IN THE MISSOURI SUPREME COURT

NO. SC 87316

UNITED PHARMACAL COMPANY OF MISSOURI, INC.,

Appellant,

v.

MISSOURI BOARD OF PHARMACY,

Respondent.

APPEAL FROM THE COLE COUNTY CIRCUIT COURT NINETEENTH JUDICIAL CIRCUIT THE HONORABLE RICHARD G. CALLAHAN

RESPONDENT'S BRIEF

RESI ONDER 1 5 BRIEF

JEREMIAH W. (JAY) NIXON Attorney General

Sharon K. Euler Assistant Attorney General Missouri Bar No. 42950

PennTower Office Center 3100 Broadway, Suite 609 Kansas City, Missouri 64111 Phone: (816) 889-5000

Fax: (816) 889-5006 (Facsimile)

Sharon.Euler@ago.mo.gov

ATTORNEYS FOR RESPONDENT

Table of Contents

Jurisc	lictional States	ment
State	ment of Facts	
Stand	ard of Review	⁷ 9
Legal	Argument	
I.	Missouri La	w Requires Upco Be Licensed as a Pharmacy to
	Distribute V	eterinary Legend Drugs
	A.	Chapter 338, RSMo regulates all prescription drugs,
		including the drugs UPCO distributes
	B.	The trial court did not err in looking to other statutes 18
	C.	The Pharmacy Board properly regulates dispensing of prescription
		drugs
	D.	No authority exists for the Veterinary Board to regulate dispensing
		legend drugs
	E.	Subsection I.6 of UPCO's brief cites no relevant law or fact 24
	F.	Rule of Lenity inapplicable to the case at bar
II.	Chapter 338	Violates No Constitutional Provision
Sumn	nary	
Certif	ication of Ser	vice and Compliance with Rule 84.06(b) and (c)
Appe	ndix	30

Table of Authorities

Cases:

Bodenhausen v. Missouri Board of Registration for Healing Arts,
900 S.W.2d 621 (Mo banc 1995)
Callier v. Director of Revenue, 780 S.W.2d 639 (Mo banc 1989)
Conseco Finance Servicing Corp. v. Missouri Department of Revenue,
98 S.W.3d 540 (Mo banc 2003)
Conseco Finance Servicing Corporation v. Missouri Department of Revenue, S.W.3d, 2006 WL 1605014 (Mo banc June 16, 2006) 26
Fisher v. Reorganized School District No. R-V of Grundy County,
567 S.W.2d 647 (Mo banc 1978)
Foremost-McKesson v. Davis, 488 S.W.2d 193 (Mo banc 1972)
Greenbriar Hills Country Club v. Director of Revenue,
935 S.W.2d 36 (Mo. banc 1996)
In re Schottel, 159 S.W.3d 836 (Mo. banc 2005.)
Kansas City v. Graybar Electric Company, 454 S.W.2d 23 (Mo banc 1970) 6, 25
Landman v. Ice Cream Specialties, 107 S.W.3d 240 (Mo banc 2003)
Murphy v. Carron, 536 S.W.2d 30 (Mo banc 1976)
Pullitzer Publishing Company v. McNeal, 575 S.W.2d 802
(Mo. App. St. Louis Dist. 1978)
State ex rel. Rothermich v. Gallagher, 816 S.W.2d 194 (Mo. banc 1991)

State v. Rowe, 63 S.W.3d 647 (Mo. banc 2002)
Tendai v. Missouri State Board of Registration for the Healing Arts,
161 S.W.3d 358 (Mo banc 2005)
United Pharmacal Company of Missouri, Inc. v. Missouri Board of Pharmacy,
159 S.W.3d 361 (Mo banc 2005)
Wolff Shoe Company v. Director of Revenue, 762 S.W.2d 29 (Mo banc 1988) 11, 12
<i>Xerox Corp. v. Travers</i> , 529 S.W.2d 418 (Mo. banc 1975)
Statutory Provisions:
Chapter 195
Chapter 330, RSMo
Chapter 332, RSMo
Chapter 338, RSMo
Chapters 196 and 195, RSMo
Section 195.060.1, RSMo
Section 195.070.2, RSMo
Section 196.010(5), RSMo,
Section 338.010 et. seq, RSMo
Section 338.095, RSMo
Section 338.220.1(1), RSMo
Section 338.220, RSMo
Section 340.200, RSMo

