

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

IN RE: DIET DRUGS (PHENTERMINE /	:	MDL DOCKET NO.
FENFLURAMINE/DEXFENFLURAMINE)	:	2 :15 MD1203
PRODUCTS LIABILITY LITIGATION	:	
-----	:	
	:	
SHEILA BROWN, ET AL.	:	
v.	:	CIVIL ACTION
AMERICAN HOME PRODUCTS	:	99-20593
CORPORATION	:	
-----	:	
	:	
Appellant:	:	
Arbitration No.:	:	REPORT AND AWARD
Claim No.: 183/00	:	OF ARBITRATOR
	:	

**FINDINGS OF FACT**

1. On [redacted] the AHP Settlement Trust (“Trust”) issued a Final Post-Audit Determination, approving the claim of [redacted] (“Claimant”) for Matrix Compensation Benefits at Matrix A Level I, but denying her claim for Benefits at Matrix A Level III. Claimant originally asserted a claim for Benefits at Matrix A Level IV, but by letter dated [redacted] (at page 3), amended her claim to seek Matrix A Level III Benefits.

2. On [redacted] an appeal was filed on behalf of [redacted] from the decision of the Trust denying Matrix A Level III Benefits, requesting that the United States District Court (“Court”) refer this matter to Arbitration. The appeal was assigned docket number [redacted]

3. On [redacted] the claim of [redacted] was referred by the Court to Arbitration pursuant to VI. C. 4 (h) & (i) of the Nationwide Class Action Settlement Agreement with American Home Products Corporation.

4. On [redacted] an Arbitration Hearing was held concerning the claim of [redacted]

did not participate but was represented by

### ANALYSIS

1. Claimant seeks benefits pursuant to Matrix A Level III, subsection (c), on the grounds that she suffered a stroke due to bacterial endocarditis after ingestion of Pondimin and/or Redux (“diet drugs”). *See* Settlement Agreement Section IV.B.2.c.(3)(c). The Trust does not dispute that [REDACTED] suffered a stroke due to bacterial endocarditis after ingestion of Pondimin but claims that [REDACTED] is not entitled to Matrix Level III Benefits because a diagnosis of FDA positive must precede the qualifying medical condition, which in this case was [REDACTED] stroke. *See* Settlement Agreement Section IV.B.1.a.

2. In order to receive Matrix Compensation, a Claimant must be both eligible and qualified to receive Matrix-Level Benefits. In order to be eligible, a Diet Drug Recipient must fit within one of two categories: (1) Diet Drug Recipients diagnosed by a Qualified Physician as FDA Positive or as having mild mitral regurgitation by an echocardiogram performed on or before January 3, 2003, provided the Diet Drug Recipient registered for settlement benefits by May 3, 2003; or (2) Diet Drug Recipients who by September 30, 2005 have been diagnosed by a Qualified Physician as having Endocardial Fibrosis and who have registered for Fund B Benefits by January 31, 2006. *See* Settlement Agreement, Section IV.B.1. [REDACTED] claims eligibility based on the first of these two categories. In order to be diagnosed as FDA Positive, a Diet Drug Recipient must suffer mild or greater aortic valve regurgitation and/or moderate or greater mitral valve regurgitation. *Id.* at Section I.22.

3. There appears to be no dispute that claimant was a diet drug recipient. The

claimant's Pink Form states that . . . ingested Pondimin (Fenfluramine) for sixty-one days or more. This is confirmed by pharmacy records which reflect that . . . was dispensed Pondimin (Fenfluramine) on seven dates starting on . . . and ending on . . .

4. . . . was diagnosed by a Qualified Physician as FDA Positive by an echocardiogram performed on or before January 3, 2003 and there is no dispute that she registered for settlement benefits by May 3, 2003. Both of these facts are supported by the available evidence. In support of her claim, . . . submitted five Green Forms.

1) Green Form #1 was signed by claimant on . . . was signed by Board-Certified Cardiologist . . . on . . . was based on an echocardiogram, and was received by the Trust on . . .

2) Green Form #2, a supplemental form, was signed by claimant on . . . and received by the Trust on . . .

3) Green Form #3, also a supplemental form, was signed by claimant on . . . was signed by Board-Certified Cardiologist . . . on . . . was based on the . . . echocardiogram, and was received by the Trust on . . .

