[Cite as *State ex rel. Honda of Am. Mfg., Inc. v. Indus. Comm.*, 2013-Ohio-286.]

IN THE COURT OF APPEALS OF OHIO

TENTH APPELLATE DISTRICT

State ex rel. Honda of America Mfg., Inc.,	:	
Relator,	:	
v.	:	No. 12AP-268
Industrial Commission of Ohio and Nathan R. Lawson,	:	(REGULAR CALENDAR)
Respondents.	:	

D E C I S I O N

Rendered on January 31, 2013

Vorys, Sater, Seymour and Pease LLP, and *Robert A. Minor*, for relator.

Michael DeWine, Attorney General, and *Andrew J. Alatis*, for respondent Industrial Commission of Ohio.

Agee, Clymer, Mitchell & Laret, Eric B. Cameron, Robert M. Robinson, Katherine E. Ivan and C. Russell Canestraro, for respondent Nathan R. Lawson.

IN MANDAMUS
ON OBJECTIONS TO THE MAGISTRATE'S DECISION

KLATT, P.J.

{¶ 1} Relator, Honda of America, Mfg., Inc., commenced this original action in mandamus seeking an order compelling respondent, Industrial Commission of Ohio ("commission"), to vacate its order granting the motion of respondent, Nathan R. Lawson

("claimant") for authorization of payment for Lidoderm patches, and to enter an order denying said motion.

{¶ 2} Pursuant to Civ.R. 53(C) and Loc.R. 13(M) of the Tenth District Court of Appeals, we referred this matter to a magistrate who issued a decision, including findings of fact and conclusions of law, which is appended hereto. The magistrate found that (1) neither the Ohio Bureau of Workers' Compensation's ("bureau") Lidoderm policy nor the FDA's limited approval of Lidoderm's use for treatment of postherpetic neuralgia ("PHN") prohibited the commission from authorizing payments for Lidoderm patches in a claim that is not allowed for PHN; and (2) the commission's order does not create for relator a dilemma for which a writ of mandamus must issue. Therefore, the magistrate has recommended that we deny relator's request for a writ of mandamus.

{¶ 3} Relator has filed objections to the magistrate's decision. In its first objection, relator emphasizes that Lidoderm is only federally approved for the treatment of PHN. Relator also points out that the bureau's reimbursement guidelines permit reimbursement for Lidoderm only when PHN is an allowed condition in the claim. Because Lidoderm is not federally approved for use other than for treatment of PHN, and because the bureau only permits reimbursement for Lidoderm when PHN is an allowed condition, relator argues that Lidoderm is not a medical service reasonably related to the claimant's allowed conditions and is not reasonably necessary for the treatment of his allowed conditions as required by *State ex rel. Miller v. Indus. Comm.*, 71 Ohio St.3d 229 (1994). Therefore, relator contends that the commission abused its discretion when it authorized payment for Lidoderm. We disagree.

{¶ 4} As noted by the magistrate, the commission is not bound by the bureau's Lidoderm's policy or the FDA's limited approval of Lidoderm's use. *State ex rel. Sugardale Foods, Inc. v. Indus. Comm.*, 90 Ohio St.3d 383 (2000). Even relator agrees with this basic proposition of law. The question then becomes whether there is some evidence upon which the commission could rely to conclude that Lidoderm is medically indicated and medically necessary to treat the allowed conditions.

{¶ 5} The commission relied upon the medical opinion of Dr. May. Dr. May expressly opined that the "off-label use" of Lidoderm was medically indicated and medically necessary to treat the allowed conditions. Because Dr. May's opinion is some

evidence supporting its decision, the commission did not abuse its discretion in authorizing payment for Lidoderm. Therefore, we overrule relator's first objection.

{¶ 6} In its second objection, relator argues that the commission abused its discretion when it approved the payments for Lidoderm because the bureau's policy only permits reimbursement for Lidoderm when PHN is an allowed condition in the claim. Again, we disagree.

