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September 13, 2012

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

Re: Comments of the American Veterinary  
Distributors Association on H.R. 1406  
and FTC Pet Medication Workshop

Dear Mr. Secretary:

On behalf of the American Veterinary Distributors Association (AVDA) I am pleased to submit its comments and information pertaining to Pet Medication Workshop to be held on October 2, 2012.

AVDA was established in 1976 as the national trade organization for businesses engaged in the distribution of animal health products. The typical AVDA distributor has net sales of \$265 million, net profit before taxes of 2.2% and employs 413 people.

The primary market for veterinary supplies consists of some 55,000 veterinarians practicing in more than 25,000 veterinary practices throughout the United States. Those products include pharmaceuticals, biologicals, white goods, instruments and equipment, and pet foods. In addition, AVDA members provide vaccines, pharmaceuticals and other animal health supplies to more than 10,000 OTC re-sellers including pet specialty, ag retail and farmer cooperative locations nationwide. Active membership in AVDA is open to firms whose primary business is the wholesale distribution of animal health products, and Associate Memberships are held by those companies that manufacture the products.

### **US Animal Health Market Overview for Veterinary and OTC Products**

As a trade association, AVDA does not typically conduct studies of the pet medication market place. However, in preparation of these comments, AVDA secured the services of Axxiom LLC, a leading animal health consultancy firm, to prepare an analysis of the U.S. market for pet medications. The Axxiom market analysis is attached hereto in its entirety. This report clearly demonstrates the following points:

1. 2010 Consumer spending on animal health products for pets exceeded \$3.7b.
2. Consumers source these products from nearly 300,000 retail and veterinary clinic locations.
3. Consumers spend an estimated \$400m per year to purchase animal health products for pets and other supplies from an expanding number of internet-based pet pharmacies and pet specialty retailers.
4. Additionally, Consumers routinely fill millions of veterinary prescriptions at traditional human pharmacy locations for a variety of pet medications.
5. The market for animal health products is highly competitive, offering Consumers a broad array of options from which to source both prescription and non-prescription products.

The comments submitted to the FTC by veterinarians support the conclusions reached in this study. Throughout the comments veterinarians describe the increased number of requests by clients for written prescriptions that were provided by the veterinarians. The Principles of Veterinary Medical Ethics of the AVMA, under which all veterinarians are required to operate, states the following regarding prescription requests when a valid Veterinarian-Client-Patient-Relationship exists:

*Principles of Veterinary Medical Ethics of the AVMA Originally approved by the House of Delegates in 1867 as the AVMA Code of Ethics (Revised 8-2012\_EB/HOD)*

III. THE VETERINARIAN-CLIENT-PATIENT RELATIONSHIP

C. *Dispensing or prescribing a prescription product requires a VCPR*

1. *Veterinarians should honor a clients request for a prescription in lieu of dispensing.*
2. *Without a VCPR, veterinarians merchandising or use of veterinary prescription drugs or their extra-label use of any pharmaceutical is unethical and is illegal under federal law.*

As reflected in the attached study, this principal of providing written prescriptions is well established in practice as more than 45,000 veterinarians provided in excess of 4,000,000 prescriptions to their clients during the twelve month period from July, 2010 through June, 2011.

## H.R. 1406 Ignores Pet Safety and Interferes with the Veterinarian-Client Relationship

The entire thrust of H.R. 1406 relies upon a set of false and potentially dangerous assumptions. First, the proposed legislation assumes the traditional retail pharmacist has the requisite knowledge and support systems in the field of animal pharmacology to accurately fill veterinary prescriptions. This is an erroneous assumption given animal pharmacology differs greatly from that of humans and the standard training provided to pharmacists is not sufficient to address the breadth of issues typically presented by prescription medications for animals. The profession of "animal pharmacist" only exists in the United States to the extent that veterinarians receive extensive education in the composition, use, risks, and applications of drugs in animals.

To illustrate this point, a veterinary student in the United States will take an estimated 120 Credit Hours during the first three years of a typical veterinary training program of which more than 55% (65 hours) involve the direct or indirect application of pharmacology in the treatment of clinical diseases. The entire fourth year's curriculum (approximately 48 weeks of clinical rotations) directly involves the application of pharmacology in clinical practice.

At graduation, the average veterinary student has completed an equivalent of 2.5-3 years of their 4 year education to the physiology, pathology, and clinical application of medical and anesthetic management of the 7 major species segments: Canine, Feline, Equine, Bovine, Swine, Small Ruminants and Exotics.

Prior to being eligible for licensure in any U.S. state, every veterinary graduate must demonstrate competency in the North American Veterinary Licensing Examination (NAVLE). The NAVLE test assesses clinical assessment and application of patient management in the following species:

<b>North American Veterinary Licensing Examination</b>	
<b>Questions per Animal Species</b>	
<b><u>Species</u></b>	<b><u>Target Proportion of Test</u></b>
Canine	24%
Feline	24%
Bovine	17%
Equine	17%
Porcine	4%
Pet Birds	3%
Ovine/Caprine/Cervidae	3%
Public Health & Food Security	3%
Other Small Animals	2%
Poultry	2%
Non-Species Specific	<u>1%</u>
<b>Total</b>	<b>100%</b>

Once licensed in a given state, a veterinarian must complete specified Continuing Education requirements as mandated by the governing Board of Veterinary Medicine. Requirements vary between states but typical requirements are between 12 and 20 hours of clinical continuing education each year.

A practicing pharmacist must master the knowledge and clinical effects of hundreds to thousands of pharmaceutical agents in a single species and maintain that mastery through ongoing clinical education.

By comparison, a practicing veterinarian must master the knowledge and clinical effects of the same foundation of pharmaceutical agents but in multiple species (up to 5 or 6 for the true mixed animal practitioner); all with differing functional anatomies, physiologies, metabolic processes, and varying clinical responses to pharmacological agents or drugs. It is important to note the applications of these drugs can vary significantly both among the various animal species and versus the traditional human therapeutic uses due to markedly different efficacy and safety profiles per animal species. Relatively innocuous substances in humans can prove fatal to certain pet species due to intolerance of certain excipients or other ingredients typically used in human pharmaceutical formulations. Furthermore, veterinarians are trained to understand the interactions of drugs with a wide variety of biological agents administered as vaccinations for various infectious diseases across multiple species, another discipline in which the retail pharmacist receives no training or on-going support for continuing education.

