IN THE MISSOURI SUPREME COURT

NO. SC87316

UNITED PHARMACAL COMPANY OF MISSOURI, INC.,

Appellant,

VS.

MISSOURI BOARD OF PHARMACY,

Respondent.

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

APPELLANT'S BRIEF

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JURISDICTIONAL STATEMENT

This appeal from the Circuit Court of Cole County, Missouri, involves the question of whether the Respondent Missouri Board of Pharmacy's authority under the Missouri Pharmacy Practices Act, RSMo Chapter 338, extends beyond regulating the dispensing of drugs for human use to regulating the retail sale of *veterinary* prescription drugs for use in *animals*.

In particular, if the Pharmacy Practices Act can be construed, as the court below held, to regulate retail veterinary prescription drug sales notwithstanding the absence of any language referring to animals, then this case presents the question of whether the Act is void for being unconstitutionally vague because it fails to apprise persons of ordinary intelligence that the retail sale of veterinary drugs for use in animals constitutes the "practice of pharmacy" under Chapter 338, and that a person must be licensed as a pharmacy or employ a licensed pharmacist to sell such drugs.

Hence, this action challenges the constitutionality of Chapter 338, and jurisdiction is proper in this Court, which has exclusive appellate jurisdiction in all cases involving the validity of a statute of this State pursuant to Mo. Const. Art. 5, § 3.

STATEMENT OF FACTS

This is Plaintiff-Respondent United Pharmacal Company of Missouri, Inc.'s ("UPCO") second visit to this Court with respect to this case. It returns on the merits after this Court ordered the case transferred for lack of venue from Buchanan County to Cole County. *See United Pharmacal Company of Missouri, Inc. v. Missouri Board of Pharmacy*, 159 S.W.3d 361 (Mo. banc 2005).

This appeal arises from a declaratory judgment action brought by UPCO seeking a declaration as to whether the legislature granted the Respondent Missouri Board of Pharmacy (the "Pharmacy Board") authority to regulate the retail sale of veterinary prescription drugs. L.F. 284-91. To the extent the Missouri Pharmacy Practices Act, RSMo Chapter 338, could be so construed, UPCO alternatively challenged the Act as being unconstitutionally vague. L.F. 435-36; Tr. (10/17/02) at 21-24. Before transfer, both the Buchanan County trial court and Western District Appellate Court held that no authority to regulate veterinary drug sales could be found in the Pharmacy Practices Act. L.F. 253; United Pharmacal Company of Missouri, Inc. v. Missouri Board of Pharmacy, 2004 WL 913537, *7 (Mo. App. W.D. 2004), vacated by 159 S.W.3d 361 (Mo. banc 2005). However, the Cole County trial court, after transfer, reached the opposite conclusion, and also held that the Act is not void for vagueness. L.F. 453-58; 476. In this appeal, UPCO seeks review of the Cole County Court's decision.

UPCO is a retail store that sells animal feeds and products. <u>L.F. 287</u>, ¶ 14; <u>L.F.</u> 293, ¶ 14; <u>L.F. 474</u>. For 20 years, UPCO has sold "federal legend" (*i.e.*, prescription) veterinary drugs to consumers pursuant to lawful veterinary prescriptions for the treatment of their animals. *Id.* UPCO does not sell or otherwise dispense drugs for human use. <u>L.F. 475</u>.

The Pharmacy Board has monitored UPCO's operations for the past twenty years and was aware of these veterinary drug sales. L.F. 287 ¶¶ 15-16; L.F. 293, ¶¶ 15-16; L.F. 391. In fact, it specifically investigated UPCO in 1994 based on a complaint by a veterinarian that UPCO was selling veterinary legend drugs directly to consumers without being licensed as a pharmacy. L.F. 338; L.F. 299, ¶5; L.F. 444, ¶6. At that time, the Board determined that UPCO was not violating the Pharmacy Practices Act. L.F. 300, ¶8; L.F. 444, ¶6; L.F. 384; L.F. 338.

In 1997, the Board again investigated UPCO, and again took no action against it for selling animal legend drugs without a pharmacy license. <u>L.F. 300, ¶11; L.F. 444,</u> ¶6; L.F. 384.

Then, in 2000, Pharmacy Board Inspector Tom Glenski – on his own initiative and without the direction of the Pharmacy Board – began a third investigation of UPCO. L.F. 302, ¶23; L.F. 444, ¶8; L.F. 304, ¶36; L.F. 444 ¶ 10; L.F. 325, at 42:2-44:5; L.F. 326, at 46:1-3. Inspector Glenski directed one of his inspectors to place an order with UPCO for a veterinary legend product. L.F. 384; L.F. 303, ¶24; L.F. 444,

¶8. That inspector presented UPCO with a veterinarian's prescription for federal veterinary legend drugs, which UPCO filled. L.F. 384, 387-88. This time, in contrast to the two previous investigations, Inspector Glenski concluded that "UPCO is practicing pharmacy without a license by selling veterinary legend drugs to the public based on veterinarian orders." L.F. 385.

On June 21, 2001, the Pharmacy Board issued a "Cease and Desist Warning" to UPCO, asserting that UPCO's retail sale of veterinary legend drugs to consumers/owners of animals constituted the "practice of pharmacy" without a license in violation of RSMo §§ 338.010.1 (A30) and 338.220 (A36). L.F. 387-89; 303-04, ¶¶ 29-30; L.F. 444, ¶8. The Pharmacy Board ordered UPCO to stop selling animal legend drugs to consumers without being licensed as a pharmacy. L.F. 389; L.F. 304, ¶32; L.F. 444, ¶10. In its Cease and Desist Letter, the Pharmacy Board pointed out that, as provided in RSMo § 338.195 (A32), operating a pharmacy or practicing pharmacy without a license is a Class C felony. L.F. 388.

After receiving the Cease and Desist Letter, UPCO responded by filing a Petition in the Circuit Court of Buchanan County, Missouri – the county of its residence. <u>L.F. 13-20</u>. In its petition, UPCO sought a declaration that the Pharmacy Board promulgated a rule in excess of the authority granted by the legislature and without following proper rule-making procedures, and that the Board's demand that

UPCO cease selling veterinary prescription drugs without a pharmacy license and without hiring a pharmacist is unlawful and void. <u>L.F. 19</u>.

The Pharmacy Board moved to dismiss UPCO's Petition, asserting that because venue was improper in Buchanan County the case should be transferred to Cole County Circuit Court. <u>L.F. 21-22</u>. The Pharmacy Board's motion was later converted to a summary judgment motion. <u>L.F. 40-44</u>. UPCO filed its cross-motion for summary judgment on the merits of the case (L.F. 78-189; <u>219-237</u>), as well as an opposition to the Board's summary judgment motion. <u>L.F. 190-218</u>. At oral argument on the cross-motions for summary judgment, UPCO's counsel argued, among other things, that the Pharmacy Practices Act did not clearly apprise UPCO that it must be licensed as a pharmacy to sell veterinary prescription drugs. <u>Tr.</u> (10/17/02) at 21-24.

The Buchanan County trial court found that venue was proper and therefore reached the merits of the cross motions for summary judgment. <u>L.F. 252-54</u>. Construing the Pharmacy Practices Act, the trial court stated that it "fails to discern any express legislative intent [in Chapter 338] to extend the powers of the Defendant to encompass the regulation of drugs to other than patients (humans) upon the prescription by physicians and other human health-care professionals." <u>L.F. 253</u>.