4) Green Form #4, also a supplemental form, bears the claimant's name and identifying information, but contains neither the claimant's signature nor the signature of a Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon. It was received by the Trust on . . .

5) Green Form #5, also a supplemental form, was not signed by claimant but was . . .

signed by Board-Certified Cardiologist on  
 was based on a echocardiogram, and was received by the Trust on

The file also contains a single, unattached, Green Form  
 signature page, bearing claimant's signature and dated Since all  
 prior Green Forms were received by the Trust prior to that date, it is reasonable to  
 conclude that the signature page is intended to accompany Green  
 Form #5.

During the Arbitration Teleconference, both parties agreed that it is Green Form #5 (hereinafter  
 "Green Form") on which the Trust based its final determination, and which is therefore in issue  
 in this Arbitration. See also Letter of dated to AHP Settlement  
 Trust, in which he confirms reliance on the Green Form received on and refers  
 to an unattached signature form mailed to the Trust on

In claimant's Green Form, Board-Certified Cardiologist stated that based  
 on a echocardiogram had no mitral regurgitation but did suffer from  
 moderate aortic regurgitation. See Green Form, Page 8, Question C. 3. The actual  
 echocardiogram report shows both mild mitral regurgitation and moderate aortic regurgitation.

See Echcardiogram Report, Health Center (physician

The conflict regarding the existence of mitral regurgitation is immaterial, however, because both  
 the Echocardiogram Report and statement in claimant's Green Form confirm a  
 finding of moderate aortic regurgitation. The existence of moderate aortic regurgitation provides  
 a sufficient basis to conclude that was diagnosed as FDA positive before the end of the  
 Settlement screening period. Thus, was eligible for Matrix Compensation pursuant to  
 Settlement Agreement, Section IV.B.1.

5. In addition to being eligible for Matrix benefits, in order to receive Matrix compensation a claimant must also have a qualifying disease. seeks Benefits at Matrix Level III. Matrix Level III is left sided valvular heart disease requiring surgery or conditions of equal severity, and is defined in subsection (c) as “Qualification for payment at Matrix Level I(b) (as described in Section IV.B.2.c.(1)(b) . . .) or Matrix Level II and, in addition, a stroke due to bacterial endocarditis contracted after use of Pondimin and/or Redux or as a consequence of chronic atrial fibrillation with left atrial enlargement as defined in Section IV.B.2.c.(2)(b)(ii) which results in a permanent condition which meets the criteria of AHA Stroke Outcome Classification Functional Level II, determined six months after the event.” Settlement Agreement Section IV.B.2.c.(3)(c). Certain items are not in dispute.

6. The parties agree that suffered a stroke on or about During the teleconference, the parties agreed that stroke followed use of Pondimin and that her stroke resulted in a permanent condition which meets the criteria of AHA Stroke Outcome Classification Functional Level II, determined six months after the event. This finding is supported by evidence in the record. Following her stroke, was diagnosed with infective endocarditis. Although during the teleconference the Trust declined to characterize its position as a concession, the Trust does not contest the fact that claimant’s stroke was due to the bacterial endocarditis. See Final Post-Audit Determination Letter, dated .

Moreover, three facts support a finding that the stroke was due to bacterial endocarditis. First, there is no evidence to rebut contention that prior to she was in relatively good health with no prior diagnosis of valvular heart disease and no known history of other causes of valvular heart disease. See Letter From to AHP Settlement Trust, dated at page 3. Second, it is the professional

opinion of [REDACTED] that [REDACTED] stroke was due to bacterial endocarditis, an opinion not contradicted by any evidence on behalf of the Trust. *See* Letter from [REDACTED]

[REDACTED] Third, a conclusion that [REDACTED] stroke was due to bacterial endocarditis is not disputed by the Trust's auditing cardiologist, [REDACTED] who concluded that [REDACTED] was wrong when, on Green Form Question F.11.a., he said there was no basis for concluding that [REDACTED] had suffered a stroke resulting in Stroke Outcome Classification Level II. *See* Attestation of Auditing Cardiologist, dated [REDACTED] at page [REDACTED]

2. The implication of [REDACTED] conclusion is that it is [REDACTED] professional opinion that [REDACTED] did fit Outcome Classification Level II, which was dependent on a conclusion that [REDACTED] had suffered a stroke due to bacterial endocarditis contracted after taking Pondimin.