If the passing of the proposed bill results in an increase in veterinary prescriptions filled at traditional human pharmacies, it will present several challenges. First, pharmacists working in human pharmacies typically do not have any training in veterinary pharmacology. When presented with a prescription for a pet, a diligent pharmacist will take the extra time required to verify the information required during a drug utilization review (DUR). A veterinary DUR will likely take longer because (1) the pharmacist is unlikely to be familiar with the specific veterinary applications of the prescribed medication (such as dosing, species differences, and toxicities) and (2) traditional pharmacy software used for these reviews does not include this type of veterinary information. This will present a significant challenge for a pharmacy system generally regarded as already overloaded with its existing patient load. Secondly, a pharmacist who lacks adequate reference materials for obtaining dosing information could be putting both their license and the pet's health at risk by filling the prescription. In fact, some pharmacists may not be willing to dispense the medication if they are unable to validate dosing. It would be naïve to think that a human pharmacist would be able to verify a veterinary prescription in the same capacity as a human prescription without significant levels of additional in-depth training. The knowledge base is simply

not in place nor has the industry deployed the resources necessary to support the pharmacist in this respect.

The Federal Trade Commission's July 9, 2012 Federal Register notice contains the following:

*"When a veterinarian writes a prescription for a medication to be dispensed and subsequently administered by a pet's owner, the prescription must be filled with the correct medication and dosage and the owner must have access to relevant information about the medication and proper administration techniques."*

Clearly, the human pharmacy industry is not adequately prepared to assure pharmacists have the necessary training, expertise and on-going support to deliver the appropriate level of care and protection to the Consumer for their pets as is required for human patients. While the traditional human pharmacy has an important role to play in fulfilling certain prescriptions, particularly in those instances where the veterinarian is prescribing a standard human pharmaceutical product or a specialty compounding application, it is equally evident the veterinarian is the only medical professional sufficiently trained to judge the pharmacological agent to be used, its dosage, the duration of treatment and any other special considerations which may be unique to that species or even a given breed of pet.

To be proficient as a veterinary pharmacist, it is necessary that a traditional human pharmacist expand their clinical knowledge base 5- 6 times for a volume of prescriptions that will make up less than 10% of their day-to-day activities. A mandated expansion of the role of human pharmacies designed to increase participation in the veterinary prescriptions market would necessitate clinical pharmacists demonstrate the same level of competency for veterinary medicine as currently required for human health. This would require:

- Clinical pharmacology programs integrate animal health pharmacology into their training programs in a substantive manner so as to enable students to master physiology in numerous species and body systems
- Establish national and state testing mechanisms to ensure competency of this knowledge base
- Establish requirements for on-going continuing education requirements to maintain mastery of this massive expansion of required knowledge

In addition to the initial and on-going training obligations needed for the pharmacists, the pharmacies must significantly expand their inventory of veterinary medications, stocking veterinary labeled items specifically designed and approved for use in animal species so as to avoid harmful substitutions of non-approved or inappropriate medications.

H.R. 1406 does not provide any assurance to the pet owner that a person, other than the veterinarian, filling that prescription is trained in animal pharmacology and capable of correctly filling the prescription despite the FTC's foregoing admonishment.

Failure to understand the differences of pharmacological applications in veterinary and human medicine can result in serious mistakes; sometimes with tragic consequences. Consider the following:

Four cases of errors by pharmacists resulting serious health issues for pets have been recently reported to the Oregon Veterinarian Medical Association ("OVMA").

- A female Chihuahua mix named "Boogie" had been diagnosed with idiopathic epilepsy. The veterinarian wrote a prescription for 15 mg of Phenobarbital b.i.d. (*e.g. twice daily*), and his client had the veterinary prescription filled at a local pharmacy. The client returned to the pharmacy at a later date and mentioned to the pharmacist that her dog seemed to be lethargic. (Lethargy can be an initial side effect of the drug.) According to the veterinary client, the pharmacist, without consulting the veterinarian, suggested that she reduce the dose in half which resulted in sub-therapeutic treatment. The dog suffered additional seizures for the next two weeks until the client took "Boogie" back to the veterinarian. At that time the veterinarian corrected the dose to his original prescription. The same veterinarian and his associates have experienced many other occasions where pharmacists have given his veterinary clients inaccurate information about prescribed drugs – most notably thyroid medications. Some pharmacists who are concerned with the dosage contact the practice, as they should. But more often than not the pharmacist changes the dosage and the clients become upset with the veterinarian for "over-dosing" their pets.
- A client brought her cat to a practice for training to administer insulin, as her cat had been diagnosed with diabetes. The veterinarian prescribed glargine (Lantus) insulin. When the client went to pick up the insulin at the local pharmacy, the pharmacy staff told her that Glargine and Humulin-N were equivalent products, and that

Humulin-N was much less expensive. On the recommendation of the pharmacist, the veterinary client bought the Humulin-N instead of the original prescriptive product. While Humulin-N is less costly than Glargine insulin, the two insulin products ARE NOT interchangeable. Fortunately, upon a re-check with the cat, the veterinarian corrected the insulin to the appropriate product for her patient. The client sought to return the Humulin-N to the pharmacy, but she was told that was not allowed.

- A veterinary dermatologist in the Portland area has patients with serious diseases (actinomycosis, cutaneous tuberculosis, systemic lupus) that require long-term medications – for 3 to 6 months. The veterinary dermatologist has experienced a number of pharmacists who have changed the prescriptions without notification, resulting in serious relapses for patients and additional cost and hardship for clients.
- For veterinary dermatologists, most of the therapeutic treatments are with human drugs, as there are no veterinary drug equivalents. Because 60% of this veterinarian's clients live more than two hours away, the veterinarian often writes a prescription for the client to have filled at a pharmacy of the client's choice. Because of these negative experiences with pharmacists adjusting drug dosages, the veterinarian and her staff have had to take extra measures to reduce the possibility of this occurring (no longer call in a prescription to a pharmacy).
- In another example from the same veterinarian, the patient was being treated for an auto-immune disease. One of the results of the dog's illness was loss of hair – alopecia. When the client mentioned the dog's hair loss to her pharmacist, he suggested that she consider using Rogaine. Minoxidil is the drug in Rogaine and can cause cardiomyopathy in dogs.
- Many clients of this veterinarian are registered pharmacists and they call with questions about filling a veterinary prescription because they are unaware of side effects of the drugs. In one case, the veterinarian prescribed niacinamide for a dog with lupus, but the pharmacist owner bought niacin instead. He thought the products were identical, but they are not; and the dog suffered from cardiac side effects.
- It is important to note that changes for script medications by the pharmacist absent consultation with the issuing practitioner is illegal

and subject to disciplinary action or even prosecution by state authorities and the boards of pharmacy. Yet, these types of incidents generally go unaddressed, leaving unsuspecting pet owners subject to further abuse at the hands of perhaps well intended but grossly ill-informed pharmacists.

