IN THE SUPREME COURT, STATE OF WYOMING

2005 WY 155

OCTOBER TERM, A.D. 2005

December 2, 2005

IN THE MATTER OF THE WORKER'S COMPENSATION CLAIM OF:	)	
MICHAEL TARRAFERRO,	)	
Appellant (Petitioner) ,	)	
v.	)	No. 05-53
STATE OF WYOMING, ex rel., WYOMING MEDICAL COMMISSION and WYOMING WORKERS' SAFETY AND COMPENSATION DIVISION,	)	
Appellee (Respondent) .	)	

Appeal from the District Court of Laramie County
The Honorable E. James Burke, Judge

Representing Appellant:

Bill G. Hibbler, Cheyenne, Wyoming.

Representing Appellee:

Patrick J. Crank, Attorney General; Steve Czoschke, Senior Assistant Attorney General; and J.C. DeMers, Special Assistant Attorney General. Argument by Mr. DeMers.

Before HILL, C.J., and GOLDEN, KITE, and VOIGT, JJ., and GUTHRIE, D.J.

HILL, Chief Justice.

[¶1] Appellant, Michael Tarraferro (Tarraferro), contends that the Medical Commission (Commission) erred in considering inadmissible and incompetent evidence that it generated after the hearing on this matter had concluded, and that its decision that Tarraferro failed to meet his burden of proof that his use of the medication Marinol "was not experimental," as well as that its use "was necessary and reasonable," is erroneous. The only competent evidence of record requires that we reverse the Commission's order, as well as the district court's order affirming that decision, and direct that this matter be remanded to the Commission with directions that it void its decision to deny Tarraferro his Marinol prescription, and enter an order to the opposite effect.

ISSUES

[¶2] Tarraferro raises these issues:

> I. Whether the Medical Commission order is supported by substantial evidence?
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> II. Whether the Medical Commission order is contrary to law because it is based upon evidence gathered sua sponte by the panel outside of the hearing, in violation of Wyoming Statute § 16-3-107(j), (o) or (r) and/or § 16-3-108(c) or (d)?
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> III. Whether the Medical Commission order is contrary to law because it is based upon an issue not referred to and before it?
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> IV. Whether the Medical Commission order is arbitrary or capricious because it ordered payment of medical benefits even though it concluded payment of those benefits is contrary to Wyoming Statute § 27-14-102(a)(xii)?
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> V. Whether the Medical Commission order is contrary to law because the Workers' Compensation Division violated Wyoming Statute § 27-14-605(a), by improperly redetermining either the necessity, reasonableness or experimental use of Mr. Tarraferro's Marinol prescription?

The Workers' Compensation Division (Division) poses these issues:

> Is [Tarraferro] aggrieved or adversely affected for purposes of judicial review when the Medical Commission ordered payment of the actual claim at issue?
>
> Is the Medical Commission's finding that [Tarraferro] failed to prove entitlement to Marinol, a prescription drug, as a result of his 1998 left inguinal hernia reasonable and supported by substantial evidence?

FACTS AND PROCEEDINGS

[¶3] On February 28, 2003, Tarraferro submitted a claim to the Division so as to be reimbursed for a pain medication, Marinol, prescribed for him by his attending physician, a pain management specialist. At the time he submitted this claim, he had been taking Marinol for 22 months. The cost of a 30-day supply of Marinol at that time was $1,037.74.

[¶4] The Division denied the claim on the basis that: "THIS MEDICATION IS DENIED AS IT IS TO BE USED TO ASSIST CANCER AND AIDS PATIENTS. CURRENT SYMPTOMS DO NOT APPEAR TO MEET THE CRITERIA FOR MARINOL USE PER THE FDA GUIDELINES." That notice advised Tarraferro of his right to a hearing if he disagreed with that determination. On March 19, 2003, Tarraferro asked for a hearing. The Commission issued an order appointing counsel for Tarraferro on June 5, 2003, and scheduled a hearing for February 18, 2004. A hearing was held and the Commission issued findings of fact and conclusions of law, affirming the Division's denial of Tarraferro's claim. Tarraferro further appealed his case to the district court, and the district court issued an order affirming the Commission's order.