Other:

4 CSR 270-6.011	5
Article V, Section 3	5
Websters Third New International Dictionary (1993)	7

JURISDICTIONAL STATEMENT

The case, as briefed by appellant, UPCO, involves the validity of a statute and therefore, Article V, Section 3 of the Missouri Constitution grants this Court jurisdiction. *Tendai v. Missouri State Board of Registration for the Healing Arts*, 161 S.W.3d 358, 364 (Mo banc 2005). But, UPCO failed to preserve any constitutional challenges to Chapter 338, RSMo (2000), as amended, in that this challenge is first raised in this appeal and has not been preserved throughout the pendency of this action. Therefore, Appellant waived any constitutional challenge. *Kansas City v. Graybar Electric Company*, 454 S.W.2d 23, 25 (Mo banc 1970).

STATEMENT OF FACTS

UPCO sells prescription drugs to consumers. LF, p. 287. UPCO employs no licensed pharmacist nor does UPCO hold a license as a pharmacy. LF pp. 431 and 436. These drugs are sometimes referred to as "federal legend" or "legend drugs" in that they are regulated by the federal Food, Drug and Cosmetic Act and may only be dispensed upon a prescription. UPCO Brief, p. 41, fn 7. These prescription drugs are for animal use. LF p. 287.

In 2000, the State Board of Pharmacy (the "Pharmacy Board") conducted an investigation and determined that UPCO sold legend drugs, but had no license to practice as a pharmacy nor did it employ a licensed pharmacist. LF pp. 387-389. As a result of this investigation, the Pharmacy Board issued a "Cease and Desist Warning" to UPCO by letter dated June 21, 2001. LF pp. 387-389.

This action ensued. As set forth in detail in UPCO's brief, this case has a long procedural history. However, this Court vacated and set aside the judgments previously entered by the Buchanan County Circuit Court and the Western District Court of Appeals. *United Pharmacal Company of Missouri, Inc. v. Missouri Board of Pharmacy*, 159 S.W.3d 361 (Mo banc 2005). The only matter before this Court for review is the "Final Judgment and Order" entered by the Circuit Court of Cole County on August 19, 2005. LF pp. 453-458. In this case, UPCO sought a declaratory judgment that selling legend drugs to consumers upon the prescription of a veterinarian does not constitute the practice of pharmacy pursuant to Chapter 338, RSMo (2000), as supplemented. The Circuit Court

of Cole County ruled that "UPCO may not sell veterinary legend drugs directly to the consumer (animal owner) based on a prescription without being licensed as a pharmacy in the state of Missouri." LF, p. 458. This Final Judgment and Order made no ruling on any constitutional issue. This appeal followed.

STANDARD OF REVIEW

The standard of review in a declaratory judgment action, such as this case, is the same as in any other court tried case. The reviewing court determines interpretations of law de novo. The decision of the trial court is upheld unless there is no substantial evidence to support it, it is against the weight of evidence, it erroneously declares the law, or it erroneously applies the law. *Conseco Finance Servicing Corporation v. Missouri Department of Revenue*, 98 S.W.3d 540 (Mo banc 2003); *Murphy v. Carron*, 536 S.W.2d 30, 32 (Mo banc 1976). The party raising the challenge bears the burden of proof. *Foremost-McKesson v. Davis*, 488 S.W.2d 193, 197 (Mo banc 1972).

LEGAL ARGUMENT

I. MISSOURI LAW REQUIRES UPCO BE LICENSED AS A PHARMACY TO DISTRIBUTE VETERINARY LEGEND DRUGS

(Responds to Point I)

This case involves no dispute of fact. UPCO distributes legend drugs; drugs which require a prescription to be dispensed. LF p. 192. UPCO holds no license as a pharmacy nor does it employ a licensed pharmacist. Missouri law requires a licensed pharmacy dispense legend drugs regardless of whether the end user of those drugs is a human or an animal. Section 338.010 et. seq, RSMo (2000), as amended. UPCO's conduct thus violates Missouri law.

A. Chapter 338, RSMo¹ regulates all prescription drugs, including the drugs UPCO distributes.

UPCO argues that it possesses an exemption from requiring a pharmacy license because veterinary drugs are not specifically included in the provisions of Chapter 338, RSMo. This argument serves as a sword rather than a shield. Chapter 338, RSMo, requires a licensed pharmacy and a licensed pharmacist to dispense all drugs that require a prescription. Section 338.010, RSMo. There is no specific exclusion of veterinary

¹All statutory references are to the Revised Statutes of Missouri (2000), as supplemented, unless otherwise indicated.

drugs and thus, veterinary drugs must be included as they fall squarely within the bounds of the statute.

