



April 26, 2016

TO: Members, Subcommittee on Commerce, Manufacturing, and Trade

FROM: Committee Majority Staff

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

I. INTRODUCTION

On April 29, 2016, at 9:45 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Commerce, Manufacturing, and Trade will hold a hearing entitled “The Pet Medication Industry: Issues and Perspectives.”

II. WITNESSES

The Subcommittee will hear from the following witnesses:

- Tara Koslov, Deputy Director, Office of Policy Planning, Federal Trade Commission;
- Nathan Smith, Vice President, True Science; and,
- Dr. John H. de Jong, Chair Board of Directors, American Veterinary Medical Association.

III. BACKGROUND

A. Introduction

Over 79 million U.S. households own a pet.¹ Since 1988, the percentage of U.S. households that own a pet has increased nine percent to sixty-five percent.² In 2015, Americans spent over \$60 billion on their pets, including food, supplies, over-the-counter medicine (OTC), veterinary care, grooming, and boarding.³ In 2015, pet owners spent \$7 billion on their pets’ medication, both prescription and OTC.⁴

¹ “Pet Industry Market size & Ownership Statistics” American Pet Products Association http://www.americanpetproducts.org/press_industrytrends.asp.

² *Id.*

³ *Id.*

⁴ Package Facts – Pet Medications in the U.S., 4th Ed., Oct. 2015, Table 1-1 and Table 2-1.

Pet owners receive medications for their pets from multiple sources, including their veterinarians, brick-and-mortar retailers, and online retailers.⁵ Estimates indicate over six million prescriptions are filled by retail pharmacies annually.⁶

Veterinary practices and pharmacies are generally regulated at the state level by agencies and independent boards. Veterinarians are required to have a license in each jurisdiction where they practice from the state or territories' licensing board.⁷ Each licensing board has independent licensing and enforcement laws and rules.⁸

In all states, veterinarians are authorized to dispense pet medications for patients when they have an established veterinarian-client-pet relationship, and pharmacists are authorized to dispense both human and animal prescription drugs with a valid prescription.⁹

B. Federal Activity

Several Federal agencies are involved in the dispensing of animal care medications. The Federal Food, Drug, and Cosmetic Act (FDCA) established standards for companion animal pharmaceutical products, as well as animal feed and veterinary devices, through the Federal Drug Administration's Center for Veterinary Medicine.¹⁰ The U.S. Department of Agriculture and the Environmental Protection Agency also regulate biological products (e.g. vaccines and diagnostics) and pesticides (e.g. flea and tick) for companion animals respectively.¹¹

On October 2, 2012 the Federal Trade Commission (FTC) held a workshop "Competition & Consumer Protection Issues in the Pet Medications Industry." The workshop focused on topics including distribution of pet medications and portability of prescription pet medications. The FTC received 722 public comments after the workshop from pet owners, animal hospitals, veterinarians, pet medication manufacturers, retailers, and others.¹²

⁵ "Competition in the Pet Medications Industry: Prescription Portability and Distribution Practices" FTC Staff Report, May 2015, at 13, n. 37. <https://www.ftc.gov/system/files/documents/reports/competition-pet-medications-industry-prescription-portability-distribution-practices/150526-pet-meds-report.pdf>

⁶ *Id.* at n.30.

⁷ <https://www.aavsb.org/DLR/>

⁸ As an example, Michigan's Department of Licensing and Regulatory Affairs includes information for a range of activities, http://www.michigan.gov/lara/0,4601,7-154-72600_72603_27529_27555---,00.html.

⁹ *Supra* note 5 at 15.

¹⁰ <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm>. Section 503(f) of the FDCA, 21 U.S.C. 353(f), regulates drugs restricted to use by or on the order of a licensed veterinarian. The effect of this requirement is that prescriptions are required for certain animal drugs. The "Green Book" is an annual publication from the FDA listing animal drug products approved for safety and effectiveness. The Animal Medicinal Drug Use Clarification Act of 1994 allows veterinarians to prescribe extra-label use of approved human drugs for animals. The Generic Animal Drug and Patent Term Restoration Act provides for the approval of generic copies of new animal drug products that have been previously approved and shown to be safe and effective when used according to their approved labeling.

¹¹ *Supra* note 5 at 17.

¹² <https://www.ftc.gov/policy/public-comments/initiative-433>

In May 2015, the FTC released a report “Competition in the Pet Medications Industry” complete with an overview of the industry and a discussion of prescription portability and distribution practices in the pet medications industry.¹³ The report included a discussion of additional areas of study that could further inform the debate including pet medication pricing, pet medication dispensing errors, automatic release requirements, and the secondary distribution system.¹⁴

On July 23, 2015, Rep. Chaffetz introduced H.R. 3174, Fairness to Pet Owners Act of 2015.¹⁵ H.R. 3174 would require the FTC to write rules requiring a veterinarian to give a copy of a prescription to both a pet owner, whether or not it is requested, and to a pharmacy, if requested on behalf of the pet owner.¹⁶ Under the legislation, veterinarians would not be permitted to require the pet owner to purchase the animal drug from that veterinarian; require payment in addition to, or as part of, the fee for an examination as a condition of providing the prescription; or requiring the pet owner to sign a waiver or disclaim liability as a condition of receiving the prescription.¹⁷

C. State Activity

Generally, states have retained jurisdiction to legislate around pet medication dispensing and veterinarian distribution practices. Thirty-six states have statutes, rules, or agency policy statements regarding a veterinarian’s responsibility to release a prescription to their clients.¹⁸ The American Veterinary Medical Association’s “Principles of Veterinary Medical Ethics” states that “[a] veterinarian shall honor a client’s request for a prescription or veterinary feed directive in lieu of dispensing, but may charge a fee for this service.”¹⁹

The most recent state legislative activity is an Illinois statute enacted on July 31, 2015, stating that “[v]eterinarians shall honor a client’s request for a prescription in lieu of dispensing a drug when a veterinarian-client-patient relationship exists and the veterinarian has determined that the drug is medically necessary.”²⁰ California is the only state that requires a prescriber to offer a written prescription to the pet owner “that the patient may elect to have filled by the prescriber or by any pharmacy” prior to dispensing.²¹

IV. ISSUES

The following issues may be examined at the hearing:

¹³ *Supra* note 5.

¹⁴ *Supra* note 5 at 107.

¹⁵ <https://chaffetz.house.gov/press-release/chaffetz-introduces-legislation-help-pet-owners-save-money>

¹⁶ H.R. 3174 Section 3(1).

¹⁷ H.R. 3174 Section 3(2).

¹⁸ <https://www.avma.org/Advocacy/StateAndLocal/Pages/veterinary-prescription-orders.aspx>

¹⁹ <https://www.avma.org/KB/Policies/Pages/Principles-of-Veterinary-Medical-Ethics-of-the-AVMA.aspx>

²⁰ 225 ILCS 115/19.2 <http://www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=022501150K19.2>

²¹ California Business and Professions Code Section 4170(a)(6), <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=bpc&group=04001-05000&file=4170-4175>.

- What issues are unique to the pet medication industry?
- What is the typical structure of the supply chain for prescription and OTC animal drugs?
- What, if any, consumer protection issues exist for consumers and their pets in the current marketplace? Safety issues?

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Paul Nagle or Melissa Froelich of the Committee staff at (202) 225-2927.