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

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

FINDINGS OF FACT

1. On , the AHP Settlement Trust ("Trust") issued a Final Determination in the matter of the Estate of (sometimes hereinafter "Claimant") and awarded Claimant compensation in the amount of $140,534 pursuant to Matrix B-1, Level III.

2. On , Claimant filed an appeal from the award of benefits by the Trust, and requested that the United States District Court ("Court") refer this matter to Arbitration. The appeal was assigned docket number

3. On , the claim of the Estate of 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 , an Arbitration Hearing was held concerning the claim of the Estate of The Estate of was represented by , son of , was a non-participating observer.

ANALYSIS

1. The issue presented in this Arbitration is uncomplicated yet extremely difficult: whether Claimant established that she ingested Diet Drugs for 61 days or more, this issue determining whether benefits are paid on the A-1 Matrix or the B-1 Matrix.

2. There is no dispute about Claimant's entitlement to compensation at Level III.[1]

ı (also sometimes hereinafter "Claimant") was a Diet Drug Recipient. This is established by Claimant's pharmacy records, which confirm that she was dispensed 90 Pondimin on November 17, 1996. In support of her claim for Matrix compensation, Ms. submitted a GREEN Form, completed by a Board-Certified Cardiologist. Because ıad severe mitral regurgitation, she met the definition of FDA Positive, thus making her eligible for Matrix Compensation. *See* Settlement Agreement at Section I.22 and Claimant's GREEN Form, Question C.3.a. Because after ingestion of Pondimin Claimant had an ejection fraction of 40-49% and severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the mitral valve (but the surgery was not performed because the patient declined to consent to surgery), Claimant was qualified to receive Matrix-Level III benefits. *See* GREEN Form, Questions F. 8 and F.10.

3. The dispute in this matter is about whether Claimant's compensation should be paid on Matrix A-1 or Matrix B-1. To be eligible for compensation on Matrix A-1, a Diet Drug Recipient must have ingested Diet Drugs for 61 days or more. *See* Settlement Agreement, Section IV.B.2.d.(1). Diet Drug Recipients who ingested Diet Drugs for sixty days or less

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[1] In her GREEN Form, Claimant sought compensation at Level IV on Matrix A-1. In the Arbitration Statement of the Case, Claimant concedes that payment should be made at Level III.

receive compensation on Matrix B-1. *Id.*, at IV.B.2.d.(2)(b). Claimant's position is that

ook Pondimin for more than sixty days, that accordingly her claim should be paid at Level III on Matrix A-1, and that the Trust erred in placing the claim at Level III on Matrix B-1.

4. The Settlement Agreement imposes on the Claimant the burden of proving the length of time that Diet Drugs were ingested (Settlement Agreement at Section VI.C.2.d.) and requires that the proof include one of the following:

> 1) Pharmacy Records: If the Diet Drug was dispensed by a pharmacy, the identity of each pharmacy that dispensed Diet Drugs to the Diet Drug Recipient, including its name, address, and telephone number, and a copy of the prescription dispensing record(s) from each pharmacy, which should include the medication name, quantity, frequency, dosage and number of refills prescribed, prescribing physician's name, assigned prescription number, original fill date and each subsequent refill date. *Id.*, at VI.C.2.d.(1).
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> 2) Prescribing Physician Information: If the Diet drug was dispensed directly by a physician or weight loss clinic, or the pharmacy record(s) is unobtainable, the identity of each prescribing physician, including the prescribing physician's name, address, and telephone number and a copy of the medical record(s) prescribing or dispensing the Diet drug(s). The medical record(s) must include records which identify the Diet Drug Recipient, the Diet Drug name, the date(s) prescribed, the dosage, and duration the drug was prescribed or dispensed. *Id.* at VI.C.2.d.(2).
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> 3) Defined Alternatives: 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). *Id.*, at VI.C.2.d.(3).

Claimant's pharmacy records show that 90 Pondimin were dispensed to Claimant on November 17, 1996. The pharmacy records do not reveal frequency or dosage, which Settlement Agreement Section VI.C.2.d.(1) requires.