[¶5] We need not detail the severe and disabling injury that Tarraferro suffered, because the fact that he suffered such an injury, and was receiving worker's compensation benefits for it, is not at issue here. The only issue was whether Tarraferro's attending physician properly prescribed Marinol for his patient's pain symptoms. The following is a physician's description[1] of what brought Tarraferro to the use of Marinol:

[1] Of course, one of the limitations of medical science is that the body's five classic senses cannot provide any information to a diagnostician: "The examiner cannot see the pain, hear the pain, touch the pain, taste the pain, or smell the pain. Worse yet, though in an age of medical miracles, we cannot X-ray the pain, measure it like serum levels of hemoglobin or sodium, plot it on graph paper like an EEG, or cut it out like a tumor. There are no measuring devices like voltmeters to tell us whether a patient is experiencing mild, moderate, or severe pain. In short, there is no objective direct tangible physical evidence for pain itself." 6B *Lawyers' Medical Cyclopedia of Personal Injuries and Allied Specialties*, § 44A.1, at 251 (LEXIS Publishing 2000).

> This is a 40 year old gentleman who reports significant pain in the penis, scrotal and perineal areas ever since a severe pelvic crush injury 2 ½ years ago. This pain is always there, it is up to a 10 out of 10.[2] He describes it as a vise grip squeezing to the penis and testis. It seems to be worse following treatment with FLOMAX or SAW PALMETTO. No alleviating factors except pain medications. Associated symptoms are pain, nausea, rash.

STANDARD OF REVIEW

[¶6] Our review of an administrative decision is limited to those matters specified in Wyo. Stat. Ann. § 16-3-114(c) (LexisNexis 2005):

> (c) To the extent necessary to make a decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. In making the following determinations, the court shall review the whole record or those parts of it cited by a party and due account shall be taken of the rule of prejudicial error. The reviewing court shall:
>
> (i) Compel agency action unlawfully withheld or unreasonably delayed; and
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> (ii) Hold unlawful and set aside agency action, findings and conclusions found to be:
>
> (A) Arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law;
>
> (B) Contrary to constitutional right, power, privilege or immunity;
>
> (C) In excess of statutory jurisdiction, authority or limitations or lacking statutory right;
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> (D) Without observance of procedure required by law; or
>
> (E) Unsupported by substantial evidence in a case reviewed on the record of an agency hearing provided by statute.

[2] This one to ten scale is recognized as a measurement tool, wherein "they could probably assign a value of eight on a scale of ten to the usual pain level on the first day after surgery." 6B *Lawyers' Medical Cyclopedia of Personal Injuries and Allied Specialties*, *supra*, at 253.

The standard of review we apply when both parties present evidence at an administrative hearing was set forth in *Newman v. State ex rel. Wyoming Workers' Safety and Compensation Division*, 2002 WY 91, 49 P.3d 163 (Wyo.2002).

> In appeals where both parties submit evidence at the administrative hearing, *Newman* mandates that appellate review be limited to application of the substantial evidence test. *Newman*, 2002 WY 91, ¶22, 49 P.3d 163. This is true regardless of which party appeals from the agency decision. In addition, this court is required to review the entire record in making its ultimate determination on appeal. *Newman*, at ¶19 and ¶¶24-26.

The substantial evidence test to be applied is as follows:

> "In reviewing findings of fact, we examine the entire record to determine whether there is substantial evidence to support an agency's findings. If the agency's decision is supported by substantial evidence, we cannot properly substitute our judgment for that of the agency and must uphold the findings on appeal. Substantial evidence is relevant evidence which a reasonable mind might accept in support of the agency's conclusions. It is more than a scintilla of evidence."

Newman, at ¶12 (*quoting State ex rel. Workers' Safety and Compensation Div. v. Jensen*, 2001 WY 51, ¶10, 24 P.3d 1133, ¶10 (Wyo.2001)).