The Western District Court of Appeals affirmed the trial court's judgment both as to venue and the merits. *United Pharmacal Company of Missouri, Inc. v. Missouri*

Board of Pharmacy, 2004 WL 913537, *7 (Mo. App. W.D. 2004), vacated on other grounds by 159 S.W.3d 361 (Mo. banc 2005). Like the trial court, the Western District also failed to discern any legislative intent to grant the Pharmacy Board authority to regulate veterinary drugs, stating:

The trial court decided the issue correctly. If the legislature does intend to extend pharmacy law to include the business practice of Pharmacal, it may do so, taking into consideration existing statutes pertaining to veterinarians, Sections 340.200 to 340.330, and particularly, Section 340.216.

United Pharmacal, 2004 WL 913537, at *7.

On the Pharmacy Board's application, this Court accepted transfer of this case. *United Pharmacal Company of Missouri, Inc. v. Missouri Board of Pharmacy*, 159

S.W.3d 361, 363 (Mo. banc 2005). This Court held that venue was improper in Buchanan County, and remanded the case for transfer to the Cole County Circuit Court. *See id.* at 367. This Court did not address the merits of this action in the first appeal. *See id.*

After transfer to Cole County Circuit Court, UPCO amended its Petition (<u>L.F.</u> 277, 284-91) and again filed a motion for summary judgment, arguing that the Pharmacy Practices Act does not authorize the Pharmacy Board to regulate the sale of veterinary drugs. <u>L.F. 298-427</u>; 428-42. UPCO expressly argued that any contrary construction would render the Pharmacy Practices Act unconstitutionally vague (<u>L.F.</u>

435-36), as the Western District court intimated when it stated: "[T]he general assembly is invited to reexamine the entire statutory scheme of chapter 338, so that those who must abide by licensure are clearly and fully aware of what types of conduct and businesses practices are expected." *United Pharmacal*, 2004 WL 913537, at *7.

After oral argument, the Cole County trial court denied UPCO's Motion for Summary Judgment. <u>L.F. 453-58</u>. Construing Chapter 338, the court held that the sale of veterinary legend drugs is the "practice of pharmacy" and thus within the purview of the Pharmacy Board. <u>L.F. 458</u>. UPCO timely moved for rehearing to draw the Court's attention to overlooked facts and arguments, which motion was denied after oral argument. <u>L.F. 459-71</u>; 476.

UPCO timely filed its Notice of Appeal to this Court on December 9, 2005.

L.F. 477-88.

POINTS RELIED ON

I. The trial court erred in construing the Pharmacy Practices Act, Chapter 338, as providing that the retail sale of veterinary prescription drugs to consumers for use in animals pursuant to a veterinarian's prescription constitutes the "practice of pharmacy," and that Plaintiff UPCO must therefore be licensed as a pharmacy to engage in such conduct, because the legislature neither expressly nor impliedly granted the Pharmacy Board authority to regulate such conduct in that the plain and ordinary meaning of the words used does not evince a legislative intent to grant such authority to the Pharmacy Board; the Pharmacy Practices Act is not ambiguous and therefore the trial court's resort to rules of statutory construction was improper; and even if the Pharmacy Practices Act were ambiguous, the words "drugs" and "patient" as used in the Act cannot be construed in the same manner as the Controlled Substances Act, the Food, Drug and Cosmetic Act and/or the Veterinary Practices Act, as the court below held, because those Acts serve different goals than the Pharmacy Practices Act; and any ambiguities in this penal statute should be construed against the Pharmacy Board.

Director, Missouri Dep't of Public Safety v. Murr, 11 S.W.3d 91 (Mo. App. W.D. 2000)

Smith v. Shaw, 159 S.W.3d 830 (Mo. banc 2005)

State ex rel. Kelsey v. Smith, 75 S.W.2d 832 (Mo. banc 1934)

State ex rel. Cairo Bridge Comm'n v. Mitchell, 181 S.W.2d 496 (Mo. banc 1944)

RSMo § 338.010 (2000)

RSMo § 338.210 (2000)

RSMo § 338.210 (Cum. Supp. 2005)

RSMo § 338.220 (Cum. Supp. 2005)

RSMo § 340.216 (2000)

II. The trial court erred in ruling that the Pharmacy Practices Act, RSMo Chapter 338, is constitutional because the Act violates the due process clauses of the Missouri Constitution, Art. I, § 10, and the Fourteenth Amendment to the United States Constitution in that is unconstitutionally vague because it fails to apprise UPCO and other persons of ordinary intelligence that the retail sale of veterinary prescription drugs to consumers for use in animals pursuant to a veterinarian's prescription constitutes the "practice of pharmacy," and that retailers such as Plaintiff UPCO must therefore be licensed as a pharmacy to engage in such conduct.

State v. Dunn, 147 S.W.3d 75 (Mo. banc 2004)

U.S. Const. 14th Amendment

Missouri Const. Art. I, § 10

ARGUMENT

The trial court erred in construing the Pharmacy Practices Act, Chapter I. 338, as providing that the retail sale of veterinary prescription drugs to consumers for use in animals pursuant to a veterinarian's prescription constitutes the "practice of pharmacy," and that Plaintiff UPCO must therefore be licensed as a pharmacy to engage in such conduct, because the legislature neither expressly nor impliedly granted the Pharmacy Board authority to regulate such conduct in that the plain and ordinary meaning of the words used does not evince a legislative intent to grant such authority to the Pharmacy Board; the Pharmacy Practices Act is not ambiguous and therefore the trial court's resort to rules of statutory construction was improper; and even if the Pharmacy Practices Act were ambiguous, the words "drugs" and "patient" as used in the Act cannot be construed in the same manner as the Controlled Substances Act, the Food, Drug and Cosmetic Act and/or the Veterinary Practices Act, as the court below held, because those Acts serve different goals than the Pharmacy Practices Act; and any ambiguities in this penal statute should be construed against the Pharmacy Board.

A. Standard of Review

A trial court's interpretation of a statute is reviewed *de novo*. *Smith v. Shaw*, 159 S.W.3d 830, 833 (Mo. banc 2005).

B. Argument

 There Is No Express Language in Chapter 338 Granting the Pharmacy Board Authority to Govern the Retail Sale of Veterinary Drugs

The place to begin in construing a statute is its express language. The legislature's intent is to be determined from the plain and ordinary meaning of the language used in the statute. *See Smith v. Shaw*, 159 S.W.3d 830, 833 (Mo. banc 2005); *State ex rel. Nixon v. Alternate Fuels, Inc.*, 181 S.W.3d 177, 181 (Mo. App. W.D. 2005). Only if the statute is ambiguous are the rules of statutory construction to be applied. *Smith*, 159 S.W.3d at 833; *Alternate Fuels, Inc.*, 181 S.W.3d at 181.

There is no express language in Chapter 338 granting the Pharmacy Board the authority to govern the sale of veterinary drugs for use in animals, as the Pharmacy Board candidly admits. <u>L.F. 333-34</u>; <u>L.F. 395</u>; <u>L.F. 309</u>, ¶ 62, 64; <u>L.F. 446</u>, ¶ 19.

RSMo § 338.220 declares it unlawful for persons to operate or maintain a "pharmacy" without a license:

It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate or

maintain any *pharmacy*, as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy.