5. The Trust is correct that the Claims Processing Procedures state that "If the claimant's Claim Form or medical records reveal that the drug was used for 60 days or less, the claim would fall in the 60 days or less category, even if the prescription were written for longer

than 60 days." Claims Processing Procedures, Duration of Use, ¶ 4. The Claims Processing Procedures also state that "A claimant may rebut the presumption that the claimant ingested the diet drugs for 60 days or less with credible proof that the drug was ingested on more days than shown in the prescription." *Id.* at ¶ 2. The Claims Processing Procedures further provide that "The Parties agree that a medical record contemporaneous with use indicating longer-term use would be sufficient to rebut the presumption." *Id.* at ¶ 3. Consistent with this, in both its Arbitration Statement Outline and Calculation of Benefits and its Response to Appellant's Statement of the Case, the Trust cited Claimant's medical records as evidence of Diet Drug use. During the Arbitration Hearing, the Trust's representative confirmed that such consultation is the Trust's usual procedure. The question to be resolved here is what those medical records show. The Trust asserts that the medical records show at most 55 days of Diet Drug usage, with the final Pondimin pill being ingested on February 6, 1997.

6. After the November 14, 1996 entry showing that Claimant was prescribed Pondimin, Claimant's medical records show interrupted use of Pondimin. The December 5, 1996 entry in Claimant's Medical Records states that Claimant "went off Pondimin" (no date given), to be restarted in January, with an instruction to take Pondimin at dinner for 1-2 weeks, then add a lunch pill. The entry on February 6, 1997 is of key importance. The record shows a prescription for Zoloft (50 mg), and below it an entry for Claimant to discontinue taking Pondimin while on Zoloft. The problem is that the medical records after this are silent on further use of Pondimin. Nor do Claimant's medical records reveal when – or if – Claimant took the prescribed Zoloft.

Tragically, ı passed away. The dispensing pharmacy is no longer in business. Dr. ', who was the prescribing physician, is unable to help as she no longer has

any personal knowledge of claimant beyond the information in her office records.

7. Claimant's position is that the total of the evidence submitted justifies a finding of Diet Drug use in excess of 60 days. In addition to the Pharmacy and Medical records, Claimant relies as evidence of Pondimin ingestion in excess of 60 days on her BLUE Form; her GREEN Form; a letter from Claimant's cardiologist, Dr. , written to Claimant's counsel, dated October 13, 2004; and a certification of , dated March 20, 2009. Though no doubt sincere, these additional items are insufficient to sustain Claimant's Burden of Proof.

In her BLUE Form, Claimant stated under penalty of perjury that she had ingested Pondimin for 61 days or more. *See* BLUE Form, Questions 7 and 8. I agree with the Trust that statements in the BLUE Form, even under penalty of perjury, do not meet the required method of proving either the fact or duration of Diet Drug use. *See* Settlement Agreement at Section VI.C.2.d.; *see also* ¶ 4, above. *And see* PTO #7779, Bartle, J. During the Arbitration Hearing, Claimant asserted that her GREEN Form, attested to by , a Board-Certified Cardiologist, lent added weight to her claim of use of diet drugs in excess of 60 days. I agree with the Trust that the purpose of the GREEN Form is to establish a Claimant's medical condition, and is not an accepted means to establish either the fact or duration of Diet Drug ingestion. *See* Settlement Agreement at Section VI.C.2.d.; *see also* ¶ 4, above.

In his letter to Claimant's Counsel dated October 13, 2004, Dr. Claimant's cardiologist, stated that claimant "had taken Pondimin in 1996 and had taken a total of 90 tablets. She was taking 20 mg on a daily basis for 90 days." Dr. letter is not a contemporaneous medical record, as is contemplated by Claims Processing Procedures, Duration of Use, ¶ 3. Moreover, there is no basis from which to conclude that Dr. had any

contemporaneous knowledge of 's use of Pondimin. Indeed, a fair conclusion is that his assertion is merely the report of information he received from in 2004, made after the litigation had ensued and the significance of length of usage was known.