> Even when the factual findings are found to be sufficient under the substantial evidence test, *Newman* further concludes this court may be required to apply the arbitrary-and-capricious standard as a "safety net" to catch other agency action which prejudiced a party's substantial right to the administrative proceeding or which might be contrary to the other [Wyoming Administrative Procedural Act] review standards.

> *Loomer v. State ex rel. Wyoming Workers' Safety and Compensation Division*, 2004 WY 47, ¶15, 88 P.3d 1036, ¶15 (Wyo.2004).

Berg v. State ex rel. Wyoming Workers' Safety and Compensation Division, 2005 WY 23, ¶7, 106 P.3d 867, 870 (Wyo. 2005).

DISCUSSION

[¶7] It was agreed by all parties and the Commission that the sole issue at the hearing was, "Whether Employee Claimant's use of Marinol is necessary and reasonable."

Is Tarraferro Aggrieved or Adversely Affected by the Commission's Decision

[¶8] Because this poses a threshold question which would render unnecessary further consideration of the other issues raised in this matter, we will address this question first. At the outset, we note that this issue was not called to the attention of the Commission, nor was it addressed by the district court. Until this appeal was brought before this Court, the Division, the Medical Commission, Tarraferro, and the district court perceived this to be a justiciable controversy, as well as that he was aggrieved and adversely affected by the Division's and the Commission's respective decisions. This contention is premised upon the Commission's following finding: "However, because the Division paid for 22 months of medication and denied further benefits after Mr. Tarraferro refilled his prescription, this **last** prescription refill should be paid by the Division." (Emphasis added.) It was apparently the Medical Commission's conclusion that, given these circumstances, the Division should have paid for the immediate prescription, but it further determined that any future benefits in this regard should be denied. To conclude that the Medical Commission's digression deprives this Court of jurisdiction to hear this appeal elevates form over substance to an extent with which we simply cannot agree. In *Jacobs v. State ex rel. Workers' Safety and Compensation Division*, 2004 WY 136, ¶8, 100 P.3d 848, 850-51 (Wyo. 2004) we held:

> Until Jacobs is actually denied benefits for his abdominal pain, that issue is not ripe for our review.
>
> The ripeness doctrine is a category of justiciability "developed to identify appropriate occasions for judicial action." 13 Wright, Miller & Cooper, Federal Practice and Procedure: Jurisdiction § 3529, p. 146 (1975). The basic rationale of the ripeness requirement, like that of the justiciability requirement,

> " * * * is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties. The problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 87 S.Ct. 1507, 1515, 18 L.Ed.2d 681 (1967).
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> *Industrial Siting Council of State of Wyo.*, 660 P.2d at 779. Benefits for Jacobs' chronic abdominal pain have not been denied and no decision determining that issue has been formalized. Until a final determination is made by the appropriate administrative agency, the issue is not fit for our review. This Court cannot reverse or affirm a denial of benefits that has not occurred.

[¶9] We conclude that Tarraferro's circumstances are readily distinguishable from the concerns we expressed in *Jacobs*. Here, the Commission paid the immediate claim, but added an unequivocal conclusion that no future benefits would be paid in that regard. Our resolution of the issues brought before the Court is not premature, and a refusal to consider them at this juncture would operate as a hardship to this claimant, as well as similarly situated future claimants. By issuing conclusions such as those at issue here, the Division and the Commission could introduce delay in the final resolution of worker's compensation claims for years at a time. The instant claim was denied on March 13, 2003, and some two and one-half years have already passed since that decision was made. During that time, Tarraferro has been deprived of the benefits of the Marinol prescription.

Is the Medical Commission's Decision Based on Competent Evidence

[¶10] An independent medical examination commissioned by the Division revealed that, "… Dr. Perakos believed that Mr. Tarraferro was in fact suffering from chronic pain and there was a causal relationship between his complaints and the occupational injury." On April 12, 2000, Tarraferro began seeing Harlan Ribnik, M.D. Dr. Ribnik is a pain management specialist, and that was Tarraferro's sole reason for consulting with him. Dr. Ribnik identified Marinol as an appropriate and documented treatment for pain, although he was unable to cite to specific literature or studies at his deposition. He also noted that such treatment is not "experimental." Dr. Ribnik also testified that he did not

