

THE IMPACT OF FEDERAL AND STATE REGULATIONS ON THE  
MANAGEMENT OF A VETERINARY PHARMACY

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Introduction

This paper is a review of the federal and state regulations which affect hospital pharmacies associated with colleges of veterinary medicine. Aspects of the regulations which impact the pharmacist in performing their professional responsibilities in the veterinary setting will be identified and discussed.

The pharmacy profession is one of the most regulated in this country. The reasons for the high degree of regulation are many and diverse in origin. Major origins stem from the intent to protect the general public from inappropriate use (i.e. safe and effective drugs) and to reduce the abuse of drugs.

Federal regulations which primarily affect the veterinary hospital pharmacy are the Food, Drug and Cosmetic Act, the Controlled Substances Act, and the Hazardous Substance Labeling Act. The effect of these Acts in the veterinary setting are similar to the human pharmacy settings.

State regulations which affect the veterinary hospital pharmacy are primarily enforced by the state Boards of Pharmacy. However, the application of these regulations varies considerably from state to state.

This paper will primarily discuss those Federal and State regulations affecting pharmacies in the United States. These regulations are different for our Canadian colleagues. For example, the Canadian pharmacies are regulated by Federal regulation only, thus providing a more consistent legal basis for their practice settings.

Federal Regulations - Food, Drug and Cosmetic Act

The major federal law which impacts pharmacies is the Food, Drug and Cosmetic Act. This law regulates drug manufacturing and marketing, provided drugs have been shown to be safe and effective.

In recent Veterinary Research Communication,<sup>1</sup> Richard Teske of the Bureau of Veterinary Medicine summarized the history and current status of the Federal regulations of veterinary drugs in the United States. A brief review of the summary follows.

The regulation of drugs started with the Food and Drug Act of 1906 when the trafficking of adulterated and misbranded food and drugs was banned from interstate commerce. The Food and Drug Administration (FDA) was established in 1927. Since then, four major amendments to the Food and Drug Act have formed the basis for the major regulation affecting veterinary drug delivery in the United States.

In 1936, the existing Food, Drug and Cosmetic Act established the controlling regulation for the manufacturing of drugs by implementing standards of manufacturing practices and factory inspections. The new Act required the manufacturer to provide evidence of product safety before distribution and stipulated the establishment of tolerance levels for unavoidable poisonous substances.

In 1958, the "Delaney Clause" elevated the concern for drugs which could cause cancer if ingested directly by man or animals. This meant the addition of a carcinogenic agent to food was prohibited. Thus, the ban extended to the use in food animals of a drug or feed additive which could cause cancer. Initially the ban did not stipulate detectable residues. In 1962 the "Delaney Clause" was modified to focus on compounds producing detectable residues.

During the 1970's and 1980's, methodology of detecting drug residues improved. Now regulations specifying criteria and procedures to be used in evaluating assay methods for carcinogenic residues in food producing animals have been and are being developed.

These procedures define methods that are to be used in establishing safe levels of exposure. With this approach, the lowered limits of sensitivity required for the assay methods, hopefully, will assure that no residues occur in food and animal products.

Also, the 1962 amendments provided that new drugs marketed had to have demonstrated evidence of safety and effectiveness.

The Animal Drug Amendments of 1968 contained a new section, "The New Animal Drug," which consolidated all the various parts of the Act relating to drugs for administration to animals and to animal feeds containing a new animal drug.

Once the drug is approved to be marketed, then the pharmacy and the pharmacists become involved in the legal distribution of the medication. In the veterinary college setting, the pharmacist in his dispensary role must insure that the approved medication and/or approved species is understood by the prescribing veterinarian. The pharmacists, as teachers in the colleges, must insure that students understand their legal limitations for prescribing drugs for nonapproved indications.

Also, the drugs used in the food-producing animals require the prescriber to understand and adhere to drug withdrawal times which the pharmacist must relate at the time of dispensing. These additional aspects of the dispensary role is a natural part of the pharmacist's responsibility of insuring compliance.

The concept of proper compliance is relatively new to the pharmacist's dispensary role and requires extra effort in the veterinary setting to insure that these legal liabilities are understood and followed by the veterinary clinician and the client.

The pharmacist can be a valuable resource in his dispensary role to assist the veterinary clinician in the prescribing of drugs for extra-label use. The written prescription can be evidence of the existence of a bonafide veterinary-client/patient relationship. Thus, proper use of drugs in animals is assured. This is particularly important when the veterinarian must use drugs approved only for human use and use veterinary drugs in non approved species.

Federal Regulations - The Controlled Substances Act

The Controlled Substance Act regulates the veterinary pharmacy basically the same as in the human pharmacy setting. The Controlled Substances Act is actually the middle section of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970. The Act defines "controlled substances" as drugs or substances subject to (or having potential for) abuse or physical/physiological dependence.

Essentially, the Controlled Substances Act regulates the manufacture, distribution and dispensing of narcotics and/or dangerous drugs by way of a federal registration of all persons in the legitimate chain of procurement, distribution and dispensing, except the ultimate user or patient. While the ultimate user or patient is not required to register, the Act prescribes the conditions under which narcotics and/or dangerous drugs may be lawfully used or possessed by him.

The purpose of this Act was to put Federal control of both narcotics and/or dangerous drugs under one organization. The only exception is the FDA which regulates drugs for efficacy and safety as discussed above.

In the veterinary pharmacy setting, the chief pharmacist becomes "the keeper of the narcotics." The pharmacist assures that the college is correctly registered; that the controlled substances are stored properly; that control procedures are developed and followed for the dispensing and the administration of controlled substances in the college's laboratories and hospitals.