The first rule of statutory construction is to look to the plain meaning of the words in the statute to carry out the legislative intent. *Landman v. Ice Cream Specialties*, 107 S.W.3d 240, 251 (Mo banc 2003); *Wolff Shoe Company v. Director of Revenue*, 762 S.W.2d 29, 31 (Mo banc 1988). The plain meaning of the provisions of Chapter 338, RSMo, is that the legislature intended them to apply to all prescription drugs, human or animal.

We begin with Section 338.010.1, RSMo, which defines the "practice of pharmacy" to include all prescription drugs:

The 'practice of pharmacy' shall mean the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; . . . 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 the compounding or dispensing of his own prescription.

Section 338.010.1, RSMo, thus includes as "the practice of pharmacy" the dispensing (i.e., the sale or distribution of) all drugs that require a prescription, i.e., legend drugs or controlled drugs.

Chapter 338, RSMo does not define "drug" so the Court must look to the plain, ordinary meaning of the word. Wolff Shoe, 762 S.W.2d at 31. The dictionary defines "drug" to be "a substance other than food intended to affect the structure or function of the body of man or other animal." Websters Third New International Dictionary (1993). Neither the dictionary nor any pertinent statute differentiates between a drug used on an animal and a drug used on a human. Thus, the "practice of pharmacy" includes dispensing all prescription drugs. That the legislature intended the "practice of pharmacy" statute to apply to veterinarians as well as to doctors of humans is confirmed by the specific exclusion of veterinarians. The statute specifically excludes from the "practice of pharmacy" a veterinarian compounding his or her own prescription drugs. All words of a statute are presumed to have meaning. Tendai v. Missouri State Board of Registration for the Healing Arts, 161 S.W.3d 358, 369 (Mo banc 2005). No statute contains unneeded words or superfluous language. Landman, 107 S.W.3d at 252. If the legislature had not intended Chapter 338 to apply to veterinarian drugs, there would have been no reason to exempt veterinarians.

The "practice of pharmacy" covers only the dispensing of drugs by "prescription." So, next we turn to Section 338.095, RSMo, which defines "prescription" – again, without differentiating between prescriptions for humans and ones for animals:

1. The terms 'prescription' and 'prescription drug order' are hereby defined as a lawful order for medications or devices issued and signed by an authorized prescriber within the scope of his professional practice

4. Nothing in this section shall be construed to limit the authority of other licensed health care providers to prescribe, administer, or dispense medications and treatments within the scope of their professional practice.

Again, this statute refers to all licensed health care providers granted authority to write prescriptions. This statute makes no distinction between human and animal health care providers. Veterinarians must possess licenses issued by the state to provide health care and possess authority to write prescriptions – i.e., they are "authorized prescribers." Section 340.200, RSMo, defines what constitutes the practice of veterinary science to include prescribing drugs for animals:

(28) "Veterinary medicine", the science of diagnosing, treating, changing, alleviating, rectifying, curing or preventing any animal disease, deformity, defect, injury or other physical or mental condition, including, but not limited to, the prescription or administration of any drug, medicine, biologic, apparatus, application, anesthesia or other therapeutic or diagnostic substance or technique on any animal, including, but not limited to, acupuncture, dentistry, animal psychology, animal chiropractic, theriogenology, surgery, both general and cosmetic surgery, any manual, mechanical, biological or chemical procedure for testing for pregnancy or

for correcting sterility or infertility or to render service or recommendations with regard to any of the procedures in this paragraph; (underlining added for emphasis)

Again, "prescriptions" as the term is used in Section 338.095, RSMo, include prescriptions written by veterinarians, "authorized prescriber[s] within the scope of their professional practice." Sections 340.200 and 338.095, RSMo.

The statute that defines "pharmacy", Section 338.210, RSMo, is worded as broadly as "practice of pharmacy":

- 1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:
- (1) Where the practice of pharmacy is offered or conducted;
- (2) Where drugs, chemicals, medicines, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at retail;
- (3) Where the words 'pharmacist', 'apothecary', 'drugstore', 'drugs', and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;
- (4) Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling,

transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons.

