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Via Electronic Submission

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

Re: Comments in Response to the Workshop on Pet Medication Issues

Dear Sir or Madam:

The law firm of K&L Gates, LLP submits these comments, on behalf of an affected client, to the Federal Trade Commission (FTC) regarding the Commission's "Workshop on Pet Medication Issues" (the "Workshop").[1] Our law firm provides regulatory advice to several generic drug manufacturers and distributors. One of these clients operating in the animal drug space has identified issues that relate to the upcoming Workshop. We appreciate the opportunity to share our client's views with the FTC.

I. Background

In recent years, the importance of companion animals in the American household has increased dramatically. As our nation's population begins to age, many households have taken in pets to provide comfort and companionship. New advances in animal drugs and veterinary treatment practices have allowed these pets to live longer and healthier lives. But, these advances come at a financial cost to pet owners. The cost of responsible pet ownership has skyrocketed and as a result consumers are searching for new ways to reduce those costs. As discussed in these comments, generic animal drugs dispensed by retail pharmacies provide an alternative to inject price competition into the animal drug distribution/dispensing system while maintaining the high standards of safety and quality that pet owners rightly demand.

[1] *See* 77 Fed. Reg. 40,355 (July 9, 2012).

Certain high volume animal drugs intended for regular use in companion animals, such as heartworm preventive drugs, are routinely dispensed by veterinarians and less frequently by retail pharmacies. This is not due to any inability on the part of pharmacists to dispense animal drugs safely. Rather, the current distribution and dispensing practices are the result of a combination of veterinarians' desire to dispense directly to their clients and animal drug companies' marketing efforts that cater to that desire. As discussed in the responses below, the current distribution practice works to the benefit of the veterinarians and the drug manufacturers servicing this channel. Veterinarians benefit from the profit margin on the drugs they dispense, and drug manufacturers benefit from veterinarian support of the branded drugs without the need to compete with generic products dispensed by pharmacies or retail outlets. The real loser, however, is the consumer who pays a higher price to receive the brand pet medication from his or her veterinarian when an equivalent generic drug could have been purchased from a pharmacy at a much lower price absent this arrangement.

One of the challenges in supplying pet medications to pharmacies outside the veterinary channel is the lack of consistent and clear regulation to guide veterinarians and pharmacies through the efficient and cost effective distribution of quality animal drugs to consumers. This is not an issue about supplanting the veterinarian's role in treating the pet. It is not about giving any additional power to the pharmacy to make treatment decisions. It is about providing clear guidelines to veterinarians and pharmacists alike to ensure that veterinarians are communicating with the consumer and the pharmacist, and that the pharmacist has the information that he or she needs to fill the prescription and make appropriate generic substitutions. Fundamentally, and most critically, the guidance should ensure that pets receive high quality, suitable and affordable prescription products. The Fairness to Pet Owners Act[2] is a first step in ensuring that quality, low cost animal medications—including essential preventives that address the zoonotic spread of disease—will be available to a greater population of consumers and their pets in much the same way that low cost pharmaceutical alternatives are made available for humans.[3]

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[2] *See* Fairness to Pet Owners Act, H.R. 1406, 112th Cong. (2011).

[3] It is instructive to understand the parallel human generics business, which is largely credited for bringing down the high cost of human drugs. As proprietary protection expires on a drug, the generic company makes the generic product available to the pharmacy. It does not require a sales force because the FDA has approved the product as substitutable for the branded product and the physician is entitled to rely on this approval or tell the pharmacist that they must fill the prescription with the branded product. The generic is duly listed in the FDA's Orange Book. Between the Orange Book, the educational material provided by the generic manufacturer and the third party payer, the pharmacist has the information on the substitutable product readily available to him or her. The third party payers negotiate reimbursement to the pharmacist, driving the price down on behalf of the consumer. The generic company can provide a more affordable product because it did not incur the research and development costs of the innovator and it simply has to distribute the product to

Prior to addressing the Commission's specific questions, we believe it would be helpful to briefly touch on the animal drug approval process relative to the human drug approval process.