The veterinary pharmacy can be registered under several types of registration (i.e. hospital/clinic, teaching, research, retail or practitioner). The following are results of a survey<sup>2</sup> of 26 veterinary schools in the United States.

Table 1.	<u>Type of DEA Registration</u>	<u>Number</u>
	Hospital/Clinic	19
	Research	7
	Teaching	6
	Retail	2
	Practitioner	1

Several schools hold more than one type of registration. There are valid reasons for this duplication. However, the lesser number of registrations is desired.

The veterinary pharmacists should assist the college to reduce the unnecessary duplication. Valid reasons for the duplicate registrations include use of the teaching and research interests in excess of 10% of the total volume of controlled substances used. Also, in some states, duplicate Federal registration is required (i.e. New York). Further, there are situations which are best left undisturbed.

The Hospital/Clinic Registration provides the maximum flexibility to meet the needs of most veterinary colleges. Special circumstances, though, must be accommodated for other types of registration (i.e. research and teaching).

The pharmacist in charge should be responsible for all of the controlled substances used within the college. The proper storage and maintenance of good procedures for these controlled substances can best be done under the direction of the pharmacist.

The veterinary setting presents very few differences in the handling of controlled substances when compared to the human setting. A major difference is that the veterinarian can only legally prescribe for animals (i.e. those patients he is licensed to medically treat).

#### Federal Regulation - Hazardous Substances Labeling Act

This Act affects pharmacy operations primarily through the "prohibited acts" of the law. The specific requirements for the labeling of drug containers are covered in the Food, Drug and Cosmetic Act. The Hazardous Substances Labeling Act specifically prohibits the use or reuse of any container identified as a food, drug or cosmetic container. "The reuse (use) of a food, drug or cosmetic container as a container for a hazardous substance shall be deemed to be an act which results in the hazardous substance being a misbranded hazardous substance." The veterinary pharmacist must follow all labeling regulations to the same extent as the human pharmacist.

The Hazardous Substances Labeling Act deals primarily in the labeling of prepackaged medications. As long as there is a prescription involved in the transaction, prescription labeling is the only requirement. However, in those settings where prepackaged medications may be issued without a prescription the labeling requirements fall under the Hazardous Substances Labeling Act which prohibits the use of drug containers for hazardous substances. For the prepackaged drugs to be issued from the pharmacy, they must be treated as prescriptions and appropriately labeled.

#### State Regulations

The state pharmacy laws across the United States vary considerably. In general terms there are two consistent regulations which can be found in each State. They are: the requirement of a pharmacist to be registered and the pharmacy (location) to be registered. The following two tables show the current status of 26 colleges in the United States and the 3 Canadian schools.

Table 2.                      Colleges with Registered Pharmacists on Staff

Yes	26
No	3

Currently one of the three colleges without a registered pharmacist is recruiting for their first chief pharmacist.

Table 3. Colleges Having Pharmacies Registered with a State Board of Pharmacy

Yes	18 (62%)
No	11 (38%)

The high number of colleges having both registered pharmacists and pharmacies was pleasing although somewhat of a surprise. There are valid reasons for certain pharmacies not to be registered. Some states exempt state schools from registration (i.e. California). Unfortunately, some state Boards of Pharmacy ignore the veterinary settings. Then, in some schools, budgetary constraints may limit a school's ability to be issued a pharmacy permit because minimum standards for such a permit cannot be met. This is particularly true in states in which the law requires a pharmacist to be present in the pharmacy when open. The human hospital pharmacies in past years have had the same problem. As more colleges of veterinary medicine learn to utilize the pharmacist and his valuable drug knowledge base for both teaching and patient care activities, there will be an increase in pharmacists and legally registered pharmacies in place.

Many states also have their own Controlled Substance registration. The survey indicated:

Table 4. Schools with State Controlled Substance Registration

Yes	11
No	18

These registrations usually are somewhat of a burden for the paperwork required relative to the benefit of such a registration.

#### Other State Registrations Affecting Veterinary Pharmacy

Two states reported they had licenses in the pharmacy for other reasons.

Colorado has a license for the issuance of pesticides.

New York licenses pharmacies for the purchase and dispensing of needles and syringes.

#### Conclusions

The federal regulations have an additive impact on veterinary pharmacy in only two areas. The first being that the prescriber must be made aware of approved indications and species when extra-label use of a drug is being used. As pointed out above, the pharmacy can serve as an effective way of establishing practitioner-client/patient relations by use of the prescription, hopefully providing good patient care. Secondly, the food animal patient also requires that the practitioner and client understand and adhere to the

withdrawal times for such drugs. Both of these responsibilities place the pharmacist closer to the patient care activities, which is where he or she should be. Thus, these regulations provide good rationale for increased and effective utilization of the pharmacists in the veterinary patient care settings.

The state regulations, though somewhat inconsistent, do not impact the veterinary pharmacy setting any differently than other institutional pharmacy practices. In fact, the regulations can be used to justify proper staffing.

More importantly, the colleges of veterinary medicine need to continue to recognize and exploit the value of the pharmacist on their clinical staffs. Besides fulfilling the institution's legal responsibilities, the pharmacist's expertise must be more actively utilized in the clinical setting. This expertise includes good management techniques in providing top quality drug delivery to the hospitalized patients. The pharmacist's resource of drug information and support of good rational drug therapy in the animal health world is where the real value lies.

#### References

1. Teske, Richard H., Regulations of Veterinary Drug in the U.S.A., Veterinary Research Communications 7(1983) 383-384.
2. Personnel Communications by S.P. Stephen.