IN THE MISSOURI SUPREME COURT

No. SC86104

UNITED PHARMACAL COMPANY OF MISSOURI, INC.

Respondent,

vs.

MISSOURI BOARD OF PHARMACY,

Appellant.

Appeal from the Buchanan County Circuit Court
The Honorable Weldon C. Judah

APPELLANT'S SUBSTITUTE REPLY BRIEF

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I.

The Board of Pharmacy's perception regarding the scope of the applicable statutory provisions is not a rule, because it is not a "statement," and is not itself the State's basis for the application of the standard set forth. (Relates to Point I).

To defend the circuit court's decision holding that FAQ 8 constitutes a rule, United Pharmacal broadens the holding beyond its express language. United Pharmacal maintains that the FAQ is merely the embodiment of a rule; that the actual rule is the change in the Board's thought process concerning the applicability of particular statutory sections to the conduct in question. United Pharmacal maintains that the act of the current Board members perceiving the statute in a manner different from the collective perception of past Board members constitutes a policy change, and is therefore a rule.

United Pharmacal admits that 536.010(4) defines rule as "**a statement** of general applicability. . . ." United Pharmacal never explains how the Board's change in perception constitutes "a statement." United Pharmacal's position appears to be colored by its perception that since a prior Board, to United Pharmacal's benefit, did not take action against United Pharmacal, the current Board should be prohibited from taking action. However, an administrative agency is not bound by stare decisis. *McKnight Place Extended Care, L.L.C., v. Missouri Health Facilities Review Comm.*, 2004 WL 1959605 (Mo. App. W.D. 2004). Courts are not concerned with alleged inconsistency between current and prior decisions of an administrative agency so long as the action taken is not otherwise arbitrary or unreasonable. *Id., State ex rel. GTE North, Inc. v. Missouri Public Service Comm'n,* 835 S.W.2d 356, 371

(Mo. App. W.D. 1992), *City of Columbia v. Missouri State Bd. Of Mediation,* 605 S.W. 2d 192, 195 (Mo. App. W.D. 1980), *Mitchell v. City of Springfield,* 410 S.W.2d 585, 589-90 (Mo. App. Spring. 1966).

The current Board's position that the statutes forbid United Pharmacal from dispensing veterinary legend drugs should be judged on its own merit, and not dismissed based on the fact that a prior Board, for whatever reason (and here we can only speculate) did not share or did not chose to act on such a reading of the statute. If United Pharmacal is correct that the statute does not empower the Board to regulate the sale of drugs for animal use, then United Pharmacal is entitled to receive a favorable ruling on a properly filed declaratory judgment seeking a declaration of the statutes applied. If, on the other hand, the Board is correct in its position, then it should likewise prevail in such action. But no previous Board's position can prevent the legislative directive from being carried out. The Board has no power to vary the force of the statutes. *See Lynn v. Dir. of Revenue*, 689 S.W.2d 45, 49, (Mo. banc 1985). (Departments prior position did not limit the State's current ability to collect taxes properly owing.)

United Pharmacal does not cite any Missouri cases that support that the Board's change in perception or the FAQ constitutes a rule. The Missouri cases cited by United Pharmacal all involve published statements in which the statement itself was the basis for the State's application of the standard set forth. *Beaufort Transfer* involved a definition of contiguous trade territories published in the Notice Register of Motor Carrier Cases. *State ex rel. Beaufort Transfer Co. v. Public Service Comm'n,* 610 S.W.2d 96, 98 (Mo. App. W.D. 1980).

Barclay involved a deductions formula published in the Missouri Division of Family Services Income Maintenance Manual. *Missouri State Division of Family Services v. Barclay*, 705 S.W.2d 518, 520 (Mo. App. W.D. 1986). *Peters* involved a list of methods for determining blood alcohol content which the Department of Health asserted at trial met its statutory obligation to approve satisfactory methods for such tests. *State v. Peters*, 729 S.W.243, 245 (Mo. App. S.D. 1987). *NME Hospitals* involved reimbursement standards published in the Missouri Medicaid Bulletin. *NME Hospitals, Inc. v. Dep't of Social Services*, 850 S.W.2d 71, 73 (Mo. banc 1993). *Tonnar* involved relocations assistance payment method published in the "Right-of-Way Manual." *Tonnar v. Missouri State Highway and Transportation Comm'n*, 640 S.W.2d 527, 530 (Mo. App. W.D. 1982). And *Mulvihill* involved license fee increases posted at the "Private Officers Licensing Section. *Kansas Ass'n of Private Investigators v. Mulvihill*, 35 S.W.3d 425, 428 (Mo. App. W.D. 2000).

