

September 14, 2012

**Submitted via – <https://ftcpublic.commentworks.com/ftc/petmedsworkshop>**

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

**Re: Workshop on Pet Medications Issues – October 2, 2012**

The Animal Health Institute (AHI) submits these comments in response to the request for comments by the Federal Trade Commission (FTC) in advance of the October 2, 2012 Workshop on Pet Medications Issues. AHI is the national trade association representing research-based manufacturers of animal health products – the pharmaceuticals, vaccines, feed additives and pesticides that keep pets and livestock healthy and that are used in modern food production. Our member companies represent the bulk of the US domestic market for these products.

#### **COMPLEXITY AND SIZE OF THE ANIMAL HEALTH PRODUCTS MARKET**

The companion animal market for animal health products is complex and diverse. Unlike products intended for human use, animal health products are labeled for use across a wide variety of species and indications. Additionally, veterinarians, who are uniquely trained in the physiology and clinical pharmacology issues that entail, may appropriately use these products in a manner that differs from their approved labeling.

Pharmaceutical products are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act. These include so-called pioneer and generic products, conditionally approved products for minor uses and minor species, indexed products for minor uses and minor species, legally marketed unapproved products and veterinary devices. They may be labeled for over-the-counter use, for prescription use, or according to conditions set forth by FDA in “no objection” letters for the legal marketing of unapproved animal drugs. The intended species for these products may range from dogs and cats, livestock and horses to an extremely diverse range of minor species such as ferrets, ornamental fish and rhinoceroses. There are many dosage forms including oral (solid or liquid), injectable, topical and pet food. The spectrum of intended uses for these products is staggering. For example, there are products to prevent, treat or control disease, infection, parasitic infestation, cancer, obesity, and behavioral conditions.

Biological products for companion animals, typically vaccines and diagnostics, are regulated by the US Department of Agriculture under the Virus-Serum-Toxin Act. They may be licensed or conditionally licensed. They may carry restrictions on their licenses that require their distribution in each state to be limited to authorized recipients designated by proper state officials under such additional conditions as they require. The intended uses for these products range from the diagnosis, control and prevention of disease and parasites to treating cancer.

Pesticides are regulated by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act. These products are typically directed at the control of external parasites and come in a variety of dosage forms including spot-on products for topical application.

Despite the number of species and products, the size of the market is much smaller than that for human health products. Our understanding of the best estimates for the total animal health products market ex-manufacturer across all species and all products for 2011 is approximately \$7.5 – 8 billion. It is unclear, but the figure utilized in the Federal Register Notice for the workshop of almost \$7 billion for prescription and OTC pet medications appears to be attributing the entire animal health products market for all species to the companion animal segment. Our understanding of the best estimates for the companion animal segment for 2011 is approximately \$3.8 billion.<sup>1</sup> Likewise, the Notice appears to attribute the full extent of the US domestic companion animal market to two categories, flea & tick and heartworm preventatives. These are certainly important product categories, but do not comprise the entire companion animal market, and sweeping policy changes targeting a few products will likely have adverse unintended consequences for other medications. Our understanding of the size of the parasiticide market, which includes flea & tick products, heartworm preventatives and products to control internal parasites, for 2011 is approximately \$2.4 billion.

#### **DISTRIBUTION OF ANIMAL HEALTH PRODUCTS**

Manufacturers utilize a variety of distribution channels to sell animal health products. Each manufacturer independently determines the channels most effective for the distribution of its products. In the companion animal market, manufacturers currently sell their products through distributors or directly to veterinarians, veterinary hospitals, retailers, and pharmacies (both on-line and bricks & mortar). Some companies limit the channels utilized for the sale of some of their products and some utilize different outlets for different categories of products. These types of practices are among those that the FTC has publicly acknowledged as appropriate and common across industries.<sup>2</sup>

Across all species there are more than 130 distributors of animal health products selling to more than 70,000 veterinary purchasers. There are also large numbers of retail and pharmacy outlets that sell animal health products. There is also a “grey” market where some products are resold. The FTC podcast advertising the Pet Medications Workshop acknowledges that animal health products are

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<sup>1</sup> Our understanding of the estimates for the companion animal market comports with those utilized by PetMed Express, Inc. See PETMED EXPRESS, INC. INVESTOR PRESENTATION at slide 13, available at <http://investor-relations.petmeds.com/pet-meds-investor-presentation.html>.