Claimant also submitted a certification of , dated March 20, 2009. was Claimant's close personal friend for approximately 40 years. In her Certification, stated that she and Claimant attempted to lose weight together and were both prescribed Pondimin in November, 1996. She further stated that within the first month Claimant stopped using the Pondimin because she developed dry mouth and dizziness, a fact noted in Claimant's medical record of December 5, 1996. further stated in her Certification that within several days of stopping the medication, Claimant resumed taking Pondimin. Although she could not state with certainty that Claimant completed usage of her prescription, did state with certainty that appellant used Pondimin at least through Valentine's Day on February 14, 1997. I am unpersuaded by assertions for two reasons. First, by her admission confirms that at some point stopped taking Pondimin because of undesired side effects. Though asserts that resumed taking Pondimin within "several" days, she does not specify how she knows this. Nor does she acknowledge awareness of Claimant's removal from Pondimin in December, 1996, which Claimant's medical records confirm. Most importantly, even taken in the light most favorably to the Claimant, the Certification of establishes that, as of Valentine's Day 1997, was pleased with the effects of Pondimin. Even if one accepts as true that was pleased with Pondimin's effects on Valentine's Day, 1997, such a conclusion establishes only her state of mind; it does not establish that use of Pondimin continued up to and including the time of the Valentine's Day conversation.

8. The determination of this matter thus turns on Claimant's medical records. It is the position of the Trust, reasserted during the Arbitration hearing, that the state of the evidence compels the conclusion that the last Pondimin pill was ingested on February 6, 1997, and that Claimant has proved, at most, 55 days of Pondimin use. *See* Trust Arbitration Statement Outline and Calculation of Benefits at V. According to the Trust, it arrived at this conclusion as follows:

> The Rx Place prescription labels document that Claimant filled a prescription for 90 20mg tablets of Pondimin on 11/17/96. The Progress Notes document that Claimant took Pondimin from 11/17/96, when the prescription was filled, through (at most) 12/5/96, and indicate that Pondimin was restarted on or about 1/2/97 and was taken through 2/6/97 (when Claimant was instructed to discontinue taking Pondimin while taking Zoloft). *Id.*

Based on its calculation, "The Trust determined that the Rx Place records and Progress Notes, taken together, support fifty-five (55) days of use." *Id.* On this basis, the Trust awarded Claimant Level III benefits on Matrix B-1.

9. I accept the Trust's method of analysis. I disagree, however, with its conclusion that the evidence fails to establish Pondimin use after February 6, 1997. In order for the Claimant's medical records to overcome the rebuttable presumption of the pharmacy record (that the 90 Pondimin pills were consumed), the medical records would have to have commanded a cessation of Diet Drug usage. They do not. Rather, the February 6, 1997 medical records Progress Note instructs Claimant to discontinue Pondimin ingestion *while on Zoloft* (emphasis supplied). The clear meaning of this is not that Pondimin should be stopped irrespective of events (e.g. no matter what), but that Pondimin use should be discontinued only if and so long as a particular condition (use of Zoloft) exists. The clear implication is that once the condition ceases to exist, Pondimin use should be resumed, and if the condition never comes into existence Pondimin use should be continued. The Trust's position, however, is that because there is no

evidence that Claimant filled the Zoloft prescription or that Claimant ever resumed taking Pondimin, Claimant has failed to meet her burden of proof. Thus, in the Trust's view, the silence of the medical records after February 6, 1997, is a fact that favors the Trust. The Trust's argument would be persuasive if additional notations in the medical records would be expected. The instruction to Claimant, however, was complete as recorded: Pondimin was to be discontinued while on Zoloft. If Claimant were to resume taking Pondimin upon cessation of Zoloft use, no further entry was required. If Claimant were to continue taking Pondimin prior to ingesting the prescribed Zoloft, no further entry was required. So while it is true that the medical records do not affirmatively document completion of the 90 Pondimin, the silence does not alter the plain text of the February 6, 1997 Progress Note. I find that "Discontinue while on Zoloft" implies at most temporary interruption rather than a permanent cessation of Diet Drug ingestion and that the medical records support Claimant's claim that she completed the dispensed Diet Drugs.[2]

10. The remaining question is whether the Claimant has met her burden of proving that completion of the dispensed Diet Drugs took 61 days or more, and here I find Claimant has not sustained her burden of proof. The Trust has conceded that the medical records establish 55 days of Diet Drug use. If, therefore, the medical records establish six additional days of use, Claimant would be entitled to compensation on Matrix A-1. I do not believe the medical records carry the burden of establishing use for six additional days. Viewed in the light most favorable to

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[2] I reject Claimant's assertion (in its Statement of the Case) that claims that did not begin taking Zoloft until after she had finished the Pondimin, along with statements made to her physicians, sustains her burden of proof. The point is subtle, but real. My conclusion is that the record establishes that either continued taking Pondimin and not Zoloft, or returned to taking Pondimin after stopping Zoloft. The evidence does not favor one conclusion over the other. Therefore, I reject Claimant's assertion that the evidence supports a finding that Pondimin was continued prior to ingestion of Zoloft.

the Claimant, the medical records establish Diet Drug ingestion as follows:

11/17/96 through 12/5/96 = 19 days

1/2/97 through 2/6/97 = 36 days

This totals 55 days of usage. The December 5, 1996 entry in Claimant's Medical Records instructs Claimant to restart Pondimin in January 1997, with an instruction to take Pondimin at dinner for 1-2 weeks, then add a lunch pill. The last instruction presents the problem.