Other examples can be found among the comments submitted by veterinarians to the FTC, to wit:

- An example, submitted by a veterinarian, told how a prescription was erroneously filled by a pharmacist and resulted in the death of a champion breeding dog. (Submission No: 561891-00074)
- In another comment, the veterinarian related a case where the pharmacist recommended chocolate syrup to aid in the administration of a medication. Chocolate is known to be toxic to dogs. (Submission No. 561891-00036)

### **Veterinary Concerns**

The concerns expressed in the comments submitted by veterinarians must not be ignored. Many acknowledge that clients can and do have prescriptions filled at a local pharmacy and online. However, their concerns are universally centered on the pet.

These can be summarized as follows: It is not standard for retail pharmacists to be trained in the physiologies of dogs, cats and other animals and their unique responses to medications. The marked variations in dosages, treatment durations, and safety tolerances versus human applications have resulted in inappropriate and, at times, dangerous modifications of the veterinarian's instructions by retail pharmacists. State law requires that prescriptions not be altered without the agreement of the prescribing physician including veterinarians. If a pharmacist has any question about a veterinary prescription – the drug, dosage, treatment duration or even interactions with other drugs – it is incumbent upon the retail pharmacist to contact the veterinarian with such concerns. Under no circumstance should a retail pharmacist change a drug intended for an animal to another product or adjust the dosage of a prescribed product or recommend to the pet owner to adjust the dosage of a drug without consulting with the veterinarian and receiving his or her authorization. When a retail pharmacist adjusts the dosage of a veterinary prescription, the resulting treatment may be compromised by delivery of either too much or too little medication over too short or too long of a treatment period. In many instances, this requires that the veterinary patient receive extended treatment for its condition with additional cost and unnecessary expense to the Consumer.



## **H.R. 1406 and the Veterinarian/Client Relationship**

H.R. 1406 is so vague that it interferes with the veterinarian client relationship and subjects the veterinarian to accusations of violating its provisions where he or she merely provides medical advice to a client. The proposed bill contains two provisions that are detrimental to both the pet owner and the veterinarian. Section 2(1) (a), requires that the veterinarian must provide a written prescription and disclosure that the pet owner may have it filled through another pharmacy "determined by the pet owner". How does the pet owner determine whether or not another 'source' is qualified to fill the prescription? Is it permissible for the veterinarian to comment on a proposed source or would that constitute a disclaimer or waiver under Section 2(2) (iii)? It should be noted that the U.S. Food and Drug Administration ("FDA") has established a proactive program to advise pet owners particularly with respect to online pet pharmacies. The FDA has created a website at <http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm203000.htm> to assist pet owners who may be considering whether or not to order pet medications through an online pharmacy. The site warns Consumers about illegal online pharmacies that may sell medicines that are "counterfeit, outdated, mislabeled, incorrectly formulated, improperly made or stored". It should be noted that many of the comments submitted by veterinarians raised these same issues.

A striking example of the shortfalls encountered when the human pharmacy industry seeks to address veterinary issues can be found in the Veterinary-Verified Internet Pharmacy Practice Sites (Vet-VIPPS) program sponsored by the National Association of Boards of Pharmacy (NABP). According to the NABP website, the Vet-VIPPS program "accredits online pharmacies that dispense prescription drugs and devices for companion and non-food producing animals and assures your customers that they are purchasing drugs and devices from an online pharmacy that is properly licensed and complying with state and federal laws and regulations." The site further states: "Pharmacies displaying the Vet-VIPPS Seal comply with Vet-VIPPS criteria, which address a customer's right to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between customers and pharmacists." Unfortunately, the current certification criteria have no meaningful requirements as it relates to sourcing of pharmaceuticals to assure exclusion of counterfeit and sub-standard products. The Vet-VIPPS applicant is required to provide a vendor list of entities from which product will be sourced but there is no systematic process by which NABP verifies whether the identified sources carry gray market, counterfeit or otherwise unauthorized products. This point is further demonstrated in the 20+ page policy and procedure checklist for which applicants must submit a copy of their corresponding internal policies and procedures. While criteria exist for storage (Temp/Hum), VCPR, recall handling,

confidentiality, and a myriad of other issues, there are no criteria addressing the critical safety issue of product sourcing. As with the pharmacist, the application of traditional human pharmacy standards to veterinary medicine fall well short of any standards sufficient to assure the health, safety and welfare of the pets treated as patients by these institutions.

The FDA is obviously aware of the dangers posed to animals as a result of unscrupulous or inadequately trained providers when it comes to prescription medications. With the creation of the A.W.A.R.E. program, the FDA seeks to assist Consumers with a structured approach to review and critically assess online pharmacies. The FDA advises the Consumer "Before you purchase online, talk with your veterinarian!" The FDA encourages the Consumer to talk with his or her veterinarian to find out if he or she trusts the internet site, worked with the pharmacy or if other clients used the site. The FDA site contains cautions to pet owners and lists a number of issues to be determined by the pet owner before purchasing which include:

- Are veterinary prescriptions required?
- Is a licensed pharmacist available to answer questions?
- Is there a physical business address, phone number, and contact information?
- Whether or not the site is based in the U.S.?
- Is the site licensed by the State Board of Pharmacy in which it is based?