<sup>2</sup> See, e.g. CONSUMER PROTECTION AND COMPETITION ISSUES CONCERNING THE CONTACT LENS INDUSTRY, Prepared Statement of the Federal Trade Commission before the Subcommittee on Commerce, Trade, and Consumer Protection, U.S. House of Representatives at 12 (September 15, 2006), available at [http://www.ftc.gov/os/testimony/060915\\_v040010cpccontactlensindustryhouse.pdf](http://www.ftc.gov/os/testimony/060915_v040010cpccontactlensindustryhouse.pdf). (“It is important to note that limited distribution policies – including those that limit online distribution – are common across industries.) and *Id.* at 14 (“Indeed, as the Supreme Court has stated, “[a] manufacturer of course generally has a right to deal, or refuse to deal, with whomever it likes as long as it does so independently.”” (quoting *Monsanto Co. v. Spray-Rite Service Co.*, 465 U.S. 752, 761 (1984)).

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widely available.<sup>3</sup> The very large number of sales outlets creates an environment of rigorous competition and choice. PetMed Express, Inc., which operates 1-800 PetMeds and calls itself America's largest pet pharmacy, acknowledges that increased retail and on-line competition is a challenge for them.<sup>4</sup> Indeed, one of the strategies it has identified for coping in this highly competitive environment is to evaluate the use of private labeled products.<sup>5</sup>

### ROLE OF THE VETERINARIAN

The veterinarian plays a critical role in our industry, particularly related to product selection for companion animals. Matching the correct product with the correct patient is critical for many products. The FTC Notice for the workshop acknowledges: "All industry participants agree that pets should be properly examined and diagnosed by a veterinarian to determine the most appropriate course of treatment for any medical condition, including whether any medication should be prescribed."<sup>6</sup> Moreover, the importance of having a veterinarian determine the appropriate medication extends beyond prescription products and encompasses many other types of animal health products, particularly as veterinarians frequently and appropriately use these medicines in a manner that differs from the approved labeling such as treating a different species, or using a different dosage regimen or a different indication for use.

In this environment, the veterinarian is the primary source of information about animal health products for pet owners. Veterinarians have typically counseled clients regarding the use of products and many manufacturers have invested tremendous resources to educate veterinarians about their products. Veterinarians also have ongoing close interaction with their clients and have been the primary monitors of patient use of medication including evaluation for interactions and adverse events. They often train clients to administer products that are dispensed. These roles for the veterinarian are understandable as veterinarians are uniquely trained in the physiology and pharmacology for the various species they treat. Products that are safe for one species may be toxic to another and products that can be utilized in combination in one species may not be safe in another. This involvement of the veterinarian should not be discounted, as many in the industry believe that the safety and efficacy profiles for certain animal health products are positively impacted by the comprehensive role of the veterinarian.

### INNOVATION

The FTC asks whether industry distribution practices affect innovation in the pet medications market. The answer is no. The pet medications market is a competitive industry, with competitors continuing to invest in developing new and improved products. In 2010 AHI member companies invested approximately \$690 million in research and development. In 2011 the International Federation for Animal Health conducted a benchmarking survey of the leading animal health products manufacturers and identified the most important factors impacting innovation as access to new technology and

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<sup>3</sup> See PODCAST TRANSCRIPT ON FTC'S PET MEDICATIONS WORKSHOP at page 1, available at <http://www.ftc.gov/opp/workshops/petmeds/petmedtranscript.pdf>.

<sup>4</sup> See PETMED EXPRESS, INC. INVESTOR PRESENTATION at slide 22, available at <http://investor-relations.petmeds.com/pet-meds-investor-presentation.html>.