If Claimant consumed one Pondimin per day for each of the 55 days, she would have had 35 Pondimin remaining, more than enough to have exceeded 60 days of Pondimin ingestion before or after use of Zoloft. The medical records, however, instructed the Claimant to "add a lunch pill" after resuming Pondimin use in January, 1997. The evidence, thus, establishes the following.

If Claimant consumed one Pondimin per day for the first nineteen days, she would have had 71 Pondimin remaining from the initially prescribed amount. If Claimant resumed taking Pondimin in January, 1997 (as instructed) and took one Pondimin per day for a week (as the medical records can be read to suggest), that would have left 64 Pondimin. If Claimant then added a lunch pill (as the medical records instructed) for the remainder of the 29 days, consuming two Pondimin per day for a total of 58 Pondimin, that would have left, after February 6, 1997, six Pondimin from the initial prescription. Taking two pills per day, Claimant would have consumed Pondimin for a total of 58 days.

If, after consuming one Pondimin per day for the first nineteen days, Claimant resumed taking Pondimin in January, 1997 (as instructed) but took one Pondimin per day for *two* weeks (as the medical records can be read to suggest), that would have left 57 Pondimin. If Claimant then added a lunch pill (as the medical records instructed) for the remaining 22 days, consuming

two Pondimin per day for a total of 44 Pondimin, that would have left, after February 6, 1997, thirteen Pondimin from the initial prescription. Taken at two per day, Claimant would have consumed Pondimin for 61 days. In chart form, this information looks as follows:

Date	# Days	# Pondimin	Total Pills Consumed
11/17/96 through 12/5/96	19	19	19
1/2/97 though 1/8/97 (One pill per day for one week)	7	7	26
1/9/97 through 2/6/97	29	58	84

By the above calculation, there would have been six Pondimin remaining after February 6, 1997, yielding a maximum of 58 days ingestion.

Date	# Days	# Pondimin	Total Pills Consumed
11/17/96 through 12/5/96	19	19	19
1/2/97 though 1/15/97 (One pill per day for two weeks)	14	14	33
1/9/97 through 2/6/97	22	44	77

By the above calculation, there would have been thirteen Pondimin remaining after February 6, 1997, enough to have exceeded 60 days of ingestion.

The problem is that there is no basis from which to determine when Claimant followed her physician's advice to add a lunch pill to her Diet Drug regimen. If she waited two weeks, she would have had enough Pondimin to exceed 60 days. If she waited only one week, she would have had enough Pondimin for only three more days use. Sadly, there is no way to know, and the burden of proof on this issue is on the Claimant.

Claimant would have the Trust rely on its supplemental submissions to lend credence to its claim that Claimant's Diet Drug use exceeded 60 days, but the supplemental submissions do not help. The GREEN and BLUE Forms are not appropriate means of proof.

Certification does not establish the required ingestion of Diet Drugs, and one would have to

ignore Claimant's medical records in order to credit assertion that Claimant ingested Pondimin for 90 days.

In summary, I find that the Claimant's medical records show interruption, not cessation, of Pondimin ingestion. As such, Claimant has met its burden of establishing that ingested the 90 Pondimin which were dispensed to her. I do not find that Claimant has met its burden of proving that ingestion of the 90 Pondimin occurred on 61 days or more.

Accordingly, the Trust did not err in awarding Matrix Benefits on Matrix B-1, and the findings of the Trust are not clearly erroneous, as set forth in Rule 5 of the Rules Governing Arbitration Process.

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 Estate of is not entitled to payment on Matrix A-1 because of the presence of conditions that mandate compensation on Matrix B-1. Settlement Agreement, Sections IV.B.2.d.(2)(b).

Accordingly, based on all of the above, I find that the Estate of is entitled to Level III benefits payable on Matrix B-1.

3/29/10

DATE

Arbitrator