A. The Animal Drug Approval Process. Prescription animal drugs are reviewed and approved by the Food and Drug Administration (FDA) under Section 512 of the Federal Food, Drug, and Cosmetic Act (FDCA). Animal drugs containing new (i.e., not previously approved) active ingredients are approved via the New Animal Drug Application (NADA) process, while generic animal drugs are approved through the Abbreviated New Animal Drug Application (ANADA) process based on a finding of "bioequivalence" to a previously approved drug (the "pioneer" drug). Because the ANADA approval process requires an FDA finding of "bioequivalence," generic animal drugs are therapeutically equivalent to, and interchangeable with, the corresponding pioneer drug.

A similar generic drug process has been successfully used for human drugs since the passage of the Hatch-Waxman Amendments to the FDCA in 1984. Approved human drugs are listed in an FDA publication commonly referred to as the "Orange Book." The Orange Book contains "therapeutic equivalence" codes that are used by pharmacists to determine which generic and brand drugs are interchangeable. Animal drugs, however, are listed in what is called the "Green Book," which does not contain specific therapeutic equivalence codes. Nevertheless, FDA provides more than adequate information on its website for pharmacists to determine whether a generic animal drug is interchangeable for its pioneer counterpart.

B. Generic Drug Substitution. The affordable nature of human generic drugs is a direct result of the ability of pharmacists to "substitute" a generic drug when its equivalent brand drug has been prescribed. The practice of generic substitution (or sometimes referred to as "drug product selection") is governed by state law and the applicable state Boards of Pharmacy. Some states have adopted the therapeutic equivalence codes in the Orange Book as the sole standard for determining when a pharmacist may substitute a generic for a brand drug. Other states permit pharmacists to use their professional judgment to determine whether two drugs are equivalent and interchangeable. Because approved animal drugs are not listed in the Orange Book, pharmacists who practice in states that rely solely on the Orange Book for substitution determinations are prohibited from dispensing generic animal

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wholesalers, who then supply the pharmacies. The human generics business operates under well-developed legal and regulatory processes which are designed to ensure that the lowest cost quality products are made available to the consumer as quickly as possible. This legal regulatory structure is lacking in the animal health space.

drugs when the pioneer drug is prescribed. A number of states have already rectified this issue, and a number are currently in the process of addressing this issue.

C. Animal Drug Dispensing. Like human drugs, animal drugs can be approved by FDA as either "prescription" or "over-the-counter" (OTC) drugs. This affects how, and to whom, the drug may be lawfully sold. While FDA determines whether a drug requires a prescription, state law regulates who may prescribe and dispense a prescription drug. Pharmacists in every state are permitted to dispense both human and animal prescription drugs. In fact, while veterinarians dispense many drugs, most veterinarians also write prescriptions for human drugs to be administered to their animal patients. Pharmacists have historically dispensed these human drugs directly to the animal patient's owner.

II. Responses to FTC Questions

Below please find responses to some of the FTC's specific questions that are applicable to our client's business.

A. Distribution Practices

1. *How are pet medications distributed to customers?*

Prescription pet medications must be "dispensed" to a customer in accordance with applicable state law concerning the dispensing of prescription drugs. Pharmacists are permitted to dispense prescription animal drugs when presented with a valid prescription from a veterinarian. Veterinarians can also dispense directly to their clients, but must comply with certain labeling and recordkeeping requirements when doing so.

Historically, veterinarians have dispensed most of the drugs that they prescribe. This allows the veterinarian to make product margin (additional profit) when selling the drugs. The current distribution process also permits veterinarians and their office staff to benefit from various incentive programs sponsored by the manufacturers of the animal drugs that the office dispenses. Veterinarians typically stock only those drugs that they prefer to dispense which does not encompass all of the animal drugs that the veterinarian may need to prescribe. Likewise, veterinarians frequently prescribe human drugs for their patients. When a veterinarian's patient requires a drug that the veterinarian does not stock, the veterinarian will typically write a prescription for the drug, which can be filled by any state-licensed pharmacy. As a result, pharmacies already dispense many animal drugs and human drugs that are prescribed for animal use.

