



September 14, 2012

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Ave., NW
Washington, DC 20580

Re: Pet Medications Workshop, Project No. P12-1201

Dear Sir or Madam:

I am writing on behalf of the Texas Veterinary Medical Association (TVMA) to provide insight and answer some of the questions posed by the Federal Trade Commission in connection with their Pet Medications Workshop. TVMA was established in 1903 and is one of the largest state veterinary medical associations in the nation. As a not-for-profit association established to advance the science and art of veterinary medicine, TVMA is the voice of the Texas veterinary profession. Our membership covers a myriad of areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military and public health services. A disproportionately large number of our private practice members may be negatively impacted by the proposed bill HR 1406, which prompted this investigation by the FTC.

Texas veterinary practitioners have serious concerns about a federal mandate for veterinarians to write prescriptions.

The Texas Veterinary Medical Association recognizes the American Veterinary Medical Association (AVMA) Principles of Veterinary Medical Ethics (PVME), which assert that veterinarians should honor client requests for written prescriptions when the decision is made to treat a patient with a particular prescription drug. However, federally mandated prescription writing is an unwarranted one-size-fits-all approach to medicine that will add significant administrative burdens to the practice of veterinary medicine while doing nothing to protect animal health and welfare.

TVMA appreciates the opportunity to provide the following answers to some of the question asked by the Federal Trade Commission.

How are pet medications distributed to consumers?

When a veterinarian has determined that a patient needs a prescription drug, the drug can be distributed by dispensing directly from the clinic inventory, by dispensing from the clinic's

online store (inventory supplied by a third-party distributor), by providing a written prescription to the client, by prescribing telephonically or electronically to a pharmacy or by signing a pharmacy's faxed prescription upon a request from a pharmacy, as allowable under individual state veterinary medical and pharmacy rules. In the case of controlled substance prescriptions, the Drug Enforcement Administration and state rules apply. Direct dispensing, as well as written, faxed and oral prescriptions, is allowable for Schedules III-V. Schedule-II controlled substances may only be dispensed directly by the veterinarian or prescribed in writing before being dispensed by a pharmacy.

What are the business rationales for various pet medication distribution practices?

Business decisions regarding distribution are first dependent upon the FDA's classification of either prescription or over-the-counter status of a drug. Specifically, the FDA says that "since adequate directions for safe and effective lay use cannot be written for animal prescription drug products, such products can only be sold on the prescription or other order of a licensed veterinarian [Federal Food, Drug and Cosmetic Act] (Section 503(f)). Prior to being sold or dispensed, they must remain in the possession of a person or firm regularly and lawfully engaged in the manufacture, transportation, storage or wholesale or retail distribution of animal prescription drug products. The drug products may be distributed only by persons or firms authorized by state and local laws." ²

Once a drug is approved by the FDA, the subsequent business decisions regarding distribution are made by manufacturers or distributors, not by the veterinary profession.

The current state of veterinary medicine requires products to treat many conditions in a number of different species, some of which are known to have unique physiological characteristics. As a result, sometimes needed animal drugs are not commercially available or FDA-approved, and there may be no version that, when used as labeled or in an extra-label fashion in its available dosage form and concentration, will appropriately treat the patient. Therefore, in order to treat a specifically diagnosed occurrence of a disease or condition that threatens the health of the animal or will cause suffering or death if left untreated, a veterinarian with an appropriate veterinary-client-patient relationship acting according to state and federal laws may compound themselves or order a prescription that must be filled by a compounding pharmacy.

How do these practices affect product supply and quality?

Texas does not have any legal restrictions that might prevent properly licensed pharmacies from dispensing pet prescription products with a valid prescription.

If pharmacies acquire FDA-approved products through legal channels and store and ship them in the appropriate manner per manufacturer guidelines and Texas state pharmacy rules, there should not be a concern for the safety or quality of the products. However, as the FDA has recognized in the past, quality can be a major concern. Prescription products obtained from unlicensed pharmacy retailers pose a risk to the animal's well-being and create an ethical, and potentially legal, conundrum for the prescribing veterinarian.