<sup>5</sup> See *Id.* At slide 23.

<sup>6</sup> WORKSHOP ON PET MEDICATIONS ISSUES, 77 Fed. Reg. at 40356 (July 9, 2012).

intellectual property, development costs and time to market, and regulatory uncertainty. A common figure used to describe all animal health products is that it can take up to 10 years and direct costs (excluding capital expenditure apportionment and failed product amortization) of up to \$100 million to develop a new product. For companion animal products, the mean period for regulatory review is 6.4 years with associated direct costs of up to \$70 million for a pharmaceutical product, 4 to 5 years and up to \$25 million for a biological product and 3.5 years and up to \$65 million for a pesticide product. The compounded increase in costs to develop a companion animal product from 2006 to 2011 was 171% and the typical time to market for this category has increased by 5 years since 1991. Similar to the human pharmaceutical and biologics industry, animal health products are highly regulated, and it can take some time to develop and market new products.

#### **PRESCRIPTION PORTABILITY AND CONSUMER AWARENESS**

It is our view that under current law and practice veterinarians will provide written prescriptions to clients upon request. The code of ethics for the veterinary profession requires doing so and requires veterinarians to place the interests of the client above their own.<sup>7</sup> A little more than half of the states require veterinarians to honor a client's request for a prescription either by statute or rule of the state board that regulates the veterinary profession. We believe an even greater number would view a refusal to provide a prescription upon request as a violation of general rules of professional conduct.

We also believe that consumers are generally aware of their ability to obtain animal health products from sources other than their veterinarian. Indeed, there has been more than \$200 million spent by a single pharmacy on a multi-year advertising campaign directed at consumers to ensure they are educated on this point, and they attribute the growth in their business to this effort.<sup>8</sup>

When one considers that veterinarians are legally and/or ethically bound to provide prescriptions, that pharmacies and retailers can and do advertise their ability to provide products and fill prescriptions, and that the products are readily available, it is clear that current distribution practices do not limit or impact prescription portability and consumers' choices or awareness.

#### **DIFFERENCES BETWEEN ANIMAL HEALTH PRODUCTS AND CONTACT LENSES**

The FTC podcast advertising the workshop asks: "OK, you just lost me. What do contact lenses have to do with pet meds?"<sup>9</sup> We agree with the tone of the question and believe the answer is that the animal health products market and the human contact lenses markets are not comparable. Animal health products intended for use in companion animals span three federal agencies; can be subject to additional state regulation relative to their use and distribution; and impact every conceivable physiologic system across a wide variety of animal species. The human contact lens market represents a single category of medical devices that are used topically on a single organ system for vision correction,

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<sup>7</sup> See PRINCIPLES OF VETERINARY MEDICAL ETHICS, American Veterinary Medical Association, III(c)(1) and V available at <https://www.avma.org/KB/Policies/Pages/Principles-of-Veterinary-Medical-Ethics-of-the-AVMA.aspx>.

<sup>8</sup> See PetMed Express, Inc., Welcome to Fellow Investors, available at <http://investor-relations.petmeds.com>.

<sup>9</sup> See PODCAST TRANSCRIPT ON FTC'S PET MEDICATIONS WORKSHOP at page 3, available at <http://www.ftc.gov/opp/workshops/petmeds/petmedtranscript.pdf>.

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where the distinction among products primarily involves differing plastic polymers and differing shapes. These differences may have real meaning as to oxygen diffusion, fit and feel, and their ability to correct vision, but they impact a single system and carry a low likelihood of significant adverse events. Moreover, it is our understanding that generally the contact lens rule relates to the ability of a consumer to order standardized contact lenses, which are manufactured and distributed by a variety of companies. Once the consumer obtains a prescription, the consumer can order the lens from any manufacturer/distributor and it is not necessary for the consumer to see a doctor about how to use the lens. In contrast, due to the complexity of the practice of veterinary medicine and prescribing animal health products, it is critical for many products that a veterinarian follows the patient's care, and educates the pet owner on the proper utilization and dosage. These are not tasks that pharmacists are typically trained to handle.