Again, this statute defines pharmacies by the activity related to drugs, not by the end user of those drugs. UPCO falls within this statute because it dispenses and offers prescription drugs for sale at retail. App. Brf., p.11, 1st paragraph.

UPCO argues that the use of the word "patient" in various portions of Chapter 338, RSMo, evidences that Chapter 338 regulates only drugs used on humans. This argument fails. The dictionary defines "patient" as "a sick individual." Websters Third New *International Dictionary* (1993). Nothing in the definition requires that it be a human individual. Furthermore, veterinarians commonly refer to their animal clients as "patients." The Professional Code of Conduct for the Practice of Veterinary Medicine found in 4 CSR 270-6.011 repeatedly refers to the animal clients as the "patients" and their human owners as "clients." Subsection (8) of 4 CSR 270-6.011 states that "All diagnostic assessments, treatment plans, medications and other pertinent information regarding the treatment of the patient shall be recorded in the patient's medical record and a copy of the record shall be made available to the client upon request." And, (10) of this same regulation states: "Although a licensee may choose whom to serve, once the care of a patient has been undertaken, the licensee has an obligation to provided reasonable services or treatment to stabilize[d] the patient or to prevent unnecessary suffering or pain." Similarly, (19) of this regulation states: "A licensee shall obtain the informed

written consent of the client prior to placing any patient under anesthesia or performing any surgical procedure, or both, except in an emergency." 4 CSR 270-6.011.

Also, Section 338.210 uses "patient" only in an alternative section. It's enough that UPCO engages in the practice of pharmacy under (1) and (2). Sub-paragraph (4) is then irrelevant.

UPCO further cites the definition of physician as controlling in this case as the statute under which the original cease and desist order was issued includes the word "physician." This older statute is not controlling in this case as it is no longer in effect and has no impact. *Fisher v. Reorganized School District No. R-V of Grundy County*, 567 S.W.2d 647, 649 (Mo banc 1978). UPCO cites no vested right that entitles it to rely on the older statute and therefore, the current version of the statute is the one which should be applied. *Id*.

But, even if this older version was in effect for this case, the use of the word physician does not exempt UPCO from the regulation of Chapter 338. The dictionary does indeed define "physician" as "a person skilled in the art of healing." Websters Third New International Dictionary (1993). This dictionary definition does not limit that healing to only humans. The dictionary defines "veterinarian" as "one skilled in or treating diseases and injuries of animals." Websters Third New International Dictionary (1993). Applying simple logic, veterinarians are persons "skilled in the art of healing." Veterinarians are a subset of the larger pool of physicians just as a podiatrist or a psychiatrist is a physician. Physician is the general, generic term.

UPCO next argues that it must be exempt from the provisions of Chapter 338, RSMo, simply because there is no class of pharmacies listed on Section 338.220, RSMo, that applies only to veterinarian pharmacies. UPCO distributes drugs that require a prescription. No sub-category is necessary for them to seek licensure as a pharmacy. Veterinarians in Missouri write prescriptions all the time that may be filled by any community pharmacy because in many instances, the drugs prescribed for humans come out of the same bottle as the drugs prescribed for animals. Community pharmacies are "class A" pharmacies pursuant to Section 338.220.1(1), RSMo. To say that a separate classification is necessary for veterinary prescriptions to be filled is analogous to saying that a separate type of pharmacy is required to fill prescriptions for allergies or prescriptions for heart patients. No classification of pharmacies found in Section 338.220 uses the word "human" or any other word to imply or state that only human drugs are dispensed from any of the classifications. It is not the end user that determines whether a pharmacy license is required; it is the activity of dispensing or compounding drugs pursuant to a prescription that triggers the requirement for licensure.

B. The trial court did not err in looking to other statutes.

The trial court appropriately utilized other statutory sections in order to determine the legislative intent for whether veterinary drugs fall within the bounds of Chapter 338, RSMo.

In interpreting statutes, a court must both strive to implement the policy of the legislature and also harmonize all provisions of the statute. *In re Schottel*, 159 S.W.3d

836, 842 (Mo banc 2005). Also, all consistent statutes relating to the same subject should be read together, in pari materia, to be consistent and harmonious. *State ex rel. Rothermich v. Gallagher*, 816 S.W.2d 194, 200 (Mo banc 1991). Lastly, the legislature is presumed to intend a logical and reasonable result. *Pullitzer Publishing Company v. McNeal*, 575 S.W.2d 802, 811 (Mo. App. St. Louis Dist. 1978).