7. The parties agree that [REDACTED] meets the initial Matrix Level III requirement that she qualify for payment at Matrix Level I.(b). *See* Final Post-Audit Determination Letter, dated [REDACTED]

[REDACTED] This finding is amply supported by evidence in the record. Payment at Matrix Level I(b) requires FDA Positive valvular regurgitation with bacterial endocarditis contracted after commencement of Pondimin and/or Redux use. Settlement Agreement, Section IV.B.2.(c)(1)(b). The Trust accepts the statement of claimant's physician in the Green Form (Section II, Question F.1.) that claimant developed FDA Positive valvular regurgitation with bacterial endocarditis after taking Pondimin and/or Redux and on this basis offered claimant payment at Matrix A Level I. *See* Final Post-Audit Determination Letter, dated [REDACTED] footnote 6 and accompanying text, at page 2. Thus, by qualifying for payment at Matrix Level I(b), [REDACTED] meets the first requirement for payment at Matrix Level III(c).

8. Matrix Level II is an alternative predicate qualification for payment at Matrix [REDACTED]

Level III. Matrix II(a) is moderate or severe aortic regurgitation with pulmonary hypertension secondary to severe aortic regurgitation with certain peak systolic pulmonary artery pressures, abnormal left ventricular end-systolic dimension, and/or an ejection fraction of < 50%. Matrix Level II(b) is moderate or severe mitral regurgitation with pulmonary hypertension secondary to valvular heart disease with certain peak systolic pulmonary artery pressures, abnormal left atrial supero-inferior systolic dimension > 5.3 cm or abnormal left atrial antero-posterior systolic dimension > 4.0 cm, abnormal left ventricular end-systolic dimension  $\geq$  45 mm, an ejection fraction of  $\leq$  60%, or cardiac arrhythmias. Settlement Agreement, Section IV.B.2.c.(2).

Although claimant's physician stated that claimant had moderate regurgitation of the aortic valve, the physician stated that claimant did not have any of the aggravating conditions qualifying claimant for payment under Matrix Level II(a). *See* Green Form Section II, Questions F. 2, 4 and 8.

The Trust also asserts that claimant does not qualify for payment under Matrix Level II(b). In claimant's Green Form, her physician stated that claimant did not have mitral valve regurgitation, thus disqualifying claimant for payment at Matrix Level II(b). *See* Green Form Section II, Question C.3.A and Trust Calculation of Benefits. In addition to her Green Form, [REDACTED] also submitted Gray Form #2, completed by [REDACTED] in which he stated that she had mild mitral regurgitation and mild aortic regurgitation. [REDACTED] however, is not Board-Certified in either cardiology or cardiothoracic surgery. Claimant thereafter submitted an additional Gray Form, completed by Board-certified Cardiologist [REDACTED].

[REDACTED] Gray Form states that [REDACTED] has no mitral valve regurgitation. Despite the conflicting Green and Gray Forms, it is reasonable to conclude that claimant did have mild mitral regurgitation. This conclusion is based on a review of claimant's Echocardiogram Report,

which confirms that she suffered from mild mitral regurgitation. Echocardiogram Report, Health Center (physician) Nevertheless, for mitral valve regurgitation to form the basis of Matrix Level II(b) Benefits, the regurgitation must be moderate or severe, and mitral valve regurgitation was reported as mild. If mitral regurgitation were moderate (as is asserted by claimant in her letter of at page 4), her ejection fraction of  $\leq 60\%$  (see Green Form, Question F. 8) would qualify her for payments at Matrix Level II(b). See Settlement Agreement, Section IV.B.2.c.(2)(b). Other than claimant's assertion, however, there exists no basis for concluding that her mitral regurgitation was moderate.

Accordingly, there is insufficient basis to conclude that qualified for Matrix Level II(a) or II(b) benefits. Because the Trust concedes that she qualifies for Matrix I(b) benefits, claimant's failure to qualify for either category of Matrix II benefits does not disqualify her for Matrix III benefits.

Thus, based on the above analysis, there is ample basis for finding that eligible *and* qualified to receive Matrix Level III benefits. The issue is whether the Settlement Agreement requires that her eligibility have occurred at a time *before* she experienced the medical condition that makes her qualified.

9. Claimant argues that although the Settlement Agreement imposes a dual requirement for Matrix benefits (eligibility and qualification), nowhere is there express language specifying that one must precede the other and in support relies on the language of Matrix Level III(c).

