

DOCKET NO. 453-03-4081.M4
MDR Tracking No. M4-03-2822-01

VONO	§	BEFORE THE STATE OFFICE
	§	
v.	§	OF
	§	
UTICA MUTUAL INSURANCE	§	ADMINISTRATIVE HEARINGS
COMPANY	§	

DECISION AND ORDER

VONO seeks review of the decision by the Medical Review Division (MRD) of the Texas Workers' Compensation Commission (Commission) declining to order Utica Mutual Insurance Company (Carrier) to pay VONO additional reimbursement for dispensing carisoprodol, a muscle relaxant, to injured worker ___ (Claimant). VONO contends that it should be reimbursed at a higher rate for the eight prescriptions of carisoprodol, because the dispensed drug was generic. The Carrier reimbursed the prescriptions as if they were a brand name drug, resulting in reimbursement that was \$381.59 below the amount billed by VONO; this is the amount in dispute in this case. After considering the evidence and arguments of the parties, the Administrative Law Judge (ALJ) finds that VONO has not shown by a preponderance of the evidence that it should be reimbursed for the medication as if it were generic. Therefore, the ALJ declines to order additional reimbursement.

I. BACKGROUND

On the dates of services in issue, Claimant was being treated for a compensable, work-related injury. As part of his treatment, Claimant was prescribed carisoprodol, a muscle relaxant.¹ VONO billed the Carrier a total of \$3,013.20 for eight separate prescriptions of carisoprodol, and Carrier reimbursed VONO the total sum of \$2,631.61 for the prescriptions, leaving a difference of \$381.59. Carrier calculated its reimbursement by classifying the carisoprodol as a brand name drug and paying it accordingly. VONO requested medical dispute resolution, contending that the drug was actually generic and should have been reimbursed as a generic. Under the Commission's guidelines, the formula for calculating prescription drug reimbursements results in a higher payment ratio for generics than for brand name drugs.² Specifically, the Commission's rules provide in relevant part:³

¹ There is no dispute in this case that a muscle relaxant was medically necessary to treat Claimant's compensable injury.

² This means that generic drugs are reimbursed at a higher percentage of the actual wholesale price than are brand name drugs. While this may seem counterintuitive at first glance, it makes sense because generic drugs are usually priced significantly lower than brand name drugs. So, the system rewards the use of generic drugs by allowing for a higher reimbursement ratio for generic drugs compared to brand name drugs.

³ 28 TEX. ADMIN. CODE § 134.503(a).

(a) The maximum allowable reimbursement (MAR) for prescription drugs shall be the lesser of:

(1) The provider's usual and customary charge for the same or similar service;

(2) The fees established by the following formulas based on the average wholesale price (AWP) determined by utilizing a nationally recognized pharmaceutical reimbursement system (e.g. Redbook, First Data Bank Services) in effect on the day the prescription drug is dispensed.

(A) Generic drugs: $((\text{AWP per unit}) \times (\text{number of units}) \times 1.25) + \4.00 dispensing fee ' MAR;

(B) Brand name drugs: $((\text{AWP per unit}) \times (\text{number of units}) \times 1.09) + \4.00 dispensing fee ' MAR;

(C) A compounding fee of \$15 per compound shall be added for compound drugs; or

(3) A negotiated or contract amount.

After conducting medical dispute resolution, MRD denied any additional reimbursement. VONO appealed, requesting a hearing before the State Office of Administrative Hearings (SOAH). On October 2, 2003, ALJ Craig R. Bennett convened a hearing in this case. VONO appeared through its designated representative, Nicky Otts. Carrier appeared through its designated representative, Kenneth Sack. The hearing concluded and the record closed that same day.