Some veterinarians have sought to protect the income stream derived from dispensing by refusing to issue prescriptions for drugs that are stocked by the veterinarian. Some internet pharmacies have attempted to work around this problem by obtaining the telephone number of the consumer's veterinarian when an order is placed, and then calling the veterinarian to request a prescription. In some instances, veterinarians have refused to provide a prescription to a mail-order internet pharmacy in order to protect the veterinarian's dispensing income even at the risk of losing the client.

2. *What are the business rationales for various pet medication distribution practices?*

The current practice allows veterinarians to realize an additional income stream via the sale of prescription drugs; both through the standard 100% markup and the incentive programs sponsored by the animal drug manufacturers.

For drug manufacturers who market exclusively in the veterinary channel, potential competition is reduced because the veterinarian can be driven to sell their product through incentives, marketing tactics, and simply outspending their potential competing lower cost alternatives. The current practice requires animal drug manufacturers to market directly to veterinarians. This typically means maintaining an expensive sales force that calls on numerous small businesses or operating through the veterinary distributors. By cutting the pharmacy out of the supply chain, pioneer animal drug manufacturers have largely denied generic companies the ability to provide their more affordable products to consumers and thereby maintained their higher prices. In the human drug space, one reason generic drugs are more affordable is because they do not require a sales force.

In this distribution model, there is no incentive for any player in the model to protect the consumer by pointing out that substitutable equivalent generic drugs are available through the local retail pharmacy. In most states, the pharmacist can substitute with the generic when the pioneer is prescribed. This substitution process has saved consumers and third-party payers millions of dollars on human drugs, but consumers are denied those savings on animal drugs as a direct result of the current dispensing and distribution practices.

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

With the bulk of the pet medicines dispensed by veterinarians, generic pet medications are typically sold under a brand name and marketed directly to veterinarians alongside the branded pioneer product. But there is no incentive for the veterinarian to select the generic product for the customer. However, unlike human drugs, the brand drug

manufacturers can employ incentive programs to buttress their position and there is no third party payer pressure to drive down prices. Further, the current distribution practice fails to take advantage of the highly efficient wholesaler/pharmacy distribution system that is in place for human drugs. As a result, one does not see the same degree of competition and savings for generic animal drugs as we see for generic human drugs.

4. *How do these practices affect product supply and quality?*

In many of public comments submitted to this docket, veterinarians have expressed concern about the supply and quality of animal drugs dispensed outside of the veterinarians' office. There are unsavory websites promising "low, low prices without the need for a prescription" for pet products, just as there are for human drugs. In many cases, these websites may be selling counterfeit or otherwise compromised products. However, limiting prescription portability and impeding the market for generic equivalents does not protect the consumer from these illegal and/or unethical practices. Quite the opposite. The market for these counterfeit and low quality products is only encouraged by the lack of availability of low price alternatives in readily available retail outlets (i.e., pharmacies). There is no better way to protect against these low quality alternatives than by making affordable, high quality products readily available in retail pharmacies that are equipped to identify and eliminate counterfeits and evaluate substitutions within established guidelines.

5. *How do these practices affect consumer choice?*

The current practices, and specifically veterinarian reluctance to provide portable prescriptions, deny consumer access to affordable generic drugs that are dispensed at the retail pharmacy. While it is true that many state-level veterinary practice ethical rules call for veterinarians to provide a prescription upon customer request, these rules fail to take into account the natural trepidation that pet owners feel in requesting a prescription. In actual practice, if the prescribed drug is stocked by the veterinarian, the office staff typically provides the drug at check-out without any mention of the customer's other options. Only when the veterinarian elects not to stock the prescribed drug is the customer typically provided with a prescription. Thus, the veterinarians' reluctance to an *obligation* to provide notice of the availability of a prescription is not based in safety. If it were, veterinarians would presumably stock all necessary drugs and write no prescriptions. Rather, the stated reluctance is based in economics and the potential profits provided by veterinarian-dispensed drugs.