RSMo § 338.220 (Cum. Supp. 2005) (A37).

The term "pharmacy" is defined in § 338.210. At the time the Cease and Desist Warning Letter was issued to UPCO, § 338.210 defined "pharmacy" as follows:

As used in sections 338.210 to 338.300 "*pharmacy*" shall mean any pharmacy, drug, chemical store, or apothecary shop, conducted for the purpose of compounding, and dispensing or retailing of any drug, medicine, chemical or poison when used in the compounding of a *physician's* prescription.

RSMo § 338.210 (2000) (A33) (emphasis added).

Section 338.210 was amended effective on July 10, 2001 – after the Cease and Desist Letter but before UPCO filed its Petition in this case. Section 338.210 now defines a "pharmacy" as follows:

- 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.

RSMo § 338.210 (Cum. Supp. 2005) (A34) (emphasis added).

The "practice of pharmacy" is defined in § 338.010.1:

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; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with

patients and other health care practitioners about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his duties. This assistance in no way is intended to relieve the pharmacist from his responsibilities for compliance with this chapter and he will be responsible for the actions of the auxiliary personnel acting in his assistance. 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.

RSMo § 338.010.1 (2000) (A30) (emphasis added).

As evident from a plain reading of Sections 338.010, 338.210 or 338.220, neither they nor any other provision of Chapter 338 – either before or after the 2001

amendments – expressly empower the Pharmacy Board to regulate the sale of drugs for *animal* use pursuant to *veterinary* prescription.

Indeed, the Pharmacy Board admits that neither § 338.010 nor § 338.210 specifically state that an entity must be licensed as a pharmacy or hire a licensed pharmacist to sell veterinary legend drugs for the treatment of animals. L.F. 333-34; L.F. 395; L.F. 309, ¶ 62-64; L.F. 446, ¶ 19. When asked where, in § 338.010, there was any such language, Pharmacy Board corporate designee and Executive Director Kevin Kincade responded: "Those exact words are not in the statute, no." L.F. 333. Likewise, when asked where such language appeared in § 338.210, Mr. Kinkade again admitted there was none:

Q: And again anywhere in 338.210 which is pharmacy defined does that statute contain the language contained in frequently asked question and answer number eight?²

¹ L.<u>F. 315-16</u>.

L.F. 315-16.

² Frequently Asked Question No. 8 ("FAQ #8) is a reference to the following question and answer that were first posted on the Pharmacy Board's public information website in 2001:

A: It does not.

Q: And was that then the staff's interpretation of that statute?

A: Yes.

L.F. 334, at 77:12-16; L.F. 309, ¶ 64; L.F. 446, ¶ 19; L.F. 333, at 73:22-25.

2. Authority Cannot Be Inferred from the Plain Language

Nor can it properly be inferred from the language of Chapter 338 that the legislature intended to give the Pharmacy Board authority over veterinary prescription drug sales. Chapter 338 refers to "patients" (and formerly referred to "physicians"), but not to "animals" or "veterinarians." Undefined words in a statute are to be given

8. Does an entity have to be licensed as a pharmacy to sell veterinary legend drugs to the consumer/owner of the animal(s)?

Yes. Veterinary legend drugs may only be sold based on the order/prescription of a veterinarian. An entity may not sell veterinary legend drugs directly to the consumer (owner of animal) based on a prescription without being licensed as a pharmacy. . . .

L.F. 382; L.F. 307-08, ¶¶ 54-55; L.F. 445, ¶ 17; L.F. 331-32.

³ The only reference to veterinarians in Chapter 338 is in the last sentence in § 338.010.1:

their plain and ordinary meaning as found in the dictionary. *Laws v. Secretary of State*, 895 S.W.2d 43, 46 (Mo. App. W.D. 1995). A "patient" is defined in Webster's Unabridged Dictionary as "(1) a sick individual, esp. when awaiting or under the care and treatment of a physician or surgeon . . . (2) a client for medical service (as of a physician or dentist)" Webster's Third International Dictionary of the English Language Unabridged, p. 1655. The plain meaning of "patients" is *human* patients, not animals.

A "physician" is defined as "a person in skilled in the art of healing . . . a doctor of medicine" *Id*. at 1707. The plain meaning of "physician" is a doctor who

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.

RSMo § 338.010.1 (A30). But this solitary reference to veterinarians – which simply identifies professionals whose pharmaceutical dispensing practices are not regulated by the Pharmacy Board – cannot be reasonably be construed as indicating a legislative intent to grant the Pharmacy Board authority to regulate veterinary drug sales.

treats human patients, not animals. Indeed, the doctor who provides treatment to animals is commonly known and referred to as a "veterinarian," not a "physician." Giving the words their plain meaning, a reasonable reader of Chapter 338 would not interpret "patients" to include animals, or "physician" to include a veterinarian.

3. No Pharmacy License Classification Exists for Retail
Veterinary Pharmacies, Thus Showing that the Legislature
Did Not Intend the Pharmacy Board to Regulate Such
Businesses

The fact that the legislature did not intend to grant the Pharmacy Board authority to regulate retail veterinary prescription drug sales can also be gleaned from the statutory scheme. In particular, § 338.220 contains a list of eleven classifications of pharmacy licenses that the Pharmacy Board may issue. *See* RSMo § 338.220 (Cum. Supp. 2005) (A37). But none of those classifications apply to persons or businesses engaged in the retail sale of veterinary drugs. Instead, all eleven license classifications relate to *human* patient care and treatment. For example, under

The eleven classifications are:

- (1) Class A: Community/ambulatory;
- (2) Class B: Hospital outpatient pharmacy;
- (3) Class C: Long-term care;

subpart (2), a license may be issued for a "hospital outpatient pharmacy." *See id.* This obviously refers to a facility where humans may obtain medicine on an outpatient basis, not a veterinary clinic where animals may receive "outpatient" treatment. Subpart (4) is for a pharmacy license for "home health care," which also obviously would not apply to animals. *See id.* Had the legislature intended the Pharmacy Board to govern businesses such as UPCO, there should be a separate classification of pharmacy license applicable to retail veterinary pharmacies. There is none.

"[A]n administrative agency enjoys no more authority than that which is granted to it by statute." *Director, Missouri Dep't of Public Safety v. Murr,* 11 S.W.3d 91, 96 (Mo. App. W.D. 2000) (citation omitted). "A power may be implied

- (4) Class D: Home health care;
- (5) Class E: Radio pharmaceutical;
- (6) Class F: Renal dialysis;
- (7) Class G: Medical gas;
- (8) Class H: Sterile product compounding;
- (9) Class I: Consultant services;
- (10) Class J: Shared Services;
- (11) Class K: Internet.

RSMo § 338.220 (Cum. Supp. 2005) (A37).

'only if it necessarily follows from the language of the statute." *Id.* (citation omitted). It does not *necessarily* follow from any language within Chapter 338 that the legislature intended to grant the Pharmacy Board authority to regulate retail veterinary drug sales. This should be the end of the inquiry, and the trial court's judgment should be reversed.

