

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
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:
SHEILA BROWN, ET AL. :
v. :
AMERICAN HOME PRODUCTS CORPORATION : CIVIL ACTION NO.
:
-----:
99-20593
:
Appellant: : REPORT AND AWARD
Arbitration No: : OF ARBITRATOR
Claim No.: :

FINDINGS OF FACT

A. Background

1. On _____ the AHP Settlement Trust (Trust) issued a Post-Audit Final Determination-Denial of Matrix Claim Benefits (Final Determination) on the Claim of _____ (Claimant) for Matrix Compensation Benefits.
2. On _____, Claimant filed an appeal from the Final Determination to the United States District Court (Court) requesting that the Court refer this matter to Arbitration.
3. On _____ the Court referred Claimant's claim to Arbitration pursuant to sections VI.C.4.(h) & (i) or VI.D.1.(f) & (g) of the Nationwide Class Action Settlement Agreement with American Home Products Corporation (Settlement Agreement).
4. An Arbitration Hearing on Claimant's claim was held on _____ Claimant was represented by Counsel.

5. In Green Form dated (Green Form , Claimant requests Matrix Compensation Benefits based on medical symptoms and conditions allegedly caused by use of the Diet Drugs. The Green Form indicates that Claimant believes that is entitled to Matrix A-1, Level II Benefits. Green Form Part I, Questions 5-6.

6. Claimant based claim on an echocardiogram dated In a second Green Form signed by Claimant on Green Form), the Attesting Physician stated that this echocardiogram showed that the Claimant had moderate mitral valve regurgitation. Green Form Part II, Question C.3. The Attesting Physician also stated that the echocardiogram showed evidence of left atrial enlargement. Green Form Part II, Question F.5.

7. The Final Determination stated that "[b]ased on the documentation submitted to the Trust in support of Diet Drug use, including Claimant's Contest Materials, the Trust concludes that [Claimant's] Contest fails to establish Diet Drug usage in accordance with the Settlement Agreement." Final Determination at 5. The Final Determination stated further that "[b]ased on [the Auditing Cardiologist's] findings and observations, the Trust concludes that [Claimant's] Contest fails to establish a reasonable medical basis for [the Attesting Physician's] Green Form representations that [Claimant has] moderate mitral regurgitation." Final Determination at 7. Accordingly, the Final Determination denied Claimant's Claim for Matrix Compensation Benefits. Claimant thereupon chose to contest the Final Determination.

8. Claimant's Contest was bifurcated between a Show Cause Proceeding and this Arbitration.

B. Relation of This Arbitration and the Show Cause Proceeding

9. On the Court issued an "Order to Show Cause Relating to Audited Claims of the Above-Referenced Claimants," including Claimant. In re Diet Drugs Products Liability Litigation,

CA No. 99-20593, Pre-Trial Order .
Claimant's challenge to the Trust's ruling that Contest had failed to establish a reasonable medical basis for the Attesting Physician's assertions is now pending in that Show Cause proceeding.

10. As noted in Paragraphs 2 and 3 above, Claimant also filed an appeal from the Final Determination to the Court, and the Court referred that matter to arbitration on . Pending in this Arbitration is only Claimant's appeal of the Trust's determination that had failed to establish Diet Drug usage.

11. The bifurcation of Claimant's contest between the Show Cause proceeding and this Arbitration is required by the Rules for the Audit of Matrix Compensation Claims, approved by the Court in 2003. Rule 18, In re Diet Drugs Products Liability Litigation, CA No. 99-20953, Pre-Trial Order 2807 (March 26, 2003).

C. Claimant's Diet Drug Usage

12. Claimant has represented that Diet Drugs were dispensed to by of , and were dispensed and prescribed to by a . Blue Form, Questions 10.a and 10.b, :

13. After three separate written requests by the Trust for proof of Diet Drug usage (on), Claimant responded by submitting four affidavits with respect use of Diet Drugs. See Letter of to AHP Settlement Trust, (cover letter for affidavits). One affidavit was from the Claimant one from the dispensing pharmacist, and two from employees who worked at pharmacy during the relevant time period and knew Claimant personally. Claimant provided these affidavits in lieu of pharmacy or medical records because the relevant pharmacy and medical facility had long been out of business.