The FDA reports in its online article "Purchasing Pet Drugs Online: Buyer Beware" that "Some of the Internet sites that sell pet drugs represent legitimate, reputable pharmacies...but others are fronts for unscrupulous businesses operating against the law. The FDA has found companies that sell unapproved pet drugs and counterfeit pet products, make fraudulent claims, dispense prescription drugs without requiring a prescription and sell expired drugs."³

What efficiencies or inefficiencies are associated with these practices?

The availability of animal drug products from various retailers likely creates both efficiencies and inefficiencies for veterinarians.

One efficiency with regard to faxed prescription requests is the time saved by simply signing the request, versus spending time calling, faxing or writing the prescription. At the same time, inefficiencies are created for the veterinarian when the dispensing pharmacist has follow-up questions.

Other inefficiencies associated with distribution practices are largely geared toward animal health concerns. Specifically, treatment with medications dispensed directly from a veterinary clinic can be started promptly and there are no anticipated concerns associated with the quality of the drug product. For products purchased on site, a veterinarian is available to advise clients on how to best administer the medication.

On the other hand, if a prescription drug is not obtained from a pharmacy immediately or at all, or if it is later realized that the pharmacy does not stock the needed medication, then treatment may be delayed to the detriment of the animal's health.

In addition, pharmacists are not required to have training in animal pharmacology. Whereas veterinarians have been trained to be cognizant of unique pharmacologic needs across species, including the idiosyncrasies of different animal species such as feline sensitivity to acetaminophen, pharmacists might not have this awareness. We have learned that on occasion, this has resulted in incorrect counseling, wrong dosages or unauthorized drug substitutions that could harm the animal patient and yield the need for additional treatment that would have been unnecessary if the correct medication or information had been dispensed from the start.

What, if any, product safety or counterfeiting issues exist with respect to these practices?

Have there been instances in which false or misleading information about product safety risks was disseminated to consumers?

The FDA has expressed concern about counterfeit drugs and product safety issues associated with unscrupulous Internet businesses acting unlawfully. (See above answer to **How do these practices affect product supply and quality?**) TVMA members have anecdotally reported problems with out-of-state pharmacies contacting their clients and advising them that their animals need certain prescriptions thereby generating false demand for a particular product. To legally prescribe a prescription drug in Texas, a veterinarian must have a valid veterinary-client-

patient relationship with animal and have determined that the prescription drug is therapeutically indicated for the health and/or well-being of the animal.

Are there other factors that should be considered when analyzing the competition and consumer protection issues related to the distribution of pet medications?

There are many other factors that should be considered when analyzing the competition and consumer protection issues related to the distribution of pet medications.

HR 1406 should not be rightly compared to the contact dispensing law of 2003. Pets cannot tell their owners when they are sick or uncomfortable while when a person uses incorrect contact lenses and they are uncomfortable or in pain, they can simply take out the lenses.

Another major consideration should be the training and ability of pharmacists to adequately and appropriately serve pets and their owners. A consumer merely sees a licensed professional filling a prescription whether it's a veterinarian or a pharmacist. However, these two professionals have wildly different areas of expertise. While veterinary students receive substantial training in veterinary medical pharmacology, pharmacy students do not receive such formal training. In human medicine, pharmacists not only bear the responsibility for dispensing medications but also for advising and educating consumers on their use and interactions. Animal pharmacology and human pharmacology are very different, and most pharmacists are not trained to provide similar advice to pet owners. Major problems could result from any change made by a pharmacy to the number of tablets or capsules, milligram size of the unit, volume and/or concentration of liquid or number of authorized refills that differ from the request by the veterinarian.

The Texas Occupations Code and Veterinary Rules of Professional Conduct maintain that it is unprofessional conduct for a licensed veterinarian to prescribe, or dispense, deliver or order delivered, any prescription drug without first having established a valid veterinarian-client-patient relationship (VCPR) according to the statute (TX OCC. CODE 801.351, TX ADMIN. CODE, Rule 573.41). This ensures that the veterinarian has examined the patient, assumed responsibility for medical judgments and is familiar with the patient's condition and history in order to make the proper diagnosis and treatment, including prescribing the veterinary drugs in appropriate circumstances. TVMA asserts that the decision for use of a prescription drug in an animal should be made by the veterinarian – not a pharmacist – within the confines of a VCPR.