4. The Three Bases Underlying the Trial Court's Decision Do Not

Overcome the Absence of an Express or Implied Grant of

Authority to the Pharmacy Board

The Pharmacy Practices Act is not ambiguous, nor did the trial court expressly find it to be so. Nevertheless, the trial court reached outside the four corners of the Act in an attempt to find authority where none exists in the plain language of the Act. Specifically, the court identified three reasons for its holding. Two of them involved borrowing definitions of undefined words from other chapters. The third was a finding that the Controlled Substances Act somehow shows a legislative intent that pharmacies will fill veterinary prescriptions. Even if it were proper for the trial court to have resorted to rules of statutory construction – which it was not – none of the trial court's bases permit a construction that gives the Pharmacy Board any authority beyond that which the legislature expressly granted.

a. The Trial Court Improperly Extrapolated the Definitionof "Drugs" from Other Statutes

In some circumstances it is permissible for a court, in construing an ambiguous statute, to look to how undefined terms in a statute are defined in other chapters. Weber v. Missouri State Hwy Comm'n, 639 S.W.2d 825, 829 (Mo. 1982). However, "the same words, occurring in different statutes of somewhat similar character, do not necessarily bear the same interpretation." State ex rel. Kelsey v. Smith, 75 S.W.2d 832, 833 (Mo. banc 1934). "Their meaning is influenced by the particular context, and sometimes by the object to be attained by the statute itself." Id.

Here, the trial court extrapolated the definitions of "drugs" from two unrelated statutes, the Controlled Substances Act, RSMo Chapter 195, and the Missouri Food, Drug and Cosmetic Act ("FDCA"), RSMo Chapter 196. Both chapters expressly define "drugs" as including pharmaceuticals not only for humans, but also for animals. *See* RSMo § 196.010(5)(b) (Cum. Supp. 2005) (A27) (defining "drugs" as including "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"); RSMo § 195.010(14)(b) (Cum. Supp. 2005) (A9-10) (defining "drugs" as "substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals.").

The court incorporated these borrowed definitions into the Pharmacy Practices

Act (<u>L.F. 455-56</u>) – notwithstanding the fact that both Chapters 194 and 195 expressly

state that the definitions therein are intended to apply *only* to specified provisions within their respective chapters. *See* RSMo § 19.010 (Cum. Supp. 2005) (A8) ("The following words and phrases *as used in sections 195.005 to 195.425* . . . mean") (emphasis added); RSMo § 196.010 (2000) (A27) (prefacing the definition section with, "*For purposes of sections 196.010 to 196.120*") (emphasis added).

The rule of construction that statutes that are *in pari materia* are construed similarly rests on the presumption that they are of "one spirit and policy and were intended to be consistent and harmonious." *State ex rel. Cairo Bridge Comm'n v. Mitchell*, 181 S.W.2d 496, 499 (Mo. banc 1944). There is no indication that the words in the three Acts at issue here were intended to be construed consistently with each other.

The trial court's finding that the word "drugs" should be construed consistently with the Controlled Substances Act was based on its misperception that all drugs that require a prescription are controlled substances and hence governed by the Controlled Substances Act. *See* Tr. (11/28/05), at 7-8. But that is not accurate. Although most, if not all, controlled substances are prescription drugs, not every prescription drug is a controlled substance. L.F. 475. In particular, the prescription drugs that UPCO sells are not controlled substances. *Id*.

Moreover, the three Acts were not intended to be "consistent and harmonious" because the Controlled Substances Act and the FDCA serve entirely distinct purposes

than the Pharmacy Practices Act. This is shown by the fact that they are governed by entirely different departments of the State. Both Chapters 195 and 196 are under the Department of Health and Senior Services, whereas the Pharmacy Board is under the Department of Economic Development. See RSMo § 195.015 (2000) (A16); RSMo § 195.030 (2000) (A18) (granting the Department of Health and Senior Services rulemaking and administrative authority with respect to the Controlled Substances Act) (emphasis added); RSMo § 196.045 (2000)(A29) (granting the Department of Health rulemaking authority to enforce the FDCA); 4 C.S.R. § 220.1.010 (A45) (Pharmacy Board regulations under the Department of Economic Development); L.F. 355 (Cease and Desist letter written on Department of Economic Development letterhead); the Pharmacy Board's official website, http://pr.mo.gov/pharmacistsabout-the-board.asp ("The Missouri Board of Pharmacy is a unit of the Division of Professional Registration of the Department of Economic Development."). As the names imply, the goal of the Department of Health is the *health and safety* of the people of this State, whereas the goal of the Department of Economy Development is the State's *economic* welfare.

Unlike the Controlled Substances Act and the FDCA, each of which *expressly* (and *necessarily* given their respective purposes), encompasses drugs for animal use, the Pharmacy Practices Act neither expressly regulates nor necessarily must regulate veterinary drugs in order to serve its purposes.

Specifically, the Controlled Substances Act was designed to regulate both the legal and illegal use of "controlled substances" because the drugs so designated have been determined to be addictive or hallucinogenic and thus have the potential of being abused. *See generally* Chapter 195. The Controlled Substances Act is primarily penal in nature, establishing laws making it a crime to unlawfully possess, sell or use controlled substances. *See generally id.* Thus, the Controlled Substances Act expressly and necessarily includes all drugs, whether for animal or human use, because all such drugs may be abused by humans.

The FDCA is concerned with ensuring the *safety* of foods and drugs – regardless of whether they are consumed by humans or animals. *See generally* Chapter 196. It also expressly states that it applies not only to *human*, but to *animal*, foods and drugs, ⁶ as it necessarily must in order to serve the goal of ensuring that only safe and properly labeled foods and drugs reach consumers.

The Pharmacy Board, on the other hand, as a division of the Department of Economic Development, was created primarily to license and regulate a specific *profession*: pharmacists and pharmacies. *See* RSMo Chapter 338. Indeed, in its own

⁵ See Casey, <u>830 S.W.2d at 480</u>.

⁶ See § 196.010(5), (7) (A27).

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regulations, the Pharmacy Board describes its duties as limited to, in effect, licensing applicants and disciplining licensees for violations of the Pharmacy Practices Act. 4

C.S.R. 220-1.010 (A45). UPCO is not and never has been a licensee of the Pharmacy Board. L.F. 475.

And, unlike the Controlled Substances Act and FDCA which must necessarily govern animal drugs, the Pharmacy Board need not regulate the dispensing of veterinary drugs on the order of a veterinarian because this conduct already falls within the purview of the Veterinary Practices Act, RSMo Chapter 340. *See* Section 5, *infra*.

Because the Controlled Substances Act and FDCA serve different goals than the Pharmacy Practices Act, it is improper to look to the former in construing the latter. *See Cairo Bridges*, 181 S.W.2d at 499.

