

Statement of the Animal Health Institute

Subcommittee on Commerce, Manufacturing and Trade

Hearing on “The Pet Medication Industry: Issues and Perspectives.”

April 29, 2016

The Animal Health Institute (AHI) appreciates the opportunity to submit these comments for the record. 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.

AHI supports the goal of consumer choice. Pet owners should, and do, have the freedom to fill prescriptions for their animals’ medicine wherever they like. Because this freedom currently exists, backed up by state laws and codes of ethics, we believe the proposed Fairness to Pet Owners Act is an unnecessary solution in search of a problem.

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, and legally marketed unapproved products and veterinary devices. 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 and ornamental fish. 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 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 animal health market is much smaller than that for human health products. American consumers spent \$55.3 billion on their pets in 2013.

Pet medications and related health supplies are only approximately one-quarter of that total - about \$13 billion. The vast majority of the \$13 billion is spent on OTC products, such as heartworm and flea products.

According to the American Pet Products Association, only 54 percent of flea and tick products are purchased from the veterinarian – the rest is through a variety of retail channels, proving that the market for obtaining medications outside the veterinary office is already thriving. In addition, only a small percentage of pet medical expenses are for prescription medications sold by veterinarians.

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.

Across all species there are more than 200 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. A Federal Trade Commission podcast advertising the 2011 Pet Medications Workshop acknowledges that animal health products are widely available. 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 veterinarians hold a competitive advantage because “many pet owners may find it more convenient or preferable to purchase these products directly from their veterinarians at the time of an office visit.” Thus, consumer purchases from veterinarians are driven by convenience and preference, not lack of awareness of the availability of a prescription.

These distribution systems are constantly in flux and have been greatly impacted by the advent of e-commerce – a development benefiting consumers. A report released in May 2015 by the Federal Trade Commission, titled “Competition in the Pet Medications Industry: Prescription Portability and Distribution Practices” states that “consumers appear to have benefitted from increased competition between veterinary practices and alternative retail channels, particularly for OTC flea and tick control products and prescription heartworm products. Pet owners now have many more choices for purchasing pet medications than they did a decade ago, and several industry stakeholders believe this has led to lower prices, greater convenience, and improved service.” In fact, the 2015 FTC report found no evidence that veterinarians are withholding written prescriptions from their clients and makes no call for federal legislation to mandate veterinary prescriptions

Role of the Veterinarian

Veterinarians are ethically – and in many cases legally – bound to provide prescriptions upon request. The American Veterinary Medical Association’s principles of veterinary medical ethics require veterinarians to honor a client’s request for a prescription. Thirty-six states have State veterinarian laws, regulations, or policy statements that are related to veterinarians being required to provide pet owners with the prescription upon request. Of the remaining 14, there is no specific

law/policy/regulation, but a veterinarian who does not honor a client's request or requires the pet owner to sign a waiver, may be subject to disciplinary action based on their State's Veterinary State Board ethical guidelines.

The veterinarian plays a critical role in our industry, particularly related to product selection for companion animals. The veterinarian is the primary source of information about animal health products for pet owners. Veterinarians 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. 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.

Anecdotal evidence of harm caused to pets by misfilled prescriptions demonstrates the value of the veterinarian. In a widely publicized case in Ohio in 2013, a dog died after a drug store filled a prescription with label directions to administer "two and one-fourth teaspoons," a common human dose, when the proper veterinary dose called in by the veterinarian was "two and one-fourth CCs."

Differences Between Animal Health Products and Contact Lenses

Proponents of this legislation have compared it to similar legislation enacted by Congress for the contact lens industry in 2003. We do not believe this is an apt comparison due to the distinct differences between the animal health products market and the human contact lenses. 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, 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 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.

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

Summary

Today's pet owner enjoys an unprecedented level of choice in both the availability of veterinary medical care and the 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 winners in this competitive environment is unwarranted and could potentially adversely impact the quality of care and health of consumers' pets.

A government mandate on veterinarians who have historically and successfully been regulated at the state level, and that interferes in an existing competitive marketplace, could potentially adversely impact the quality of care and health of consumers' pets.