Moreover, none of the cases cited by United Pharmacal involve a challenged "rule" that set forth a standard independently enforceable by statute. This case is more closely analogous to *Branson R-IV School Dist. v. Labor and Industrial Relations Comm*. 888 S.W.2d 717. (Mo. App. S.D. 1994). In *Branson R-IV*, the court distinguished many of the same cases cited by United Pharmacal. *Id.* at 722-723. The Court reasoned that the Labor and Industrial Relations Commission's actions had a statutory basis and that the statute could readily be applied without further definition or clarification. *Id.* at 723. Likewise here the Board has only attempted to act based on statutes that may readily be applied to United Pharmacal's operations. United Pharmacal dispensed veterinary legend drugs based on the prescription of

a veterinarian. Pursuant to Section 338.010.1, RSMo 2000 the practice of pharmacy is defined to include "the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs . . . pursuant to prescription orders; [and] . . . the proper and safe storage of drugs. . . ."[1] Even more telling, Section 338.010.1 includes veterinarians in the list of professions that may dispense their own prescriptions without being licensed:

> This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, podiatry, or veterinary medicine, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220, RSMo, in the compounding or dispensing of his own prescriptions.

If the dispensing of drugs pursuant to a veterinarian's prescription did not constitute the practice of pharmacy, there would be no need to exempt veterinarians.

The FAQ that the Board's staff placed on the Board's website did nothing more than paraphrase the statutory requirement. The FAQ was not meant to and did not place an obligation on any individual, apart for their pre-existing obligation to comply with statutory provisions (L.F. 70). United Pharmacal in its brief attempts to obfuscate this fact by repeatedly stating that the Board admitted that United Pharmacal and others must comply with

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[1]Missouri's drug law, Chapter 195 RSMo, defines drug to include "substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals. Section 195.010(14)(b).

the statement contained in the FAQ. (Respondent's brief at 40, 42). In support of its assertion, United Pharmacal, however, merely cites its own assertion in its summary judgement motion. *Id.* United Pharmacal ignores that paragraph 67 of its motion was denied by the Board. United Pharmacal elected not to cite to the actual testimony of the Board's Executive Director:

> Q: Okay, Does an entity such as UPCO have an obligation to comply with statutes?
>
> A: Yes.
>
> Q: Is that answer on the website to the frequently asked question in your mind based on the statutes?
>
> A: Yes.
>
> Q: Apart from its basis on the statutes does UPCO have an obligation to comply with the statement because it's a frequently asked question –
>
> A: No.
>
> Q:– because it's on the Board's website?
>
> A: Because it's the Board's position that that's what requires you to be in compliance with Chapter 338 if I understand.
>
> Q: So they do not have an obligation to comply with the statement just because it appears on the website?
>
> A: No.

(L.F. at 70).

United Pharmacal also falsely asserts that failing to adhere to the FAQ could subject one to criminal prosecution. (Respondent's brief at 43). Section 338.195, RSMo 2000, makes violation of any provision of sections 338.010 to 338.315 a criminal violation, it does not make failure to comply with a FAQ a criminal violation. Moreover, the prosecutor has the independent responsibility to apply the statutes. A prosecutor could determine that UPCO actions violated the statute, even if the Board did not agree.

Lastly, if the Board's change in perception was deemed to be a rule, it is unclear how such change in perception affects the current controversy. The Board's shift in perception was superseded by the amendment of §338.210.1. Unless United Pharmacal contends that the Board's collective thoughts about §338.210.1 constitute a rule as well, the alleged change in perception doesn't affect United Pharmacal's current entitlement to dispense veterinary legend drugs.

II.

United Pharmacal misconstrues *Farm Bureau*, *Group Health Plan*, and *Levinson*, none of which support the premise that a threatened application of statute gives rise to an action under §536.050. (Relates to Point II)

In its brief, United Pharmacal misconstrues the *Farm Bureau* and *Group Health Plan* decisions. United Pharmacal first contends that *Farm Bureau* and *Group Health Plan* expressly extend §536.050 to include declaratory judgment actions concerning the threatened application of statutes. That United Pharmacal cites *Farm Bureau* for this

proposition is surprising, for there the court never mentions §536.050. *See Farm Bureau Town and County Ins. Co. of Missouri v. Angoff*, 909 S.W.2d 348 (Mo. banc 1995). *Group Health Plan* mentions §536.050, but only by way of analogy. *Group Health Plan, Inc., v. State Board of Registration*, 787 S.W.2d 745, 749 (Mo. App. E.D. 1990). Neither case stands for the proposition asserted by United Pharmacal.

The two cited cases do stand for the proposition that the threatened application of statutory provisions may give rise to subject matter jurisdiction for a declaratory judgment action. The Board does not dispute this proposition. However, the basis for such action is not §536.050. United Pharmacal filed their action under §536.050, which by its statutory language only applies to rules and not statutes. Because §536.050 is not the appropriate statutory basis for a declaratory judgment action regarding statutory provisions, the venue provision of §536.050 would not apply to such action.

