence," and that his "operative analysis indicated normal valve structure and only ring dilatation." This disparity, he concluded "suggests that his/her mitral regurgitation had been present prior to his/her myocardial infarction" (emphasis added). The use of the word "suggests" in this conclusion once again casts a tentative air to his conclusion. Indeed, when viewed as a whole, his conclusions (including his negative answer to Question D(8)) cannot be regarded as stated to a medical certainty, and should be regarded as somewhat ambiguous.

7. It would be disingenuous for **[APPELLANT]** to object to regarding **[DOCTOR B'S]** negative answer to Question D(8), when viewed in light of his letter, as possessing less than medical certainty, when he/she has characterized **[DOCTOR A'S]** affirmative answer, when viewed in light of the handwritten note, as lacking such certainty.



8. In evaluating **[APPELLANT' S]** claim, therefore, the Trust was confronted with two contradictory and ambiguous GREEN FORMS. It was thus necessary for the Trust to consider the other Medical Information submitted by **[APPELLANT]**. The most important item of Medical Information is a Consultation report by **[DOCTOR C]**, dated **[DATE]**. **[DOCTOR C]** reports **[APPELLANT]** complaining of the recent onset of a shortness of breath and chest pain. The report does not indicate a diagnosis of any kind, including diagnosis of moderate mitral valve regurgitation. The "Plan" included in the report indicated that an electrocardiogram was recommended and, depending on the results, an echocardiogram as well. Apparently, **[APPELLANT]** did not undergo an echocardiogram until **[DATE]**, at or just after the time of his/her myocardial infarction. I find that **[DOCTOR C' S]** earlier report, while indicating shortness of breath and chest pain that might be consistent with the presence of moderate mitral valve regurgitation, is not alone sufficient to establish the existence of such regurgitation, because those symptoms are also consistent with unrelated conditions. **[DOCTOR C' S]** report thus does not clarify the ambiguity created by the GREEN FORMS.

9. The Trust's determination that these ambiguous GREEN FORMS do not establish that **[APPELLANT' S]** moderate mitral valve regurgitation pre-dated his/her myocardial infarction is a reasonable interpretation of the evidence.

10. The specific question in this appeal, therefore, is whether the Arbitrator, operating under a "clearly erroneous" standard of review, may overturn a Final Determination based upon the Trust's evaluation of an ambiguous record. I find that it would be inappropriate to do so. The arbitration of this appeal is not a *de novo* review. The arbitrator is not authorized to engage in a

new review of the set of facts presented to the Trust, and may overturn the Final Determination only when the arbitrator finds that the Trust's reading of the law, its application of the law or its findings of fact are clearly erroneous. When the record evaluated by the Trust is as ambiguous as this record, it is highly unlikely that "clear" error can be found in the findings of fact or the application of the law. So long as the Trust's determination is based upon a reasonable interpretation of ambiguous facts, even if those facts theoretically could support another interpretation, the Trust's interpretation should stand. The "clearly erroneous" standard of review contemplates that the arbitrator should not lightly substitute his judgment for that of the fact finder (the Trust), particularly when its determination is based on the type of record into which the arbitrator cannot have superior insight.

**CONCLUSION**

1. The Trust's Final Determination was not clearly erroneous. **[APPELLANT]** is not entitled to a Matrix A/Level IV Benefit.
2. The Trust's Final Determination is affirmed.
3. If **[APPELLANT]** develops a condition that qualifies him/her for higher Matrix Level Benefits in the future, he/she may apply for such Benefits at that time.

October 21, 2002

Date

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REDACTED

Arbitrator