Interestingly, the FDA cautions that if the site's prices are dramatically lower than the veterinarian or other websites' prices, then it's probably too good to be true. H.R. 1406 is at odds with the FDA's position. According to the FDA, the principal knowledge resource for the pet owner is the veterinarian. However, H.R. 1406 seems to imply that the veterinarian should not talk to the Consumer. Under Section 2(a) (iii) a veterinarian may not "require the pet owner to sign a waiver or disclaim liability". What constitutes a disclaimer of liability? If the veterinarian has had a negative experience with an online or a local pharmacy can he or she inform the customer without violating 2(a) (iii)? Isn't that type of information exactly what the FDA says the Consumer should get from the veterinarian? Section 2(a) (iii) could have a chilling effect on the veterinarian's willingness to provide the Consumer with that information.

### **Analogy to the FCLA is Entirely Inappropriate**

The Fairness to Contact Lens Consumers Act (FCLA) was signed into law in 2003 but is rooted in eyeglass rules that were adopted by the FTC in 1978. Before the eyeglass rules were issued, many optometrists and ophthalmologists either refused to release prescriptions to their patients or charged an additional fee to do so. Moreover, advertising of ophthalmic goods and services, especially price advertising, was restricted by governmental or private regulation in almost every state. The FTC

eyeglass rules required prescribing eye care practitioners to, among other things, automatically issue a written prescription to every patient at no additional charge.

Congress directed the FTC to evaluate the impact of the eyeglass rules and to issue periodic reports. The FTC consistently reported a significant increase in competition, better service and lower prices for eyeglasses as a result of the rules. Contact lenses were not included in the eyeglass regulations because, at that time, contact lenses were an emerging technology. Hard lenses were predominant and were custom made for each individual. By 2003, however, approximately 85 percent of all contact lens wearers used mass-produced soft contact lenses. Consumers had a myriad of competitive options to fill contact lens prescriptions from the optometrist's office to third party sellers like pharmacies, department stores, and internet or mail order outlets.

Pet medications are more analogous to hard lenses custom made for each individual than to mass-produced soft contacts. Many mass-produced medications are prescribed for animals and humans. But medications are properly dispensed by licensed professionals who do more than simply sell drugs. Modern pharmacists advise patients and health care providers and act as learned intermediaries between a prescriber and a patient. Unfortunately, modern pharmacists are seldom trained in the field of animal health. The prescribing veterinarian is, for all intents and purposes, the animal pharmacist who is uniquely qualified to render customized services in the field of animal pharmacology.

Veterinary medicine bears little resemblance to the ophthalmic goods and services industry. The eye care practitioners occupy a narrow field of practice that involves the diagnosis and treatment of conditions relating to one organ system, the eyes. Veterinarians practice medicine in all of its varied branches from preventive care to major surgery for multiple animal species. When it comes to prescribing medication, veterinarians would be perfectly analogous to medical doctors were it not for the fact that human pharmacists are not trained in the field of animal pharmacology. Veterinarians are not only trained in the field but they are the only licensed professionals who practice in the field. Veterinarians are justifiably perplexed over the apparent perception that the very broad field of veterinary medicine would be analogized to the very narrow field of prescriptions for eyeglasses and contact lenses. Most people recognize the difference between an optometrist trained and qualified to deliver care for a single organ system in a single species and a medical doctor licensed as a general practitioner who routinely acts to prevent and treat acute and chronic illnesses throughout the body. Veterinarians are obviously more analogous to medical doctors than to optometrists but even that analogy is weakened by the fact that veterinarians are trained in and generally practice multiple species and organ systems.

The very nature of the animal and pet health care industry is significantly different than not only the ophthalmic goods and services industry but the entire human health care industry. Veterinarians practice their profession at the same highly educated and skilled level as medical doctors. But the practice of animal pharmacology has not evolved as a separate discipline like the practice of human pharmacology. Eyeglasses and contacts are relatively simple devices that will never be comparable to prescription medication. It is impossible to overstate the importance of safety issues that are unique to the practice of veterinary medicine when prescription medications are involved. While an improperly filled prescription for contact lenses could conceivably cause discomfort or even injury, catastrophic injury or death would not be a conceivable risk. Animal pharmacology occupies the other end of the spectrum where mistakes have resulted in serious injury and death. Therefore, it is entirely inappropriate to use the FLCA for any analogous or analytic comparison to veterinary pharmacology.

### **What Impact could H.R. 1406 have on Prescriptions for Humans?**

Ignored in all the discussion of pet medication is what impact H.R. 1406 may have on the safety of prescriptions for humans. Pharmacist errors are tracked by the FDA and other medical institutions. In a 2008 article in US Pharmacist (see:[www.uspharmacist.com/continuing\\_education/ceviewtest/lessonid/105916/](http://www.uspharmacist.com/continuing_education/ceviewtest/lessonid/105916/)) it was noted that “the enormous increase in prescription volume places added stress on the pharmacist and is further magnified by the nationwide shortage of pharmacists”. In addition to prescription volume, other factors were cited for causing pharmacist errors including:

- Too many customers
- Lack of concentration
- No one available to double check
- Staff shortage
- Similar drug names
- No time to counsel
- Illegible prescription
- Misinterpreted prescription

Despite the known number of pharmacist errors on the human side H.R. 1406 is solely focused on generating more prescriptions for the retail pharmacist to fill without sufficient consideration of the effect it may have on the safety of both humans and pets.

In addition, an unseen risk may exist in that many prescription products, both animal and human, have the same active ingredient, but the dosage strength, result, reactivity, and activity is significantly different for humans and animals. What looks easy is the large market pre-packaged product that is clearly animal vs. human. The

danger lies in veterinarian specific, human specific or generic drugs that can be mislabeled when human and animal pharmacies are combined in an attempt to do it all. What is being suggested is placing animal specific and animal strength products on the shelf, in the same pharmacy, with human products. This presents opportunities for additional errors to both humans and pets.

### **Conclusion**

H.R. 1406 is unnecessary legislation which fails to take into account the highly competitive market that currently exists for animal health products in general and for pet medications specifically. Further, the attempt to subvert the veterinary client patient relationship and substitute an insufficiently trained retail pharmacist into the role as "knowledgeable intermediary" for veterinary medical issues creates a credible danger to pets subjected to such practices. The market for pet medications addresses the needs of the Consumer and a bill such as H.R. 1406 would not serve the best interests of the Consumer.