United Pharmacal next argues that despite being directly contrary to the language of §536.050, and even if absent from any express holding in the decision, *Group Health Plan* must none the less be read to extend §536.050 to include declaratory judgment actions involving the threatened application of statutes. United Pharmacal argues that since the underlying action was filed in St. Louis County, and the court did not sua sponte affirm the circuit court's dismissal based on the lack of venue as an alternative basis for dismissal, the action must have been properly filed in St. Louis County, and venue in St. Louis County must have been premised on §536.050. Even if one accepts that the Court necessarily sua sponte considered venue, United Pharmacal ignores that there were multiple defendants.

United Pharmacal has neither established that Group Health Plan had a business office in St. Louis County, or that none of the defendants resided in St. Louis County.

United Pharmacal asserts the same strained analysis when addressing a third precedent, this Court's opinion in *Levinson v. State of Missouri*, 104 S.W.3d 409 (Mo. banc 2003). United Pharmacal ignores that Levinson actually involved declaratory judgment regarding an actual administrative rule; making §536.050 a proper basis for venue.

Lastly, United Pharmacal argues that it is unfair that United Pharmacal should have to file a proper action in Cole County. Appellant notes that United Pharmacal in effect had its choice of forums. The only remedy directly available to the Board to enjoin unlicensed practice is to file an injunction pursuant to §338.365, RSMo 2000. Pursuant to §338.365.2 venue for such an action is in the county in which such conduct occurred or in the county in which defendant resides. United Pharmacal could have responded to the Board by indicating it did not intend to comply with its order, or not have responded at all. The Board's only option would have been to file an injunction in Buchanan County where United Pharmacal practiced pharmacy.

III.

The Circuit Court Order expressly disregards the amended version of §338.210, RSMo. (Relates to Point III).

United Pharmacal asserts that the circuit court opinion must be construed as referring to the current provisions of Chapter 338, because there is no language to the contrary in the order, and the court is presumed to have correctly applied the law. In support of this assertion, United Pharmacal links together two separate sentences from the Circuit Court's Order. United Pharmacal ignores that the two sentences are separated by nearly two full paragraphs, and conveniently omits language in between where the court chastised the Board for suggesting the current statute be considered:

> Defendant further asserts that the revisions of Section 338.210 RSMo resulting from the 2001 amendments thereto serve to clear up any confusion as to the conduct of Plaintiff now being prohibited . . . .This Court does not find persuasive the argument that as an after-the-fact change in the law . . . might appear to justify the position the Defendant now takes, as opposed to that it took prior to the change in the law or which was not cited as the basis for the change in policy, respectively, that, therefore, Plaintiff is disentitled to relief. "Article I, Sec. 13 of the Missouri Constitution generally prohibits retrospective application of laws enacted by the legislature." Kampe v. Howard Stark Professional Pharmacy, Inc., 841 S.W.2d 223, 226 (W.D., 1992)

(L.F. at 219).

United Pharmacal also emphasized the sentence, "Likewise, the existing provisions of 4 C.S.R. 220-2.010 et seq. appear to authorize only specific regulation of pharmacists and pharmacies as classically defined by Secs. 338.010 and 338.210." (L.F. at 219). Respondent argues that the reference to *existing* regulations supports that the court applied current law. However, United Pharmacal ignores the language "*as classically defined by.*" The court's language is admittedly confusing, but a careful reading demonstrates that the court was trying merely to indicate that in its opinion the Board's FAQ went beyond the provision of the statute in place at that time, and beyond the existing regulations, as opposed to the alleged "non-existing" [unpromulgated] regulation.

The Judge during argument stated quite clearly that he understood the issue to relate to the Cease and Desist Order: "But the declaratory and injunctive relief presumably deals with this fact specific cease and desist order." (Tr. at 25). As asserted by United Pharmacal, the parties did discuss the current statute during oral argument, but the Judge apparently understood this as an after-the-fact justification for the Cease and Desist Order, and refused to consider it in reaching his decision.

CONCLUSION

For the reasons stated above, the judgment of the Circuit Court should be reversed.

Respectfully submitted,
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CERTIFICATE OF SERVICE AND COMPLIANCE

The undersigned assistant attorney general hereby certifies that:

(1) That the attached brief complies with the limitations contained in Special Rule 1(b) of this Court in that it contains 2,800 words, as determined by WordPerfect software; and

(2) That the floppy disk filed with this brief, containing a copy of this brief, has been scanned for viruses and is virus-free; and

(3) That a true and correct copy of the attached brief, and a floppy disk containing a copy of this brief, were mailed, postage prepaid, this 18th day of October, 2004, to:

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