6. *How do these practices affect entry into the pet medications market?*

As a result of the current practices, potential ANADA applicants must assume that they will need a sales force to sell their products, sufficient resources to competitively incentivize the veterinarians, and sufficient marketing wherewithal to market the product as a branded product. In the pet medications market it is not enough to be an FDA-approved substitute for the pioneer drug. This is in stark contrast to the human drug market where there is fierce competition among generic companies selling into the retail pharmacy trade to the benefit of consumers.

7. *How do these practices affect innovation in the pet medications market?*

Because pioneer companies are able to use the current distribution/dispensing system to greatly limit competition from affordable substitutable products, there is less incentive to develop new animal drugs. A portable prescription system would ensure that competition, in the form of generic drugs dispensed at retail pharmacies, would enter the marketplace as soon as all patents on a pioneer drug expire and thus stimulating pioneer companies to develop new and better proprietary products.

8. *What efficiencies and inefficiencies are associated with these practices?*

Veterinarian dispensing is still a viable option that should be preserved for those consumers who are willing to pay a higher price for the convenience of receiving their pet's drugs before they leave their veterinarian's office. The process of veterinarian dispensing, however, suffers from numerous inefficiencies. Pharmacies are set up to dispense drugs in an efficient, cost-effective and compliant manner. Pharmacies are generally able to stock more products than veterinarian offices and provide better pricing due to the larger volume of drugs that they dispense. The current practices deny consumers the savings that could be achieved as a result those greater efficiencies.

B. Prescription Portability

Before addressing the specific issues of prescription portability, we would like to respond to the statement in the Commission's *Federal Register* notice that "some observers believe ... veterinarians alone should dispense prescription pet medications to their clients." 77 Fed. Reg. 40, 355, 40,356 (July 9, 2012). Pharmacists are trained professionals who operate within very stringent state law requirements concerning the dispensing of drugs.

Pharmacists routinely communicate with medical doctors about the human drugs they prescribe. There is no reason to believe that pharmacists could not, or would not, similarly communicate with veterinarians when it is necessary to do so. In fact, pharmacists already safely dispense significant numbers of animal drug products and human drugs for animal patients. The assertion that animal drugs can only be safely dispensed by a veterinarian is simply unsupportable and runs counter to reality.

1. *How varied are current veterinarian practices with respect to providing written, portable prescriptions to clients?*

Our client believes that current veterinarian practices vary considerably. Certainly, there are veterinarians who adhere to very high ethical standards and provide prescriptions to their clients upon request. However, there are frequently barriers to consumers obtaining a prescription. For example, our client has identified: (1) a general reluctance from clients to "demand" a prescription in deference to the veterinarian as a professional; (2) veterinarians putting up barriers to receiving a prescription, e.g., front-office staff stating a policy of not issuing prescriptions and/or insisting that the animal be brought in for a check up even though sufficiently current laboratory results are in the animal's file; (3) veterinarians calling and attempting to change a client's mind about obtaining drugs from other sources; and (4) veterinarians indicating that they are not familiar with the products sold into the retail pharmacy and thereby instilling doubts about safety or efficacy of those products. Furthermore, many clients simply do not know that they can obtain a prescription from their veterinarian and purchase their pet's drugs from their local pharmacy.

2. *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?*

California and Arizona are the only two states which currently mandate aspects of prescription portability. California requires that a veterinarian, "prior to dispensing, offer[] to give a written prescription to the [client] that the [client] may elect to have filled by the prescriber or by any pharmacy." Cal. Bus. & Prof. Code § 4170(a)(6). The California law also requires that a veterinarian 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 of the [client's] choice." *Id.* at § 4170(a)(7).

Arizona law requires dispensing veterinarians to notify animal owners that "some prescription-only drugs and controlled substances may be available at a pharmacy," but does

not specifically require a prescription be provided to the client. Ariz. Admin Code R3-11-801.

