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August 22, 2012

Federal Trade Commission
Donald S. Clark, Secretary of The Commission
Room H-113 (Annex X)
600 Pennsylvania Ave. NW
Washington, DC 20580

RE: Workshop On Distribution Of Pet Medications, October 2, 2012

Dear Secretary Clark:

Please see the attachment for our comments regarding the distribution of pet medications and veterinary drugs.

This workshop "to examine how pet medications are distributed to pet owners and how these practices affect consumer choice and price competition," has considerable merit. Pet medications comprise one part of the larger veterinary drug distribution trade. The same denial of consumer choice exists in the distribution of pet medications, equine medications and food animal medications.

In our opinion, the current veterinary drug distribution system harms animal owners. It limits their choices and costs them more than necessary for veterinary drugs.

Respectfully,

Arnold G. Nagely, DVM^U
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Licensed pharmacies have evolved in recent years to meet consumer demand for filling valid veterinary prescriptions. These pharmacies are licensed by the respective State Boards of Pharmacy to fill prescriptions from practicing veterinarians.

In addition, the National Association of Boards of Pharmacy (NABP) administers an accreditation for Veterinary-Verified Internet Pharmacy Practice Sites (Vet-VIPPS). The inspection, certification and licensing by the State Boards of Pharmacy and the NABP ensure high levels of competency in these pharmacies.

Prescription medications for animals are regulated by the FDA and are required to show the standard statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." For a veterinarian to make a valid determination that a prescription drug be used for a given patient, that veterinarian must have a veterinarian-client-patient relationship (VCPR), as per practice guidelines of the American Veterinary Medical Association (AVMA).

A valid VCPR requires: (1) that the veterinarian takes responsibility for medical and treatment judgments for the animal(s) and that the client agrees to follow the veterinarian's instructions; (2) that the veterinarian has close knowledge of the animal(s) and their medical condition obtained by examination; and (3) that the veterinarian be available for follow up visits or have emergency coverage in the event of adverse reactions or failure of the treatment regimen.

Thus, when a valid VCPR exists, the veterinarian may appropriately prescribe legend products for the client to administer to the animal patient(s). The client may choose to purchase the prescription product(s) from the veterinarian clinic, or from a properly licensed veterinary pharmacy. In human medicine, almost all such prescriptions are filled at a licensed pharmacy, rather than by the practitioner.

The Problem: Denial of Consumer Choice. It is common for practicing veterinarians to make it difficult or impossible for the client to purchase their prescription products from a source other than the attending veterinarian. This is especially true for food animal veterinarians, who traditionally derive considerable revenue from dispensing. Veterinarians use a variety of manipulative tactics to deny the client the free-market option of filling their prescription at a licensed pharmacy. When the client asks the veterinarian to provide a prescription, some veterinarians make the unfounded claim that "those pharmacies may be providing bogus pharmaceuticals, so we will not write a script." Other veterinarians refuse, saying "it is not our practice policy." Some groups of veterinarians in a county or city collude to reduce competition by taking a uniform position: "We do not provide prescriptions; you need to purchase drugs from us."

Some veterinarians provide the prescription reluctantly, and charge a substantial fee for writing the prescription. Others are known to threaten the client with a statement such as, "If you don't buy your drugs from me, who are you going to call when you need veterinary service after hours?"

Some practicing veterinarians attempt to restrict consumer choice and maintain pricing by forming an anti-competitive alliance with an "affiliate pharmacy". Under this approach, the veterinarian refuses to write an open prescription for the consumer to fill where he or she chooses, and directs the consumer to the affiliate pharmacy. The prescribing veterinarian receives a kick-back or portion of the revenue.

Industry Manipulation: A few of the major veterinary pharmaceutical companies have joined with the veterinary practitioners in collusion to keep their prescription pharmaceutical dispensing within the veterinary clinics, to the exclusion of licensed pharmacies. Their unwritten message to the practicing veterinarians is, "You choose our brand in your practice and we will limit your clients' consumer choice and competitive pricing options." This sales policy is implemented under the pretense it is necessary to ensure a VCPR. That is a fallacy, as a valid VCPR must exist at the time a prescription is written. Prescriptions in the practice of human medicine are written by physicians with a similar doctor-patient relationship.