Had the legislature intended to grant the Pharmacy Board the authority to regulate the dispensing of animal drugs, it would have and should have done so expressly, as it did when it enacted the Controlled Substances Act and FDCA. Indeed, it is telling that in § 195.070 of the Controlled Substances Act (establishing who is authorized to dispense controlled substances), the legislature treated veterinarians separately from all other practitioners who are also authorized to dispense controlled substances (*i.e.*, physicians, podiatrists, dentists and certain optometrists), enacting a separate subsection applicable only to veterinarians. *Compare* § 195.070.2 (A21) with

195.070.1 (A21). Thus, the legislature recognized that the dispensing of veterinary drugs is different than dispensing drugs intended for human use. But even though the legislature was plainly aware of those differences and the need to differentiate between human and veterinary pharmaceutical practices, it never expressly stated that the Pharmacy Board was authorized to govern both human and veterinary drugs. This suggests strongly that it did not intend to grant the Pharmacy Board such authority.

b. The Plain Meaning of "Patient" as used in Chapter 338 Does Not Include Animals

The court below also erred in borrowing the definition of the word "patient" from other chapters. Consistent with the term's use in the Controlled Substances Act and Veterinary Practices Act, the trial court similarly construed "patient" as used in the Pharmacy Practices Act to mean both humans and animals. This, too, was improper because the word "patient" is not ambiguous in the context used, and therefore resort to other chapters is improper. *See Smith*, 159 S.W.3d at 833; *Alternate Fuels, Inc.*, 181 S.W.3d at 181. Even if the word "patient" were ambiguous, it should not be given the same meaning used in the Controlled Substances Act or Veterinary Practices Act, both of which serve completely different purposes than the Pharmacy Practices Act.

The court's finding that an animal can be a "patient" under the Controlled Substances Act was based on a provision in § 195.100.4 addressing the labeling of

prescriptions. That section states that a pharmacist, when dispensing a prescription drug, must include on the label "the name of the patient or, *if the patient is an animal*, the name of the owner of the animal" *See* RSMo § 195.100.4 (2000) (A22). From this, the court illogically reasoned, it necessarily follows that when the legislature used the term "patient" in the Pharmacy Practices Act, it necessarily meant to include both humans *and* animals. But that conclusion does not necessarily follow from the premise.

Again, the two acts serve entirely different goals. Because the Controlled Substances Act expressly regulates both human and animal drugs, it must necessarily address labeling of drugs for both. In contrast, the word "patients" as used in the Pharmacy Practices Act does not expressly include animals, nor must it necessarily include animals. Instead, the interests of consumers in their animals' health and treatment are served by the Veterinary Medical Board. *See* Section 5, *infra*.

The court below also construed "patient" as used in Chapter 338 to include animals because an animal is considered the "patient" under the Veterinary Practices Act. *See* L.F. 457 (citing the definition of "veterinarian-client-patient relationship" in RSMo § 340.200(23) (Cum. Supp. 2005) (A41)). However, the legislature expressly stated that the definitions in § 340.200 apply only to the Veterinary Practices Act. *See* § 340.200 (A39) ("When used in sections 340.200 to 340.330, the following terms mean . . . ") (emphasis added). Moreover, for obvious reasons, the Veterinary

Practices Act must necessarily encompass animals, whereas the Pharmacy Practices
Act need not govern veterinary prescriptions because, again, such is more properly
governed under the Veterinary Practices Act.

For these reasons, the words "drugs" and "patient" as used in the Pharmacy Practices Act cannot be properly be given the same meaning as in the Controlled Substances Act, the FDCA and/or the Veterinary Practices Act.

c. The Pharmacy Board Does Not Have Exclusive

Jurisdiction to Regulate Every Person who Dispenses

Drugs

The third and final basis for the trial court's holding that the Pharmacy Practices Act governs veterinary drug sales was its finding that Controlled Substances Act not only "contemplates" but "requires" that pharmacies will fill prescriptions for veterinary drugs. *See* L.F. 456-57. The court found that the Controlled Substances Act and Pharmacy Practices Act "limit the class of persons/entities that may fill and dispense prescriptions" to pharmacists/pharmacies, drug manufacturers, drug wholesalers, and authorized prescribers (*i.e.*, physicians, podiatrists, dentists, optometrists, veterinarians). L.F. 456. Because, the court reasoned, UPCO does not fall within any of these categories, UPCO is not authorized to sell veterinary prescription drugs, and therefore is regulated by the Pharmacy Board. L.F. 458. There are two flaws with this analysis.

First, the issue is not whether UPCO is authorized to sell veterinary prescription drugs. The question is: Did the legislature, by the words used in Chapter 338, vest the authority to regulate such sales in the Pharmacy Board? The mere fact that a court believes UPCO's conduct *should* be regulated does not mean that the legislature has actually granted the authority to do so to any agency, let alone to the Pharmacy Board. Nor does it give the court the power to engraft any authority to regulate on a particular agency where the legislature has neglected to do so. Stated differently, the court's authority is limited to interpreting whether there is an existing grant of authority, not creating a new one. Indeed, "courts are without authority to read into a statute a legislative intent that is contrary to the intent made evident by giving the language employed in the statute its plain and ordinary meaning." Murr, 11 S.W.3d at 96. To the extent any agency has been vested with authority to regulate the sale of veterinary drugs, it is the Veterinary Medical Board, not the Pharmacy Board. See Section 5, infra.

Essentially, the court below reasoned that because UPCO's conduct *should* be regulated, it necessarily falls to the Pharmacy Board to do so. But, importantly, the Pharmacy Board does not have exclusive jurisdiction to govern the dispensing of pharmaceuticals. As the trial court itself recognized, pharmacists and pharmacies are not the only persons/entities authorized to dispense drugs. <u>L.F. 456</u>. The Controlled Substances Act also expressly authorizes physicians, podiatrists, dentists,

optometrists, and veterinarians, as well as drug manufacturers and drug wholesalers, to dispense controlled substances. *See* RSMo § 195.070. Yet the Pharmacy Board does not regulate those professions. Physicians, podiatrists, optometrists and veterinarians are licensed and regulated by separate agencies under their own statutory schemes. *See Casey v. State Board of Registration for the Healing Arts*, 830 S.W.2d 478, 480-81 (Mo. App. E.D. 1992) (citing Chapters 334, 332, 330, and 340). The Pharmacy Practices Act regulates only pharmacists, pharmacies, drug manufacturers and wholesale drug dealers. *See* Chapter 338. The fact that the Pharmacy Practices Act does not govern all persons who are authorized to sell or dispense prescription drugs establishes beyond any doubt that the legislature did not intend that every person who dispenses prescription drugs be governed by the Pharmacy Practices Act.

Section 195.400.8(2) of the Controlled Substances Act also undeniably establishes that not everyone who dispenses veterinary drugs must be a pharmacist or pharmacy regulated by the Pharmacy Board. Section 195.400.8(2) refers to [a]ny pharmacist, pharmacy, *or other authorized person* who sells or furnishes a substance.

. . upon prescription or order of a physician, dentist, podiatrist or veterinarian.
§ 195.400.8(2) (Cum. Supp. 2005) (A25) (emphasis added). Like § 195.070, this statute clearly contemplates that persons other than pharmacists or pharmacies are authorized to sell veterinary drugs upon a veterinarian's prescription. Because the Pharmacy Practices Act does not govern *every* person who is authorized to dispense

veterinary drugs, it cannot be said, as the trial court did, that the Controlled Substances Act evinces a legislative intent that the Pharmacy Practices Act govern retail veterinary drug distributors like UPCO.

The second flaw with the trial court's analysis is that the Controlled Substances Act only limits who may dispense "controlled" substances, i.e., narcotic, hallucinogenic or addictive drugs that are prone to abuse. See RSMo § 195.030 (2000) (A18) (granting the Department of Health and Senior Services the authority to promulgate rules regarding "control of the . . . dispensing of controlled substances within this state." (emphasis added)); § 195.060 (Cum. Supp. 2005) (A20) ("a pharmacist . . . may sell and dispense *controlled substances* to any person only upon a prescription of a practitioner as authorized by statute " (emphasis added)); § 195.070 (Cum. Supp. 2005) (A21) (authorizing physicians, dentists, certain optometrists and veterinarians to dispense "controlled substances."); § 195.100 (2000) (A22) ("Whenever a pharmacist or practitioner sells or dispenses any controlled *substance* on a prescription issued by a physician . . . or veterinarian " (emphasis added)).