14. Specifically, the affidavits submitted were those of:

15. The _____ affidavits do not identify the dates, quantity, dosage frequency or numbers of prescriptions or refills of the Diet Drugs allegedly dispensed to Claimant.

16. The _____ affidavit does state that:

... although I, _____, believe that _____ had Pomdomin (sic) prescriptions filled by me at _____ of _____, I cannot, as a policy matter, swear to this fact due to the non-existence of any records of _____ of _____

Affidavit, paragraph 5.

ANALYSIS

A. Adequacy of the Affidavits as Proof of Ingestion

1. Only persons who have ingested Diet Drugs are members of the Settlement Class eligible to submit a claim for Matrix Compensation Benefits. Settlement Agreement §II.B.

2. The Settlement Agreement provides that, in order to sustain a claim for Matrix Compensation Benefits,

each Class Member must submit documentary proof to the Trustees and/or Claims Administrator(s) of the period of time for which the Diet Drugs PONDIMIN® and/or REDUX™ were prescribed and dispensed to the Diet Drug Recipient.

Settlement Agreement §VI.C.2.d.

3. The Settlement Agreement contemplates that a Claimant will use pharmacy records or a physician's medical records as documentary

proof of the period of ingestion of Diet Drugs, but recognizes that such records may be unobtainable. The Settlement Agreement thus provides that in those circumstances a Claimant may rely upon other documentation, as specified:

If the pharmacy records and medical records are unobtainable, an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy identifying the Diet Drug Recipient, the drug(s) prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the Diet Drug(s).

Settlement Agreement SVI.C.2.d(3).

4. Because pharmacy and medical records were unobtainable, Claimant provided the and affidavits as proof of the period of time for which ingested Diet Drugs.

5. The Trust concluded in the Final Determination that:

Claimant's Affidavit is not acceptable as proof of Diet Drug use as the Settlement Agreement explicitly provides for submission of an affidavit from "the prescribing physician or dispensing pharmacy," and Claimant is neither.

Final Determination at 4 (quoting Settlement Agreement SVI.C.2.d(3)).

6. The Trust concluded further that:

the affidavits of , and are not acceptable as proof of Diet Drug use because, even if the affidavits of and were accepted as affidavits of the "dispensing pharmacy," none of the affidavits identify the "date(s), frequency, dosage and number of prescriptions or refills of the Diet Drug(s)." affidavit in fact concedes that cannot swear that Pondimin was dispensed to [Claimant] at Pharmacy.

Final Determination at 4 (quoting Settlement Agreement SVI.C.2.d(3)).

7. The Trust thus held correctly that "under the plain language of the Settlement Agreement, the documentation provided to the Court is insufficient to establish Diet Drug use." Final Determination at 4.

8. In Appellant's Statement of the Case, dated (Appellant's Statement), Claimant (referred to herein as "Appellant") argues the following with respect to proof of ingestion of Diet Drugs:

Appellant has submitted four (4) affidavits - one from the dispensing pharmacist and two (2) from employees who worked at the pharmacy and who are likely in a better position than even the pharmacist to provide such proof. Add to this the fact that two (2) Board Certified Cardiologists have determined that Appellant has the very heart condition (moderate mitral regurgitation and a 55% ejection fraction) caused by ingestion of the drug and it certainly appears, even under the "totality of circumstances" test, that Appellant has met burden of proof.

Appellant's Statement at 2.

9. This argument is without merit. Its reliance on the four affidavits ignores the plain language of the Settlement Agreement requiring the documentation to include specific information about Claimant's Diet Drug usage. Even if that language were to be ignored, and the so-called "'totality of the circumstances' test" used, the complete lack of information provided by the affidavits as to the key factors of how long and in what quantities the Diet Drugs were dispensed or ingested makes them of little, if any, probative value. Finally, under no aspect of the Settlement Agreement does the mere attestation that Claimant has conditions such as moderate mitral valve regurgitation and a 55% ejection fraction itself establish proof of ingestion.