Applying these well settled principles, the trial court properly looked to statutes outside of Chapter 338 to determine the intent of the legislature for Chapter 338, RSMo. Chapters 196 and 195, RSMo, also regulate drugs in Missouri. Chapter 196 contains provisions to protect the public by ensuring that drugs are accurately labeled and pure and clean. Sections 196.095 and .100, RSMo. Chapter 196 should harmonize with Chapter 338 because both statutes serve to protect the public in drug usage. It is very appropriate to look to the definition of "drug" found in 196.010, RSMo, to assist the court in defining drug for the purposes of Chapter 338. Section 196.010(5), RSMo, defines "drug" as:

- (a) articles recognized in the official United States

 Pharmacopoeia, Official Homeopathic Pharmacopoeia of the

 United States, or official National Formulary, or any

 supplement to any of them; and
- (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(c) articles, other than food, intended to affect the structure or any function of the body of man or other animals; and(d) articles intended for use as a component of any articles specified in clause (a), (b), or (c); but does not include devices or their components, parts or accessories.

This definition shows that "drug" includes those used by man or animal. Because this definition is consistent with the dictionary definition of drugs, it confirms the plain and ordinary meaning of the word. Again, "drug" includes those drugs used for either animals and humans.

Similarly, Chapter 195 provides regulation for dispensing certain drugs in Missouri. Chapter 195 must be read together with Chapter 338 as Chapter 195 also regulates the conduct of pharmacies in Missouri. And Chapter 195 – which addresses "controlled substances" – applies to human and animal use.

Controlled substances are subject to more stringent control than legend drugs. The trial court properly considered the provisions of Chapter 195, RSMo, in its determination that UPCO falls under the regulation of Chapter 338, RSMo. First, Section 195.070.2, RSMo, states that a veterinarian may prescribe controlled substances in the course of his professional practice. This correlates with the provisions of Section 340.200, RSMo, which allows a veterinarian to prescribe drugs. Second, Section 195.060.1, RSMo, contemplates that controlled substances may be prescribed for an animal as well as for a human and requires that the pharmacist filling the prescription notate the species of

animal on the label of the prescription. This shows legislative intent that veterinarian drugs be dispensed by a licensed pharmacy and a licensed pharmacist.

Lastly, the definition of "drug" found in Section 195.010(14), RSMo, defines "drug" consistently with Section 196.010(5), RSMo. In fact, the only difference in the definitions is that Section 196.010(5), RSMo, uses the word "articles" and Section 195.010(14), RSMo, uses the word "substances" to refer to the material making up the drug. Both of these definitions include materials "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals." Sections 196.010(5) and 195.010 (14)(b), RSMo.

All statutes should be read together to show one legislative intent and purpose. *Xerox Corp. v. Travers*, 529 S.W.2d 418, 422 (Mo banc 1975)(statutes that deal with the same subject are presumed to be governed by "one spirit and policy" and are intended to be "consistent and harmonious in their several parts and provisions"). All statutes should be harmonized to a logical and consistent result. *Id.* Chapters 195 and 196, RSMo, define "drug" to include drugs used for both humans and animals. Chapter 338, RSMo, provides the mechanism for the state to regulate those who dispense drugs, controlled and legend drugs. These statutes must be read in *pari materia* as they deal with the same subject matter and are governed by "one spirit and policy." It would be inconsistent and contrary to well settled law to apply a different meaning to the word "drug" for the purposes of Chapter 338, RSMo, than the legislature applied in Chapters 195 and 196, RSMo.

If UPCO sells controlled drugs, it must comply with Chapter 195, RSMo. If UPCO sells legend drugs, it still must have a license to do so because the legislature used the word "drug" consistently to mean all prescription drugs that are subject to regulation by the provisions of Chapter 338, RSMo, regardless of whether the end user is a human or an animal. UPCO fails to meet its burden to show otherwise.