The Controlled Substances Act does not purport to regulate who may dispense drugs, like veterinary legend drugs that UPCO sells, that are *not* controlled

substances. Not all prescription (a/k/a "legend") drugs are controlled substances, as the court below erroneously believed. L.F. 475, ¶ 5; see Tr. (11/28/05) at 7-8. UPCO does not sell controlled substances/narcotic drugs. L.F. 475, ¶ 5. It sells only federal legend veterinary drugs that are not controlled substances/narcotics. L.F. 474, ¶ 3. Because the Controlled Substances Act only governs who may dispense *controlled substances*, it cannot define who may or may not dispense *non*-controlled substances, such as the federal legend veterinary drugs sold by UPCO.

In sum, none of the trial court's stated grounds supports its judgment, and that judgment should be reversed. However, there are three additional reasons supporting reversal, as discussed in the following sections.

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A "legend" drug is a drug which, under the federal Food, Drug and Cosmetic Act, may only be dispensed by or upon a prescription and, in the case of a veterinary legend drug, must be labeled: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." *See* 21 U.S.C. § 353(f)(4) (A51-52); 21 C.F.R. § 201.105(b)(1) (A54). *See also* L.F. 474, ¶3; Tr. (11/28/07), at 7; *Arkansas State Board of Pharmacy v. Patrick*, 423 S.W.2d 265, 266 & n.2 (Ark. 1968) (although the case did not deal with the sale of veterinary drugs, "legend" drug was defined generally as a drug requiring a prescription and labeled that it may only be dispensed on prescription of a doctor, dentist or veterinarian).

5. The Legislature Granted the Missouri Veterinary Medical Board the Authority to Regulate Veterinary Drug Sales

Assuming that the Pharmacy Practices Act is found to be ambiguous such that a reviewing court may look outside the four corners of the Act to construe it, it is appropriate to look to other legislation for evidence of legislative intent when construing statutes creating and governing an agency. *Casey*, 830 S.W.2d at 480. Here, the Pharmacy Practices Act cannot be read as governing the sale of veterinary drugs because such authority was granted instead to the Veterinary Medical Board pursuant to the Veterinary Practices Act, RSMo Chapter 340.

In contrast to the Pharmacy Board, which could not identify any specific language within the Pharmacy Practices Act from which a legislative intent to grant authority to regulate the sale of animal drugs can be found, UPCO finds language within the Veterinary Practices Act showing that the legislature vested the Veterinary Medical Board with that authority. Specifically, § 340.216 of the Veterinary Practices Act provides, in pertinent part:

1. It is unlawful for any person not licensed as a veterinarian under the provisions of sections 340.200 to 340.330 to practice veterinary medicine or to do any act which requires knowledge of veterinary medicine for valuable consideration, or for any person not so licensed to hold himself or herself out to the public as a practitioner of veterinary

medicine by advertisement, the use of any title or abbreviation with the person's name, or otherwise

RSMo § 340.216.1 (2000) (A43) (emphasis added).

"Veterinary medicine" is defined as:

[T]he science of diagnosing, treating, . . . or preventing any animal disease, . . . or other physical or mental condition, including, but not limited, to the *prescription* or administration of any drug, . . . on any animal . . . or to render service or recommendations with regard to the any of the procedures in this paragraph.

RSMo § 340.200.28 (Cum. Supp. 2005) (A42) (emphasis added).

UPCO's conduct in rendering a service related to the prescription of a drug for an animal falls squarely within the purview of the Missouri Veterinary Medical Board.

Further, § 340.216.1(4) implicitly authorizes the Veterinary Medical Board to regulate veterinary prescription drug sales. It provides, in pertinent part:

- 1. It is unlawful for any person not licensed as a veterinarian under the provisions of sections 340.200 to 340.330 to practice veterinary medicine . . . except that nothing in sections 340.200 to 340.330 shall be construed as prohibiting: * * *
- (4) Any merchant or manufacturer from selling drugs, medicine, appliances or other products used in the prevention or treatment of

animal diseases if such drug, medicine, appliance or other product is not marked by the appropriate federal label. Such merchants or manufacturers shall not, either directly or indirectly, attempt to diagnose a symptom or disease in order to advise treatment, use of drugs, medicine, appliances or other products.

RSMo § 340.216.1(4) (2000)(A43) (emphasis added).

A "federal label" or "legend" drug is a prescription drug that may only dispensed with a label as required by the federal Food, Drug and Cosmetic Act. *See* footnote 7. Stated differently, § 340.216.1(4) provides that a merchant may sell veterinary drugs as long as they are not prescription drugs. 8 The necessary reverse implication is that if the merchant *is* selling veterinary prescription drugs, then his conduct *would* be regulated by the Veterinary Practices Act.

Indeed, when faced with a similar question, the Tennessee Attorney General held that the sale of veterinary prescription drugs by an unlicensed person falls within

⁸ For example, a merchant may sell over-the-counter veterinary drugs.

the purview of that State's Veterinary Practice Act. Tenn. Op. Atty. Gen. No. 03-135, 2003 WL 22422453 (Tenn. A.G.).

As a matter of public policy, it is improbable that the legislature, after so carefully vesting authority to govern the dispensing of animal pharmaceuticals in the Veterinary Medical Board, intended by the general, non-specific language of Chapter 338 to grant other licensing boards concurrent jurisdiction to regulate the same conduct. Where one statute deals with a particular subject in a general way, and a second statute treats a part of the same subject in a more detailed way, the more general should give way to the more specific. *Casey*, 830 S.W.2d at 481.

The Pharmacy Board's demand that UPCO establish a pharmacy and hire a licensed pharmacist defies common sense as well as legislative intent when the same conduct is regulated under Chapter 340 by the Veterinary Medical Board. A construction that both the Veterinary Medical Board and Pharmacy Board have

The Attorney General also held that the conduct was also proscribed by the Tennessee Pharmacy Practice Act. But, importantly, unlike Missouri's Pharmacy Practices Act, Tennessee's Pharmacy Practice Act expressly defines "drug" and "prescription drug" as including drugs for the treatment of animals. *See* Tenn. Code Ann. § 63-10-404(14), (33). Thus, it is distinguishable in this critical respect from Missouri's Pharmacy Practices Act.

concurrent jurisdiction would present a very real potential of inconsistent obligations on licensees. For example, if UPCO were to hire a pharmacist licensed under the Pharmacy Practices Act to dispense veterinary prescription drugs, that pharmacist might very well be deemed to be violating the Veterinary Practices Act by engaging in the practice of veterinary medicine without appropriate licensing and training.

A review of the Veterinary Practices Act, Chapter 340, strongly suggests the Pharmacy Board, in attempting to regulate the sale of drugs and medications for animals, is overstepping its legislative authority and invading the province of the Veterinary Medical Board. The trial court's judgment should be reversed for this additional reason.

