



September 10, 2012

1931 N. Meacham Rd.
Suite 100
Schaumburg, IL
60173-4360
phone 847.925.8070
800.248.2862
fax 847.925.1329
www.avma.org

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 American Veterinary Medical Association, established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, the AVMA is the recognized national voice for the veterinary profession. The AVMA's more than 82,500 members, representing over 83% of all veterinarians in the United States, are involved in a myriad of areas of veterinary medical practice, including private, corporate, academic, industrial, governmental, military, and public health services.

The Federal Trade Commission is seeking public comments in connection with a workshop to examine competition and consumer protection issues in the pet medications industry. The workshop will consider how current industry distribution and other business practices affect consumer choice and price competition for pet medications, the ability of consumers to obtain written prescriptions that they can fill wherever they choose, and the ability of consumers to verify the safety and efficacy of pet medications that they purchase. The workshop will also examine the extent to which recent changes to restricted distribution and prescription practices in the contact lens industry might yield lessons applicable to the pet medications industry.

The AVMA has concerns with mandatory prescription writing for veterinarians. Veterinarians are already writing prescriptions for clients, which is supported by state laws and the Principles of Veterinary Medical Ethics of the AVMA.¹ The AVMA asserts that veterinarians should honor client requests for written prescriptions when the decision is made to treat a patient with a particular prescription drug. However, mandated prescription writing is unwarranted.

Our utmost concern is the well-being of our patients. Therefore, the AVMA is taking several steps to promote optimal outcomes for consumers obtaining prescription drugs for their pets from independent pharmacies:

- We are interacting with pharmacy stakeholders to help ensure that licensed pharmacists understand their roles and responsibilities for counseling and educating clients when filling a veterinary prescription, including verification with the prescribing veterinarian should the pharmacist have any questions about the medication or dosage.

- We educate veterinarians through various communication channels about prescription drug rules and the importance of following the Principles of Veterinary Medical Ethics of the AVMA and state rules.
- We are interacting with pharmacy stakeholders to determine how best to train licensed pharmacists on basic veterinary pharmacology issues.

We offer our current thinking on some of the questions the FTC has posed concerning the distribution of pet medications.

How are pet medications distributed to consumers?

For the purposes of this letter, we define the term *pet medication* as being synonymous with the term *animal drug*, which is defined in the Fairness to Pet Owners Act of 2011 (HR 1406),² in part, as being “a drug intended to be administered to an animal...” Drugs are under the jurisdiction of the US Food and Drug Administration and are defined under the Federal Food, Drug, and Cosmetic Act as being substances “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.”³ We would refer you to individual drug manufacturers, the Animal Health Institute, individual distributors, or the American Veterinary Distributors Association as better sources of specific information on the distribution of pet medications.

Veterinary drug dispensing— 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 via telephone or electronically to a pharmacy, or by signing a faxed prescription from a pharmacy upon request, as allowable under individual state veterinary medical and pharmacy rules. In the case of controlled substance prescriptions, US Drug Enforcement Administration and state rules apply. Direct dispensing as well as written, faxed, and oral prescriptions, is allowable for Schedule III, IV, and V controlled substances. Schedule II controlled substances may only be dispensed directly by the veterinarian or prescribed in writing before being dispensed by a pharmacy.

How has competition to sell medications to pet owners evolved in light of these distribution practices?

We do not have specific data regarding changes in competition of drug product sales; however, it appears that more options for pet medication sales are available to consumers.

How do these practices affect product supply and quality?

Assuming that pharmacies acquire FDA-approved products through legal channels and store and ship them in the appropriate manner per manufacturer guidelines and state pharmacy rules, there should not be a concern with product safety or quality. We are unaware of any legal restrictions preventing pet prescription products from being dispensed by nonveterinary retail pharmacies. The key requirements are that the pharmacy is compliant with pharmacy laws and regulations and the prescriber must be authorized to provide the prescription.

That said, wide availability of drugs through various retailers appears to be associated with quality concerns in some situations. In the online article *Purchasing pet drugs online: buyer beware*, the FDA reports, “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.”⁴

How do these practices affect consumer choice?

The consumer would be anticipated to have more purchasing options.

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. Given that not all veterinarians, particularly mobile practitioners, are able to stock every prescription product they might prescribe for their patients, there is an efficiency associated with pharmacies carrying certain prescription products.

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. 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, we understand that pharmacists are not required to have training in animal pharmacology. Whereas veterinarians have been educated to be cognizant of unique pharmacological needs across species, including the idiosyncrasies of different animal species (eg, feline sensitivity to acetaminophen and lagomorph sensitivity to certain antimicrobials), pharmacists might not have this awareness. We have learned that this has resulted in incorrect counseling, wrong dosages, or unauthorized drug substitutions, which could harm animal patients and create the need for additional treatment that would have been unnecessary had the correct medication or information been dispensed initially.

Faxed prescription requests from pharmacies also create inefficiencies. These requests are generated by the client or pharmacies, and veterinary clinics can receive numerous faxes a day. These faxes require the review of patient medical histories before authorization can be granted or denied. Additional inefficiencies associated with faxed requests include when the dispensing pharmacist has follow-up questions for the veterinarian.