Matrix Level III(c) Benefits require qualification for payment at Matrix Level I(b) or Matrix Level II "*and, in addition*", a stroke due to bacterial endocarditis contracted after use of



diet drugs. *See* Settlement Agreement Section IV.B.2.c.(3)(c) (emphasis supplied). Claimant first makes a textual argument that the conjunction, “and”, connects two clauses or phrases (in this case, because there are no verbs, the word cluster is a phrase) but that the word “and” does not impose a temporal relationship on the two elements. The Trust argues that taken as a whole, the meaning of the language of III(c), requiring qualification for I(b) *and, in addition*, a stroke, requires that qualification for I(b) *precede* the stroke. The Trust argues that this same requirement exists in Section V(d), the provision at issue in Memorandum and Pretrial Order 3913, January 7, 2004, Bartle, J. (PTO 3193), on which the Trust by analogy relies.

Matrix Level V(d) reads in part as follows: “The individual otherwise qualifies for payment at Matrix Level II, III, or IV and suffers from ventricular fibrillation . . .”. Settlement Agreement, Section IV.B.2.c.(5)(d). argues that when used without a comma, the conjunction “and” commonly signifies that the connected elements are dependent but when set off by commas, “and” implies that the corresponding phrases or clauses are independent.

It was undisputed that at the time she suffered ventricular fibrillation, the claimant in PTO 3193 was not qualified for Matrix Level II, III or IV payments. Later, when claimant became eligible for Matrix Level II payments, she sought to use the initial Level V condition and subsequent Level II qualification to obtain Matrix-Level V benefits. In ruling the for the Trust, Judge Bartle stated that words must be given their plain meaning, unless to do so would lead to an unreasonable or absurd result. *See* PTO 3193. Accordingly, he concluded that use in Section V(d) of the present tense verbs “qualifies” and “suffers” joined by the conjunction “and” imposed a requirement that the two joined clauses (criteria for Level II benefits and Level V ventricular fibrillation) must exist concurrently. *Id.* Despite Judge Bartle’s ultimate ruling in favor of the Trust, finds support in the Judge Bartle’s reasoning in PTO 3193 that qualification for

payment at Matrix Level II, III or IV and ventricular fibrillation, where the “and” is not set off by commas, must exist concurrently.                    argument is that V(d), with no commas, is unlike III(c), which has commas, and therefore III(c) should not be read to require concurrence or precedence. The Trust, in contrast, finds support in the Court’s ruling in PTO 3193.

During the teleconference, the Trust conceded that the facts of PTO 3193 are different from those of the instant case and did not argue, as it had in its Post-Audit Determination Letter of                    that PTO 3193 was the law of this case. Rather, the Trust’s position is that PTO 3193 applies by analogy and that its general theme, that a claimant must first be eligible in order to determine qualifying Matrix Levels, applies in this case as well.

I do not find PTO 3193 to be apposite to this case. Even if this case turned on the meaning of Section III(c)’s language, the III(c) phrase “and, in addition”, and the V(d) text that was at issue in PTO 3193, are critically different. Section V(d) contains present tense verbs, and both the verbs and their tense were important to Judge Bartle in concluding that ventricular fibrillation and qualification at Matrix Levels II, III or IV must exist concurrently. The pertinent portion of Section III(c), by contrast, has no verbs. The absence of verbs deprives the text of action words from which one could infer a sense of timing. Thus, PTO 3193, which turns so notably on verbs and their tense, is inapposite.

Analyzing the text of Matrix III(c), I do not find the language “and, in addition” to self-evidently impose a temporal relationship that would require qualification at Matrix Level I(b) to have taken place before the stroke. The Trust, however, does not base its argument on the text of Matrix Level III(c), but rather relies on Section IV.B., and argues not that claimant failed to prove that she qualified for Matrix Level I(b) prior to suffering a qualifying disease, but that claimant failed to prove that she was eligible for *any* Matrix compensation at a time prior to

suffering a qualifying medical condition at any Matrix level. It is the Trust's position that Section IV.B.1. is a predicate to any of the Matrix Levels and that it is with this section that claimant failed to comply. I agree.