The Solution: Supported by law, consumers need the ability to obtain written, portable prescriptions that they can fill in a properly licensed pharmacy wherever they choose. Recent changes to restricted distribution and prescription portability practices in the contact lens industry might provide useful guidelines for the pet and food animal medications industry.

The proper licensing of veterinary pharmacies provides safety and efficacy for the consumer purchasing animal medications (pet, equine and food animal). Full cooperation and validation in product distribution from veterinary drug manufacturers would further ensure product validity, safety and efficacy. Mandatory EDI sales reporting (a common practice) from licensed pharmacies back to pharmaceutical manufacturers could provide tracking of product sales to the end user for added distribution security and assurance.

Provisions similar to H.R. 1406 seem to be appropriate to ensure pet, equine and food animal prescription portability for consumer choice and price competition.

- Provide the pet, equine or food animal owner a copy of the veterinary prescription;
- Provide the pet, equine or food animal owner with a written disclosure that the animal owner may fill the prescription through the prescriber (if available) or through another pharmacy determined by the pet, equine or food animal owner; and
- Provide or verify the prescription by electronic or other means consistent with applicable state law, if requested by any person designated to act on behalf of the animal owner.

Appropriately, such an Act (e.g. H.R. 1406) would prohibit veterinarians from setting the following conditions for providing a copy of the prescription or verifying a prescription:

- Requiring the purchase of the drug from the prescriber or from another person;
- Requiring payment in addition to, or as a part of, the fee for an examination and evaluation; and
- Requiring the animal owner to sign a waiver or disclaim liability of the prescriber for the accuracy of the veterinary prescription, or delivering to the animal owner a notice waiving or disclaiming such liability.

Distractions: Certain segments of organized veterinary medicine and veterinary practitioners will oppose a mandate for written, portable prescriptions. These interest groups and individuals argue that veterinary product sales should be limited to the veterinarian's clinic to ensure proper medical care, and client information. But these needs are met in a valid VCPR.

Some food animal veterinarians contend that food animal drug sales should only be made by practicing food animal veterinarians, in order to assure label compliance and avoid food residues. Those directions and safeguards are satisfied when a prescription is written by the food animal veterinarian, as federal law requires this information be transferred to the prescription label, whether the prescription is dispensed by the veterinarian or by a licensed pharmacy. And if the customer requires additional guidance in administering the prescription drug, he/she can consult with the prescribing veterinarian.

A recent AVMA letter to State Boards of Pharmacy raised a question regarding communication. In modern pharmacy practice it is common for pharmacists to consult with the prescribing veterinarian, by telephone or otherwise, to verify medications and dosages.

And the claim that pharmacists may not be equipped to fill a veterinarian's prescription as written because the pharmacist has not trained in veterinary pharmacology or physiology is overstated. Pharmacists complete rigorous training and continuing education, and are well equipped to fill any health provider's valid prescription. In addition, the veterinarian with a VCPR has the knowledge and ultimate responsibility for prescribing the proper medication and dosage.

The AVMA took a stand in opposition to H.R. 1406, the Fairness to Pet Owners Act, in September 2011. The AVMA called the bill "unnecessary and redundant" because the association has a long-standing policy of encouraging veterinarians to write a prescription in lieu of dispensing when asked by a client. In reality, the AVMA position does very little to effectuate written portable prescriptions, or to ensure consumer choice or price competition. That will only happen when mandated by law.

Penalties: Penalties for failure to comply with the law must be significant enough to deter noncompliance. Without adequate penalties or enforcement, the legislation will be ineffective.

Two critical points that any legislation should address are:

1. the denial of a written portable prescription for food animal use, equine use, or pet use; and
2. the denial of food animal, equine, or pet product sales to licensed veterinary pharmacies from veterinary pharmaceutical manufacturers.