Respectfully submitted,

American Veterinary Distributors Association

By: \_\_\_\_\_  
General Counsel

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**American Veterinary Distributors Association  
Addendum to Comments Re: HR. 1406**

The Federal Trade Commission has asked that AVDA respond to the following questions as part of its submission of comments to H.R. 1406. The deadline for filing comments is September 14, 2012 and AVDA had substantially completed its comments prior to receipt of these questions.

1. Can the AVDA or individual AVDA members describe the relationships between manufacturers and authorized distributors with respect to OTC and prescription medications for companion animals? Are these – or how commonly are these – exclusive? What are the business rationales for exclusive distribution agreements or other vertical restraints on distribution?

Response: Contracts between distributors and manufacturers often require that prescription and OTC products be sold to licensed veterinarians. Manufacturers feel that such products should be dispensed by practicing veterinarians within the context of a valid veterinarian-client-patient relationship in order to ensure consistency of treatment, continuity of care and proper application to ensure efficacy.

2. How have distributors responded to requests that they sell OTC and prescription medications for companion animals to retail pharmacies?

Response: Authorized distributors abide by terms of contracts with a manufacturer and many do sell certain products to pharmacies.

3. Have any authorized distributors estimated the potential revenues of selling OTC and prescription medications for companion animals directly to retail pharmacies?

Response: Based upon discussions with a number of AVDA distributor members, none have undertaken a study of this issue.

4. How would authorized distributors react if manufacturers decided to sell OTC and prescription medicines for companion animals to retail pharmacies? For example, what, if any, has been the response of authorized distributors to Bayer's decision to sell companion animal medicines to retail pharmacies?

Response: In 2010, Bayer made a change in its distribution policy for its OTC flea and tick products for cats and dogs, not a change with respect in its prescription products. To date, AVDA distributors are not aware of any change in Bayer's policies with respect to the sale of prescription animal

medications. The fact that millions of prescriptions for companion animal medications have been issued and presumably filled by retail pharmacies has not triggered any noticeable reaction on the part of distributors.

5. What factors will affect sales opportunities for authorized distributors going forward?

Response: AVDA cannot answer this question since, to the extent any distributor has undertaken a study of this subject, the results of same would constitute proprietary information of that distributor.

6. What would be the potential costs and benefits, to distributors, of passage and implementation of HR 1406?

Response: AVDA firmly believes that HR 1406 is ill advised legislation and passage would be detrimental to pet owners and their pets for reasons that are fully explained in AVDA's formal submission to which this addendum is attached.

**US ANIMAL HEALTH MARKET OVERVIEW FOR VETERINARY AND OTC PRODUCTS**  
**PREPARED BY AXXIOM LLC**  
**September 10, 2012**

Axxiom LLC is a leading animal health executive consulting firm specializing in business strategy, licensing, and market analysis for the US animal health industry. At the request of the American Veterinary Distributor's Association, Axxiom LLC has prepared the following assessment of certain aspects of the US animal health market. Axxiom LLC utilized animal health distributor sales information, publically available manufacturer information, industry surveys and other knowledgeable sources to prepare this comprehensive overview of the US animal health market.

The following spending statistics are gathered by the American Pet Products Association ([www.americanpetproducts.org](http://www.americanpetproducts.org)) from various market research sources and are not included in the organization's bi-annual National Pet Owners Survey.

**Actual Sales within the U.S. Market in 2011**

	<u>Annual Revenues</u>	<u>Purchasing Locations</u>
Food	\$ 19.85 billion	Grocery, Big Box Retail, Pet Specialty, On-Line, Vet
Supplies/OTC Medicine	11.77 billion	Grocery, Big Box Retail, Pet Specialty, On-Line, Vet
Vet Care	13.41 billion	
Live animal purchases	2.14 billion	
Pet Services: groom & board	<u>3.79 billion</u>	
	\$ 50.96 billion	

Additional information was also provided detailing annual consumer spending by category by species. According to the [2011-2012 APPA National Pet Owners Survey](#), basic annual expenses for dog and cat owners in dollars include:

	<u>Dogs</u>	<u>Cats</u>
Surgical Vet Visits	\$407	\$425
Routine Vet	\$248	\$219
Food	\$254	\$220
Kennel Boarding	\$274	\$166
Vitamins	\$ 95	\$ 43
Travel Expenses	\$ 78	\$ 48
Groomer/Grooming Aids	\$ 73	\$ 34
Food Treats	\$ 70	\$ 41
Toys	\$ 43	\$ 21