3. *What price and non-price benefits can accrue to consumers from prescription portability for pet medications?*

Prescription portability will provide both price and non-price benefits to consumers. As to price, it is axiomatic that allowing retail pharmacies to compete with veterinarians will result in lower prices. Expanding the market to include retail pharmacies will also allow true generic drugs (i.e., sold without the cost of veterinary sales force) to enter the market for the first time. Consumers will have the option of paying more for the pioneer/brand drug or saving money with the substitutable generic drug. Veterinarians who believe their patients must have the pioneer drug for medical reasons will have the option of preventing substitution when writing the prescription (states have various means for a prescriber to prevent generic substitution). More companies will be incentivized to enter the channel and increase product selection and price competition.

Portability will also provide consumers with another option on how to purchase their pets' medications. Currently, most pet owners have only two real options. They can purchase their pet's drugs directly from their veterinarian or they can obtain them from an on-line pharmacy. H.R. 1406 would give them another option. Namely, they would be able to purchase their pet's drugs from the same pharmacy that fills their own prescriptions. Many pet owners may be uncomfortable purchasing their pet's drugs from an internet pharmacy. These pet owners may be foregoing considerable savings because they do not trust the internet or find this outlet non-appealing for other reasons. Prescription portability would allow pet owners to obtain affordable drugs directly from the same local pharmacy that they trust to fill their own prescriptions. In so doing, H.R. 1406 would level the playing field and allow retail pharmacies to compete directly with internet pharmacies and dispensing veterinarians.

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

During the consideration of H.R. 1406, numerous alleged risks to pets have been raised if prescription portability were required. For example, various comments have alleged that:

- Pharmacists make mistakes;
- Pharmacists do not understand the significance of the differences between animal species, size issues and metabolic issues;

- Pharmacists will not (or cannot) provide counseling about the use of animal drugs or provide follow up to monitor efficacy of such drugs;
- There is no way to ensure reliable accurate information has been given to the client prior to using the prescribed drug; and
- Customers will delay filling prescriptions and the animal patient will be denied the required treatment.

These allegations are without merit. Human drugs have been safely and effectively dispensed by pharmacies based on physician prescriptions for decades. The pharmacy environment is efficient and safe. The veterinarian is not abdicating the veterinary-patient relationship to the pharmacist any more than a physician would abdicate the physician-patient relationship to the pharmacist in the human context. If the pharmacist has a question about a prescription or a dose, they would call the veterinarian, just as they would call a physician about a human prescription. Responsible pet drug manufacturers provide pharmacists with educational material and programs to ensure that pharmacists are equipped to counsel consumers about their product. The FDA-approved product insert that accompanies each animal drug also provides information about species, weight and potential metabolic issues as well as concerns about dosing.

There is simply no supportable argument for the position that pharmacies cannot safely dispense animal drugs. In fact, pharmacies are generally better suited to dispensing drugs than veterinarians. Pharmacies are routinely inspected by the state Boards of Pharmacy and have developed highly efficient inventory and dispensing systems to minimize errors. While errors by pharmacists are cited in the comments, it goes without saying that veterinarians also make mistakes.

Obviously, veterinarians can also safely dispense drugs and there will always be a place for vet-dispensed drugs. The problem with the current system is that it allows a license to practice veterinary medicine to be a grant of a monopoly on the dispensing of animal drugs. Such monopolies are inefficient, anti-competitive and costly to consumers.

5. *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?*

Yes. Pet owners rightly place a great deal of trust in their veterinarians. They should believe that their veterinarian is acting in the best interest of their pet. History has shown, however, that not all veterinarians have lived up to that noble standard. Disclosure is the proper remedy in this instance. Veterinarian dispensing has been the norm for so long that many pet owners may not be aware of the fact that their pet's drugs may be available at a

lower price from their local pharmacy. H.R. 1406 would ensure that veterinarians cannot preserve their monopoly by remaining silent and relying on their position of authority to prevent competition.

6. *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?*

Restrictions on fees and waivers are necessary to prevent their use as means to indirectly prevent competition. Veterinarians are free to charge whatever they wish for their services, but charging a client an additional fee for writing a prescription serves only an anti-competitive purpose. Presumably, no such fee would be charged if the client opted to purchase its drugs directly from the veterinarian. Yet, the administrative costs associated with dispensing (e.g., labeling, recordkeeping, etc.) are surely as high, if not higher, than the costs resulting from writing and recording a prescription. The sole purpose for charging such a fee would be to discourage clients from requesting a prescription and thereby preserving the veterinarians' monopoly.