How varied are current veterinarian practices with respect to providing written, portable prescriptions to clients?

The practices of individual veterinary clinics vary with respect to prescription writing across the state of Texas. Some veterinarians do not stock prescription products, so all of their prescriptions are written and must be filled at a pharmacy. Others offer the written prescription before dispensing and some maintain their own pharmacies. If a consumer is not satisfied with the current prescription practices of an individual veterinarian, there is a robust market of veterinary practitioners to choose from. TVMA recommends that our member veterinarians

follow AVMA's Principles of Veterinary Medical Ethics, which state that veterinarians should honor a client's request for a prescription in lieu of dispensing (Section III-C)¹.

To what extent are consumers aware that they can request a portable prescription from their veterinarian and have the prescription dispensed elsewhere?

Aside from anecdotal stories or conducting a voluntary survey, there is no way to confirm the quantitative extent to which pet owners realize they can go elsewhere to fill prescriptions. Advertisements for public consumption have been observed in various communication vehicles for several years. In addition, most big-box retailers have prominent advertisements on their websites for pet prescriptions.

Due to the plethora of advertisements for pet medications, most consumers are likely aware that they can shop around for pet medications but prefer to purchase from their veterinarian because it saves them an extra trip, especially when their pet is with them.

What risks or inefficiencies may be posed by prescription portability for pet medications?

There are potential risks associated with portability of prescriptions to retailers external to the veterinary clinic. One risk is a result of the lack of formalized veterinary medical pharmacology training requirements for pharmacists. (See above answer to "Are there other factors that should be considered when analyzing the competition and consumer protection issues related to the distribution of pet medications?")

A second is the potential for delay in treatment should the preferred pharmacy not carry the needed medication or if the client is delayed in picking up the drug from the preferred pharmacy.

Next, federal regulators are not in a position to know what a reasonable, ordinary and prudent veterinarian faced with a like circumstance would do in a particular situation. There is likely not a nationwide standard of care in veterinary medicine. This is why individual states have veterinary licensing boards that govern the practice of veterinary medicine. Federal intrusion into the traditional realm of these licensing boards will lead to confusion and ultimately litigation about whether a particular provision of a state's veterinary practice act and/or board regulations are or are not pre-empted by H.R. 1406 if the issue in controversy does not pertain to verification of a veterinary prescription.

Further confusion will result when clients demand that a veterinarian issue a prescription for a legend drug or a controlled substance that the veterinarian does not feel in their medical judgment is therapeutically indicated for a particular animal. Regulation of this sort can be used as a tool to pressure a veterinarian to act against their medical judgment or face a federal investigation. Upon complaint to the FTC, who will investigate this charge? Will the complaint be evaluated to see what the particular standard of care is in that geographic area? Will the investigative authorities be veterinarians or government regulators, and will they have any knowledge about what is or is not the permissible practice of veterinary medicine?

Is it appropriate to deny veterinarians the ability to charge a fee or require a waiver of liability for providing a written prescription to clients?

The TVMA contends that it is not appropriate to deny veterinarians the ability to charge a fee or to require a waiver of liability for providing a written prescription to clients. Writing prescriptions and subsequent follow-up work, including phone calls with pharmacists, takes extra time that would be unbillable under the proposed law. It is unfair to require a veterinarian to do extra work and deny them the right to charge for that work. This will simply cause prices to rise for everyone across the board as those costs are passed along in other forms.

The decision to require a liability waiver should be left to the business judgment of the clinic owner rather than be dictated by federal law. Federal regulation will not bar any liability that a practitioner may face as a result of an improperly filled prescription. Regardless of the legal outcome, the veterinarian will still face the time and expense of disposing of the lawsuit. In addition, some practitioners consider a liability waiver to be part of the informed consent counseling that they may provide the client so that the client is prepared for all risks and complications that may arise during the course of treatment of their animal.