II. DISCUSSION AND ANALYSIS

A. Parties' Arguments

The sole issue in this case is whether the carisoprodol provided by VONO is a generic drug or a brand name drug. VONO argues that it is a generic drug, citing to the 2002 *Redbook*, published by Thomson Healthcare, which purportedly lists the carisoprodol manufactured by GM Pharmaceuticals as a generic. At the hearing, VONO's witness, Nicky Otts, testified that GM Pharmaceuticals previously marketed carisoprodol under the brand name "Vanadom" but, in 2000 or 2001, revised its packaging and package amounts and started marketing the product as a generic. Accordingly, VONO contends that it is now a generic and VONO is entitled to be reimbursed for it as such.

Carrier responds by arguing that the drug sold by GM Pharmaceuticals is the same product, with the same product code, previously marketed as Vanadom. Carrier witness Kenneth Sack testified that Carrier's reimbursement was based on the NDC code (essentially a product code that identifies the maker, the product, and the product quantity) used by VONO. Because the NDC code for the carisoprodol in issue is the exact same code as the drug marketed as Vanadom by GM Pharmaceuticals, Carrier argues that it is simply Vanadom disguised as a generic, but still sold at a brand name price. Carrier points out that the carisoprodol sold by GM Pharmaceuticals costs nearly five times as much as the generic carisoprodol sold by other drug manufacturers, thus reflecting the

reality that it is still priced as a brand name drug.⁴ Carrier argues that it attempted to obtain information from VONO that might establish whether VONO actually ordered Vanadom by name from GM Pharmaceuticals, as opposed to simply purchasing generic carisoprodol, but asserts that VONO has refused to provide such information.

B. ALJ's Analysis

After considering the arguments and evidence, the ALJ finds that VONO has failed to establish by a preponderance of the evidence that the carisoprodol provided in this matter was, in fact, a generic drug entitled to be reimbursed under the Commission's generic drug reimbursement formula. Accordingly, the ALJ declines to order additional reimbursement.

Past SOAH decisions have recognized Vanadom as a brand name drug.⁵ The NDC code for the carisoprodol purchased from GM Pharmaceuticals is the exact same as that used for Vanadom, indicating that the two are actually the same. While the Commission's rules do not clearly define and distinguish brand name drugs from generics, generics are generally recognized as being cheaper in cost and lacking in a recognized product name. In this case, the GM Pharmaceuticals carisoprodol certainly does not appear to be cheaper. Petitioner's Exhibit 1 shows that the 500-count, 350 mg form of carisoprodol distributed by GM Pharmaceuticals has a wholesale price of \$1,370.65, while comparable carisoprodol by Able, Duramed and Geneva Pharmaceuticals are priced at \$291.00, \$289.28, and \$286.38, respectively. Other manufacturers provided comparable generic drugs at even less. Even the most expensive of the other carisoprodol generics in the *Redbook* was priced at only \$318.20, still less than 25% of the price of GM Pharmaceuticals' carisoprodol for a comparable amount.

Moreover, GM Pharmaceuticals' carisoprodol is associated with the recognized branded product name of Vanadom, even when not called by that name. It is true, as VONO alleges, that the *Redbook* identifies the carisoprodol from GM Pharmaceuticals with other generics; however, immediately under the listing, it also references Vanadom, and the evidence shows that the two products have the exact same NDC code, thus making the drugs indistinguishable except in the name used. The ALJ is not persuaded that simply because GM Pharmaceuticals stopped packaging its carisoprodol as "Vanadom" the drug is now "generic" within the meaning of the Commission's rules. VONO has presented no authority to support this position. In fact, both parties failed to present significant legal authority or evidence to support their positions. Because the burden of proof is on VONO, ultimately this proves fatal to its case; the ALJ simply cannot conclude that the preponderance of the evidence establishes GM Pharmaceuticals' carisoprodol as a generic drug. In support of this determination, the ALJ makes the following findings of fact and conclusions of law.

⁴ See Petitioner's Exhibit 1, at 7-8.

⁵ See *HighPoint Pharmacy v. University of Texas System*, 453-02-1896.M5, Decision and Order, at 8 (September 30, 2002) (ALJ Church); *EZ Rx Pharmacies v. University of Texas System*, 453-02-1803.M4, Decision and Order, at 4 (October 24, 2002) (ALJ Landeros).