B. Detrimental Reliance

10. The Settlement Agreement provides that the Trust must "afford each Class Member at least three (3) separate opportunities to supply any missing or omitted information and documentation ...

necessary to support a Claim" Settlement Agreement §VI.C.3.b.
The Appellant's Statement asserts that:

Appellant's proof of ingestion was submitted to the Trust by letter dated . Since that time Appellant has received no deficiency notice as to missing information or documentation and has been afforded no opportunity (let alone three) to supply same.

Appellant's Statement at 1. That Statement then concludes that:

The Trust should not be allowed to, on one hand, ignore the express written provision of the Settlement Agreement, while, on the other hand, use the very terms of the Settlement Agreement in an effort to "stick it to" the Appellant.

Id. Appellant's Statement argues furthermore that the Trust not only "failed to comply with the terms of the Settlement Agreement as to Appellant's proof of ingestion, but has also allowed the claim to be processed, audited and to proceed through 'show cause' and 'contest.'" Id. Appellant's Statement concludes that "due to the actions, and lack thereof, by the Trust any issue as to proof of ingestion should be waived, as Appellant has detrimentally relied on such action or lack thereof." Id. At 2.

11. While the Appellant's Statement does not make Claimant's argument clear, it seems that Claimant is asserting that: (1) the Trust failed to comply with the Settlement Agreement's notice requirements, (2) thereby inducing detrimental reliance on Claimant's part, and (3) creating (or requiring) a waiver of the proof of ingestion requirement. That argument is based on a misreading of the Settlement Agreement, an unsubstantiated assertion of detrimental reliance and an unsupportable demand for waiver of proof of ingestion. It is without merit.

12. The Trust complied with Settlement Agreement Section VI.C.3.b by providing Claimant with three separate written notices of need to supply appropriate documentation regarding proof of ingestion. See Paragraph 13 supra. Claimant supplied documentation intended to provide that proof on . Claimant now seems

to be arguing that the Trust had an obligation to inform three times of the insufficiency of her documentation *after* it had been submitted and before the Post-Audit Determination of her Claim.

13. The Settlement Agreement does not support such an argument. Claimant had previously received the required three notices and responded to them by supplying four affidavits on The Settlement Agreement does not explicitly or implicitly require the Trust to evaluate the sufficiency of such documentation and then notify the Claimant of any deficiency before a Post-Audit Determination is reached. That evaluation takes place during the Post-Audit Determination process itself, and any deficiency is noted in the determination letter. By means of that letter, a Claimant is notified of any deficiency in proof of Diet Drug usage and given the opportunity to challenge that ruling by contesting the Post-Audit Determination. Claimant received a Post-Audit Determination dated informing that documentation failed to establish proof of ingestion. Claimant thereupon availed herself of the opportunity to contest that determination. The Settlement Agreement required nothing more of the Trust.

14. Claimant's assertion of detrimental reliance does not identify any detriment suffered by the Claimant as a result of the Trust's actions, alleged inactions or representations. Claimant received the opportunities to present case and the full range of due process required by the Settlement Agreement, including the opportunity to contest the Post-Audit Determination. Nothing in the record indicates that the Trust did anything to hamper Claimant in finding further documentary proof of ingestion. Claimant does not explain what would or could have done differently had not relied on whatever she believes the Trust did or did not do. In short, nothing in the record or Claimant's arguments at the Arbitration Hearing establishes any kind of detrimental reliance.

15. Finally, the Claimant's demand for waiver of the proof of ingestion requirement fails because the Trust has no authority

under the Settlement Agreement to waive that requirement. Even if it had such authority, "[allowing] the claim to be processed, audited and to proceed through 'show cause' and 'contest,'" all as required by the Settlement Agreement, hardly constitutes a basis for finding any kind of waiver.

CONCLUSION

1. The Trust's Final Determination is not clearly erroneous. Claimant is not entitled to Matrix Level Benefits.

2. The Trust's Final Determination is Affirmed.

DATE

ARBITRATOR