Northeast Indiana Veterinary Emergency and Specialty Hospital

September 14, 2012

Federal Trade Commission Bureau of Competition Chairman Jon Leibowitz 601 New Jersey Ave., Room 7117 Washington, DC 20580

Dear Chairman and Members of the Pet Medications Workshop:

As a Diplomate of the American College of Veterinary Internal Medicine, I am a practicing specialty veterinarian who prescribes medication to animal patients for treatment of acute and chronic diseases. Also, I have practiced as a general practice veterinarian and prescribed preventative medications. I am in disagreement with H.R. 1406, "Fairness to Pet Owners Act of 2011" for the following reasons.

First, I am concerned about compliance and safety. For example, after a medication to treat hypertension is prescribed, blood pressure should be monitored within 14 days. If, according to H.R. 1406, I prescribed and filled 14 days of the blood pressure medication and provided the pet owner with a written prescription for the same medication, the pet owner is able to obtain an additional 14 days of the blood pressure medication. A breach in compliancy may occur since the pet owner will have access to 28 days of medication and the blood pressure may not be monitored appropriately. Safety of the animal patient may be compromised. Also, in my practice halving and quartering of tablets is performed at no extra charge for pet owners as a means to improve safety and compliance. When my clients have obtained medication for their pets at human pharmacies, the tablets are not halved or quartered.

A common emergency in veterinary medicine is reaction to over-the-counter flea products for use in dogs that are applied by pet owners to cats. These products cause severe muscle tremors and seizure activity in cats. Often cats suffering this toxicity are hospitalized for 24 to 48 hours and require extensive nursing care that results in increased cost to the pet owner. These products state, on the label, do not apply to cats and there is a no cat symbol on the label. If pet owners are not able to appropriately apply over-the-counter flea prevention products that are currently available, they should not have access to additional products that could cause harm if used incorrectly. Another example includes herding breeds, such as Shetland Sheepdogs and Collies that have a MDR 1 gene mutation resulting in a lack of P-glycoprotein in the blood-brain barrier. These dogs can have neurotoxicity when given drugs in the class, macrocyclic lactones such as ivermectin or moxidectin

which can be costly to treat and may be fatal. There is increased risk of this type of neurotoxicity when the pet owner is able to obtain these products from sources other than veterinarians. Guidance and pet owner education by a veterinarian at the time of prescribing preventative products is necessary and distribution by pharmaceutical companies to only veterinarians should be continued.

Secondly, there is increased cost for the veterinary business when a copy of a veterinary prescription is produced. The increased cost includes materials needed to produce the prescription, veterinarian and veterinary technician time in writing the prescription and time involved in explaining to each pet owner about the prescription.

Thirdly, pet owner education will be compromised when pet owners obtain pet medication outside of the veterinary hospital. When I prescribe and fill medications in the hospital, a veterinary technician or myself shows the medication to the client, explains why it is being given and explains how the medication should be administered which often includes demonstration. For liquid medications, syringes are marked to indicate the appropriate quantity that should be given. Will this level of education occur when the medication is obtained from a human pharmacist? According to the Bureau of Labor Statistics, pharmacists dispense prescription medications to patients and offer advice on their safe use. This definition does not include pet owners or pets. The education veterinarians and I provide to the pet owner is a result of extensive veterinary education and training in pharmaceuticals used in pets.

In addition, having been through undergraduate college, veterinary college, an internship, and a residency, I am dedicated to a career in veterinary medicine. This level of education allows me to provide the highest level of information to pet owners about medications being prescribed to treat their pets. As a veterinarian, after years of study and dedication, I appropriately charge for my services including pet medications that I prescribe. The value to the pet owner is that when all veterinarians including myself dispense prescription medications to animal patients it improves compliance, increases safety and efficacy is preserved.

In regard to the discussion of the pet medication industry and the Fairness to Contact Lens Consumers Act, veterinary prescription medication and contact lenses are not synonymous. Veterinary prescription medication is a pharmaceutical drug or chemical substance used in prevention or treatment of disease. Contact lenses are medical devices. According to the U.S. Food and Drug Administration (FDA) there is a clear distinction between a medical device and other FDA regulated products such as drugs.⁴ If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. The Federal Food, Drug, and Cosmetic Act defines medical devices as "an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component, part, or accessory thereof, which is intended for use in the diagnosis of disease or other conditions; in the cure, mitigation, treatment, or prevention of disease in man or other animals; or which is intended to affect the structure or any function of the body of man or other animals."

Further, a device "does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals, and is not dependent upon being metabolized for the achievement of any of its principal intended purposes." Veterinary prescription medications are drugs and not devices, therefore, comparing the pet medication industry to the contact lens industry is erroneous.

Thank you for considering and using this information as part of the workshop, Competition and Consumer Protection Issues in the Pet Medications Industry.

Sincerely,

Amy Totten DVM, Diplomate ACVIM (Internal Medicine)

References:

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- 4. www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm
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