6. The Pharmacy Board Itself Cannot Definitively Articulate a Basis for its Purported Authority

In construing a statute, it is also sometimes appropriate to consider the agency's interpretation of its own statutes. However, for at least *twenty years* – until 2001 -- the Pharmacy Board never interpreted the Pharmacy Practices Act as applying to the sale of veterinary legend drugs to animal owners. Even though there had been no interim change in the definition of "pharmacy," or "practice of pharmacy," ¹⁰ the

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When specifically asked whether the Board decided to pursue UPCO because of a change in the law, the Board's corporate designee replied: "The only information I

Pharmacy Board abruptly reversed its position in 2001and began asserting that it has authority to regulate veterinary drug sales. Given the Pharmacy Board's ambivalence about the scope of its authority, its interpretation of Chapter 338 is not entitled to any weight.

The Pharmacy Board has known for decades that UPCO and other businesses in Missouri routinely sold veterinary drugs to consumers pursuant to veterinary prescriptions without a licensed pharmacist on the premises. L.F. 287, ¶ 15-17; L.F. 292, ¶ 15-17; L.F. 307, ¶ 50; L.F. 445, ¶ 15; L.F. 391; L.F. 444, ¶ 6. Yet, as the Pharmacy Board admits, before 2001 it never sought to enjoin any entity from selling veterinary legend drugs to consumers pursuant to a veterinarian's prescription because that entity did not have a licensed pharmacist. L.F. 392-93, 324, at 38:25-39:5. In fact, the Pharmacy Board twice determined – in 1994 and 1997, after investigating UPCO's business practices — that UPCO was not in violation of the Pharmacy Practices Act licensing requirements for dispensing veterinary legend drugs to consumers. L.F. 299, ¶ 5; L.F. 300, ¶ 8-11; L.F. 444, ¶ 6.

have is that they reviewed the information in this case, discussed the [*Chariton*] case . . . and they made a determination at that point by motion and vote to follow that action. I don't have any information other than that." *See* L.F. 324, at 39:6-16.

Likewise, until 2001, the Pharmacy Board never took any action against West Plains Veterinary Supply, Inc., which had engaged in the same conduct as UPCO for 15 years with the Pharmacy Board's knowledge. L.F. 410-11. In fact, in 1994, the Pharmacy Board actually told a licensed drug distributor that it *could* sell veterinary legend products to customers with a veterinarian's prescription. L.F. 415-18, ¶2; L.F. 198-99, ¶51; L.F. 245, ¶51.

And, in August 2001, in a verified pleading, the Pharmacy Board admitted it had no authority to regulate the sale of veterinary drugs: "For purposes of this action, the Board maintains it has jurisdiction over the dispensing of human legend drugs, but it does not assert similar authority for dispensing of veterinary legend drugs." L.F.

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During discovery in this matter, the Pharmacy Board provided a letter to UPCO's counsel listing seven other times the Board has handled an incident involving the sale of veterinary drugs. L.F. 415-18. Of those incidents, there was only one, a 1993 incident, in which the Board sent a cease and desist letter to an entity selling veterinary drugs before the Board's change in policy sometime between 1998 and 2001 (L.F. 415, ¶ 1; L.F. 406, ¶ 2(d)). See Section 6, infra. That case is inapposite, however, because it involved a "licensed drug distributor" who voluntarily complied with the Board's cease and desist warning, and the letter does not indicate that the distributor was dispensing drugs pursuant to a veterinarian's prescription.

344, ¶ 15 (emphasis added). *Missouri Board of Pharmacy v. Chariton Vet Supply, Inc.*, Circuit Court of Randolph County ("Chariton"), L.F.301, ¶ 14; L.F. 444, ¶ 7.

Notwithstanding its admission in *Chariton* that it had no authority to regulate the dispensing of veterinary legend drugs, the *Chariton* case somehow became the basis for the Pharmacy Board's present assertions of such authority. Since the consent judgment was entered in *Chariton*, the Pharmacy Board has relied on *Chariton* as the basis for issuing cease and desist warnings to UPCO and other retailers for selling animal legend drugs. For example, Inspector Glenski stated in Investigation Report relating to UPCO:

[B] ased on a recent court case the Board believes that the sell [sic] of veterinary legend drugs based on a veterinarian's order would be considered the practice of pharmacy and the product could only be dispensed by a pharmacist in a pharmacy or the prescribing veterinarian.

L.F. 384-85 (emphasis added); L.F. 303, ¶¶ 26, 28; L.F. 444, ¶ 8; see also L.F. 384 ("Based on a recent court interpretation that the sale of legend veterinary drugs is the practice of pharmacy") (emphasis added); L.F. 324, at 37:17-39:16; L.F. 328, at 55:8-10.

Similarly, in an observation report with respect to West Plains Veterinary Supply, the Pharmacy Board stated: "A recent court case held that only dispensing veterinarians or pharmacies may dispense veterinary legend drug items to 'end

users." <u>L.F. 413</u>. The "recent court case" and "recent court interpretation" to which all of these documents refer was the *Chariton* case. <u>L.F. 329</u>; at 59:3-8; <u>L.F. 303</u>, ¶ 27; <u>L.F. 444</u>, ¶ 8.

In addition, the Pharmacy Board relied on the *Chariton* case as the authority for its statement posted on its website in FAQ #8 advising the public that entities must be licensed as a pharmacy to sell veterinary prescription drugs. <u>L.F. 332-33</u>, at 72:19-73:6; <u>L.F. 382</u>.

There are two problems with the Pharmacy Board's reliance on *Chariton* as authority for its asserted right to regulate veterinary drug sales. Not only is *Chariton* factually inapposite, the *Chariton* court did not, as the Pharmacy Board contends, actually hold that the sale of veterinary medicine is the "practice of pharmacy."

In 2001, the Pharmacy Board filed suit against Chariton for selling *human* legend drugs at *wholesale* to certain wholesale and retail veterinary suppliers, veterinarians and the Pharmacy Board's inspectors when Chariton was not licensed as a wholesale drug distributor. L.F. 301, ¶ 12; L.F. 444, ¶ 7; L.F. 340-54. Only one allegation related to the sale of *veterinary* legend drugs, Panalog and Otomax. L.F. 349. With respect to those drugs, the Pharmacy Board alleged that Chariton's sale of those drugs to a Board inspector violated the Pharmacy Practices Act not because the Act prescribes the retail sale of veterinary drugs to consumers, but because Chariton sold them at wholesale without being licensed as a wholesale drug dealer. L.F. 350,

¶52. This is a critical distinction because, as the Pharmacy Board noted in *Chariton*, although the Board "does not assert . . . authority for dispensing of veterinary legend drugs," it *does* "maintain[] it has jurisdiction over wholesale drug distributors for distribution of both human legend drugs and veterinary legend drugs." <u>L.F. 344</u>, ¶15-16.

In settlement of the *Chariton* lawsuit, the Pharmacy Board and Chariton entered into a Consent Agreement wherein Chariton agreed not to practice pharmacy or operate a pharmacy without a license, and the court entered a judgment accordingly. L.F. 368-72; 376-77; L.F. 301, ¶¶ 15-16; L.F. 444, ¶7. Thus, the court's order was not a determination by the court that Chariton had violated any licensure laws. Rather, it merely reflected a voluntary agreement between the parties. L.F. 302, ¶18; L.F. 444, ¶7.