While it is true that a casual reading of both Sections IV.B.1. (the eligibility provision) and IV.B.2.c.(3)(c) (the pertinent qualification provision) appears to produce the same outcome, the provisions are not duplicative. Both sections address the sequence in which a claimant must demonstrate that she was FDA positive and suffered a qualifying medical condition. In this case, claimant was first diagnosed as FDA positive by a echocardiogram. Her bacterial endocarditis was diagnosed on or after that date. Sequentially, it occurred as follows:

Stroke, FDA Positive Status, Bacterial Endocarditis.

The Trust takes the position that both IV.B.2.c.(3)(c) and IV.B.1. require a sequence that would look like this:

FDA Positive Status, Bacterial Endocarditis, Stroke.

As mentioned, I disagree that Section IV.B.2.c.(3)(c) imposes such a requirement. I find, however, that Section IV.B.1. does impose such a requirement.

The requirement that FDA Positive Status precede a qualifying medical condition is not express. Section IV.B.1. has no provision that a claimant must meet eligibility requirements (in this case, FDA Positive Status) before she experiences a qualifying medical condition. Section IV.B.1. says "The following Class Members, and only such Class Members, shall be entitled to the compensation benefits from Fund B ("Matrix Compensation Benefits)". Thus it is clear that as an analytical matter, one must first be eligible before assessing qualification. But whether a claimant have been physically eligible before a medical condition rendered them qualified is a different matter. Section IV.B.1. does not say "The following Class Members and only *if first*

such Class Members . . .”, which is language that would clearly express the relationship between eligibility and qualification. Without the italicized language, or words to similar effect, Section IV.B.1.’s express language renders eligibility at best a co-requisite, but not a prerequisite, to qualification.

Section IV.B.2. provides: “For purposes of provided Matrix Compensation Benefits to those Class Members eligible to receive such payments, the following four payment matrices [] are established. . .” *Id.* at IV.B.2. As a matter of syntax, this provision is similar to that Matrix III(c); it lacks a verb to clarify when Class Members must be eligible. Therefore, as an express matter, Section IV.B.2. does not clearly require that Class Members be eligible before the advent of a qualifying Matrix condition.

Words, however, do not exist in a vacuum, and in the absence of express language, I find it appropriate to consider the intent of the Settlement Agreement as a whole. Despite the absence of express language, I find that the intent of the Settlement Agreement was that eligibility actually precede, not just analytically precede, qualification. My reasoning is the painfully precise language of Section IV.B.1: “The following Class Members, and only such Class Members, shall be entitled to the compensation benefits from Fund B (“Matrix Compensation Benefits”). *Id.* If all that were required were that claimants meet eligibility requirements at some point in time and have a qualifying medical condition at some point in time, the two categories should have been simply sequentially described, essentially providing two requirements for compensation. The Settlement Agreement, however, does not read that way. It does not say, in essence, that a claimant must be eligible (defined as such) and qualified (defined as such). Rather, the eligibility section emphasizes that only eligible class members are entitled to benefits. Additionally, the Benefits section is more than the second of two unrelated requirements. It does

not simply add a second requirement: that a claimant qualify on one of the four Matrices. Rather it states “For purposes of providing Matrix Compensation Benefits to those Class Members eligible to receive such payments, the following four payment matrices [] are established. . .” *Id.* at IV.B.2. The implication of the provision’s language is that the Matrices are relevant to, and limited to, those people who are (not who will at some point in the future be) eligible to receive payments.

To credit claimant’s position would require a conclusion that qualification and eligibility were co-equal requirements for the entirety of the Settlement class, and that claimants with medical conditions listed on one of the Matrices could work backwards and, if ever FDA positive, be entitled to Matrix benefits. Moreover, if eligibility and qualification were co-equal, meaning no more than that both were required, use of the word “only” in Section IV.B.1. would be redundant. I do not find it redundant. I find that the phrase “only such Class Members” reflects an intent that eligibility be a predicate condition to qualification for Matrix Level Benefits

### CONCLUSIONS

1. The findings of the Trust are not clearly erroneous, as set forth in Rule 5 of the Rules Governing Arbitration Process.
2. Based upon the findings above, the claimant not entitled to Matrix III Benefits because the conditions that are required for recovery of Matrix-Level III Benefits are not present in this claim. (Settlement Agreement, Sections IV.B.2.c.(3)).

Accordingly, based on all of the above, I find that claimant is entitled to Matrix Compensation Benefits at Matrix Level I(b).

July 25, 2005  
DATE

Arbitrator