The scope and practice of companion animal veterinary medicine is very large and includes the diagnosis, prevention, control and treatment of all animal diseases and conditions, performing medical imaging, surgical and other interventional procedures, as well as advising pet owners about how to keep their pets healthy and follow treatment plans. In the course of such practice most companion animal veterinary hospitals are analogous to human hospitals providing inpatient, outpatient and emergency care, with surgical, medical imaging and clinical laboratory services. In this context a very wide variety of animal health products will be utilized for many different purposes. Requiring veterinarians to provide unsolicited written prescriptions makes no sense and would add a cumbersome layer interfering with the efficient delivery of veterinary care. On the other hand the interaction of eye care professionals with their patients relative to fitting contact lenses is on an outpatient basis and is typically limited to an examination of the eye to “[d]etermine eye health, lens power, and contact lens curvature and diameter.”<sup>10</sup>

Pharmacists are an integral part of the delivery of human health care and their training is primarily oriented to human health. However, pharmacists are not trained in the physiology and pharmacology of companion animals in a manner similar to veterinarians and their participation in the delivery of veterinary health care has accordingly always been very limited. Pharmacists are not trained in the species-specific differences in drug metabolism and interactions in a manner similar to veterinarians. According to the Bureau of Labor Statistics, pharmacists typically do the following:<sup>11</sup>

- *Fill prescriptions, verifying instructions from physicians on the proper amounts of medication to give to patients* – Pharmacists fill a similar role in filling prescriptions from veterinarians.
- *Check whether the prescription will interact negatively with other drugs that a patient is taking or conditions the patient has* – Pharmacists are not trained for this for all products and species in a manner similar to veterinarians.

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<sup>10</sup> See THE STRENGTH OF COMPETITION IN THE SALE OF PRESCRIPTION CONTACT LENSES: AN FTC STUDY at footnote 16 (Feb. 2005), available at <http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf>.

<sup>11</sup> See WHAT PHARMACISTS DO, Bureau of Labor Statistics available at <http://www.bls.gov/ooh/Healthcare/Pharmacists.htm#tab-2>.

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- *Instruct patients on how and when to take a prescribed medicine* – Pharmacists are not generally trained in instructing pet owners about how to medicate their animals. Teaching a pet owner to administer a pill to a cat is not the same as telling them to give it orally.
- *Advise patients on potential side effects they may experience from taking the medicine* – Pharmacists are not generally trained to counsel pet owners about the potential side effects of medications for all companion animal species for all uses.
- *Advise patients about general health topics, such as diet, exercise, and managing stress, and on other issues, such as what equipment or supplies would be best for a health problem* – Pharmacists are not generally trained in these areas relative to companion animals.
- *Complete insurance forms and works with insurance companies to be sure that patients get the medicines they need* – The pharmacist's relation to this for veterinary medicine is tenuous.
- *Oversee the work of pharmacy technicians and pharmacists in training (interns)* – Pharmacists can't train others in areas in which they are not trained.
- *Keep records and do other administrative tasks* – Pharmacists can certainly keep records. However, we do not believe they are generally trained in the variations of label requirements for differing uses of animal health products and the specific label requirements for dispensing that may attach to different types of animal health products.
- *Teach other healthcare practitioners about proper medication therapies for patients.* Pharmacists are not generally trained in proper medication therapies for companion animals.

For contact lenses, the dispenser must be familiar with a single product category for a single species. The task is much less daunting.

### CONCLUSION

There is vigorous competition in the animal health products market across many manufacturers and sales channels. The consumer has benefited and is able to obtain an unprecedented level of veterinary medical care with the aid of a range of safe and effective animal health products. Veterinarians are legally and/or ethically bound to provide prescriptions to clients upon request. Pharmacies and retailers have effectively advertised and merchandised their businesses. Consumers have responded to these efforts and purchase many animal health products from pharmacies and retailers. Government intervention to pick the winner in this competitive environment is unwarranted and could potentially adversely impact the quality of care and health of consumers' pets.