What compliance costs would veterinarians face if H.R. 1406 were enacted?

Compliance costs are anticipated to be substantial. There is an administrative burden associated with writing the prescription every time the veterinarian determines a prescription drug is needed, regardless of whether the client has even decided whether he or she wants to, or can, go elsewhere.

The amount of time taken to write, call in or fax a prescription currently adds a few minutes to every appointment when it occurs. The time is multiplied when patients require multiple medications. Should H.R. 1406 pass, there would be a substantial impact on the scheduling of appointments to make allowances for the cumulative time taken for prescription writing for each patient. Dedicating either or both professional and support staff time for prescription writing activity changes staffing duties and responsibilities. Alterations in appointment flow to account for the time required to comply with prescription writing would need to be made. Extending office hours to offset the resultant time lost to prescription writing would result in business costs associated with such a decision.

The verification requirement, including follow-up phone calls from the pharmacies, for every prescription will also create an administrative burden and further impacts appointment scheduling.

The requirement that veterinarians provide a written prescription to clients who choose to have their prescription filled at the veterinarian's clinic adds another layer to the cost of compliance. Veterinarians would have to take measures to store or properly dispose of these written prescriptions in accordance with state laws, taking into account efforts to prevent misuse and to document that a prescription was properly dispensed to the client.

One unintended consequence we can foresee is the increased chance of prescription abuse and fraud. While complying with the provisions of H.R. 1406, veterinarians will have to take measures to mitigate circumstances in which clients use the requirement as an opportunity to acquire inappropriate numbers of prescriptions. Although prescriptions are written now for clients, the sheer number of prescriptions being written would be expected to increase because, unlike the current situation, under H.R. 1406 a prescription would be required in each and every instance the decision is made for a prescription drug. Increased numbers of prescriptions given to clients, recycled or discarded if not needed by the client could yield increased opportunities for fraud using written prescriptions.

Conclusion

The Texas Veterinary Medical Association appreciates careful analysis of how H.R. 1406, the Fairness to Pet Owners Act, would affect veterinary practitioners and the availability and access to drugs used in small animal medicine. While TVMA is supportive of a client's right to fill a prescription at their pharmacy of choice, we are strongly opposed to any federal mandate that requires a written prescription be provided, regardless of whether the client chooses to, or can, go elsewhere. TVMA believes H.R. 1406 is redundant and will cause undue regulatory and administrative burdens on veterinary practices. It is burdensome and unnecessary to require a written prescription be provided, as well as a written notification that the prescription may be filled elsewhere, regardless of whether or not the client is having the prescription filled by the veterinarian.

- The provision requiring verification of prescriptions, regardless of whether the pharmacy is accredited or licensed, places the veterinarian in both a legal and ethical dilemma. At the same time, it puts consumers at risk.
- H.R. 1406 encroaches on state jurisdiction; state pharmacy and veterinary practice laws already govern compliance by veterinarians.
- Clients already have the flexibility to fill a prescription at their veterinary clinic or off-site at a pharmacy of their choice. TVMA is supportive of a client's right to choose where they have their prescription filled.
- TVMA believes that veterinarians are uniquely trained to provide the best professional guidance and education to pet owners when dispensing prescription products.

Thank you for your time and consideration. TVMA appreciates the opportunity to comment and would like to continue the dialog on this and other important matters. For further clarification on TVMA's comments, please contact our office at 512/452-4224.

Respectfully,

Orlando Garza, DVM

TVMA President

References

1. AVMA Principles of Veterinary Medical Ethics <https://www.avma.org/KB/Policies/Pages/Principles-of-Veterinary-Medical-Ethics-of-the-AVMA.aspx>
2. (<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268128.htm>, accessed July 26, 2012).
3. Buyer Beware (<http://www.fda.gov/forconsumers/consumerupdates/ucm048164.htm>, accessed July 26, 2012)