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 How do these practices affect product supply and quality?). The AVMA has observed foreign prescription drugs available on nonpharmacy retail websites. In 2009, the AVMA submitted a letter⁵ to eBay in response to our observation of foreign-source heartworm preventive drugs made available for purchase by the public without a prescription. This would create an animal health concern if, for example, the drug were stored inappropriately or used in a heartworm-positive dog.

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

Other factors should be considered when analyzing the competition and consumer protection issues related to the distribution of pet medications. Specifically, although veterinary students receive substantial education in veterinary medical pharmacology, pharmacy students do not necessarily receive such formal education. The AVMA is currently reaching out to pharmacy stakeholders to help ensure optimal communications and interactions between individual prescribing veterinarians and pharmacists for the well-being of our patients.

In addition, state authorities need to enforce rules with regard to prescription drug sales. Almost all states require a valid veterinarian-client-patient relationship (VCPR) for a veterinarian to prescribe or dispense medications for their patients.⁶ This ensures that the veterinarian is familiar with the patient's condition and history to make the proper diagnosis and decide on treatment, including prescribing the veterinary drugs in appropriate circumstances. However, based on information AVMA and state veterinary medical associations have received from members over the years, pharmacists have allegedly dispensed prescription products without the veterinarian of record's knowledge. The AVMA 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?

Twenty-six states⁷ have specific laws, agency regulations, or policy statements that require veterinarians to provide their clients with a written prescription upon request. In addition, veterinarians in other states are at risk of state board discipline for unprofessional conduct in general for failure to honor a client's request for a prescription.

Within the confines of state laws, veterinary practices vary with respect to providing written prescriptions to clients. Some veterinarians do not stock prescription products, so all of their prescriptions are written and must be filled at a pharmacy, whereas others offer written prescriptions before dispensing; others fall on a spectrum in between.

Veterinarians who are AVMA members are expected to follow the AVMA Principles of Veterinary Medical Ethics,¹ which state that veterinarians should honor a client's request for a prescription in lieu of dispensing (Section III-C). In addition to the threat of discipline against their licenses, veterinarians have other incentives to honor clients' requests for prescriptions. A veterinarian who denies such a request risks alienating clients and harming his or her practice. In cases where the patient's condition may worsen quickly without medication and the client wishes to purchase the medication at a pharmacy, denial of a written prescription may place the veterinarian at legal risk.

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 estimates or conducting a voluntary survey, there is no way to quantitatively determine the 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.

Which states require prescription portability for pet medications? Which do not? Are there states in which a proposal for prescription portability for pet medications was rejected by the legislature and, if so, why?

The AVMA is aware of 26 states with statutes, rules, or agency policy statements that require veterinarians to provide their clients with a written prescription upon request.⁷ California and Arizona laws additionally require a prescriber to provide a client with written disclosure that the client has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy.

Even in states that have not adopted formal laws or regulations in this area, state boards of veterinary medicine could find in acting on a complaint that failure to honor a client's request for a prescription constitutes unprofessional conduct, leading to discipline against a veterinarian. Unprofessional conduct refers to a departure from or failure to conform to the standards of acceptable and prevailing practice of veterinary medicine.

In 2011, a bill in the Maine Senate, An Act To Enact Requirements Concerning Veterinary Prescriptions (S 207; legislative document 676),⁸ which proposed mandatory prescription writing for veterinarians, much like HR 1406, was defeated. A similar bill, An Act Concerning Veterinarians and Supplementing Chapter 16 of Title 45 of the Revised Statutes (A 2995),⁹ was introduced in the New Jersey Assembly on May 24, 2012, and has not advanced in that state's legislature.

In states that do require prescription portability, what recourse do consumers have if a veterinarian refuses to provide a written, portable prescription?

Consumers may file a complaint for unprofessional conduct with the state's veterinary licensing and disciplinary board. In some states, state veterinary medical associations offer consumers the opportunity to file complaints with ethics or grievance committees. In addition, some states provide consumers a private cause of action for violation of a statutory right. Consumers also may attempt to get assistance from their state's attorney general in enforcing the state's laws.

What evidence exists to support a need for federal legislation requiring veterinarians to provide written prescriptions to their clients?

We believe that state regulatory mechanisms pertaining to veterinary prescription writing are adequate and that there is no need for a federal mandate. Both veterinary medicine and pharmacy practices have traditionally been regulated by the states. A federal mandate would be a dramatic and unwarranted departure from state professional regulation and should be done only if there is a particular problem that needs to be addressed. We are not aware of consumers widely being denied their requests for prescriptions and see no need for a federal mandate that would undercut existing state regulation of veterinary medicine and pharmacy practices.

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

Potential risks associated with prescription filling at pharmacies include those pertaining to lack of formalized veterinary medical pharmacology educational requirements for pharmacists. Untrained pharmacists can unknowingly provide incorrect counseling or substitute inappropriate medications to the detriment of the patient. Another risk is the potential for delay in treatment should the preferred pharmacy not carry the needed medication or should the client be delayed in picking up the drug from the preferred pharmacy. Additionally, we have concerns that written prescriptions can

result in increased instances of prescription drug abuse or fraud when filled outside of the veterinary clinic.