C. The Pharmacy Board properly regulates dispensing of prescription drugs

UPCO argues that the Pharmacy Board may not regulate the dispensing of prescription drugs when a veterinarian writes the prescription. UPCO's real argument in this case is that drugs used for animals should be wholly unregulated in the State of Missouri. UPCO seeks to have the right to dispense any legend drug, many of which are the same drugs used by humans, without any controls or safeguards to ensure proper use of the drugs. This argument fails. Chapter 338, RSMo, grants the Pharmacy Board authority to regulate all dispensation of prescription drugs and specifically states that individual health care providers, including veterinarians, may also dispense these drugs. Section 338.010, RSMo. The fact that veterinarians, and other doctors, have separate regulatory agencies, does not affect the authority of the Pharmacy Board. The Missouri State Board of Podiatric Medicine regulates podiatrists. Chapter 330, RSMo. The Missouri State Dental Board regulates dentists. Chapter 332, RSMo. Both podiatrists and dentists are authorized to write prescriptions. Sections 330.010 and 332.361, RSMo,

respectively. Yet, no special language is required in Chapter 338, RSMo, to allow pharmacists to fill prescriptions from a dentist. UPCO fails to meet its burden to show that Chapter 338, RSMo, does not apply to filling prescriptions written by veterinarians. Veterinarians are simply another type of licensed health care provider like dentists or podiatrists. Chapter 338, RSMo, encompasses prescriptions written by all licensed health care providers.

D. No authority exists for the Veterinary Board to regulate dispensing legend drugs

The veterinary practice act, found in Chapter 340, RSMo, authorizes veterinarians to write prescriptions just like the practice acts regulating other health care providers authorize them to write prescriptions as discussed above. No provision of the veterinary practice act grants authority to dispense legend drugs as a pharmacy would. And, even if it did, UPCO makes no assertions that it dispenses legend drugs under authority of Chapter 340, RSMo. An agency created by statute possesses only those powers granted to it by statute. *Bodenhausen v. Missouri Board of Registration for Healing Arts*, 900 S.W.2d 621, 622 (Mo banc 1995). Chapter 340, RSMo, grants no authority to veterinarians to fill prescriptions; rather, Chapter 338, RSMo, controls the filling of prescriptions.

The other statute UPCO cites states that a merchant may sell non-prescription drugs. This is consistent with the provisions of Chapter 338, RSMo. No provision of the veterinary practice act authorizes the Veterinary Board to regulate the dispensation of

legend drugs. As UPCO states, a more specific statute takes precedence over a general statute. *Greenbriar Hills Country Club v. Director of Revenue*, 935 S.W.2d 36, 38 (Mo banc 1996). Chapter 338, RSMo, specifically regulates prescription drugs; Chapter 340, RSMo, makes no mention of dispensing prescription drugs. Therefore, Chapter 338, RSMo controls dispensation of prescription drugs, including legend drugs, and the Pharmacy Board acts within its legislative authority to regulate the dispensing of prescription drugs for both humans and animals.

E. Subsection I.6 of UPCO's brief cites no relevant law or fact

UPCO spends much time detailing what happened in the *Chariton* case. This bears absolutely no relevance to the present matter. *Chariton* was a circuit court case involving different parties than the case at bar and was resolved by settlement agreement between the parties. This case has no precedential or persuasive value whatsoever. Furthermore, whether the Board has pursued enforcement actions against UPCO before or against any other company before is also totally irrelevant since the Board has authority to exercise discretion in its enforcement efforts. This portion of the brief should be ignored.

F. Rule of Lenity inapplicable to the case at bar

The Rule of Lenity applies only to criminal prosecutions. It gives a criminal defendant the benefit of a lesser penalty where there is an ambiguity in the statute allowing for more than one interpretation. *State v. Rowe*, 63 S.W.3d 647, 650 (Mo banc 2002). This is not a criminal prosecution and there is no issue of lesser or greater penalty

nor is there an ambiguity in the statute. This rule has no bearing on this case.

II. CHAPTER 338 VIOLATES NO CONSTITUTIONAL PROVISION (Responds to Point II)

UPCO failed to preserve any constitutional challenges and therefore, Point II of its brief must be denied.

To raise a constitutional question on appeal, a constitutional question must 1) be raised at the first available opportunity; 2) designate specifically the constitutional provision claimed to have been violated; 3) state the facts showing the violation; and 4) preserve the constitutional question throughout for appellate review. *Callier v. Director of Revenue*, 780 S.W.2d 639, 641 (Mo banc 1989). A mere reference to a violation of the constitution that fails to specify the articles and section or that fails to quote the provision itself fails to raise the question for appellate review. *Id.* at 641, 642.