prescribe it as a treatment for nausea, but that turned out to be a secondary benefit of the Marinol, as Tarraferro also complained of nausea that accompanied his pain. Dr. Ribnik testified that Tarraferro had not responded well to narcotic drugs and continued him on Marinol because it was "efficacious," meaning, of course, that it worked. Available literature indicates that many different medications are used to treat pain, including non-narcotic analgesics, acetaminophen, non-steroidal anti-inflammatory drugs, $Alpha_2$ agonists, Ketamine, Dextromethorphan, Lidocaine, anticonvulsants, narcotic analgesics, and antidepressants. 6B *Lawyers' Medical Cyclopedia of Personal Injuries and Allied Specialties*, § 44A.4- 44A.11 (LEXIS 2000).

[¶11] The essence of the Medical Commission's findings was that Marinol was not reasonable and necessary, was contraindicated in Tarraferro's case, and it was experimental. For this proposition, the Medical Commission relied on the *Physicians' Desk Reference* (Thomson 2005) (generally known as the *PDR*) and "FDA guidelines," although there are no "FDA guidelines" in the record (nor can we locate any such authority by that citation). A brief perusal of the Forward to the *PDR* reveals that the *PDR* is not designed to function in the way the Commission applied it:

> *Physicians' Desk Reference* is published by Thomson PDR in cooperation with participating manufacturers. The *PDR* contains Food and Drug Administration (FDA) approved labeling for drugs as well as prescription information provided by manufacturers for grandfathered drugs and other drugs marketed without FDA approval under current FDA policies. Some dietary supplements and other products are also included.
>
> Each full-length entry provides you with an exact copy of the product's FDA-approved or other manufacturer supplied labeling. Under the Federal Food, Drug and Cosmetic (FD&C) Act, **a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer for only those uses for which the drug's safety and effectiveness have been established**. The Code of Federal Regulations Title 21 Section 201.100(d)(1) pertaining to labeling for prescription products requires that for *PDR* content "indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant warnings, hazards, contraindications, side effects, and precautions" must be "*same in language and emphasis*" as the approved labeling for the products. The FDA regards the words *same in language and emphasis* as requiring VERBATIM use of the approved labeling providing such

> information. Furthermore, information that is emphasized in the approved labeling by the use of type set in a box, or in capitals, boldface, or italics, must be given the same emphasis in *PDR*.
>
> **The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may choose to prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling**. In the case of over-the-counter dietary supplements, it should be remembered that this information has not been evaluated by the [FDA], and that such products are not intended to diagnose, treat, cure, or prevent any disease.
>
> The function of the publisher is the compilation, organization, and distribution of this information. Each product description has been prepared by the manufacturer, and edited and approved by the manufacturer's medical department, medical director, and/or medical consultant. In organizing and presenting the material in *Physicians' Desk Reference*, the publisher does not warrant or guarantee any of the products described, or perform any independent analysis in connection with any of the product information contained herein. *Physicians' Desk Reference* does not assume, and expressly disclaims, any obligation to obtain and include any information other than that provided to it by the manufacturer. It should be understood that by making this material available, the publisher is not advocating the use of any product described herein, nor is the publisher responsible for misuse of a product due to typographical error. Additional information on any product may be obtained from the manufacturer. [Emphasis added.]

Physicians' Desk Reference (59th ed. 2005). The Commission's reference to the PDR does not support its decision.

[¶12] The Medical Commission also referenced the use of Medline® as a part of its independent gathering of evidence after the hearing concluded. Tarraferro was not given notice of that independent research. We take note here that the record reveals that the

Commission had no "specialized knowledge" as to the medical specialty of pain management. Indeed, its misuse of the *PDR* and Medline® specifically demonstrates a lack of expertise. Moreover, Wyo. Stat. Ann. § 16-3-107(o)(p)(q) and (r) (LexisNexis 2005) provide:

> (o) The record in a contested case must include:
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> (i) All formal or informal notices, pleadings, motions and intermediate rulings;
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> (ii) Evidence received or considered including matters officially noticed;
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> (iii) Questions and offers of proof, objections and rulings thereon;
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> (iv) Any proposed findings and exceptions thereto;
>
> (v) Any opinion, findings, decision or order of the agency and any report by the officer presiding at the hearing.
>
> (p) In all contested cases the proceeding including all testimony shall be reported verbatim stenographically or by any other appropriate means determined by the agency or the officer presiding at the hearing.
>
> (q) Oral proceedings or any part thereof shall be transcribed on request of any party upon payment of the cost thereof.
>
> (r) Findings of fact shall be based exclusively on the evidence and matters officially noticed.