Likewise, requiring a waiver of liability would only serve an anti-competitive purpose. Pharmacists are liable for any medication errors that they make when dispensing a drug product. Veterinarians do not need any special liability protection. Rather, the true purpose of such a waiver would be to scare pet owners into believing that filling their prescription at a pharmacy is going to put their pet at risk. The waiver, like the fee, would simply be a tool to indirectly stifle competition from retail pharmacies.

7. *How might the passage of H.R. 1406 affect price, consumer choice, and other forms of competition in the pet medications market?*

For far too long consumers have been denied access to affordable pet medications. The internet pharmacies have made some in-roads, but they remain a relatively small outlet because many pet owners are reluctant to use the internet and want to purchase their animal drugs from their trusted local pharmacist. Veterinarians and pioneer drug companies have set up a distribution and dispensing system that prevents competition and restricts consumer choice. Without a federal law requiring prescription portability and disclosure of the consumers' options, pet owners are unlikely to ever enjoy the cost savings that FDA-approved generic animal drugs provide. Veterinarians and retail pharmacies should be allowed to compete on equal grounds. The FDA approval of equivalent generic animal drugs and the state laws that permit the substitution of such drugs should be allowed to have their intended effect – namely cost savings for consumers.

8. *To what extent would H.R. 1406 affect veterinarians' sales of pet medications?*

H.R. 1406 would not affect veterinarians' ability to sell pet medications. Veterinarians would still be permitted to sell drugs directly to their clients. The bill would merely require veterinarians to compete with retail pharmacies on an equal footing. The veterinary profession has enjoyed nearly total isolation from competition on drug sales for decades. The pioneer drug manufacturers have facilitated that isolation to their pecuniary benefit. Competition is seldom welcomed into such an environment. But, the veterinary profession and the pioneer drug industry have no right to demand continued protection from competition and consumers are right to look to Congress and the FTC to level the playing field.

9. *What compliance costs would veterinarians face if H.R. 1406 were enacted?*

The additional compliance costs flowing from H.R. 1406 would be minimal at most. Ethical veterinarians already provide prescriptions to their clients when requested to do so. The requirement to provide a prescription would only affect those veterinarians who seek to use their professional license to block lawful competition. The costs associated with purchasing prescription pads and instituting recordkeeping procedures would not be new costs because virtually all veterinarians currently write at least some prescriptions. At most, it would be the incremental cost of a potential increase in the number of prescriptions. However, a veterinarian could avoid even that incremental cost by opting to sell its drug products at a competitive price.

10. *How might the passage of H.R. 1406 affect pet medication distribution practices?*

H.R. 1406 would open up a whole new distribution channel that has previously been closed to animal drugs. By allowing retail pharmacies to directly compete with dispensing veterinarians, the bill, if enacted, would provide an incentive for prescription drug wholesalers and pharmacies to add animal drugs to their purchasing and inventory systems. The considerable efficiencies of the wholesaler/pharmacy distribution system would inject more choice and competition into the market and provide consumers with increased access to affordable pet medications.

11. *Should possible amendments to H.R. 1406 be considered?*

The pro-competitive effect of H.R. 1406 could be greatly enhanced by a provision requiring FDA to publish therapeutic equivalence codes for animal drugs in the same manner as the agency does for human drugs. As noted above, FDA makes bioequivalence determinations for generic animal drugs, and it is possible to locate those findings on FDA's website. However, by publishing its bioequivalence determinations in a form that is familiar to pharmacists (i.e., the therapeutic equivalence codes published in the human drug *Orange Book*), FDA could facilitate consumer access to generic animal drugs that the agency has determined are fully interchangeable with their pioneer counterparts.

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On behalf of our client, we thank the Commission for providing this opportunity to comment on the issues related to H.R. 1406 and the Workshop.

Sincerely,

Michael H. Hinckle

MHH