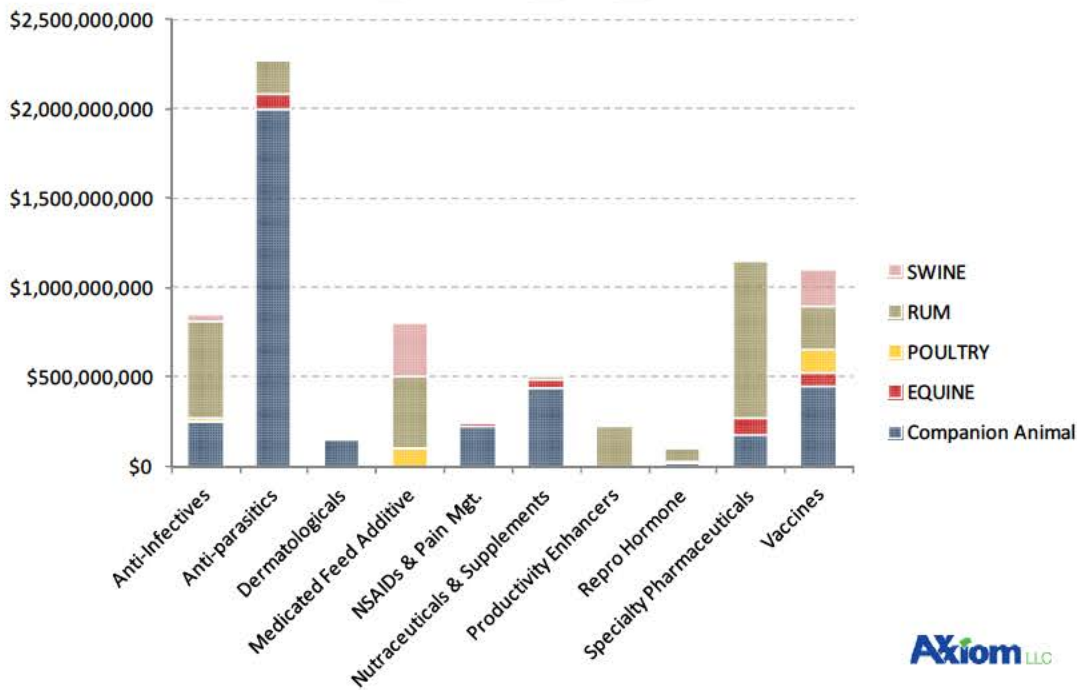


Category	Anti-Infectives	Anti-parasitics	Dermatologicals	Medicated Feed Additives	NSAIDs & Pain Mgt.	Nutraceuticals & Supplements
Companion Animal	250,000,000	2,000,000,000	150,000,000		225,000,000	440,000,000
Equine	5,000,000	80,000,000	5,000,000		20,000,000	50,000,000
Poultry	15,000,000	5,000,000		100,000,000		
Ruminants	540,000,000	185,000,000	2,500,000	400,000,000	5,000,000	10,000,000
Swine	45,000,000	5,000,000		300,000,000		
<b>Total</b>	<b>\$855,000,000</b>	<b>\$2,275,000,000</b>	<b>\$157,500,000</b>	<b>\$800,000,000</b>	<b>\$250,000,000</b>	<b>\$500,000,000</b>

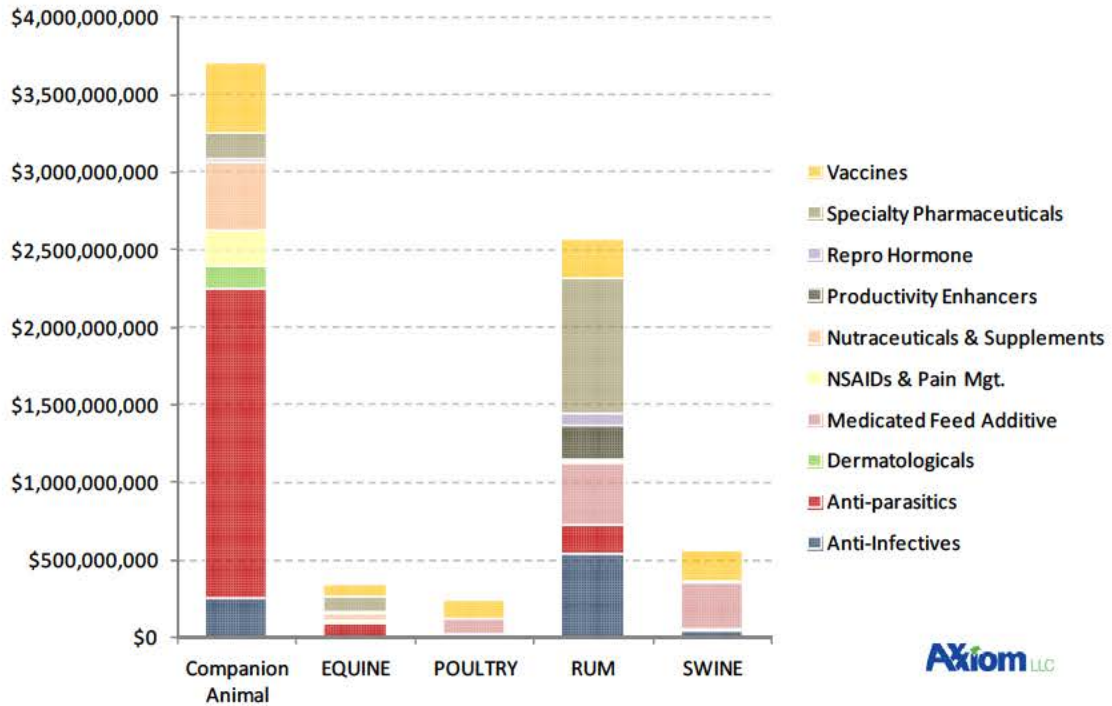
Category	Productivity Enhancers	Repro Hormone	Specialty Pharmaceuticals	Vaccines	Grand Total
Companion Animal		20,000,000	175,000,000	450,000,000	<b>\$3,710,000,000</b>
Equine		10,000,000	100,000,000	75,000,000	<b>\$345,000,000</b>
Poultry				125,000,000	<b>\$245,000,000</b>
Ruminants	225,000,000	75,000,000	875,000,000	250,000,000	<b>\$2,567,500,000</b>
Swine		10,000,000		200,000,000	<b>\$560,000,000</b>
<b>Total</b>	<b>\$225,000,000</b>	<b>\$115,000,000</b>	<b>\$1,150,000,000</b>	<b>\$1,100,000,000</b>	<b>\$7,427,500,000</b>



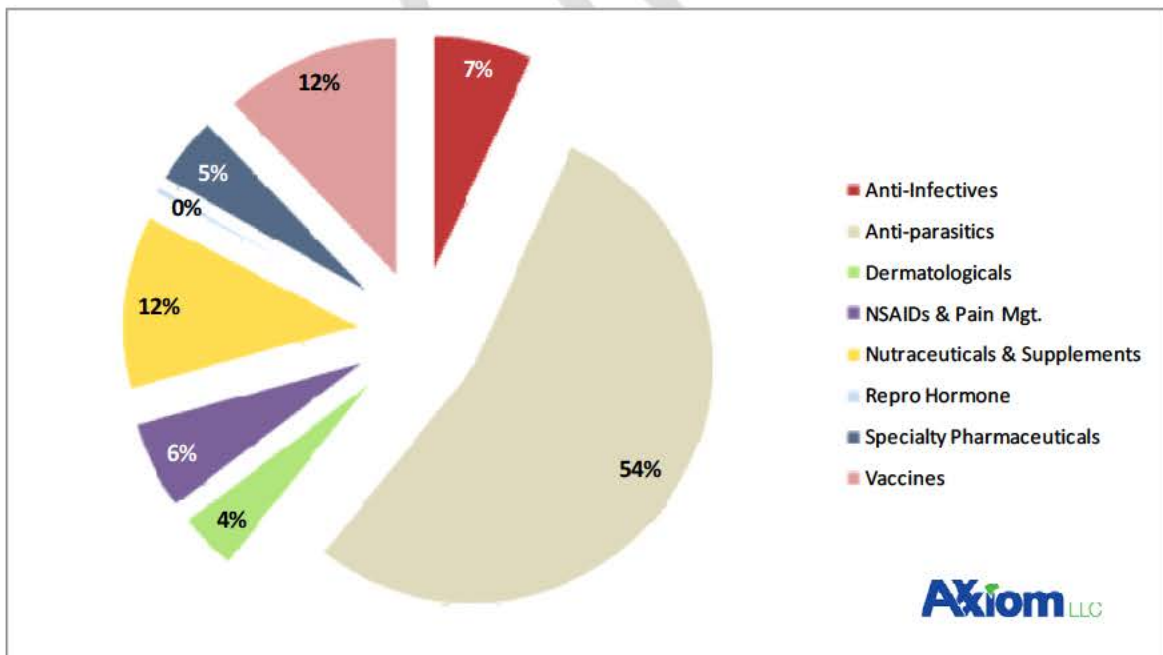
Estimated US Animal Health Revenues by Category by Species as Measured in Ex-Manufacturer Dollar Sales for 2010 / Copyright © 2012 Axiom LLC. All Rights Reserved