UPCO first raises these constitutional questions on appeal. These questions were not raised in their "First Amended Petition" filed in the Circuit Court of Cole County (LF p 284-291) nor were they raised in "Plaintiff's Motion for Summary Judgment" filed in the Circuit Court of Cole County (LF, pp. 298-311). The citation to the record UPCO makes on page 10 of its brief regarding a constitutional challenge fails to rise to the necessary standard in that it simply says that "[t]o construe the Pharmacy Practices Act to govern the sale of veterinary drugs for the treatment of animals <u>would invite</u> a constitutional challenge to the Act." (Emphasis added). UPCO never challenged the constitutionality of the Act; it merely threatened such a challenge at a later date. LF, p.

435. A constitutional question must be raised in the court below and cannot be raised for the first time on appeal. *Kansas City v. Graybar Electric Company*, 454 S.W.2d 23, 25 (Mo banc 1970). The questions must be preserved throughout the proceeding. *Id.* UPCO did not preserve this question for review throughout these proceedings and the brief does not provide a sufficient statement of facts showing the violation. By failing to meet these standards, UPCO waived any constitutional challenge to the Pharmacy Practice Act.

As more fully discussed above, the Pharmacy Practice Act provides sufficient notice that anyone dispensing drugs requiring a prescription must comply with the provisions of Chapter 338. UPCO cites the decision of the Western District and the Buchanan County Circuit Court in support of its position, however, both of those decisions were reversed and vacated by this Court's previous ruling. *United Pharmacal*, 159 S.W.3d 361. Furthermore, UPCO asserts that Chapter 338, RSMo, in its entirety, is unconstitutional but fails to provide any factual or legal support to show how each and every provision is unconstitutional. Statutes are presumed constitutional and will not be overturned absent a showing of clear and undoubtable violation. *Conseco Finance Servicing Corporation v. Missouri Department of Revenue*, --- S.W.3d ----, 2006 WL 1605014 (Mo banc June 16, 2006). UPCO's brief fails to provide sufficient argument for Respondent to properly address and respond.

To the extent Respondent can respond, all provisions of Chapter 338, RSMo, that are at issue in this case survive any challenge for being void for vagueness in that, as fully discussed above, the plain and ordinary meaning of the provisions of Chapter 338, RSMo,

requires that all legend drugs be dispensed by a pharmacy, regardless of whether the end user is a human or an animal. The test to determine whether a statute is void for vagueness is "whether the language conveys to a person of ordinary intelligence a sufficiently definite warning as to the proscribed conduct when measured by common understanding and practice." *Cocktail Fortune, Inc. v. Supervisor of Liquor Control*, 994 S.W.2d 955, 957 (Mo banc 1999). However, the court must hold valid any statute capable of being given effect by any "reasonable and practical construction." *Id.* In addition, this doctrine is most commonly used in criminal proceedings, which this is not. However, the doctrine can be applied in civil cases, but a greater tolerance is to be given as the "consequences of imprecision are qualitatively less severe." *Id.* The language contained in Chapter 338, RSMo survives any challenge for void for vagueness as it relates to this case.

UPCO fails to meet its burden to show that Chapter 338, RSMo, violates any provision of the Missouri or United States Constitution.

Summary

The decision of the Circuit Court should be upheld.

Respectfully submitted,

JEREMIAH W. (JAY) NIXON Attorney General

Sharon K. Euler Assistant Attorney General Missouri Bar No. 42940

PennTower Office Center 3100 Broadway, Suite 609 Kansas City, Missouri 64111 Telephone: 816-889-5000

Telefax: 816-889-5006

E-mail: sharon.euler@ago.mo.gov

Certification of Service and Compliance with Rule 84.06(b) and (c)

The undersigned hereby certifies that on this ____ day of June, 2006, one true and correct copy of the foregoing brief, and one disk containing the foregoing brief, were mailed, postage prepaid, to:

R. Dan Boulware R. Todd Ehlert Sharon Kennedy 3101 Frederick Ave. St. Joseph, Missouri 64506

The undersigned further certifies that the foregoing brief complies with the limitations contained in Rule No. 84.06(b), and that the brief contains 5074 words.

The undersigned further certifies that the labeled disk, simultaneously filed with the hard copies of the brief, has been scanned for viruses and is virus-free.

Assistant Attorney General	

APPENDIX

Chapter 338		\- 1
4 CSR 270-6	A	\- 2
4 CSR 270-6		\ -3