[¶13] Wyo. Stat. Ann. § 16-3-108(c) and (d) (LexisNexis 2005) provide:

> (c) A party may conduct cross-examinations required for a full and true disclosure of the facts and a party is entitled to confront all opposing witnesses.
>
> (d) Notice may be taken of judicially cognizable facts. In addition notice may be taken of technical or scientific facts within the agency's specialized knowledge or of information, data and material included within the agency's files. The parties shall be notified either before or during the hearing or after the hearing but before the agency decision of material facts noticed, and they shall be afforded an opportunity to contest the facts noticed.

[¶14] The product of the Commission's independent gathering of evidence is not reflected by the record. We consulted the Medline® website, but it appears to be little

more than the information contained in the *PDR*, but in a more abbreviated format. However, through access to an authoritative database available through the Wyoming State Library, we found information on clinical pharmacology that corroborated Dr. Ribnik's testimony, i.e., that studies have identified Marinol as an appropriate medication for pain management, Alzheimer's disease, and muscle spacticity/spasm associated with multiple sclerosis (Search: http://www-wsl.state.wy.us/; select "WYLD Databases;" select EBSCO Host; select "clinical pharmacology;" search Marinol (Dronabinol, THC)). In addition, the U.S. Drug Enforcement Administration has a website devoted to "Medical Marijuana" (i.e., Marinol), wherein it states: "In the meantime, the DEA is working with pain management groups, such as Last Acts, to make sure that those who need access to safe, effective pain medication can get the best medication available." (Search: http://www.usdoj.gov/dea/ongoing/marinol.html). Of course, this Court cannot gather evidence off the record to support its decision any more than may the Medical Commission. We make reference to these authorities to demonstrate only that the Commission not only acted improperly and contrary to governing law, but to the extent it did so, was also wrong. Thus, there is nothing in the record to sustain a conclusion that Dr. Ribnik's testimony was flawed, as the Commission concluded. His credentials as a pain management expert and his avowed knowledge of pharmacology, particularly as it relates to pain, are unchallenged by any evidence properly of record.

[¶15] The Commission's findings continued:

> Because the panel finds the use of Marinol under these facts is experimental, we need not reach the issue of whether the use of Marinol is necessary and reasonable. Contrary to assertions by counsel for Mr. Tarraferro, this decision is not based on the cost of Marinol. Several medications routinely approved for injured workers are more expensive than Marinol."
>
> Not all "off label" uses of medications are experimental. The conclusion of Marinol being experimental under these facts is based on the lack of any studies, publications, etc., which indicate such use for pain control is recognized or effective. As to the issue of whether such is necessary and reasonable, given Mr. Tarraferro's weight, other health issues, some history of substance abuse, and depression, Marinol is contraindicated. As such, the Panel would find Marinol as not being necessary and reasonable under the facts presented.

> Mr. Tarraferro has not met his burden of proof that his use of Marinol was not experimental and that its use was necessary and reasonable.

[¶16] The issue of whether Marinol was experimental in these circumstances finds its origin in Wyo. Stat. Ann. § 27-14-102(a)(xii) (LexisNexis 2005):

> (xii) "Medical and hospital care" when provided by a health care provider means any reasonable and necessary first aid, medical, surgical or hospital service, medical and surgical supplies, apparatus, essential and adequate artificial replacement, body aid during impairment, disability or treatment of an employee pursuant to this act including the repair or replacement of any preexisting artificial replacement, hearing aid, prescription eyeglass lens, eyeglass frame, contact lens or dentures if the device is damaged or destroyed in an accident and any other health services or products authorized by rules and regulations of the division. "Medical and hospital care" does not include any personal item, automobile or the remodeling of an automobile or other physical structure, public or private health club, weight loss center or aid, **experimental medical or surgical procedure**, item of furniture or vitamin and food supplement except as provided under rule and regulation of the division and paragraph (a)(i) of this section for impairments or disabilities requiring the use of wheelchairs; [Emphasis added.]