Estimated Category Sales per Species Reflected Ex-Manufacturer Dollar Sales for the period 2010  
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Estimated Species Sales per Category Reflected in Ex-Manufacturer Dollar Sales for the period 2010  
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Estimated % of Total Revenues by Segment for Companion Animals Reflected in Ex-Manufacturer Dollar Sales for the period 2010 / Copyright © 2012 Axxiom LLC. All Rights Reserved

## Overview of US Animal Health Sales Channels and Product Access for Consumers

Axxiom LLC completed an assessment of animal health purchasing opportunities in the United States for the following two channels:

- 1) Veterinary product sales through non veterinary hospital channels
- 2) Veterinarians issuing prescriptions to be filled through retail pharmacies

Three options for veterinary product sales through non-veterinary hospital channels were considered in this assessment:

- 1) The ag retail segment (e.g. Tractor Supply Company, Universal Cooperatives, etc...) which routinely offers a comprehensive portfolio of non-prescription animal health products for livestock, horses and pets, which include pharmaceuticals, vaccines, nutraceuticals / supplements, dermatologicals and in-feed medications.
- 2) Traditional retail outlets including Big Box retailers such as Wal-Mart, Target and similar companies which offer primarily pet health products, but can and do, in certain markets, offer horse products such as diets, nutraceuticals and a limited number of pharmaceuticals.
- 3) On-line veterinary pharmacy and retailing operations including 1-800-PETMEDS and similar internet-based providers.

### **Ag Retail and Farm / Feed Stores:**

The Ag Retail and Farm Store segment consists of two general categories: 1) the traditional animal feed store which supplies feedstuffs, fertilizers, fuel and general farm supplies; and 2) the more consumer oriented ag retail store which sells general supplies for suburban and exurban customers. The feed store segment continues to consolidate over time, based on the continued decline in the number of full time farming operations in the US. Conversely, the ag retail segment continues to grow with the increasing number of "flashlight farmers" (e.g. part time operators with smaller cattle and goat operations) and horse ranchettes that surround many urban areas. Both types of retail operations typically offer a broad array of animal health products for livestock and pets.

An overview of the leading ag retail organizations and farmers cooperatives with retail operations indicated the following number of store locations:

<b>Ag Retail Chain</b>	<b>Number of Stores</b>	<b>States Served</b>
Tractor Supply Company	1,130	45
Rural King	58	7
Blain's	35	3
Atwood's	50	4
Heritage Trading affiliated stores	800	23
Midstate's Distributing affiliated stores	600	48
<b>Total</b>	<b>2,673</b>	



Typically, these locations offer animal health products for both pets and livestock without veterinary subscriptions. These items include dewormers, vaccines and specialty pharmaceuticals not requiring a prescription. Flea and tick, deworming, nutraceuticals, vaccines and dermatological products for companion animals are readily available in these locations.

As for the farm store segment, many of the current locations are affiliated with what remains of the former state Farmer’s Co-op systems. While some of these locations are more oriented toward livestock producers, many are adapting their product offering based on the changing demographics of their state. Fewer full time farmers, more “flashlight farmers” and horse owners and increased competition from the Ag Retail segment has forced the farm store to service the pet and horse owner to a much greater extent. While many long established co-op operations have disappeared from this segment (Farmland Industries and Agway as examples) there remains a widespread and robust farmer’s co-op system that competes for animal health sales with the local veterinarian.

An abbreviated review of the leading US farmer’s cooperative organizations indicated the following number of retail locations:

Farmer owned Co-Op	Stores	States Served
Alabama Farmer’s Co-op	90	1
Intermountain Farmer’s Co-op	54	8
Missouri Farmer’s Co-op	133	3
Southern States Co-Op	1,200	23
Tennessee Farmer’s Co-Op	160	4
<b>Total</b>	<b>1,637</b>	

As with the Ag Retail organizations, these locations generally stock a robust portfolio of non-prescription items including dewormers, vaccines and specialty pharmaceuticals for livestock as well as flea and tick, deworming, nutraceuticals, vaccines and dermatological products for companion animals.

**Pet Specialty, Grocery and “Big Box” Retail Locations:**

Historically, the focus of the leading US retailers toward the animal health market has been pet food, dermatologicals and flea and tick control products in addition to toys, grooming supplies and other ancillary equipment. As the number of Big Box retailers and buying clubs (e.g. Costco, Sam’s Club) has continued to grow, they have expanded their pet offerings to include newer versions of flea and tick products formerly available only through the veterinarian. An online search of product availability among the leading Big Box retailers generally revealed ready access to the leading flea and tick product brands in both the retail locations and via the company’s on-line retail operations. *In this survey, there were no prescription requirements listed on any of the web sites visited for flea and tick control products.*

A brief analysis of the leading US retail organizations reveals more than 260,000 store locations at which consumers may purchase a broad array of the leading US animal health product brands across multiple categories:

Store	US locations	Categories Available
BJ’s	190	Flea, Tick
Costco	438	Flea, Tick



Grocery & Mass	250,000+	Flea, Tick, Dermatologicals, Dewormers, Nutraceuticals & Supplements
Lowe's	1,700+	Flea, Tick
PetCo	1,100+	Flea, Tick, Dermatologicals, Dewormers, Nutraceuticals & Supplements
Pet Smart	1,100+	Flea, Tick, Dermatologicals, Dewormers, Nutraceuticals
Other Pet Specialty Retailers	6,400+	Flea, Tick, Dermatologicals, Dewormers, Nutraceuticals & Supplements
Target	1,700+	Flea, Tick, Dermatologicals, Dewormers, Nutraceuticals
Wal-mart / Sam's Club	4,500	Flea, Tick, Dermatologicals, Dewormers, Nutraceuticals

These stores sell animal health products primarily for pets with some limited access to equine and livestock products in certain instances. All are non-script items. Among the grocery channel, retailers have traditionally maintained a significant presence for pet items with health care products, nutraceuticals and dermatologicals generally marketed alongside pet foods, treats, toys and other items.