Is there a need for federal legislation requiring veterinarians to notify clients that they have the right to fill their prescriptions at the pharmacy of their choice?

At this time, the AVMA does not believe there is the need for federal legislation requiring veterinarians to notify clients that they have the right to fill their prescriptions at the pharmacy of their choice. State pharmacy and veterinary practice laws already govern veterinary prescription writing.

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 AVMA contends that it is not appropriate for federal law to deny veterinarians the ability to charge a fee or to require a waiver of liability for providing a written prescription to clients, although we have not seen evidence of widespread use of such waiver forms. Writing prescriptions and subsequent follow-up work, including phone calls with pharmacists, takes time and it is not unreasonable to charge a fee for that time. The decision to require a waiver should be left to the business judgment of the clinic owner, subject to state liability laws, rather than be dictated by federal law.

How might the passage of HR 1406 affect price, consumer choice, and other forms of competition in the pet medications market?

We are unable to determine how passage of HR 1406 would be expected to affect price, consumer choice, and other forms of competition.

How can the prices charged to consumers for pet medications by veterinary clinics and retailers best be quantified and compared?

We do not have data regarding prices charged to consumers by veterinary clinics for comparison to those charged by retailers and are not certain whether quantifying and comparing such data would be feasible. Veterinary business models range from small, single doctor practices to large, multidocor, multifacility practices as well as from practices that treat only one species to practices that treat multiple species.

To what extent do retailer prices for pet medications affect the prices of medications sold at veterinary practices or other aspects of veterinary clinic operations?

Given the variety of veterinary business models, we are unable to comment on how retailer prices for pet medications affect prices of medications or other aspects of individual veterinary clinic operations.

To what extent would HR 1406 affect veterinarians' sales of pet medications?

We are not certain how HR 1406 would affect veterinary sales of pet medications. Small animal veterinary practices have varied business models, ranging from large hospitals with substantial in-patient tertiary care to house-call businesses with minimal dispensing of drugs. To that end, veterinarians' sale of pet medications differs just as broadly, making speculation difficult.

What compliance costs would veterinarians face if HR 1406 were enacted?

Compliance costs are anticipated to be substantial. An administrative burden is 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 HR 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 professional or support staff time or both to 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 impact 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 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. In complying with the provisions of HR 1406, veterinarians will have to take measures to mitigate circumstances where 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 HR 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 by use of written prescriptions.

Should possible amendments to HR 1406 be considered?

The AVMA is strongly opposed to HR 1406 and does not believe any amendments should be considered. The AVMA wishes to engage in dialog with relevant stakeholders should any amendments to HR 1406 be offered.

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

We would again like to underscore the applicable education and knowledge that the veterinarian of record has with regard to veterinary medical pharmacology and, in particular, the medical history of his or her individual patients. Veterinary medications dispensed in the veterinary clinic come from a qualified veterinary team who can answer the client's questions and assure clients they have the proper drug for the patient. Our primary goal is to ensure that our clients receive the best quality information about their pet's medications.

Aside from pharmacists' lack of formal education in veterinary pharmacology, not all pharmacies have state licensure in good standing. 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.

Part of the AVMA's mission is to improve both animal and human health, and we are concerned with possible human health ramifications that could result from mandated prescription writing. We are concerned about scenarios wherein the client leaves the clinic with prescription in hand, only to call the clinic back and claim that the prescription has been lost; rewriting the prescription for the benefit of the animal is acceptable but could unknowingly lead to drug diversion. The sudden increase in volume of written prescriptions could increase the chance that individuals will be able to fraudulently and illegally procure prescription drugs.

In closing, the AVMA appreciates the FTC's careful analysis of how the Fairness to Pet Owners Act of 2011 (HR 1406) would affect veterinary practitioners and the availability and access to drugs for treating household pets, including dogs, cats, birds, and certain exotic species. Although the AVMA 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. The AVMA believes HR 1406 is redundant and will cause undue regulatory and administrative burdens on veterinary practices. It is burdensome and unnecessary to require a written prescription as well as a written notification that the prescription may be filled elsewhere, regardless of whether 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.
- HR 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 at a pharmacy of their choice. The AVMA is supportive of a client's right to choose where to have a prescription filled.
- The AVMA believes that veterinarians are uniquely educated to provide the best professional guidance and education to pet owners when dispensing prescription products.

Thank you for your time and consideration. The AVMA appreciates the opportunity to comment and would like to continue the dialog on this and other important matters. For further clarification on the AVMA's comments, please contact either Dr. Ashley Morgan (202-289-3210; amorgan@avma.org) or Dr. Lynne White-Shim (800-248-2862 ext. 6784; lwhite@avma.org).

Respectfully,



W. Ron DeHaven, DVM, MBA
Executive Vice President and CEO

WRD/LAW

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3. US FDA. Animal drugs: a brief overview of CVM's drug approval process. Available at: www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268128.htm. Accessed Jul 26, 2012.
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