[¶17] What the statute intends to convey by "experimental" is not further defined. However, we conclude that it is a term of art in this context, and that the Commission was incorrect as to that matter as well. 1A *Lawyers' Medical Cyclopedia of Personal Injuries and Allied Specialties*, § 2.53 at 2-138 – 139 (LEXIS 2001) provides just the sort of context that is needed in a case such as this:

> To understand this area of law, it is important to distinguish between concepts that are frequently commingled and confused. Unfortunately, there is no universally accepted terminology, so that it is often difficult to know what any one author means when using the words "experimentation," "research," and "novel technique." For the sake of clarity and understanding, these terms will have the following definitions in this discussion unless stated otherwise.

> *Experimentation* is the use of a medicine or procedure, which is yet to be adequately tested for the purpose for which it is intended. An experiment may or may not have a therapeutic goal, and it may or may not be designed to yield useful scientific information. Thus, "experimentation" has a very broad definition. In the legal and medical literature, "experimentation" is used to mean everything from the malicious use of patients as guinea pigs to the noble treatment of an incurable patient by the most scientifically advanced methods.
>
> *Research* is a form of "experimentation" that includes only studies designed to produce useful scientific data. A research project may or may not offer therapeutic benefits to the human subjects involved, but it is always designed to obtain information beneficial to humankind in general.
>
> *Novel techniques*, on the other hand, are always intended to be therapeutic or diagnostic, relative to a particular patient's medical problem. Like experimentation, novel techniques have varying degrees of incomplete prior testing. The categories of novel techniques may be divided into (1) new approaches to otherwise untreatable conditions and (2) new approaches to treatable conditions (where it is hoped that the new technique will offer some new advantage).

[¶18] It is clear from Dr. Ribnik's testimony that the use of Marinol to treat severe and persistent pain was reasonable, necessary, and not experimental. It is also clear from his testimony, based on an unchallenged expertise in the area of pain management, that its use in Tarraferro's case was not experimental. On the continuum described above, its use might be considered a "novel technique," but according to Dr. Ribnik's testimony, it was an accepted practice among physicians specializing in pain management.

[¶19] Despite the fact that the Division's own evidence confirmed that Tarraferro's pain was caused by his industrial accident, as well as the surgeries necessitated by that accident, and despite the Commission's specific finding that the pain was caused by the accident, the Division continues to argue in its brief that the pain was not a result of the work-related accident and its aftermath. In addition, the Division and the Commission have ignored Dr. Ribnik's unequivocal testimony that Marinol was not prescribed to treat nausea (only the pain, but that as an additional benefit it did help control Tarraferro's pain-associated nausea) and conclude that Marinol is not a reasonable or necessary anti-nausea medication. That argument simply is beside the point. The Division and the Commission conclude that the pain may also have been caused by Tarraferro's prostatitis.

There is evidence that Tarraferro suffered from prostatitis, but it suggests that it was at most a secondary source of Tarraferro's pain problems. The Division and the Commission want to blame the pain on Tarraferro's obesity, even though the only evidence on this point was to the effect that he was always a very large man, although he did steadily gain weight after he became almost completely sedentary after suffering his injuries. Dr. Ribnik testified only that weight gain could "potentially" increase Tarraferro's pain.

[¶20] In sum, the evidence properly of record will support only one conclusion: That Marinol was a reasonable and necessary, non-experimental treatment for Tarraferro's pain.

CONCLUSION

[¶21] We reverse the order of the district court affirming the Medical Commission's decision. We remand this matter to the district court with directions that it enter an order reversing the Commission's decision. That order shall include further directions that the Medical Commission enter an order reversing the Division's decision to disallow Tarraferro's claim for Marinol.