{¶ 7} The commission is the adjudicatory arm of Ohio's Workers' Compensation system. R.C. 4121.34(B)(3) gives the commission's district hearing officers original jurisdiction over all matters that are contested under R.C. Chapter 4123. "The bureau gives way to the commission when a party contests an award, necessitating a weighing of evidence and a judgment. The bureau then makes the payments based upon the commission's judgments." *State ex rel. Crabtree v. Ohio Bur. of Workers' Comp.*, 71 Ohio St.3d 504, 507 (1994). The bureau's duty under R.C. 4121.39(C) to " '[m]ake payment on orders of the industrial commission and district and staff hearing officers' is consistent with the bureau's other ministerial functions." *Id.* Here, the bureau is obligated to follow the commission's order, despite the bureau's reimbursement guidelines. Therefore, the commission did not abuse its discretion and we overrule relator's second objection.

{¶ 8} Following an independent review of this matter, we find that the magistrate has properly determined the facts and applied the appropriate law. Therefore, we adopt the magistrate's decision as our own, including the findings of fact and conclusions of law contained therein. In accordance with the magistrate's decision, we deny relator's request for a writ of mandamus.

Objections overruled; writ of mandamus denied.

BROWN and McCORMAC, JJ., concur.

McCORMAC, J., retired, of the Tenth Appellate District, assigned to active duty under authority of Ohio Constitution, Article IV, Section 6(C).

APPENDIX

IN THE COURT OF APPEALS OF OHIO

TENTH APPELLATE DISTRICT

State ex rel. Honda of America Mfg., Inc.,	:	
Relator,	:	
v.	:	No. 12AP-268
Industrial Commission of Ohio and Nathan R. Lawson,	:	(REGULAR CALENDAR)
Respondents.	:	

M A G I S T R A T E ' S D E C I S I O N

Rendered on October 25, 2012

Vorys, Sater, Seymour and Pease LLP, Robert A. Minor, Carl D. Smallwood, and *Gina R. Russo*, for relator.

Michael DeWine, Attorney General, and *Andrew J. Alatis*, for respondent Industrial Commission of Ohio.

Agee, Clymer, Mitchell & Laret, Eric B. Cameron, Robert M. Robinson, Katherine E. Ivan and C. Russell Canestraro, for respondent Nathan R. Lawson.

IN MANDAMUS

{¶ 9} In this original action, relator, Honda of America Mfg., Inc. ("relator" or "Honda"), requests a writ of mandamus ordering respondent Industrial Commission of Ohio ("commission") to vacate its order granting the motion of respondent Nathan R. Lawson ("claimant") for authorization of payment for Lidoderm patches, and to enter an order denying the motion.

Findings of Fact:

{¶ 10} 1. On September 11, 2007, claimant sustained an industrial injury while employed by relator, a self-insured employer under Ohio's Workers' Compensation Laws.

{¶ 11} 2. The industrial claim (No. 07-859059) is allowed for:

> Right shoulder sprain/strain; right elbow lateral epicondylitis; severe tendinopathy right shoulder; bursitis right shoulder; impingement syndrome right shoulder.

{¶ 12} 3. On May 2, 2011, at relator's request, Marc W. Whitsett, M.D., performed a medical file review regarding the appropriateness of medications being prescribed for claimant. In his four-page narrative report, Dr. Whitsett opined:

> There is insufficient evidence to support that the Lidoderm is reasonably related or medically substantiated and appropriate for the treatment of the allowed conditions. Lidoderm is FDA approved for the treatment of pain from postherpetic neuralgia. There is no indication that Lidoderm is reasonable or supported based on the current allowed conditions.
>
> * * *
>
> There are no significant Lidoderm adverse effects on an acute or long term basis of significance.