#### **Veterinary Scripts Filled by Retail Pharmacies:**

An often overlooked and little understood part of the current animal health market are prescriptions written by the veterinarian to be filled at a retail pharmacy. Recently, AniConsilia, LLC purchased and reviewed syndicated veterinary prescription data for the period of July, 2010 through June, 2011. The underlying data set included pharmacies responsible for more than 80% of the human pharmaceutical prescriptions filled in the United States during that same period.

The key findings from this review were as follows:

- 1) During this twelve month period, more than 45,000 veterinarians provided prescriptions to be filled through a retail pharmacy location
- 2) The total number of prescriptions written were in excess of 4,000,000
- 3) These prescriptions were written in all 50 states, plus the District of Columbia, Puerto Rico and the Virgin Islands
- 4) The scripted items included products for cancer, cardiovascular disease, metabolic disorders, diabetes and the control of infectious disease

#### **Review of On-Line Pharmacy and Retail Operations**

In addition to the myriad of purchasing channels and locations cited above, consumers also have access to a robust on-line network of veterinary pharmacy and retailing operations. A review of the investor relations information available from acknowledged segment leader PetMed Express, Inc. (d/b/a 1-800-PetMeds) estimated the combined sales of prescription and over the counter animal health products through this segment exceeded \$ 400m in 2011 (<http://investor-relations.petmeds.com>).

A cursory review of more than 30 current on-line providers (as indicated below) reflected a substantial portfolio of prescription products including heartworm preventatives, antibiotics, arthritis, thyroid,

diabetes, pain and other specialty medications as well as over the counter items for flea and tick control, bone and joint care, vitamins, nutritional supplements, and hygiene products. Numerous sites offered access to prescription items with submission of a valid veterinary prescription by the on-line customer. The PetMed's sales information indicated prescription sales have shown consistent growth as a % of the company's overall sales increasing from 31% in 2009 to 35% in 2010 and 38% in 2011.

1. [www.1800petmeds.com](http://www.1800petmeds.com)
2. [www.allivet.com](http://www.allivet.com)
3. [www.allvetmed.com](http://www.allvetmed.com)
4. [www.amazon.com](http://www.amazon.com)
5. [www.bullwinkle.com](http://www.bullwinkle.com)
6. [www.centerpetpharmacy.com](http://www.centerpetpharmacy.com)
7. [www.choicepetmeds.com](http://www.choicepetmeds.com)
8. [www.diamondbackdrugs.com](http://www.diamondbackdrugs.com)
9. [www.discountpetmedicines.com](http://www.discountpetmedicines.com)
10. [www.drsfostersmith.com](http://www.drsfostersmith.com)
11. [www.endlessmeds.com/vet.html](http://www.endlessmeds.com/vet.html)
12. [www.entirelypets.com](http://www.entirelypets.com)
13. [www.heartlandvetsupply.com](http://www.heartlandvetsupply.com)
14. [www.kroger.com/pharmacy](http://www.kroger.com/pharmacy)
15. [www.kvsupply.com](http://www.kvsupply.com)
16. [www.lambertvetsupply.com](http://www.lambertvetsupply.com)
17. [www.medicine-pet.com](http://www.medicine-pet.com)
18. [www.medi-vet.com](http://www.medi-vet.com)
19. [www.nationalpetpharmacy.com](http://www.nationalpetpharmacy.com)
20. [www.petcarechoice.com](http://www.petcarechoice.com)
21. [www.petcarerx.com](http://www.petcarerx.com)
22. [www.petmedications.com](http://www.petmedications.com)
23. [www.petmedoutlet.com](http://www.petmedoutlet.com)
24. [www.PetMedsnMore.com](http://www.PetMedsnMore.com)
25. [www.petmedsshop.net](http://www.petmedsshop.net)
26. [www.petmedssource.com](http://www.petmedssource.com)
27. [www.petmedstore.com](http://www.petmedstore.com)
28. [www.petrx.com](http://www.petrx.com)
29. [www.pet-rx-meds.com](http://www.pet-rx-meds.com)
30. [www.petsupplies.nextdaypets.com](http://www.petsupplies.nextdaypets.com)
31. [www.revivalanimal.com](http://www.revivalanimal.com)
32. [www.smartpakquine.com](http://www.smartpakquine.com)
33. [www.valleyvet.com](http://www.valleyvet.com)
34. [www.vetdepot.com](http://www.vetdepot.com)
35. [www.vetmedicines.com](http://www.vetmedicines.com)
36. [www.vetrxdirect.com](http://www.vetrxdirect.com)
37. [www.vetsfirstchoice.com](http://www.vetsfirstchoice.com)
38. [www.vetsource.com](http://www.vetsource.com)
39. [www.wedgewoodpetrx.com](http://www.wedgewoodpetrx.com)

## Conclusion

US Consumers in the United States have a broad array of options from which to legally purchase regulated pharmaceuticals, vaccines and non-regulated products typically used to insure the general health and welfare pets and food producing animals. The number of options and competition for consumer spending has accelerated with the expansion of on-line retailing operations serving the animal health market over the past decade. Also notable during this period, is the expansion of sales in the traditional retailing category as manufacturers of nutraceuticals, dermatologicals, specialty pharmaceuticals and flea and tick products pursued growth strategies via these retailers.

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*Prepared by Axxiom LLC\_September 10, 2012  
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