The Pharmacy Board thereafter relied on *Chariton* as authority for its actions in regulating veterinary drug sales even though it knew that the *Chariton* court's order

To the contrary, the Consent Agreement expressly provided that if Chariton obtained a permanent wholesale drug dealer license, its conduct in "obtaining direct payment from veterinarian's patients" would not be a violation of "current state law and state regulations." <u>L.F. 369</u>.

was based on a voluntary settlement and not the court's own interpretation of "the practice of pharmacy." *See* L.F. 302, ¶ 18; L.F. 444, ¶ 7.

Thus, *Chariton* cannot supply the foundation for the Pharmacy Board's change in policy. When asked what the basis of the Board's change in policy was, the Pharmacy Board's corporate designee could not identify one. Instead, he testified that it was merely the staff's interpretation of the law:

- Q. And again the question is do you know why the Board decided to initiate court action for these types of or this type of conduct?
- A. Based on the information that the Board was provided on the first entity [*Chariton*] the Board made a decision after discussing the information that it had to pursue such an action.

* * *

- Q: Do you have any knowledge of why the Board decided to start doing this? Was it a change in the board members, was there a change in a law, a change in a rule, what was it?
- A: The only information I have is that they reviewed information in this case, discussed the case, and I'm talking about the first case that was sent for formal action, and they made a determination at that point by motion and vote to follow that action. I don't have any information other than that.

L.F. 324, 38:18-39:16. See also L.F. 334, at 77:12-19 (stating that FAQ #8 (L.F. 382) was the Pharmacy Board staff's interpretation of the Act).

Counsel for the Pharmacy Board later explained at a summary judgment hearing in this case that the Board's 180° reversal of its interpretation was simply other counsel's different interpretation of the very same law:

MR. HYLTON: Yes. The Board got good counsel finally and they decided to interpret the statute the way it says. . . .

L.F. 423.

As the foregoing reflects, the Pharmacy Board has reached diametrically opposed interpretations of the scope of its authority even though there was no interim change in the language of the statutes. In view of its long history of shifting and confusing interpretation, the Pharmacy Board's own interpretation of its authority now is entitled to no weight.

7. The Rule of Lenity Requires the Pharmacy Practices Act Be Construed Against the Pharmacy Board

The trial court's judgment should also be reversed for the separate reason that the rule of "lenity" demands it. That rule provides that ambiguities in a penal statute must be "construed against the government or party seeking to exact statutory penalties and in favor of persons on whom such penalties are sought to be imposed." *J.S. v. Beaird*, 28 S.W.3d 875, 877 (Mo. banc 2000). Although the instant action is

not a criminal case, violation of the Pharmacy Practices Act constitutes a Class C felony. RSMo § 338.195 (A32). Therefore, any ambiguities in Chapter 338 as to whether it applies to veterinary drugs must be construed against the State.

For all of these reasons, the trial court erred in ruling that the sale of veterinary drugs to consumers for use in animals pursuant to a veterinarian's prescription is the "practice of pharmacy" within the meaning of the Pharmacy Practices Act, Chapter 338, and that UPCO must therefore be licensed as a pharmacy to sell such drugs. The trial court's judgment should be reversed.

II. The trial court erred in ruling that the Pharmacy Practices Act, RSMo Chapter 338, is constitutional because the Act violates the due process clauses of the Missouri Constitution, Art. I, § 10, and the Fourteenth Amendment to the United States Constitution in that is unconstitutionally vague because it fails to apprise UPCO and other persons of ordinary intelligence that the retail sale of veterinary prescription drugs to consumers for use in animals pursuant to a veterinarian's prescription constitutes the "practice of pharmacy," and that retailers such as Plaintiff UPCO must therefore be licensed as a pharmacy to engage in such conduct.

A. Standard of Review

A trial court's interpretation of a statute is reviewed *de novo*. *Smith v. Shaw*, 159 S.W.3d 830, 833 (Mo. banc 2005).

B. Argument

To the extent the Pharmacy Practices Act is construed to grant the Pharmacy Board authority to govern the sale of veterinary drugs for the treatment of animals, as the court below did, such construction renders the Act void for being unconstitutionally vague.

A statute is unconstitutionally vague if it does not give "a person of ordinary intelligence a sufficiently definite warning as to the proscribed conduct when measured by common understanding and practices." *State v. Dunn*, <u>147 S.W.3d 75, 77</u> (Mo. banc 2004).

As set forth in Point I, there is no express language in Chapter 338 granting the Pharmacy Board – as opposed to the Veterinary Board – authority to regulate veterinary drugs. In fact, for this very reason, the trial court was forced to reach beyond the Pharmacy Practices Act and extrapolate language from unrelated statutes before it could even begin to conclude that the Pharmacy Board had authority to govern veterinary drug sales. The trial court's strained and complicated reasoning simply confirms that persons of ordinary intelligence cannot have been apprised of the statute's purported reach.

Even the Pharmacy Board could not identify any language granting it authority to regulate veterinary drugs. *See* L.F. 333-34; L.F. 309, ¶¶ 62-64; L.F. 446, ¶ 19.

Finally, neither the Western District nor the Buchanan County Circuit Court could find *any* legislative intent to authorize the Pharmacy Board to regulate the sale of veterinary drugs in their earlier reviews of the statute. As the Western District stated in the first appeal of this case, the Pharmacy Practices Act does not "clearly and fully" apprise "those who must abide by the licensure . . . of what types of conduct and business practices are expected." *United Pharmacal*, 2004 WL 913537, *7 (Mo.

App. W.D. April 30, 2004) *vacated by* 159 S.W.3d 361 (Mo. banc 2005). If four Missouri judges could not discern any language warning UPCO that its conduct was proscribed by the Pharmacy Practices Act, certainly a layperson could not be expected to do so.

Accordingly, Chapter 338, to the extent it purports to regulate the retail sale of veterinary legend drugs for animal use, violates the due process clauses of the Missouri Constitution, Art. I, § 10 (A58), and the Fourteenth Amendment to the United States Constitution (A57) and is therefore void and unenforceable.

III. CONCLUSION

The trial court's judgment should be reversed. The Pharmacy Practices Act does not grant the Pharmacy Board authority to regulate the retail sale of veterinary prescription drugs to owners of animals upon lawful veterinary prescriptions. To the extent it can now be construed to encompass the regulation of veterinary drugs, it is unconstitutionally vague and therefore void.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I did on this 3rd day of May, 2006, cause a copy of the foregoing the **APPELLANT'S BRIEF** to be sent via Federal Express, next business day delivery, postage prepaid, with a copy on floppy disk, to:

Loretta Schoutten, Esq. Assistant Attorney General 7th Floor, Broadway State Office Building 221 West High Street P. O. Box 899 Jefferson City, Missouri 65102

ATTORNEY FOR DEFENDANT-RESPONDENT MISSOURI BOARD OF PHARMACY

ATTORNEY FOR APPELLANT

RULE 84.06(C) AND (G) CERTIFICATES

I hereby certify that **APPELLANT'S BRIEF** includes the information required by Rule 55.03, and that the brief complies with the limitations contained in Rule 84.06(b). Appellant's Brief consists of 11,339 words, exclusive of the cover, certificate of service, certificate required by Rule 84.06(g), signature block and appendix, as determined by the word count of the Microsoft Word word-processing system.

I hereby certify that the floppy disk submitted by Appellant in this matter has been scanned for viruses and that it is virus free.

BY:	
	ATTORNEY FOR APPELLANT