{¶ 13} 4. On May 27, 2011, Dr. Whitsett issued an addendum to his May 2, 2011 report following his receipt and review of additional medical records. His May 27, 2011 addendum states:

> There is no indication based on this additional information that my opinion related to Lidoderm is changed. It is my medical opinion that Lidoderm is not reasonably related or medically substantiated or appropriate treatment for the allowed conditions.

{¶ 14} 5. By letter dated June 2, 2011, citing Dr. Whitsett's reports, Honda informed claimant that payment for Lidoderm was terminated as of June 2, 2011.

{¶ 15} 6. On June 13, 2011, treating physician, Charles B. May, D.O., wrote:

> [Dr. Whitsett] simply relies upon the fact that Lidoderm patches are only approved by the FDA for treatment of

> postherpetic neuralgia. He obviously does not allow for any off label prescribing of this medication. We have prescribed this topical medication for Mr. Lawson in treatment of his shoulder pain and in my medical opinion these Lidoderm patches have been successful in treating his shoulder pain. Again this is an off label use and in my medical opinion it is medically indicated and medically necessary based upon the allowed conditions in his right shoulder claim.

{¶ 16} 7. On June 27, 2011, citing Dr. May's report, claimant moved for approval of Lidoderm patches.

{¶ 17} 8. Following an August 15, 2011 hearing, a district hearing officer ("DHO") issued an order granting claimant's motion.

{¶ 18} 9. Relator administratively appealed the DHO's order of August 15, 2011.

{¶ 19} 10. Following a September 22, 2011 hearing, a staff hearing officer ("SHO") issued an order affirming the DHO's order. The SHO's order exlains:

> The Staff Hearing Officer affirms the District Hearing Officer decision to authorize payment for Lidoderm patches consistent with Bureau of Workers' Compensation cost guidelines. The Staff Hearing Officer agrees with the District Hearing Officer that this type of medication is medically reasonable and necessary to treat the allowed conditions.
>
> This order is based upon the report of Dr. May dated 06/13/2011. In that report Dr. May stated that the Lidoderm patches do have a pain relieving quality that is used to treat the Injured Worker's shoulder condition. While officially the Lidoderm patches are not prescribed for pain control, Dr. May explained that off label prescribing allows Lidoderm patched [sic] to be used to treat pain.
>
> The Injured Worker testified that these Lidoderm patches have been successful in helping to control his pain. He testified that when he uses these Lidoderm patches he does not use his pain medication. Therefore, the Staff Hearing Officer is persuaded that Lidoderm patches are an appropriate pain medication for the allowed conditions based on the aforementioned explanation.

{¶ 20} 11. On October 19, 2011, another SHO mailed an order refusing relator's administrative appeal from the SHO's order of September 22, 2011.

{¶ 21} 12. On November 30, 2011, the three-member commission, on a two-to-one vote, mailed an order denying reconsideration.

{¶ 22} 13. On March 27, 2012, relator, Honda of America Mfg., Inc., filed this mandamus action.

Conclusions of Law:

{¶ 23} The parties do not dispute that it is the policy of the Ohio Bureau of Workers' Compensation ("bureau") that reimbursement for Lidoderm will not be considered unless the claim is allowed for postherpetic neuralgia ("PHN"). It is also undisputed that the United States Food and Drug Administration ("FDA") has approved the use of Lidoderm solely for treatment of PHN.

{¶ 24} Two issues are presented: (1) did the bureau's Lidoderm policy and the FDA's limited approval of Lidoderm's use prohibit commission approval of its use in a claim that is not allowed for PHN, and (2) does the SHO's statement that Lidoderm patches are authorized "consistent with Bureau * * * cost guidelines" create for relator a dilemma for which a writ of mandamus must issue?

{¶ 25} The magistrate finds: (1) neither the bureau's Lidoderm policy nor the FDA's limited approval prohibits commission approval of Lidoderm in a claim that is not allowed for PHN, and (2) the SHO's order does not create for relator a dilemma for which a writ of mandamus must issue.

{¶ 26} Accordingly, it is the magistrate's decision that this court deny relator's request for a writ of mandamus, as more fully explained below.

{¶ 27} The parties have stipulated to the August 2003 "Pharmacy Bulletin" published by the bureau. The bulletin states in part:

> Lidoderm® (lidocaine)- BWC will only consider reimbursement for this drug when a diagnosis of postherpetic neuralgia is recognized as an allowed condition in the injured worker's claim. Postherpetic neuralgia is the sole FDA-approved indication for this drug.

{¶ 28} The parties have also stipulated to the July 2009 "Provider Update, Billing and Reimbursement" published by the bureau. The update states in part:

> We made a number of policy changes to the outpatient drug benefit for Ohio's injured workers. Our pharmacy and therapeutics committee, and health-care quality assurance

> advisory committee reviewed and approved these changes. We intend for them to ensure effective treatment and outcomes at the appropriate cost. We will include additional information regarding these policy changes in the next release of the *Billing and Reimbursement Manual*. We list the medications impacted by these changes below.
>
> Lidoderm (lidocaine) – We consider it for reimbursement if post-herpetic neuralgia is an allowed condition in the claim.

(Emphasis sic.)

{¶ 29} According to the Lidoderm website: "Lidoderm® (lidocaine patch 5%) is the only lidocaine-based patch that you can apply that is FDA-approved for pain relief from postherpetic neuralgia, commonly called after-shingles pain." http://www.lidoderm.com/Default.aspx (accessed oct. 15, 2012).

{¶ 30} In *State ex rel. Miller v. Indus. Comm.*, 71 Ohio St.3d 229 (1994), the Supreme Court of Ohio articulated a three-pronged test for authorization of medical services: (1) are the medical services reasonably related to the industrial injury, that is, the allowed conditions (2), are the services reasonably necessary for treatment of the industrial injury, and (3) is the cost of such services medically reasonable?

{¶ 31} As earlier noted, the first issue asks: did the bureau's Lidoderm policy and the FDA's limited approval of Lidoderm's use prohibit commission approval of its use in a claim that is not allowed for PHN? *State ex rel. Sugardale Foods, Inc. v. Indus. Comm.*, 90 Ohio St.3d 383 (2000) answers the question or issue.

{¶ 32} In *Sugardale*, Clyde E. Sheets ("Sheets") injured his lower back while employed with the self-insured employer, Sugardale Foods, Inc. ("Sugardale"). His orthopedic surgeon recommended fusion of the L4-5 and L5-S1 levels with the addition of Steffee plates. The surgery was performed in 1994.

{¶ 33} As of 1994, the Steffee plating procedure had not been approved by the FDA and was generally considered too experimental by the bureau to qualify as a covered expense against the state insurance fund. As a result, the bureau typically refused to authorize the procedure when requested for employees covered by the state insurance fund.

{¶ 34} Following Sugardale's refusal to pay for the surgery, Sheets moved the commission for authorization which the commission granted.

{¶ 35} Sugardale's mandamus action resulted in this court's issuance of a writ of mandamus returning the cause to the commission for further review. Upon remand, the commission again authorized the procedure, and Sugardale filed its second mandamus action in this court. This court denied the writ and Sugardale appealed as of right to the Supreme Court of Ohio.

{¶ 36} One of the issues before the Supreme Court of Ohio in *Sugardale* was whether the bureau's policy regarding the Steffee plating procedure was merely a guideline or absolutely binding upon the commission. The court answered the issue as follows:

> The BWC's policy of denying authorization for procedures that are experimental or not FDA-approved, which generated the policy to deny Steffee plating procedures, was implemented pursuant to R.C. 4123.32(D). That statute describes such policies as "guidelines" and specifies that they are not administrative rules as defined by R.C. 119.01. Thus, the policy of denying payment for Steffee plating surgery is not so legally binding that it cannot be set aside. Rather, the policy could reasonably be disregarded when medical evidence removes the usual justification for rejecting these claims.

Id. at 387.

{¶ 37} The *Sugardale* decision essentially answers the first issue here. That is, the commission was not bound by the bureau's Lidoderm policy and the FDA's limited approval of Lidoderm's use when it adjudicated claimant's June 27, 2011 motion for approval of Lidoderm.

{¶ 38} It can be noted that the *Sugardale* case was initially cited and discussed by respondents. In its reply, relator concedes as follows:

> The essential argument by Respondent is the Industrial Commission is given wide latitude and discretion to make determinations in such disputed matters and that the BWC guidelines and the Food and Drug Administrator's approval are not binding. That is true. Respondents cite State, ex rel. Miller, v. Indus. Comm. (1994) 71 Ohio St.3d 229, and its sequelae [see, State, ex rel. Sugardale Foods, Inc., v. Indus.

> Comm., (2000) 90 Ohio St.3d 383; State, ex rel. Bax Global, Inc., v. Indus. Comm. (2007) 2007-Ohio-695] as demonstrating the discretion that the Industrial Commission has and the criteria for making such determinations.

(Relator's reply brief, at 1-2.)

{¶ 39} However, in its reply brief, relator adds to the issue here by arguing that the prescribing of Lidoderm patches fails to meet the *Miller* criteria. Relator argues in its reply:

> Given the BWC Guidelines and that post-herpetic neuralgia is the sole FDA approved indication for the drug, can it be said that the medical services are reasonably related to the industrial injury, that is the allowed conditions? The answer is no.

(Relator's reply brief, at 2.)

{¶ 40} This argument is essentially a rehash of relator's initial argument. That is, if the commission is not bound by the bureau's Lidoderm policy, then the bureau's Lidoderm policy cannot prohibit a finding that the Lidoderm prescription is reasonably related to the industrial injury. Relator also argues that Dr. May's June 13, 2011 report cannot be some evidence upon which the commission can rely to approve the Lidoderm patch because Dr. May's prescription of Lidoderm is inconsistent with the bureau's Lidoderm policy. Again, this is but a rehash of the initial argument. If the commission is not bound by the bureau's Lidoderm policy, neither is Dr. May.

{¶ 41} The second issue, as previously noted, is whether the SHO's statement that Lidoderm patches are authorized "consistent with Bureau * * * cost guidelines" creates for relator a dilemma for which a writ of mandamus must issue.

{¶ 42} Relator argues as follows:

> The staff hearing officer erred in ordering payment for Lidoderm patches, because this contradictory order creates a dilemma—either Honda pays $0 (i.e., does not pay) in order to comply with the portion of the order that requires payment "consistent with Bureau cost guidelines," or Honda pays for the medication and, thereby, violates the order. Honda cannot both be consistent with Bureau guidelines and pay for the medication on the evidence in this record. The order is thus contradictory and represents error.

(Emphasis sic.) (Relator's brief, at 3.)

{¶ 43} Relator's argument assumes that the words "consistent with Bureau * * * cost guidelines" is a reference to the bureau's Lidoderm policy as expressed in the August 2003 Pharmacy Bulletin. Absent the presumption, relator's argument fails. Relator fails to present any evidence to support the presumption. There is no dilemma. The SHO's order of September 22, 2011 is clear that relator's motion is granted and that the Lidoderm patch is authorized.

{¶ 44} Accordingly, for all the above reasons, it is the magistrate's decision that this court deny relator's request for a writ of mandamus.

/S/ MAGISTRATE
KENNETH W. MACKE

NOTICE TO THE PARTIES

Civ.R. 53(D)(3)(a)(iii) provides that a party shall not assign as error on appeal the court's adoption of any factual finding or legal conclusion, whether or not specifically designated as a finding of fact or conclusion of law under Civ.R. 53(D)(3)(a)(ii), unless the party timely and specifically objects to that factual finding or legal conclusion as required by Civ.R. 53(D)(3)(b).