III. FINDINGS OF FACT

1. On ____, ____ (Claimant) suffered a compensable, work-related injury; at the time of his injury, Utica Mutual Insurance Company (Carrier) provided workers' compensation insurance coverage covering Claimant's injury.
2. Between April 17, 2002, and October 21, 2002, VONO dispensed eight separate prescriptions of carisoprodol to Claimant, pursuant to authorization from Claimant's physician.
3. The carisoprodol dispensed by VONO to Claimant was manufactured by GM Pharmaceuticals.
4. The carisoprodol dispensed by VONO to Claimant had the exact same NDC code as a drug called Vanadom, which is a brand-name carisoprodol drug previously marketed by GM Pharmaceuticals.
5. In 2000 or 2001, GM Pharmaceuticals revised its packaging and package amounts and started marketing Vanadom as simply carisoprodol.
6. The 500-count, 350 mg form of carisoprodol distributed by GM Pharmaceuticals has a wholesale price of \$1,370.65, while comparable generic carisoprodol by Able, Duramed and Geneva Pharmaceuticals are priced at \$291.00, \$289.28, and \$286.38, respectively.
7. Even the most expensive of the other carisoprodol generics in the 2002 *Redbook* is priced at only \$318.20Cstill less than 25% of the price of GM Pharmaceuticals' carisoprodolCfor a comparable amount.
8. VONO billed the Carrier a total of \$3,013.20 for the eight separate prescriptions of carisoprodol, and Carrier reimbursed VONO the total sum of \$2,631.61 for the prescriptions.
9. Carrier calculated its reimbursement by classifying the carisoprodol as a brand name drug and paying it accordingly.
10. Carrier declined to pay any additional reimbursement, and VONO appealed Carrier's decision to the Medical Review Division (MRD) of the Texas Workers' Compensation Commission (Commission).
11. On June 20, 2003, MRD declined to order Carrier to reimburse VONO any additional amount for the carisoprodol dispensed between April 17, 2002, and October 21, 2002.
12. On June 30, 2003, VONO requested a hearing regarding MRD's decision, and the case was referred to the State Office of Administrative Hearings (SOAH).

13. On July 29, 2003, the Commission issued a notice of hearing which included the date, time, and location of the hearing, and the applicable statutes under which the hearing would be conducted.
14. On October 2, 2003, Administrative Law Judge (ALJ) Craig R. Bennett conducted a hearing on the merits in this matter. VONO appeared through its designated representative, Nicky Otts. Carrier appeared through its designated representative, Kenneth Sack. The hearing concluded and the record closed that same day.

IV. CONCLUSIONS OF LAW

1. SOAH has jurisdiction over this proceeding, including the authority to issue a decision and order, pursuant to the Texas Workers' Compensation Act (the Act), specifically TEX. LABOR CODE ANN. §413.031(k), and TEX. GOV'T CODE ANN. ch. 2003.
2. The hearing was conducted pursuant to the Administrative Procedure Act, TEX. GOV'T CODE ANN. ch. 2001 and 28 TEX. ADMIN. CODE ch. 148.
3. The request for a hearing was timely made pursuant to 28 TEX. ADMIN. CODE § 148.3.
4. Adequate and timely notice of the hearing was provided according to TEX. GOV'T CODE ANN. §§ 2001.051 and 2001.052.
5. VONO has the burden of proof in this matter. 28 TEX. ADMIN. CODE §148.21(h).
6. VONO failed to establish, by a preponderance of the evidence, that GM Pharmaceuticals' carisoprodol is a generic drug and should be reimbursed as a generic drug under the Commission's guidelines.
7. Petitioner's request for additional reimbursement should be denied.

ORDER

IT IS HEREBY ORDERED THAT VONO is entitled to no additional reimbursement for the eight prescriptions of carisoprodol dispensed to injured worker ___ between April 17, 2002, and October 21, 2002.

ISSUED this 8th day of October 2003.

CRAIG R. BENNETT
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS