## THE PET MEDICATIONS INDUSTRY: ISSUES AND PERSPECTIVES

#### **HEARING**

BEFORE THE

SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE

OF THE

# COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

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## THE PET MEDICATIONS INDUSTRY: ISSUES AND PERSPECTIVES

#### FRIDAY, APRIL 29, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND
TRADE,
COMMITTEE ON ENERGY AND COMMERCE,

Washington, DC.

The subcommittee met, pursuant to call, at 9:52 a.m., in room 2322, Rayburn House Office Building, Hon. Michael C. Burgess (chairman of the subcommittee) presiding.

Members present: Representatives Burgess, Lance, Guthrie, Bilirakis, Brooks, Mullin, Upton (ex officio), Schakowsky, Clarke, Cárdenas, Welch, and Pallone (ex officio).

Also present: Representative Schrader.

Staff present: Mike Bloomquist, Deputy Staff Director; Elena Brennan, Staff Assistant; Leighton Brown, Deputy Press Secretary; Rebecca Card, Assistant Press Secretary; Graham Dufault, Counsel, Commerce, Manufacturing, and Trade; Melissa Froelich, Counsel, Commerce, Manufacturing, and Trade; Giulia Giannangeli, Legislative Clerk; Paul Nagle, Chief Counsel, Commerce, Manufacturing, and Trade; Mark Ratner, Policy Advisor to the Chairman; Olivia Trusty, Professional Staff Member, Commerce, Manufacturing, and Trade; Dylan Vorbach, Deputy Press Secretary; Michelle Ash, Democratic Chief Counsel, Commerce, Manufacturing, and Trade; Jeff Carroll, Democratic Staff Director; Elisa Goldman, Democratic Counsel, Commerce, Manufacturing, and Trade; Dan Miller, Democratic Staff Assistant; Caroline Paris-Behr, Democratic Policy Analyst; and Andrew Souvall, Democratic Director of Communications, Outreach, and Member Services.

Mr. Burgess. The Subcommittee on Commerce, Manufacturing, and Trade will now come to order. And the Chair will recognize himself for 5 minutes for the purpose of an opening statement. And I do want to welcome everyone here this morning. I certainly want to welcome our witnesses.

## OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

This morning, we will receive testimony from our witnesses about the status of the pet medication industry. It is important to start this process by understanding the status quo of the industry. From that point, we will build the necessary base to carefully examine whether additional Federal involvement is needed in the

veterinary prescription medication space. The pet medication industry is an established market, and it continues to grow.

In calendar year 2015, United States pet owners spent over \$14 billion on pet supplies and over-the-counter medications. An additional \$7 billion was spent on prescription medications. Pet care is a notable component of the family budget for well over two-thirds of the United States households.

Last year, the Federal Trade Commission wrapped up a multiyear study of competition in the pet medication industry. And perhaps this morning, the Federal Trade Commission's witness can speak to the state of the industry with regard to prescription portability and distribution practices.

In the report, the Federal Trade Commission noted that more study could be helpful in a number of areas, including pricing, dis-

pensing errors, and the secondary distribution system.

This morning, it would be helpful to understand whether any of that additional study has been undertaken to date. The veterinarian-pet ownership relationship is an important one, and another part of what we will explore today. I understand that Representative Chaffetz has introduced a bill to federally mandate the release of prescriptions that has been referred to this subcommittee. States have long held the bulk of authority over veterinary practice, and over 30 States have passed legislation dealing with prescription portability. I do remain concerned that this legislation, like legislation passed years ago mandating similar procedures for contact lenses, unduly interferes with the relationship between the doctor and their patient. Procedures currently exist in all 50 States to address the claims, issues, raised by the proponents of this legisla-

So mark me as skeptical that a Federal approach rather than one that works with State regulators truly creates an environment that is beneficial to consumers and their pets.

As we have done with other issues with State involvement, and as a matter of federalism, it is important to understand how States have addressed any of the issues raised with prescription portability and what their level of involvement has been.

[The prepared statement of Mr. Burgess follows:]

#### Prepared Statement of Hon. Michael C. Burgess

Good morning. This morning we will receive testimony from witnesses about the status of the pet medication industry.

It is important to start this process by understanding the status quo of the industry. From that point, we will build the necessary base to carefully examine whether

Federal involvement is needed in the veterinary prescription medication space.

The pet medications industry is an established market and continues to grow. In 2015, U.S. pet owners spent over \$14 billion on pet supplies and over-the-counter medications, and an additional seven billion dollars on prescription medications. Pet care is a notable component of the family budget for the 65 percent of U.S. house-

holds that own a pet.

Last year, the Federal Trade Commission wrapped up a multiyear study of competition in the pet medications industry. I hope the FTC's witness can speak to the state of the industry with regard to prescription portability and distribution practices. In the report, the FTC noted that more study could be helpful in a number of areas including pricing, dispensing errors, and the secondary distribution system. It would be helpful to understand whether any of that additional study has been

undertaken to date.

The veterinarian-pet-owner relationship is an important one and another part of what we will explore today

I understand Rep. Chaffetz has introduced a bill to federally mandate the release of prescriptions that has been referred to this subcommittee. States have long held the bulk of authority over veterinary practice and over thirty States have passed

legislation dealing with prescription portability.

I remain concerned that this legislation, like the legislation passed years ago mandating similar procedures for contact lenses, unduly interferes in the relationship between a doctor and his patient. Procedures currently exist in all 50 States to address the claimed issues raised by the proponents of the legislation. I am skeptical that a Federal approach, rather than one which works with State regulators, truly creates an environment beneficial to patients.

As we have done with other issues with State involvement, and as a matter of federalism, it is important to understand how States have addressed any issues raised with prescription portability and what their level of involvement has been.

Mr. Burgess. I will conclude my opening statement with that, and I will recognize the subcommittee ranking member, Ms. Schakowsky of Illinois, 5 minutes for an opening statement.

#### OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLI-**NOIS**

Ms. Schakowsky. Thank you, Mr. Chairman. I must disclose that I have a personal interest in this topic. My husband and I have two very energetic rescue dogs at home, siblings named Franklin and Eleanor. And like any pet owner, that means, of course, we need to buy heartworm prevention and other pet medications.

Ellie actually has Addison's disease. She has to take a pill every day and a shot every month to keep her healthy. Pet owners like me spend a combined total, as the chairman said, of \$7 billion. I feel like I definitely pay my share on pet medications in 2013. And, now, compared to the spending on human prescriptions, that number is pretty small. But it is a significant cost for pet owners. We need to consider whether consumers are well-served by the existing market.

Right now, the majority of pet meds are bought directly through a veterinarian. There may be some good reasons for this, getting prescriptions right at the vet may be more convenient. The pet owner may also want the vet to administer the medication in some cases. And when consumers prefer that convenience and service, they should buy their pet's medication through the vet. But that said, the pet medication industry needs fair competition.

The Federal Trade Commission looked at competition in the pet medication industry in a 2015 report, hoping to hear more about that. The report concluded that portable prescriptions, having your choice of where to buy your pet's medication, allows for more choice and would likely lower prices. Expanded consumer choices already, the direction we are heading, some States already require prescription portability in some form. Many vets provide prescriptions upon request, and a growing number of consumers are choosing to fill their pet's prescriptions through retailers and online pharmacies. The question is whether we are currently getting the full benefit of competition. Consumers need to be aware of the choices that they have, and that choice needs to be real. Portable prescriptions

do little good if the medications themselves are not available outside the vet's office.

The FTC highlighted exclusive distribution policies as a potential impediment to competition. There is also the related issue of whether generic medications are widely available in the first place. We need competition not only among the sellers of prescriptions, but among the makers as well if we want to see more savings for

consumers.

Now, as a dog owner, I am very mindful of safety. As we have this debate. I want to make sure that medication is safe to be dispensed to my pets. I call them my kids. I believe there is a responsibility for whoever sells medication to fill prescriptions accurately and provide the necessary information to pet owners. The FTC report lays out a good framework for today's hearing. I am interested to hear about the current state of the pet medication industry, how we can improve the market for pet owners as well.

I look forward to hearing from our witnesses, and I thank you

for your testimony.

And thank you, again, Chairman Burgess, for holding this hearing.

yield back.

Mr. Burgess. The gentlelady yields back. The Chair thanks the gentlelady.

The Chair recognizes the gentleman from Michigan, chairman of the full committee, Mr. Upton, for 5 minutes.

#### OPENING STATEMENT OF HON. FRED UPTON. A REPRESENTA-TIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman.

Yes, this hearing is on pet medication industry. It is certainly an interesting look at large industry that most of us, as has been described already, have a very personal connection to. From dogs and cats to guinea pigs, fish, turtles, horses, you name it, millions in Michigan and across the country have opened their home to pets of all shapes and sizes.

In my personal office, just down the hallway, we have always been a nine-to-Fido office. In fact, all four of my offices today have four-legged critters, and we have done that all the years on the

So, today, we have Gideon. We have a Silky Terrier, Boston Terrier, Pomeranian named Scout, who really got a buzz cut yesterday. I almost didn't recognize him.

But our beloved pets provide a constant source of joy and levity as well as companionship and unconditional love. And I forgot to bring my box of dog biscuits in this careful container that I allow

my constituents to feed our friends as well.

But to fully appreciate how large the marketplace is, and how important veterinarians are to keeping our companions healthy, all you have to do is stop and think about how many of our friends, loved ones, colleagues, and neighbors have pets. Two-thirds of American households have a pet. And in 2015, those same families spent over \$60 billion on food supplies, medications.

There is an entire ecosystem from manufacturers, distributors, retailers, veterinarians, pharmacies, all the way up to pet owners themselves. It is no surprise that over 700 public comments were filed after the FTC's workshop examining the industry back in 2012. Folks care about their pets, for sure.

But the stats reveal visits to the vets are down. The economy is still on shaky ground. After a lackluster recovery, affordable options for chronic and acute medical conditions are a kitchen-table issue. Pet safety is also of highest importance.

I should also note that one of our State universities, Michigan State, is one of the premier institutions in terms of training vets

to get to the marketplace.

We should strive to strike a balance between consumers having the marketplace of options to choose from to make sure that their pet's safety receives the care that it needs, but doing so without breaking the bank. We also need to make sure that consumers have the information that they need to make an informed decision with their vets about the best care for their pets.

So I am interested in hearing from all witnesses about the state of the pet medication industry today, what the States are doing to address these issues, and what we can learn from the FTC's deep dive into the nuances of this industry. I want to be clear that just as our pets are part of our extended families, our vets are a trusted part, too, of that equation to keep them healthy and happy.

Today, we are here to listen, understand what role, if any, the Federal Government ought to play. I think we can all agree that the health and safety of the pets is a top priority for folks not only

in Michigan, but around the country.

And I yield back.

[The prepared statement of Mr. Upton follows:]

#### PREPARED STATEMENT OF HON. FRED UPTON

Today's hearing on the pet medication industry is an interesting look at a large industry that most of us have a personal connection to. From dogs and cats, to guinea pigs, fish, and turtles, you name it—millions in Michigan and across the country have opened their homes to pets of all shapes and sizes.

In my personal office, we have always been a "nine to Fido office" where more often than not in my years on the Hill, we have had four-legged friends greeting folks from Southwest Michigan. These days we have Gideon—a silky terrier, Bugsy—a Boston terrier, and a Pomeranian named Scout. Our beloved pets provide a constant source of joy and levity as well as companionship and unconditional love.

To fully appreciate how large the marketplace is and how important veterinarians are to keeping our companions healthy, all you have to do is stop and think about how many of our friends, loved ones, colleagues, and neighbors have pets. Two-thirds of American households have a pet and in 2015 those same families spent over \$60 billion on food, supplies, medications, etc.

There is an entire ecosystem—from the manufacturers, distributors, retailers, veterinarians, pharmacies, all the way to the pet owners themselves. It's no surprise that over 700 public comments were filed after the FTC's workshop examining the industry back in 2012. Folks care about their pets.

The stats reveal visits to the veterinarian are down. The economy is still on shaky ground after a lackluster recovery. Affordable options for chronic and acute medical conditions are a kitchen table issue. Pet safety is also of highest importance.

We should strive to strike a balance between consumers having a marketplace of options to choose from to make sure their pet safely receives the care it needs, but doing so without breaking the bank. We also need to make sure that consumers have the information they need to make an informed decision with their veterinaries about the best care for their pets.

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this industry

I want to be clear that just as our pets are a part of our extended family; our veterinarians are a trusted part of the equation to keep them healthy and happy. Today we are here to listen and understand what role, if any, the Federal Government should play. I think we can all agree that the health and safety of the pets is a top priority for folks in Michigan and families across the U.S.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman. The Chair recognizes the gentleman from New Jersey, ranking member of the full committee, Mr. Pallone, 5 minutes, please.

#### OPENING STATEMENT OF HON. FRANK PALLONE. JR., A REP-RESENTATIVE IN CONGRESS FROM THE STATE OF NEW JER-

Mr. PALLONE. Thank you, Mr. Chairman.

Today's hearing is an opportunity to learn more about the present state of the pet medications industry and about the choices that are currently available to pet owners. And as has been stated by my colleagues, many pet owners consider their pet to be a member of their family. Since everybody is talking about their pets, I will have to add that our dog, Valetta, is certainly a member of the family. Although, I have to say, she likes my wife a lot better than

Mr. Burgess. We all do.

Mr. PALLONE. Thank you. Thank you, Mr. Chairman.

So, in any case, access to safe, effective, and affordable health

care for their pets is important.
In 2015, U.S. families spent more than \$60 billion on their pets, and a significant portion of those dollars were in the growing pet medication market. The pet medication industry is in a period of transition, both over-the-counter and prescription pet medications have become more widely available, including through online pharmacies and big box stores. Although retail options have expanded within the industry, many stakeholders believe that the existing system for distributing pet medications has not evolved accord-

In 2012, the Federal Trade Commission held a public workshop to explore the changes taking place in the pet medications market. The workshop received input from a variety of participants, including veterinarians, pet owners, drug manufacturers, drug distributors, retailers, and regulators. Some stakeholders argue that exclusivity agreements between drug manufacturers and distributors can artificially inflate prices and limit consumers' access to medica-

tion choice.

For example, some retail outlets report difficulties ensuring that they have brand medications available for customers, and some veterinarians report difficulties ensuring generic medications are available at their clinics. Others reported that consumers are not being sufficiently informed of the options available to them when purchasing pet medications, including the option of receiving a written copy of their pets' prescription from their veterinarian.

After holding the workshop and reviewing stakeholder comments, the FTC issued a report in 2015 on the pet medications industry. It highlighted the troubling lack of generic pet medications available for purchase, and explained that increased availability of generic pet medications could produce significant savings for con-

The comparison to the human medication market is notable. Of the top 20 human medications that lost patent protection between 2005 and 2007, 100 percent had a generic version made. Of the top 20 pet medications during that time, only 20 percent went generic.

So we know that generics have a profound impact on health care by drastically lowering drug prices and improving access to effective treatment. FTC's report suggests a number of areas for further study regarding pet medication, distribution, that may be causing inefficiencies and disincentivizing the development of new generics, and I encourage the FTC to proceed with that study.

So I am hopeful that this hearing could also address other challenges facing the pet medications industry. I look forward to hearing from our witnesses on how we can work to ensure affordable pet medications for all pet owners.

And I yield back, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

#### Prepared Statement of Hon. Frank Pallone, Jr.

Thank you, Mr. Chairman. Today's hearing is an opportunity to learn more about the present state of the pet medications industry and about the choices that are currently available to pet owners.

Many pet owners consider their pet to be a member of their family. Access to safe, effective, and affordable health care for their pets is important to them. In 2015, U.S. families spent more than \$60 billion on their pets, and a significant portion of those dollars were in the growing pet medication market.

The pet medications industry is in a period of transition. Both over-the-counter and prescription pet medications have become more widely available, including through online pharmacies and big-box stores. Although retail options have expanded within the industry, many stakeholders believe that the existing system for distributing pet medications has not evolved accordingly.

In 2012, the Federal Trade Commission held a public workshop to explore the changes taking place in the pet medications market. The workshop received input from a wide variety of participants, including veterinarians, pet owners, drug manufacturers, drug distributors, retailers, and regulators.

Some stakeholders argued that exclusivity agreements between drug manufacturers and distributors can artificially inflate prices and limit consumers' access to medication choice. For example, some retail outlets report difficulties ensuring they have brand medications available for customers, and some veterinarians report difficulties ensuring generic medications are available at their clinics.

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I am hopeful that this hearing can also address other challenges facing the pet medications industry. I look forward to hearing from our witnesses on how we can work to ensure affordable pet medications for all pet owners, and I yield back.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman. This concludes member opening statements. And the Chair would remind all members that pursuant to committee rules, members' opening statements will be made part of the record.

We want to thank our witnesses for being here this morning and

taking the time to testify before the subcommittee.

Today's hearing will consist of two panels. Each panel of witnesses will have the opportunity to give an opening statement, following which there will be questions from members. Once we conclude with the questions of the first panel, we will take a brief re-

cess to set up for the second panel.

Our first witness for today's hearing is Ms. Tara Koslov, the Deputy Director of the Office of Policy Planning at the Federal Trade

Commission.

And we appreciate you being here this morning. And, Director Koslov, you are now recognized for 5 minutes for purposes of opening statement.

#### STATEMENT OF TARA KOSLOV, DEPUTY DIRECTOR, OFFICE OF POLICY PLANNING, FEDERAL TRADE COMMISSION

Ms. Koslov. Chairman Burgess, Ranking Member Schakowsky, and members of the subcommittee, thank you for the opportunity to appear before you today. I am Tara Koslov, Deputy Director of the Federal Trade Commission's Office of Policy Planning. I am pleased to join you to discuss competition perspectives on the pet medications industry. The Commission has submitted written testimony describing the FTC's recent work in this area, including our October 2012 workshop, staff's reviewing consideration of over 700 public comments received in response to the workshop, and ultimately, our May 2015 staff report.

My oral testimony and responses to questions reflect my own views, and not necessarily those of the Commission or any indi-

vidual Commissioner.

If your household is among the 65 percent in the U.S. with a pet, you know firsthand that pet medications are a major and growing expenditure for many American consumers. Pet owners spend over \$7 billion per year on prescription and over-the-counter pet medications. And this figure is expected to grow to over 8 billion by 2018.

Most consumers purchase pet medications from their trusted veterinarians typically at the end of an office visit. Over the last decade, however, many more retail pharmacies and other retail outlets have been competing with veterinarians to sell pet medications. These new market participants include a number of online pharmacies that are owned and operated by licensed veterinarians and focus solely on filling veterinarians' prescriptions.

Existing competition between veterinarians and other retailers already appears to have led to lower prices for certain pet medications as well as better service, greater convenience, more choices, and other consumer benefits. But recognizing the size of the industry and the large number of affected American consumers, FTC staff has examined two interrelated issues that may still impact

competition for the sale of pet medications.

The first issue is whether consumers know about and have access to portable prescriptions. That means a consumer can obtain a prescription from her veterinarian, then use it to purchase pet medications somewhere other than her veterinarian's office.

Based on our findings, the Commission believes that consumers likely would benefit from increased pet medication prescription portability, which would enhance competition between veterinarians and other retailers of pet medications. Consumers are especially likely to benefit if they can shop around for the lowest prices and greatest convenience when purchasing preventive pet medications or long-term therapeutic treatments for chronic conditions.

In contrast, portable prescriptions may not be appropriate for certain acute care and specialty medications that can only be properly dispensed by veterinarians. Also, consumers may be less likely to comparison shop in an urgent care situation when a pet needs immediate short-term treatment.

The FTC staff report analyzes various arguments for and against automatic prescription release, whereby veterinarians would always be required to provide a portable prescription regardless of whether the client requests one.

As the report notes, many veterinarians already honor their clients' request for portable prescriptions as required by some State laws and ethical codes.

Some veterinarians may affirmatively offer portable prescriptions as well. But complaints persist that not all requests are honored. Also, many consumers still don't know that they can ask for a portable prescription. Other consumers may know but are uncomfortable asking, especially when their veterinarians require fees or liability waivers or make disparaging statements about competing retailers.

As the report explains, FTC staff are skeptical of some of the alleged health and safety concerns cited by opponents of prescription portability.

To the degree that these concerns are legitimate, existing regulatory measures may be sufficient to address them. We are aware of arguments that automatic prescription release may erode veterinary practice revenues, and force veterinarians to compensate by increasing their service fees. But as our report details, it is difficult to reconcile this argument with simultaneous claims that consumers already are aware of and have complete access to portable prescriptions, and that pet medication prices already fully account for the competition that exists between veterinarians and other pet medication retailers.

Thus, we believe that the greater prescription portability likely would enhance competition for the sale of pet medications and that consumers would benefit from this competition in the form of lower prices.

The second issue FTC staff have examined is that most manufacturers of pet medications have exclusive distribution policies to supply pet medications only to veterinary practices. Such policies may adversely affect competition. It appears that many nonveterinary retailers have trouble purchasing pet medications directly from manufacturers or their authorized distributors.

Often, these retailers must rely on secondary supplies, who typically buy excess products from veterinarians. Although consumers likely benefit from lower prices than if exclusive distribution were

being strictly enforced, this secondary distribution system may be inefficient, and prices might be even lower if there were no such constraints.

As the report highlights, enhanced prescription portability, may increase consumer demand to buy pet medications from nonveterinary retail sources. This, in turn, might incentivize manufacturers to change their distribution policies in response to consumer choices. Continued growth of retail distribution could, as a result, increase competition and lead to even lower prices for pet medications in both veterinary and retail channels.

Thank you for the opportunity to share the Commission's views and to discuss our efforts to promote competition and protect consumers. I am happy to respond to your questions.

[The prepared statement of Ms. Koslov follows:]



## PREPARED STATEMENT OF THE FEDERAL TRADE COMMISSION

#### Before the

UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE

"The Pet Medications Industry: Issues and Perspectives"

WASHINGTON, D.C. APRIL 29, 2016

#### I. <u>INTRODUCTION</u>

Chairman Burgess, Ranking Member Schakowsky, and Members of the Subcommittee, thank you for the opportunity to appear before you today. I am Tara Isa Koslov, the Deputy Director of the Office of Policy Planning at the Federal Trade Commission ("FTC" or "Commission"), and I am pleased to join you to discuss competition perspectives on the pet medications industry. This testimony describes the FTC's recent work in this area, including an October 2012 workshop and a May 2015 FTC staff report. This testimony also sets forth a recommended framework for evaluating the competitive impact of limitations on prescription portability for pet medications. The Commission believes that portability likely benefits consumers. Therefore, the Commission generally supports policies that would increase both consumer awareness and veterinarian release of portable prescriptions.

In 2011, FTC staff began actively looking into concerns regarding two issues that could impact competition for the sale of pet medications: first, the limited availability of portable pet medication prescriptions, which consumers may obtain from veterinarians and use to purchase prescription pet medications somewhere other than the prescribing veterinarian's office; and second, exclusive manufacturer distribution policies to supply pet medications only to veterinary practices.

At that time, proposed federal legislation would have required the FTC to issue and enforce rules providing for prescription portability for pet medications.<sup>2</sup> FTC staff began

<sup>&</sup>lt;sup>1</sup> This written statement presents the views of the Federal Trade Commission. Oral testimony and responses to questions reflect my views and do not necessarily reflect the views of the Commission or any individual Commissioner.

<sup>&</sup>lt;sup>2</sup> See Fairness to Pet Owners Act of 2011, H.R. 1406, 112th Cong. (2011). Although H.R. 1406 was not enacted, it sparked a debate among industry stakeholders regarding the need for automatic prescription release. Similar bills have since been reintroduced in both the House and Senate. See H. R. 3174, the Fairness to Pet Owners Act of 2015, introduced July 23, 2015, <a href="https://www.congress.gov/bill/114th-congress/house-bill/11/114th-congress/senate-bill/1200/text">https://www.congress.gov/bill/114th-congress/house-bill/11/114th-congress/senate-bill/1200/text</a>. In several significant ways, these bills are modeled after the Fairness to Contact Lens

compiling information concerning these issues, recognizing that American consumers spend more than \$7 billion a year on medications and related services for their pets.

Drawing on the Commission's competition and consumer protection expertise, FTC staff sought to collect information related to three questions:

- Is competition in the pet medications industry adversely affected by limited consumer knowledge of, and access to, portable prescriptions?
- Is competition in the pet medications industry adversely affected by manufacturer distribution practices that restrict non-veterinary retailers' access to pet medications?
- To the extent that competition in the pet medications industry may be adversely affected by current industry practices, are there less restrictive approaches that could enhance competition without compromising animal health and safety?

On October 2, 2012, the FTC conducted a public workshop to advance its understanding of these issues. A variety of industry stakeholders participated in the workshop, including pet medication manufacturers and distributors, veterinarians, retailers, pharmacists, and consumer advocates, representing a broad range of perspectives. In addition, the FTC received and reviewed over 700 written public comments submitted in response to the workshop.<sup>3</sup>

In May 2015, the FTC issued a report that summarizes the information reviewed by FTC staff, makes recommendations on potential policy choices concerning prescription portability, and

Consumers Act ("FCLCA"), H.R. 3140, 108th Cong. (2003), <a href="http://www.gpo.gov/fdsys/pkg/BILLS-108hr3140enr.pdf">http://www.gpo.gov/fdsys/pkg/BILLS-108hr3140enr.pdf</a> (enacted Dec. 6, 2003). The FCLCA requires contact lens prescribers to provide patients with a copy of their contact lens prescriptions, regardless of whether a portable prescription has been requested. Contact lens prescribers are not allowed to charge a separate fee or require patients to sign a waiver of liability in exchange for providing a prescription.

<sup>3</sup> See generally Pet Medications Workshop, FED.

TRADE COMM'N (Oct. 2, 2012), <a href="http://www.ftc.gov/news-events/events-calendar/2012/10/pet-medicationsworkshop">http://www.ftc.gov/news-events/events-calendar/2012/10/pet-medicationsworkshop</a>. A transcript of the proceedings is available at *Transcript of Pet Medications Workshop*, FED. TRADE COMM'N (Oct. 2, 2012), <a href="https://www.ftc.gov/sites/default/files/documents/public\_events/pet-medicationsworkshop/pet-meditranscript-1.pdf">http://www.ftc.gov/sites/default/files/documents/public\_events/pet-medicationsworkshop/pet-meditranscript-1.pdf</a>. All comments received are available at *List of Public Comments Regarding Pet Medications*, FED. TRADE COMM'N, <a href="https://www.ftc.gov/policy/public-comments/initiative-433">https://www.ftc.gov/policy/public-comments/initiative-433</a>.

identifies areas that could benefit from additional study. <sup>4</sup> The staff report is based on the workshop transcript and public comments received in response to the workshop, discussions between staff and various industry stakeholders in preparation for the workshop, and other publicly available information compiled by staff before and after the workshop.

#### II. INTEREST AND EXPERIENCE OF THE FTC

Competition is at the core of America's economy, and vigorous competition among sellers in an open marketplace can provide consumers the benefits of lower prices, higher quality products and services, and greater innovation. In furtherance of that national policy, the FTC Act grants the Commission broad enforcement authority with regard to both competition and consumer protection matters in most sectors of the economy. In addition, Section 6 of the FTC Act provides, among other things, a general authority to investigate and report on market developments in the public interest, as well as authority to make recommendations based on those investigations. This distinct charge supports the agency's research, education, and competition advocacy efforts. To fulfill its mission, the FTC seeks to identify private, public, and quasi-public restrictions that may unreasonably impede competition.

<sup>&</sup>lt;sup>4</sup> FED. TRADE. COMM'N STAFF REPORT, COMPETITION IN THE PET MEDICATIONS INDUSTRY: PRESCRIPTION PORTABILITY AND DISTRIBUTION PRACTICES (May 2015), https://www.ftc.gov/system/files/documents/reports/competition-pet-medications-industry-prescription-portability-

distribution-practices/150526-pet-meds-report.pdf.

The FTC's authority reaches "[u]nfair methods of competition" and "unfair or deceptive acts or practices" that are "in or affecting commerce." 15 U.S.C. § 45(a)(1) (2014). With some exceptions, the FTC's authority ranges broadly

<sup>&</sup>quot;in or affecting commerce." 15 U.S.C. § 45(a)(1) (2014). With some exceptions, the FTC's authority ranges broadly over "commerce" without restriction to particular segments of the economy. *Id.* at § 45(a)(2).

6 Under Sections 6(a) and (f) of the FTC Act, the FTC is authorized "[t]o gather and compile information concerning, and to investigate from time to time the organization, business, conduct, practices, and management of

concerning, and to investigate from time to time the organization, business, conduct, practices, and management of any person, partnership, or corporation engaged in or whose business affects commerce," and "[t]o make public from time to time such portions of the information obtained by it hereunder as are in the public interest." 15 U.S.C. § 46(a), (f) (2014).

#### III. FTC STAFF REPORT FINDINGS

#### A. Consumer Options for Purchasing Pet Medications Are Expanding

Historically, nearly all major manufacturers of pet medications distributed their products only to licensed veterinarians, or to authorized distributors that sold only to veterinarians. As a result, consumers purchased virtually all pet medications from their veterinarians, typically at the end of an office visit for the examination and diagnosis of their pet. This is still how most consumers purchase prescription pet medications today. Indeed, consumer surveys indicate that veterinarians remain the most trusted source for pet medications.

Local pharmacists (who are authorized to dispense both human and animal drugs) have always been part of the veterinarian-focused distribution model, but generally only to a limited extent. As several commenters at the FTC workshop have noted, veterinarians have long relied on local pharmacies to fill prescriptions for drugs that the veterinarians do not ordinarily stock, particularly human generic drugs dispensed for use in animals. In addition, veterinarians typically have maintained relationships with local compounding pharmacies to ensure their ability to meet the needs of pets requiring specialized concentrations, sizes, or flavors of medications.

Over the last decade, coinciding with increased consumer demand for pet medications, there has been a significant increase in the number of retail pharmacies and other retail outlets that compete with veterinarians to sell pet medications. In the late 1990s, online pharmacies began selling pet medications, often at discounted prices. Many of these online pharmacies are owned and operated by licensed veterinarians and focus solely on filling veterinary prescriptions. More recently, brick-and-mortar big-box retail stores, supermarkets, and chain retail pharmacies

have begun selling some of the largest-volume pet medications, and many of these retailers advertise even greater discounts than online pharmacies.

As a result of the emergence of alternative retail outlets, many consumers no longer view veterinarians as the sole source for pet medications. It also appears that veterinary practices have lost some portion of their pet medication revenues to these emerging competitors. According to one estimate, in 2014, veterinarians accounted for 58 percent of sales of pet medications, with brick-and-mortar retailers accounting for 28 percent and Internet/mail order retailers accounting for 13 percent.

## B. <u>Prescription Portability for Pet Medications Gives Consumers the</u> <u>Benefits of Competition, Including Lower Prices and More Choice</u>

The Commission believes that portability likely benefits consumers, and therefore generally supports policies that would increase consumer awareness of the availability of portable prescriptions and veterinarian release of prescriptions to consumers.

To purchase prescription pet medications from a retail pharmacy, consumers must first obtain portable prescriptions from their veterinarians. A portable prescription may take the form of a written prescription that is provided to the client, who can then present the prescription to a retail pharmacy of her choice. Alternatively, a veterinarian may transmit an electronic prescription to a retail pharmacy on behalf of a client. A veterinarian may also verify a new prescription or refill request received directly from a retail pharmacy, provided a valid veterinarian-client-patient relationship ("VCPR") exists and use of the medication is deemed appropriate.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup> The American Veterinary Medical Association ("AVMA") describes the VCPR as the basis for interaction among veterinarians, their clients, and their patients. Under prevailing ethical guidelines for the practice of veterinary medicine, a veterinarian must establish a VCPR before prescribing or dispensing a prescription pet medication. A VCPR typically exists when: (1) a veterinarian assumes responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, and the client agrees to follow the advice of the

Consumers are more likely to request portable prescriptions when seeking refills of preventative medications or long-term therapeutic treatments for chronic conditions, as opposed to treatments for acute conditions. For example, anti-inflammatory drugs and heartworm preventative medications are more commonly "shopped" by consumers seeking to save money on the long-term use of such products. Some consumers may find it more convenient to purchase pet medications from alternative retailers, such as online pharmacies, or the retail pharmacies where they normally shop for other items. On the other hand, some consumers may prefer the convenience of leaving the veterinary clinic with necessary medications in hand, especially if their veterinarian is matching prices available at retail outlets.

FTC staff's findings suggest that consumers of pet medications may already benefit, to at least some extent, from price competition between veterinarians and alternative retailers. This competition is most significant for flea and tick control products and heartworm preventatives, the two largest categories of pet medications. Likewise, the benefits of price competition could be especially important for owners of pets with chronic health conditions that require the use of long-term medications. Continued growth of retail distribution could increase competition and lead to even lower prices for pet medications in both veterinary and retail channels.

It should be noted that under some circumstances, it might not be appropriate for consumers to obtain portable prescriptions, particularly for acute care and specialty medications that can only be properly dispensed by veterinarians. For example, in an emergency care situation where the animal requires immediate short-term treatment, it could be medically

veterinarian; (2) the veterinarian has sufficient knowledge of the animal to diagnose the medical condition of the animal, which typically means that the veterinarian has examined the animal; and (3) the veterinarian is readily available, or has arranged for emergency coverage, for follow-up evaluation in the event of adverse reactions or failure of the treatment regimen. A VCPR also typically requires that veterinarians maintain medical records of their patients.

inappropriate to delay treatment so that pet owners could comparison-shop for the lowest-priced medications. In addition, consumers may be less likely to realize a significant benefit from comparison shopping in these situations because there are unlikely to be recurring medication costs associated with emergency care.

## C. The Benefits of Competition from Portable Prescriptions Can Be Limited by Exclusive Distribution Policies

Although today's hearing focuses on the portability of pet medication prescriptions, it is important to understand the interdependence of prescription portability and product distribution. The availability of portable prescriptions to consumers from their veterinarians is unlikely to have any significant effect on competition for pet medication purchases if non-veterinary retailers lack adequate access to pet medications to fill the prescriptions. Likewise, increasing distribution of pet medications to non-veterinary retail outlets is unlikely to affect competition if consumers are unable or unlikely to obtain portable prescriptions from their veterinarians. Any reduction of supply through restrictive distribution may also affect consumer demand for those alternative sources of supply, especially if consumers perceive that non-veterinarian retail sources are unreliable or slow to fill orders. Additionally, several stakeholders have suggested that a financial conflict of interest arises when the exclusive right to prescribe is combined with de facto exclusive authorization to dispense. The combination, they assert, could cause veterinarians to be reluctant to provide portable prescriptions to consumers.

Nearly all major manufacturers of pet medications appear to maintain formal policies that restrict sales of pet medications to veterinarians or veterinary distributors. Some stakeholders have reported that, despite these stated policies, large retail pharmacies and stores have been able to purchase pet medications directly from the manufacturers, although no manufacturers have confirmed to FTC staff that they engage in this practice. While some distribution through non-

veterinary retailers does occur, retail pharmacies and other retail stores have expressed the view that it remains difficult to purchase pet medications directly from manufacturers or their authorized distributors. Often, these non-veterinarian retailers must rely on secondary suppliers of pet medications, who typically purchase excess product from veterinarians. The existence of this secondary distribution system likely results in lower prices than would otherwise prevail if exclusive distribution were being strictly enforced. This secondary distribution system nevertheless has been described as inefficient, and may result in higher prices than would prevail in the absence of any constraints on sales by manufacturers to non-veterinary retailers.

As the FTC staff report highlights, efforts to enhance prescription portability may increase consumer demand for pet medications at non-veterinary retail outlets, and thereby create economic incentives for manufacturers to alter their distribution policies to be more responsive to consumer choices.

#### D. Automatic Prescription Release

If prescription release were "automatic," veterinarians would be required to provide portable prescriptions for all prescribed medications, regardless of whether clients request them. Industry stakeholders have expressed different views about the need for, and potential impact of, automatic prescription release mandated by federal or state law.

Non-veterinary retailers and consumer advocates argue that automatic prescription release is the most effective means for creating consumer awareness about the ability to obtain portable prescriptions. Furthermore, they claim that this is the best way to help ensure that all consumers receive a portable prescription when they would like one, but may be too afraid or uncomfortable to ask. In response, veterinarians contend that automatic prescription laws are

unnecessary because most consumers are already aware that they can request and obtain portable prescriptions, and because most veterinarians honor these requests.

As the FTC staff report notes, observers agree that many veterinarians provide portable prescriptions to clients upon request and, in some instances, may affirmatively offer portable prescriptions to clients. Indeed, the AVMA's Principles of Veterinary Medical Ethics state that its members should honor client requests for prescriptions whenever appropriate. This guidance is not binding, however; nor does it require veterinarians to affirmatively offer prescriptions or inform clients of the option to request a portable prescription. Some, but not all, states require that veterinarians provide prescriptions to clients upon request or provide notice to clients that they may request a portable prescription.

Complaints persist that some veterinarians do not always honor requests for prescriptions, and it is unclear to what extent statutory requirements, if they exist, are enforced by state veterinary boards. Furthermore, anecdotal evidence indicates that some consumers either are not aware that they can receive a portable prescription upon request from their veterinarian, or may be uncomfortable asking for one. Affirmatively asking for a prescription can be intimidating to consumers, and this intimidation factor can be amplified when veterinarians require waivers of liability, make disparaging statements about non-veterinary retailers (e.g., suggesting that a product may be counterfeit), or charge extra fees for prescriptions.

Veterinarians, manufacturers, and distributors generally believe that veterinarians are in the best position to dispense pet medications to consumers, and tend to oppose automatic prescription release for a variety of reasons. As analyzed extensively in the FTC staff report, opponents of automatic prescription release argue that it would threaten the integrity of the VCPR; that pharmacists typically lack training in veterinary pharmacology and are incapable of

safely dispensing pet medications; that pharmacists routinely alter pet prescriptions without authorization from the prescribing veterinarian or otherwise make dispensing errors; and that pharmacists routinely provide inaccurate information to pet owners regarding administration techniques, dosing, side effects, and potential drug interactions. Veterinarians also have expressed concerns about automatic prescription release relating to the administrative burdens and costs to comply with legislative mandates; the potential liability when pet medications are dispensed incorrectly by pharmacists or when the products that pharmacists dispense are somehow compromised (e.g., counterfeit, expired, stored improperly, or otherwise adulterated); and the potential for increased fraud and abuse of prescription pet medications by humans.

Ultimately, as explained in the report, FTC staff has concluded that the health and safety concerns expressed by some veterinarians to support limitations on prescription portability are likely exaggerated or are pretextual, at least in part. Moreover, there may already be sufficient regulatory measures to address any legitimate safety concerns.

Another common concern expressed by veterinarians is that automatic prescription release could lead to significant erosion of their revenues, and they often suggest the possibility of increasing their service fees to compensate for any lost prescription revenues. As explained in great detail in the report, FTC staff's research allows for a qualitative description of the possible economic effects of and strategic responses to automatic prescription release, but data currently available to staff do not permit a reliable quantification of the likely economic impact of automatic prescription release on veterinarians and consumers. However, there is an apparent inconsistency between two key arguments: on the one hand, the seemingly widespread concern among veterinarians that increased prescription portability would lead to a significant loss of revenue; and on the other hand, their arguments that prescription portability is not currently

constrained and that their prices for pet medications have already been adjusted to account for retail competition. With respect to portability, if most consumers already know about and exercise their ability to obtain portable prescriptions, and veterinarians already provide these prescriptions without any limitations, then proposed legislation mandating automatic prescription release should not result in any significant loss of revenues beyond what has already occurred.

#### IV. RECOMMENDED ANALYTICAL FRAMEWORK AND CONCLUSIONS

To evaluate the competitive impact of possible limitations on prescription portability imposed by veterinarians on consumers, as well as proposals for reform that would promote greater prescription portability, the Commission recommends that policymakers consider several factors, including:

- The existence and extent of any current limitations on prescription portability;
- The degree to which any such limitations impede competition and have adverse consequences for consumers;
- Whether purported health and safety concerns cited in support of any such limitations (e.g., perceived risks of harm to animals) are genuine and supported by evidence, or are instead pretextual or speculative;
- Whether any limitations on prescription portability being imposed by market participants are narrowly tailored to eliminate genuine risks of harm, or are instead more restrictive of competition than necessary; and
- The potential costs and benefits of any measures that would mandate greater prescription portability.

The Commission generally believes that the competitive process should determine output and pricing, including for pet medications and veterinary services. Consumers typically benefit from a market-based approach, driven primarily by the interaction of suppliers and well-informed consumers.

Based on the FTC workshop record and related staff research, it appears that some consumers are able to secure prescriptions and purchase their pet medications through non-veterinary retail channels, but other consumers may be unaware of their ability to secure a portable prescription or are otherwise inhibited from doing so. Both perspectives support the proposition that prescription portability for pet medications has the potential to yield significant procompetitive benefits for consumers, including lower prices, improved service, more choices, and greater convenience.

Based on the workshop record, additional information regarding the pet medications industry, observations from other industries, and the relevant economic literature, the Commission believes that there currently are constraints on prescription portability and that these constraints likely are limiting competition between veterinarians and retailers in the sale of pet medications, which may result in harm to consumers. While the workshop and comments identified some possible rationales for limiting access to prescription portability, these rationales were not supported by evidence sufficient to rebut the basic presumption favoring competition, and at least some of the limitations appear to be greater than necessary to address the concerns expressed. Although the precise degree of access to portable prescriptions is unknown, as is the magnitude of any harm from restricted access, the Commission concludes that greater prescription portability likely would enhance competition in the pet medications market, and thereby benefit consumers of pet medications.

Thank you for the opportunity to share the Commission's views and to discuss our efforts to promote competition and protect consumers.

Mr. Burgess. The Chair thanks the gentlelady for your testimony. And we will move into the question portion of the hearing. I will begin by recognizing myself for 5 minutes for questions.

Director, you mentioned the issue of liability for writing a prescription. Is that actually at issue? In the course of your study in preparing the report last May, did you come across issues of liability that a veterinarian might encounter for either writing or not writing a prescription?

Ms. Koslov. So liability for not responding to a request for a pre-

scription?

Mr. Burgess. I guess I was thinking along the lines of professional liability, for the prescription either not being filled in a timely fashion or filled correctly. Were there medical practice, or veteri-

nary practice questions that occurred?

Ms. Koslov. So as we explained in the report, our understanding is that a veterinarian would not be liable if a pharmacy made an error in filling a portable prescription. The existing regulations that govern the pharmacist would cover that if it wasn't dispensed as written.

Mr. Burgess. And that would be just part of the normal practice

of the dispensing agency, correct?

Ms. Koslov. That is correct. It would be the same as it is for a human prescription. If you take a prescription to a pharmacist, they are required to dispense it as written.

Mr. Burgess. So why would it come up that someone would ask someone to sign a release of liability if the prescription was not dis-

pensed at the office?

Ms. Koslov. So as we explained in the report, we are not sure why there would be a request for release of liability, because it is our understanding that the existing regulations would already cover it, and you would not need an additional layer of liability release.

Mr. Burgess. That would be my thought as well.

So the subcommittee really appreciates the amount of time the agency spent putting the report together. Obviously, it was a significant report.

Seven hundred public comments; is that correct?

Ms. Koslov. Over 700, yes.

Mr. Burgess. For some people to get a context, is that an unusual amount of comments, or is that about standard when you do an investigation like this?

Ms. Koslov. So it is fairly standard. It was a little bit higher than average for this type of workshop. There were a number of comments that we received that were similar to each other. It is our understanding that perhaps a number of veterinarians may have all been encouraged to send in comments, and they all did. So that was one large group, but then we received a large number of substantive comments from a variety of stakeholders as well.

Mr. Burgess. So the conclusion of all of that, and you put together the report, is there any type of economic analysis that you at the FTC do as far as the implications of the report that you are dispensing? Do you consult with any other agencies or anyone else in the administration, the Bureau of Economics, Office of Manage-

ment and Budget, about the cost of implementing the procedures in the report?

Ms. KOSLOV. Sure. So when we initiate a process of designing a workshop and holding a workshop and then generating a report, the staff team always includes a number of people from our Bureau of Economics. That is just our standard practice within the agency. And so our pet meds workshop team did include people from the Bureau of Economics. The report itself does reflect significant economic analysis by our staff internally, in particular, trying to understand the extent to which prescription portability might impact the economic of veterinary practices and also trying to understand how economic theory would predict how prescription portability might impact prices for pet medications.

Mr. BURGESS. And what are the general conclusions of the Bureau of Economics?

If you can summarize them?

Ms. Koslov. Sure. So I would absolutely refer you to the report for greater detail. It is woven in throughout the report.

On prescription portability, this is ultimately all about consumers. It is all about giving consumers information so that they can exercise their choices in the marketplace. That is kind of the fundamental principles of competition that work throughout our economy. We would think it would work the same here. If consumers have more access to information and more choices in the marketplace, they are more likely to go out and use that information to generate competition, and that should tend to drive down prices.

We think it already has. We see for some pet medication products where veterinarians may already be facing competition from alternative retail distribution, that has tended to bring down prices, and so we would expect to see more of that.

As far as the impact on veterinary practices, if they were to lose revenues from the sale of pet medications, because we understand that is a portion of their revenues right now, I think the average is probably about 20 percent of their revenues come from pet medication sales. So if they are going to lose some of those sales, they might need to adjust their service fees and raise them to compensate.

On the other hand, if, as we have heard, there is already a significant amount of competition and veterinarians already are building that competition into the price at which they sell their medications, then we would not necessarily expect them to lose very much revenues, because their prices already would reflect that competition.

Mr. Burgess. If I could just—in your report, one of the statements made is more information regarding the secondary distribution system for pet medications could allow for deeper analysis of the economic product and safety concerns.

In the years since this report was published, have you, in fact, done that deeper dive?

Ms. Koslov. We have continued to observe what is going on in the secondary distribution market.

Mr. BURGESS. And is there any supplemental statement that the FTC has at this point, a year later, from where you were last May when this report was issued?

Ms. Koslov. We do not have a supplementary statement. As best as we can tell, things have not changed very much in the year since the report was issued.

Mr. BURGESS. And I thank you for your prompt answers to the questions.

Ms. Schakowsky, you are recognized for 5 minutes, please.

Ms. Schakowsky. As you said, currently, most major manufacturers of pet medications use third-party distributors to market their products rather than selling directly to veterinarians or alternative retailers. Distributors explain that there are thousands of individual veterinary clinics across the country, and it is hard for manufacturers to reach them without a centralized distributor.

We have also heard that many manufacturers and distributors have signed exclusivity agreements that limit what products distributors can carry and who they can sell those products to.

Now, the FTC has found that exclusivity agreements are common in the pet medications industry. Could you tell us more about what

the terms of these types of agreements usually require?

Ms. Koslov. So we have not had access to or looked closely at individual contracts, so, I can't tell you precisely what the terms of those are. Our general understanding, based on the workshop record and our additional research is that a manufacturer might reach an agreement with the distributor, that that distributor would either only carry that manufacturer's product, or the distributor would carry that product but not a competing generic product.

Ms. Schakowsky. So how do these agreements affect the ability of veterinarians and alternative retailers to offer their customers choices between branded products, or between branded or generic products?

Ms. Koslov. So we do think that these exclusivity arrangements do have an effect on possible penetration of generic competition. So there are a few factors that affect generic entry, and one of them would be that if you don't have a sizable enough market for generic drugs because consumers aren't getting prescriptions for them, there might not be a big enough market to attract generic entry.

As you are well aware, on the human side, we have the Hatch Waxman system, which provides for automatic substitution of generic drugs. We also have the situation where we mostly have insurance. And so our insurance providers are constantly putting pressure to drive down drug prices, and that tends to lead to more of us seeking generic drugs or being required to use generic drugs. We don't have those two factors at play in the pet med industry. So those are two other factors that affect generic entry.

Ms. Schakowsky. OK. So I think you have answered this. We want generic drugs makers to get their products to veterinarians and retailers to have access to both branded and generic animal drugs. How can we help pet owners have that choice?

Ms. Koslov. So the position that we have taken in our report is that by enabling greater prescription portability and giving consumers more access to these choices in the marketplace, that, ultimately, that will generate more consumer demand for these alternatives, including, perhaps, more consumer demand where consumers would ask, is there a safe generic alternative? But they would have a conversation with their veterinarian as part of that trusting relationship and start to explore those options and that, in turn, might put more pressure on manufacturers and on the marketplace to create more generic alternatives.

Ms. ŠCHAKOWSKY. I am looking at this chart, I don't know who prepared it, potential savings for pet owners. And we are looking at, like, Rimadyl, generic savings, 53 percent over what would happen at the veterinary clinic, typically. So, you know, there is a lot

of money to be saved, potentially.

In the FTC report, you noted that requiring automatic prescription release without addressing the effects of exclusivity agreements would not solve the greater issue facing the pet medications market.

Can you explain why?

Ms. Koslov. The interdependence between those two issues, as I explained in my oral remarks, if you have greater prescription portability, but the distributors of the medications don't have access to enough supply to fill the prescriptions, then all the prescription portability in the world won't really help consumers. So we do see it as interrelated.

Ms. Schakowsky. So is there a way to increase the demand for generics without changing the current distribution system and the distribution channel?

Ms. Koslov. I think that by educating consumers about these options in the marketplace and, again, encouraging them to have these conversations with their trusted veterinarians, these are deep relationships between people who care deeply about the health of the animal. Access to affordable medications is a huge part of taking good care of your pet, and so I think if more consumers have those conversations with their veterinarians and talk about the price constraints they are facing, what options do I have out there in the marketplace, what can we do that is safe for my animal, I think that those conversations will ultimately start to affect the marketplace based on consumer demand.

Ms. Schakowsky. Thank you so much.

I yield back.

Mr. Burgess. The gentlelady yields back. The Chair thanks the

gentlelady.

The Chair recognizes the gentleman from New Jersey, the vice chairman of the subcommittee, Mr. Lance, 5 minutes for questions, please.

Mr. LANCE. Thank you, Mr. Chairman. And good morning to you, Director.

As I understand the issue, the bill that has been drafted may be based upon the model used regarding contact lenses. And the thought was that this would increase access to contact lenses through online sales.

But there have been some negative consequences, in my judgment, in that space, mainly, as online retailers may have abused the law to market and sell contact lenses to consumers without prescriptions, and that may have put consumers at risk by less-

ening the doctor-patient relationship.

And I am concerned that if we replicate that model, there may be concerns of safety regarding family pets. And I am interested in your views on that. And I am also interested in what the agency is doing regarding contact lenses. This is a significant issue in the district I represent. We are the medicine chest of the Nation in North Central New Jersey.

Ms. Koslov. So we do see analogies between the situation with contact lenses and the situation with pet medications.

Mr. Lance. Yes.

Ms. Koslov. We enforce the contact lens rule. We have seen in that market that enhanced prescription portability has really opened up an entire marketplace and options for consumers. So we think, generally, there has been significant benefits for consumers. I recognize the safety concerns that you are citing. As a matter of fact, just recently, in the last couple of weeks, the FTC did send out a series of warning letters related to enforcement of the contact lens rule.

Some of those enforcement letters, warning letters, went to sellers of contact lenses who might not be following the contact lens rule because they are filling expired or invalid prescriptions. However, a number of those warning letters also went to prescribers who may not be honoring the prescription portability requirements of the contact lens rule. So we are looking closely at that issue on both sides. But, obviously, safety is always a consideration.

Mr. Lance. And do you believe that you would be able to give Congress a follow-up report on what is occurring regarding the con-

tact lens situation?

Ms. Koslov. We continue to look closely at contact lenses. There is a rulemaking proceeding open right now, because the contact lens rule is up for review. So as part of that process, we have solicited and received a large number of public comments.

Mr. LANCE. I believe in that space, you have received between 600 and 1,000 comments. Is that accurate?

Ms. Koslov. That sounds about right.

Mr. LANCE. Thank you.

Mr. Chairman, I would like an analysis of this issue in relationship to the contact lens issue, because I believe there are many similarities. And I hope as the discussion moves forward, we can examine this space based upon the experience in another space.

I yield back the balance of my time.

Mr. Burgess. The gentleman yields back. I thank the gentleman. The Chair next recognizes, I believe, it is the gentleman from California, Mr. Cárdenas, 5 minutes for questions.

Mr. CÁRDENAS. Thank you very much, Mr. Chairman.

Ms. Koslov, thank you for conducting the public workshop to ad-

vance the understanding of this important issue.

Our family has three family members that are directly affected by today's committee topic. And our Chihuahua-Yorkie mix, Sophie, who thinks she is a person, really appreciates this. She will act like she understands everything we are saying. Our chocolate Lab, Coco, who knows she is a dog. She is much more well-balanced, and then also, our cat, Gracie, who knows that she rules the house,

they all appreciate it, and so do the rest of the family.

Our entire family appreciates that this committee carefully evaluating the pet medication industry today. In your testimony, Ms. Koslov, you discuss automatic prescription releases, and I have some questions.

Did the workshop that the Federal Trade Commission conducted conclude that automatic prescription release is the best way to give

a pet owner their portable prescription?

Ms. Koslov. The report did not make a judgment on what the best way would be to approach this, but we did conclude that greater prescription portability would be a very important way to enable greater competition in the marketplace.

Mr. CÁRDENAS. OK. Did the workshop evaluate what the costs passed on to veterinarians for automatic prescription release might

be?

Ms. Koslov. There is an extensive discussion in the report of potential costs and benefits, including costs that might be incurred by

veterinary practices, yes.

Mr. CÁRDENAS. OK. And, apparently, there is a great interdependence between prescription portability and product distribution. Is this second distribution system resulting in higher prices

for pet owners? What is the effect there?

Ms. Koslov. So we don't know the extent to which the secondary distribution system—we have not been able to quantify the extent to which that might be an increase in prices. Based on our economic modeling and our understanding of the dynamics of the industry, we certainly think that the way the secondary distribution system is operating right now is not as efficient as it would be if distributors had to write access to drugs from manufacturers, and that there is room to push prices down if we could fix some of the problems there?

Mr. CÁRDENAS. If product distribution remains the same, how much will portable prescriptions actually be used? What is the ex-

trapolation there?

Ms. Koslov. Portable prescriptions are already being used. There are a number of situations where veterinarians do honor the requests of their clients. There are also a number of times where a veterinarian doesn't carry a particular drug, and they offer a prescription to their client. So this is already going on. I think additional prescription portability would enhance competition and lead to even greater competition in that space. I think if consumers are asking for more product, ultimately, manufacturers may need to rethink how they are handling distribution, which may lead to more product flowing into the secondary distribution network.

Mr. CÁRDENAS. So on that point, in order to enhance choice, should manufacturers be able to sell directly to alternative retail-

 $\operatorname{ers}$ ?

Ms. Koslov. Manufacturers can choose however they would like to sell their products.

Mr. CÁRDENAS. Today?

Ms. KOSLOV. Today. They choose today. They will continue to. They can unilaterally decide what is most efficient for them, what is most cost-profit maximizing for them. I think as the marketplace

changes and evolves, I think many manufacturers may be rethinking their own economic model, their product structure, and trying to figure out how to respond to the changes in the marketplace.

Mr. CÁRDENAS. I have a good friend, Cesar Milan, who knows a lot about dogs. And he told me something interesting, that when he went to Germany, he found out that if you have a pet, the pet doesn't need a license; the human being needs a license to learn how to have that pet become a family member. I thought that was incredibly advanced.

That being said, did your report in any way analyze what best practices around the world might help us understand the dynamics

that they figured out over there that we might learn from?

Ms. Koslov. So we did not look at that licensing issue. We did

look generally——

Mr. CÁRDENAS. What I am saying, on this subject matter, like, for example, Germany, maybe they have crossed this kind of dialogue and these kinds of regulations, et cetera, in their own country. That is what I mean. With all due respect, I think us, as Americans, we think that we have done everything first or better than everybody in the world. But when it comes to pets, maybe we can learn from other countries. That is my point.

Did your analysis look at any other world practices?

Ms. Koslov. So we did look at practices in a number of other countries. In particular, we looked at the U.K., because it was an area that they were interested in as well. The FTC has extraordinary close and productive working relationships with our competition counterparts in other countries, and so we actually were talking to our counterparts in the U.K., because they were looking at the issue around the same time.

Mr. CÁRDENAS. Were we able to learn from them, and did any

of that information get into the report?

Mr. Burgess. Mr. Cárdenas, your time is about to expire. We are deep into a vote. The bells are not working in here, because of the construction. I apologize to members that we have let things go, but I wanted to let your question time go through.

Mr. CÁRDENAS. Thank you so much.

Mr. Burgess. But we are going to take a brief recess, and we will reconvene immediately after the vote series. It will not take long.

[Recess.]

Mr. Burgess. I will call the subcommittee back to order. And thank everyone for their forbearance during the vote series, and thank people for coming back.

We were in the portion of the member questions when we adjourned. So the Chair at this point would like to recognize the gentlelady from Indiana, Mrs. Brooks. Five minutes for questions, please.

Mrs. Brooks. Thank you, Mr. Chairman.

Like so many Americans, and even like some of the panel that we have heard from or members that we have heard from today, animals have been an integral part of my life since childhood, including the 10½-year-old dog, Scout, yellow lab, more than just a companion or a hunting dog with my husband, but truly a member of our family. And like a family member, we need to make sure

that he has the medicines, all the up-to-date vaccines to keep him healthy and active.

But I also know, because Indiana is the home of Elanco, one of the Nation's largest animal health distribution and manufacturing companies, that it takes a lot with respect to create medications and vaccines and so forth for our treasured pets. Whether it is price competition, medications, vet laws, I know these things not only affect consumers, but they also affect the manufacturers and the scientists in Indiana developing these products. So I am looking forward to hearing not only from you, but to the second panel as well.

Ms. Koslov, were you able to gather the information? And what have you done with respect to the analysis of the, I believe, about 36 States right now by either the State or independent licensing boards or the self-policing associations, what can you tell us about whether or not veterinarians are actually withholding prescriptions from pet owners across the country? I mean, when 36 States already have laws on the books and in place, can you share with us a bit more about what practices you are most concerned about?

Ms. Koslov. So it is our understanding that a number of States do have these laws on the books, and we realize that many veterinarians are honoring their client's requests for prescriptions. However, there are some States that do not have these rules in place. Moreover, there are no States that require a veterinarian to affirmatively offer a prescription.

And in our experience, based on the anecdotal evidence and the testimony at the workshop, we think there are a large number of consumers who just aren't aware that they have the right to ask for a prescription and that would give them the opportunity to shop around in the marketplace. And so we are looking to enhance that part of the market as well.

Mrs. Brooks. And I am sorry, I haven't studied all 36 States' requirements, but certainly of the 36 States, people who ask for a prescription, though, in all likelihood, the veterinarian is required to provide one. Would that be correct?

Ms. Koslov. It is our understanding that they would be required to provide one. However, we have received a number of anecdotes and comments, as part of the workshop, that some consumers are not, in fact, getting prescriptions when they ask for them.

Mrs. Brooks. But then wouldn't that be a licensing problem or something that the consumer would then be able to file a complaint with the licensing board, if that were to take place, at least in the 36 States?

Ms. Koslov. So consumers could choose to file some sort of complaint with the licensing board, or in some States it might actually be a law or a regulation. So it could be the board or it could be, if it is an ethical code in the State that requires veterinarians to do it, there might be other places they could complain.

Mrs. BROOKS. And do you know if those complaints have been filed in the 36 States, and if so, how many?

Ms. Koslov. So we did not do an exhaustive study of how many complaints were filed in each State.

Mrs. Brooks. Have any been filed in those 36 States?

Ms. Koslov. I am not aware of whether any have been filed in those States. I know that we did receive a number as part of our comment process

Mrs. Brooks. But would that number be in the 36 States or are they in the other States that haven't yet moved in that manner

with respect to regulations?

Ms. Koslov. I don't know which States they were in.

Mrs. Brooks. Has the FTC ever done any consumer campaign to

inform consumers that they can ask for a prescription?

Ms. Koslov. So the day that we issued the pet medications report last May, we actually did issue, at the same time, a consumer education piece that came out through our Bureau of Consumer Protection. We also shared it with a number of stakeholders in this industry and encouraged them, veterinarians and other consumer interest groups, so that consumers would get better information and be educated about their opportunities.

Mrs. Brooks. And you are aware of concerns by the FDA regarding medications obtained online for pets, and we are also aware of some safety issues regarding something that Congressman Lance from New Jersey brought up with respect to contact lenses ob-

tained online.

Has the FTC taken any steps to educate consumers about safe sources of whether it is contact lenses or whether it is online pet medications, and if so, can you please explain what the FTC has

done with respect to online purchases of medications?

Ms. Koslov. Yes. In that consumer education piece that I just mentioned, one of the guidance pieces that we gave to consumers was that it would be helpful to look for a vet that is accredited pharmacy if they are looking at purchasing pet medications online. That accreditation process involves a number of safety mechanisms to ensure the authenticity of the medications and just to make sure that the process is as safe as possible. So we did encourage consumers to look for that certification.

Mrs. Brooks. And is the FTC conducting any investigations of

online purchases?

Ms. Koslov. I can't comment on any nonpublic investigations and whether we are doing them or not. We are generally aware that there is a robust online marketplace for pet medications, and we are doing our best to keep an eye on it.

Mrs. Brooks. Thank you. I yield back. Mr. Burgess. The Chair thanks the gentlelady. The gentlelady yields back.

Seeing no other members of the subcommittee, it would now be my great honor to recognize a member of the full committee, Dr. Schrader from Oregon, 5 minutes for questions.

You may have to move to a microphone that is actually working. I promise I didn't turn yours off. And thank you for being here, Doctor.

Mr. Schrader. Thank you very much, Mr. Chairman.

And, Ms. Koslov, I appreciate you being here. A difficult position, FTC trying to talk about health safety and price competition at the same time.

I guess to make a comment here, I mean, in your own report, you acknowledge that there is increased competition in the veterinary prescription marketplace. Prices are going down already. PetMed Express claims to have 2.5 million customers, 50 percent of the business being prescription meds.

I guess I would ask, Where is the problem here? Where is the

problem here?

Ms. Koslov. We think that consumers benefit whenever they have additional information that enables them to exercise their choices in the marketplace. And based on the record that we developed as part of this workshop, although our understanding is that many consumers have a very close and trusting relationship with their veterinarians and they are already having these discussions about prescription portability, we think there is room for improvement.

Mr. Schrader. Well, there is probably always room for improvement in anything. I think it is a point of diminishing returns. And also, to be honest with you, the tone a little bit is impugning my profession. I have been a veterinarian for 35 years, and I could have made a lot more money in a lot of other professions. I went to school for an exhaustive period of time, in my opinion, and I chose veterinary medicine because I love working with animals.

The prescription piece is a small part of what we do. And I think some of the testimony, with all due respect, that you have is outdated. You know, 20 percent of the business being prescriptions, I will wager you in this day and age, it is actually much less. My own practice over time back in the dark ages when I started, yes, medications were a big part, because there weren't a lot of opportunities elsewhere. That has changed. I think it has changed for the better for, you know, frankly, a lot of the folks out there, whether the client or the actual pet itself.

And the trend in veterinary medicine, just so you are aware and my colleagues, is to pay for services, not for items dispensed. It is much like what we are seeing in human medicine, it is a value added type of reimbursement system. Veterinarians have voluntarily in recent years, last, I would say, 6, 8, 10 years reduced the number of vaccines they give, because good research has shown they don't need to be doing that. And I think that is a tribute to the profession. It is not about making money; it is about providing the best health care to the pet.

the best health care to the pet.

And I appreciate the FTC comes at it from a different standpoint, you know, your background is in competition and getting the best price, best opportunity for the consumer, and that is fair, but that is not what veterinary medicine is all about. We are about pro-

tecting the health and safety of these animals.

To be honest, as Ms. Brooks pointed out, these so-called complaints, you can't verify where they have come from, who they have come from. My guess is they come from, frankly, the PetMed type of distributors out there, who their one single motivation is to make money. You know, I respect that, this is America, it is a market system, but they do not have the best interest of the pet at all in their sights.

And the biggest thing that I would recommend the FTC also look at as they go on with this—if they are going to go on with this—is to look at, you know, what is the implication of allowing these big national distribution chains to issue prescription medications at

liberty? In other words, what we find in the veterinary field is you will have a prescription that says 30 days' worth of, you know, thyroid medication for your animal, and PetMeds will come back and give them 120 days. How does that give the veterinarian the chance to make sure that that client does not go beyond what is safe for that pet, to make sure that pet is getting the needed check, and to make sure that medication is actually working correctly for them?

There is a huge disconnect between where I think you are going with regard to how the veterinarians act, and the real culprit, the real worry is how these prescription distribution business companies are. It is purely to take advantage of the marketplace. And I am all in favor of, you know, free market enterprise. I always encourage, like I think most veterinarians, to get the best deal.

They come to us initially, you give them initial prescription, if it is chronic medication—consumers are very sophisticated these days. There may be a few that don't understand they can go online or, you know, get medications elsewhere, but I think in this day and age, most of them are very sophisticated. I have clients coming in saying, "Hey, Doc, can I get my Rimadyl or my Heartgard from somebody else?" I say, sure, because I am not making much money on it. I am probably losing money on it. You mark it up a tiny bit because of the competition that is out there, that is good. But it is there in case my clients need it in a crunch. They know I am going to be there for them. You know, PetMeds may take, you know, 24, 36 hours to get them their needed medication.

So I would just add the health and safety thing in there. I think that is something that is being totally missed in the discussion at

this point in time.

The other issue I would bring up real quick, and hopefully would be commented on in the second panel, is the idea that somehow the distribution system is limiting generics for veterinary patients or veterinary clients. Nothing could be further from the truth. I get calls all the time as a veterinarian, member of the United States Congress, on, you know, gosh, you know, we are having trouble getting generic medications. And it is not because of the distribution network, it is because, frankly, the consolidation that has gone on in the generic industry, some of the health and safety standards, some of the people that are doing these things. And that is a whole different subject.

The idea that this is a big problem for generic distributions is absolutely completely wrong. And most veterinarians, they don't deal with one distributor, they deal with multiple distributors. As a matter of fact, if you can't get it through a distributor, most of the Prednisone prescriptions, we go through a pharmacy, for goodness sakes. But that is getting to be difficult to afford compared to the old days. Prednisone used be a very inexpensive medication, wide, broad-spread effectiveness, one that you need to check on, because chronic administration can cause serious problems. So even if it is a generic medication doesn't mean that it doesn't need veterinary

supervision.

I think it is real important for the panel to understand, you know, what is going on here. The basic issue we have here is, who do you trust? Is this about trusting PetMeds, that is in this purely from a business standpoint to make money off of your pet, or is this about trusting your veterinarian, which has the best interests of you and your pet in mind? And I would urge the FTC to put a little bit of that heart into that business background that you are using as you go forward.

And with that, I yield back, Mr. Chair.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentleman from Oklahoma, Mr. Mullin. Five minutes for your questions, please.

Mr. MULLIN. I am not sure how you follow that up. I think you summed it up pretty well.

I have also got a letter here I want to present for the record from Oklahoma State University, from the dean, that also opposes this. Mr. Burgess. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. MULLIN. I also would like to follow up on a couple of questions. Was there an epidemic of people reaching out to you on asking for this to happen? I mean, was there an overswell of the public that was saying, we are being cheated, we are being taken advantage of, we want it to be required that all vets write a prescription before they can give the drug to us so we have an option? Was that taking place?

Ms. KOSLOV. So our study was prompted by legislation that was originally introduced in, I believe, 2011. And the reason that we did the study was that the—

Mr. MULLIN. Prompted by what?

Ms. KOSLOV. We don't know what it was prompted by, but the legislation, if enacted, would have given us rulemaking authority.

Mr. MULLIN. So what did your—

Ms. Koslov. And given that we would have had——

Mr. Mullin. What did the study do? What did the study come up with? I mean, did you find out that there was a large outcry from the public that was wanting this?

Ms. KOSLOV. Well, one of the things we needed to study was, given that the legislation would require prescription portability—

Mr. Mullin. No. That——

Ms. Koslov [continuing]. We needed to understand—

Mr. MULLIN. But that—I know. But when——Ms. Koslov [continuing]. How that would fit in.

Mr. Mullin [continuing]. You did the study, did the study come out and say, "Wow, there is a huge problem here"?

Ms. Koslov. We found that there were a number of consumers

who were either unaware of their right to take—

Mr. Mullin. What is the number? What is the percentage that you use? Because, look, I have lived on a farm my whole life, and this whole comparison that you are using the same legislation for contact lenses, huge difference, big difference. Contact lenses, people didn't even know they needed a prescription. They didn't understand the difference between glasses and contacts. They didn't understand the reverse effect that would happen. My kids wear contacts, and so does my wife, until she had Lasix, but they didn't understand that the different material you put in your eye could

cause problems. They didn't understand that there is a difference between one contact brand and the next contact brand.

This is vets that are there with their patient, that are prescribing the medication right then. There is already over 30 States that already have legislation in place that says that if a patient asks for it, that the vet will provide it. And I would say the other States, the vet would do it anyway. So why? Tell me the percentage to make you say that this has to be the legislation that you guys are proposing, because all it sounds like to me is just more regulation on an industry that is struggling the way that it is now. There is a shortage of vets, especially in rural America. We cannot find enough of them. And this is just another reason to keep people out of it.

Ms. Koslov. So the Commission hasn't actually taken a position on the pending legislation. So the report focused more qualitatively on what is going on in the marketplace——

Mr. MULLIN. But you already support it, so you have taken a position.

Ms. Koslov. The Commission has not come out in support of any specific legislation. We are supportive generally of measures to increase prescription portability.

Mr. Mullin. Which is essentially saying that you support the legislation without saying you support the legislation. That is the way we do it all the time up here.

So my point is, why? What was the percentage that prompted you to think that this is a good idea?

Ms. Koslov. I don't have a specific percentage for you. The report focused much more on the policy of——

Mr. Mullin. So this is just another piece of regulation that is being pushed out by a Federal agency without a need for it.

Ms. Koslov. Well, we are not pushing the legislation.

Mr. Mullin. I know that.

Ms. Koslov. We are responding to the legislation.

Mr. Mullin. But it doesn't matter.

Ms. Koslov. We identified a need from consumers. Consumers need more information in this huge marketplace to be able to exercise their options.

Mr. Mullin. Was there a lack of information being provided?

Ms. Koslov. Our understanding was that a number of consumers did not have the—

Mr. Mullin. Understanding. What was the study that showed that you are—you are speaking that there was a lack of information. So speak in specifics by saying what draw that. I don't want assumptions. What is the percentage that said that there was a lack of information being out there to the consumer?

Ms. Koslov. I don't have a percentage for you. I would point you to the record of our workshop——

Mr. Mullin. Then you can't say that there was—

Ms. Koslov [continuing]. And our 700 public comments.

Mr. MULLIN [continuing]. There was a lack of information to the public. You are making that general analysis, and you are making it off of your belief, but there is no analogy to back that up.

Ms. Koslov. We are making it based on the record of the testimony at our workshop, the 700 public comments, and the additional research that we conducted.

Mr. MULLIN. Then what was the percentage of the 700 that you got that information from?

Ms. Koslov. We did not quantify what percentage of consumers—

Mr. Mullin. Well, I think that would be pretty——

Ms. Koslov [continuing]. Had asked for this information.

Mr. Mullin [continuing]. Important. I mean, don't you? If we are going to come out in favor of legislation—which I know you haven't, but you have—wouldn't that be important for this committee to know?

Ms. Koslov. I don't think that we need to be able to quantify

a specific percentage of consumers who are—

Mr. Mullin. Well, yes, it would, because if there are a few bad apples, let's go after the bad apples, let's not go after the entire industry and use a one-size-fits-all approach that we do so often up here.

Ma'am, I appreciate the position that you are at, and I appreciate you coming here and talking to us, but even though you are not supportive, you are speaking in favor of it, yet you are not able to tell us why you are speaking in favor, other than you are saying that the consumers need it, but you can't tell us why the consumers need it.

So I yield back, Mr. Chairman.

Mr. BURGESS. The gentleman yields back. The Chair thanks the

gentleman.

Seeing no other members wishing to ask questions, I do want to thank our witness for being here today. Mrs. Brooks had to leave. And we will try to get a question for the record in writing to you. I think this is an important point of the number of complaints that were received, the type of complaints that were received. So if we can get some quantification of that, I think that would be helpful to the subcommittee.

And I do also want to stress this is not a legislative hearing. This is a hearing that was called on the basis of the report. And as you commented, you did the report because you saw legislation that would require you to enter into rulemaking. So it is proactive. And I appreciate having preventive medicine. I am a believer in having preventive medicine, but I do want to stress this is not a legislative hearing on a particular piece of legislation.

Does the gentlelady from Illinois seek to-

Ms. Schakowsky. I just wanted to make a comment. This hearing was requested by the majority based on a report that came from legislation that had been suggested. And I just felt the tone of the questioning was a bit of badgering of the witness, who, you know, is fulfilling her job, and I appreciate it, at the Federal Trade Commission.

And given the number of pet owners, I think the issue is certainly important to many, many people, regardless of whether or not there is a percentage known of how many people; and that, you know, the idea, the possibility of more competition was raised in a piece of legislation that would have affected the Federal Trade

Commission. So I want to thank you for the study that was produced. And then, of course, it is always up to us on whether or not we proceed forward with any kind of legislation.

And I yield back.

Mr. BURGESS. The gentlelady yields back. The Chair thanks the gentlelady.

Seeing no other members wishing to ask questions from our witness, I do want to thank our witness for being here today. I appreciate your forbearance through the voting recess that we took.

This will conclude our first panel. We will take a brief, underscore brief, recess to set up for the second panel, and the committee will resume at that time. The committee stands in recess.

Mr. Burgess. I will call the subcommittee back to order. I want to thank everyone for their patience, taking the time to be here today. We are going to move into the second panel for today's hearing. We will follow the same format as the first panel. Each witness will be given 5 minutes for an opening statement and then we will have questions from members.

For our second panel, we have the following witnesses: Mr. Nathan Smith, the Vice President of True Science; and Dr. John de Jong, Chair of the Board of Directors at the American Veterinary Medical Association.

We appreciate both of you being here with us this morning.

We will begin the panel with you, Mr. Smith. You are recognized for 5 minutes for an opening statement, please.

STATEMENTS OF NATHAN SMITH, VICE PRESIDENT OF STRAT-EGY AND INTERNATIONAL, TRUE SCIENCE, LLC, AND JOHN DE JONG, DVM, CHAIR, BOARD OF DIRECTORS, AMERICAN VETERINARY MEDICAL ASSOCIATION

# STATEMENT OF NATHAN SMITH

Mr. Smith. Mr. Chairman, Ranking Member Schakowsky, and members of the subcommittee, my name is Nate Smith and I am the Vice President of Strategy and International for True Science.

I appreciate you allowing me to testify today.

True Science is a pet medication and wellness company founded in 2010. We deliver premium prescription and over-the-counter pet medications and veterinarian-recommended products. We are dedicated to pet owners, the two of three American households who have at least one dog or cat. Americans love their pets. They provide us companionship and comfort.

Pets are part of our families, which begs the question: Shouldn't we have the same access to affordable medications for our pets as we do for medications for our children, the same access to generics, and the same right to choose our pharmacy? We believe we should. That is why we support the Fairness to Pet Owners Act, a bipartisan bill to give pet owners the right to copies of their pets' prescriptions so they can shop around for the price, service, and convenience which suits them best.

This bill will help pet owners and their pets. First, the 80 million American households who own pets will save money, have more choices, and better access. Second, the marketplace will be more competitive and grow. We know competition and free markets work. Third, our pets will be better off. With medications more affordable and easier to obtain, pet owners will be better able to care

for their dogs and keep them longer.

At the outset, let me make clear that we cherish our vets, as do pet owners. We entrust them with the care of the pets we love. This is not an us-verse-them type issue. We just see the market-place and its potential differently. We believe that if the market for pet medication is open to competition, everyone will benefit: manufacturers, veterinarians, pet owners, and pets alike.

Today, the market for pet medication is bifurcated between those who can afford to buy pet medication and have reasonable access to vet clinics, and those with lower incomes or who do not have

ready access.

For pet owners who get their prescriptions, the savings can be significant. If we can pull up the chart, and this is the page that was referred to earlier. Heartgard is the leading heartworm preventative. Pet owners can save around 20 percent if they buy from a big box or club store, 25 percent buying online, and 35 percent if they purchase the generic. Rimadyl is a painkiller used for treating arthritis in pets. Pet owners can save 22 percent at big box clubs or stores, 28 percent online, and 50 percent if they purchase the generic.

Mr. Chairman, in announcing this hearing, you asked whether Federal involvement is needed in the veterinary prescription medication space. That is an important question, since American households spend \$7 billion every year on pet medications, \$5.2 billion

of which requires a prescription.

The fact is the Federal Government is already involved in the pet medication space, and in a major way. The Government prevents pet owners from purchasing most pet medications without the approval of a prescriber, including medications pet owners in other industrialized countries can be purchased over the counter. If the Federal Government is going to tell pet owners, you can't buy this without a prescription, shouldn't it give those pet owners the right to copies of their prescriptions so they can shop around for the price, service, and convenience they prefer?

The problem is, anytime the Government restricts access to a product by making it available only by prescription but permits the prescriber to sell what they prescribe, it sets up a conflict of interest in which the consumer is put squarely in the middle. Pet owners must ask the veterinarian, on whom they rely for their pet's healthcare, for permission to take their business elsewhere, and

that is only if pet owners know they have a choice.

Policies and laws requiring pet owners to ask for a copy of their prescription simply do not work. We know they don't work, otherwise, far more pet owners would be buying generics and saving 50 percent, just like they do with human medications. These policies don't solve the conflict of interest. They don't let consumers know they have a choice. They lead to discriminatory prices, they deter interstate commerce, and they are unenforceable.

Rather, the solution to this is simple, it is easy, and it is proven. Simply give pet owners a right to a copy of their prescription without having to pay a fee, sign a waiver. This is no easier, more effi-

cient or more effective way to let pet owners know they have a choice. It has worked with human medications, with eyeglasses, contact lenses; it will work with pet medications.

Thank you for considering our views. I look forward to answering your questions.

[The statement of Mr. Smith follows:]

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Testimony of Nathan Smith Vice President of Strategy and International True Science LLC

Hearing on "The Pet Medication Industry: Issues and Perspectives"
Subcommittee on Commerce, Manufacturing and Trade
House Committee on Energy and Commerce
U.S. House of Representatives
April 29, 2016

Mr. Chairman, Ranking Member Schakowsky and Members of the Subcommittee, my name is Nate Smith, and I am the Vice President of Strategy and International for True Science. I appreciate the opportunity to testify before you today on the issue of the pet medication marketplace and its impact on consumers.

True Science is a pet medication and wellness company founded in 2010. Our mission is to deliver premium quality pet prescription medications, over-the-counter medications and veterinarian-recommended products at a significantly greater value to pet owners. We distribute leading medication brands and make our own value-branded equivalent medications available to retailers and pharmacies. We also manufacture and sell pet wellness products and treats.

True Science is dedicated to pet owners – the 2 of every 3 American households who have at least one dog or cat<sup>1</sup>. Americans love their pets. They provide us companionship. They provide us comfort. Pets have become part of our families.

Which begs the question: Shouldn't we have the same access to affordable medications for our pets as we do for medications for our children? The same access to generics? The same right to choose our pharmacy? I believe we should.

<sup>1</sup> See 2015-2016 APPA National Pet Owner Survey Statistics: Pet Ownership & Annual Expenses, AM. Pet Products Ass'n.

That is why we enthusiastically support the Fairness to Pet Owners Act (H.R. 3174/S. 1200), a bi-partisan bill giving pet owners a right to a copy of their pet's prescriptions so they can shop around for the price, service and convenience, which suits them best. We appreciate Mr. Chaffetz and Mr. Cartwright sponsoring this legislation, and Mr. Rush of this Subcommittee being one of the co-sponsors.

H.R. 3174 will help pet owners and their pets in three important ways:

- The nearly 80 million American households who own pets will save money. They
  will have more choices. And, they will have better access to the medications their pets need.
- The marketplace will be more competitive and grow. Pet owners will see the benefits that come from competition and free markets – innovation, competitive pricing, better service and more convenience.
- 3. Our dogs, cats and other pets will be better off. By making pet medications more affordable and easier to obtain, pet owners will be better able to care for their pets, to keep their pets longer, and be more likely to take on additional pets or replace those they lose.

At the outset, allow me to make clear that we cherish our vets – as do most pet owners. We entrust them with the care of the pets we love, they are passionate about their role in caring for our pets. This past week my vet in Springville, Utah, helped my in-laws through the painful process of first treating their dog Maggie's kidney failure then sadly putting her down as her body gave out.

This is not an "us vs. them" type issue. We just see the marketplace – and its future potential – differently. We believe that if the market for pet medication is opened to competition, everyone will benefit – manufacturers, veterinarians, pet owners and pets alike.

Today the market for pet medication is bifurcated – between those on one hand who can afford unnecessarily expensive medications and that have reasonable access to veterinary clinics.

They are spending more on their pets and driving growth in the industry.

On the other hand, there are pet owners with lower incomes whose situations are made even more challenging by stagnate real wages and the aftermath of the recession, and those who do not have ready access to vet clinics – whether that be because they are elderly and homebound or because they live in an underserved urban core or in a rural area. These pet owners are finding it tougher to care for their pets, and they are buying less veterinarian recommended medication and spending less on their pets.<sup>2</sup>

No pet owner wants to spend more for the medications recommended by their vet than they have to. Increasingly, pet owners aspire to do everything they can for their pets. The Fairness to Pet Owners Act will result in significantly lower pet medication prices and will improve access as pet medications become more available at the pet owner's family pharmacy and on-line.

Take for example, Heartgard – the leading heartworm preventative. Pet owners can save approximately 20% if they buy from a big box or club store, 25% if they buy online, and 35% if they purchase the generic equivalent.

On Rimadyl – a painkiller used for treating arthritis in pets – pet owners can save approximately 22% if they buy from a big box or club store, 28% if they buy online, and save 50% if they purchase the generic equivalent.

<sup>&</sup>lt;sup>2</sup> See George Puro, Package Facts, Pet Medication in the U.S. (4th Edition, October 2015) [hereinafter PACKAGED FACTS REPORT 4th EDITION], Table 5-4a, Table 5-4b, Table 5-5.

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Rimadyl is an expensive drug - it costs \$353.41 for a 180 count/100mg supply from the average vet clinic and \$167 for the generic at leading pharmacies - meaning pet owners can save nearly \$200.3

Despite these savings, many pet owners will continue to purchase from their vets. However, all pet owners will benefit as a robust and competitive market will result in universally lower prices. But, for pet owners who want to save money, those on tight budgets, those who need the convenience of purchasing online or at their neighborhood pharmacy, and those who want access to significant savings on generic versions of leading medications, this legislation will provide needed relief.

In announcing this hearing, Mr. Chairman, you asked: "[w]hether federal involvement is needed in the veterinary prescription medication space."

That is an important question - one that matters, since American households spend \$7 billion every year on pet medications, \$5.2 billion of which requires a prescription.<sup>4</sup>

The fact is that the Federal government is already involved in the pet medications space, and in a major way. The Federal government bars American pet owners from purchasing most pet medications without the approval of a licensed prescriber.

I am not saying this should change - that the Federal government should pull itself out of restricting how Americans can buy medications for their pets. Although I will point out that our Federal government requires a prescription for some major pet medications other industrialized countries permit their citizens to purchase over-the-counter.

<sup>&</sup>lt;sup>3</sup> True Science. Internal pricing study, March 7, 2016. <sup>4</sup> PACKAGED FACTS REPORT 4th EDITTON, at 17

But, if the Federal government is going to tell pet owners "you can't buy this without a prescription," shouldn't it give those pet owners the right to copies of their prescriptions so they can shop around for the price and convenience which suits them best?

Any time the government restricts access to a product by making it available only by prescription, but permits the prescriber to sell what they prescribe, it sets up a fundamental conflict of interest where the health care provider is also the retailer.

Pet owners are left squarely in the middle of this conflict of interest, and must ask the veterinarian – on whom they rely for their pet's health care – for permission to take their business somewhere else and buy their pet's medications from a competing pharmacy. And that is only IF pet owners know they have a choice.

The solution to this is simple. It's easy. And, it's proven. Simply give pet owners a right to a copy of the prescription and let them choose where to buy. There is no easier, more efficient, or more effective way to let pet owners know they have a choice. It has worked with human medications. It has worked with eyeglasses. And it has worked with contact lenses. It will work with pet medication.

In closing allow me to summarize in five points:

1. This is an issue which affects most Americans. Two out of every three American households have pets. They spend \$7 billion a year on pet medication. 87% of pet owners view their pets as members of their family. They want the right to comparison shop for their pet's medicines – just like they do for their own or their children's medicines. And they don't understand why they cant.

<sup>5</sup> PACKAGED FACTS REPORT 4th EDITION, at Table 2-27

2. There is a central conflict of interest where the veterinarian is also the retailer and can prescribe or recommend brands sold exclusively through prescribers. In a marketplace like this, the government must establish rules to assure consumer choice and competition – just as the government has done with eye glasses and contact lenses.

The government needs to act because the prescription requirement plus the inherent authority which comes from wearing a white coat puts the veterinarian in a unique position of power. This power can be used by the veterinarian to dictate the consumers' purchasing decisions, or, in the case of non-prescription products, to heavily influence what a consumer buys under the belief it is best for their pet's health.

- 3. Having the prescription put directly and automatically into the hands of the consumer, without requiring the consumer to ask for it, sign a waiver, or pay a fee is absolutely key. That piece of paper lets the consumer know he or she has a choice. It is the most effective, most efficient, means of creating a consciousness of choice.
- 4. Pet care is a discretionary expense. If choice is spurred and competition encouraged, prices will drop, convenience will be created, and Americans will buy more pet care to the benefit of all stakeholders to the pet owner, to the pet, manufacturers, and to the veterinarian community.
- 5. We must not lose sight of the big picture -- this is a very tough economy. Every indication is that it will remain that way for the foreseeable future. Americans at most income levels are looking to save money.

It is also a different economy. Many families are burdened by severe time constraints, so convenience matters. For many picking up their pet's medication at the store and pharmacy where they shop will be a significant benefit.

Purchasing product on the Internet, while it used to be the exception, has become essential to many. So, while a couple of decades ago, buying pet medications only from your vet may have been the only practical choice, the world is much different today.

The federal government is already involved in this marketplace – it bars pet owners from buying most medications without a prescription. I hope the government will add the consumer protections necessary to make government's role in pet medications fair and encouraging of competition. The solution provided by the Fairness to Pet Owners Act will allow this marketplace to operate like those for other prescription items – whether that is prescription drugs, eye glasses or contact lenses.

Doing so will allow consumers to reap the full benefits of technological advancements and have the freedom to purchase their pet's medications where they want -- based on the price, service and convenience which suits them best.

Thank you for considering our views. I would be pleased to respond to any questions you may have.

Mr. Burgess. The Chair thanks the gentleman.

The Chair recognizes Dr. De Jong. Five minutes for your statement, please.

### STATEMENT OF JOHN DE JONG

Dr. DE JONG. Thank you, Mr. Chairman.

Good morning, Mr. Chairman, and members of the committee. My name is Dr. John de Jong. I am the chair of the board of directors of the American Veterinary Medical Association and I am a

companion animal practitioner in Massachusetts.

The American Veterinary Medical Association represents more than 88,000 member veterinarians worldwide engaged in a wide variety of professional activities and dedicated to the art and science of veterinary medicine. Every day, my staff and I strive to serve the best interests of both our animal patients and their human owners. Whether it is a routine visit to the veterinarian or an emergency, we all want our pets to receive the very best veterinary care.

Veterinarians understand that their clients must make financial decisions when planning and paying for services and medications, which is exactly why we support policies that give our clients the flexibility to choose where they fill their prescriptions. However, the Fairness to Pet Owners Act will require veterinarians to provide a written copy of every prescription for a companion animal, whether or not the client needs or even wants it. This is unnecessary and will place undue regulatory and administrative burdens on veterinarians and small businesses.

Though not required by Federal law, the AVMA's Principle of Veterinary Medical Ethics and its policy on client requests for prescriptions call on veterinarians to write a prescription in lieu of dispensing a medication when desired by a client, and a majority of States have similar laws or policies.

In some cases, veterinary medications are only available through a veterinarian, negating the need for a written prescription. In other situations, the client might choose to have the medication dispensed by their veterinarian for a variety of reasons, including convenience and timeliness. But if this bill were to pass, veterinarians would still be required to provide the written prescription to these clients, take the piece of paper back, and then dispense the medication. This creates an administrative burden for veterinarians, who should be spending their time and resources taking care of their animal patients.

Although some of the bill's advocates claim that veterinarians are only interested in profiting from filling prescriptions in house, that is not the case. A report issued by Federal Trade Commission staff in 2015 did not find evidence of veterinarians withholding written prescriptions from their clients. Until we have real evidence showing that a problem actually exists, it is premature to consider such a sweeping Federal mandate.

Thirty-six States have laws, regulations, or policies that require veterinarians to provide their clients with a written prescription upon request. If clients feel these requirements are not met, they can file a complaint for unprofessional conduct with any State's veterinary licensing board. And even in States that have not adopted formal laws or regulations in this area, State boards of veterinary medicine could find that a failure to honor a client's request for a prescription constitutes unconditional conduct, leading to dis-

cipline against a veterinarian.

In addition to the threat of discipline, veterinarians have other incentives to honor client's requests for prescriptions. A veterinarian who denies such a request risks alienating clients and harming his or her practice. In cases where the patient's condition may worsen quickly without medication and the client wishes to fill the prescription at a pharmacy, denial of a written prescription may place the veterinarian at legal risk.

The FTC report concluded that more study is needed on whether competition in the pet medication industry is affected by consumer knowledge of and access to portable prescriptions. There is no evidence that consumers in States without a requirement are adversely affected as to price or quality of pet medication services. In addition, the consumer outcry that would demand such a dramatic

remedy simply does not exist.

If pharmacies believe consumers are unaware of the option to obtain products from them, then they are free to market and adver-

tise their services, much like they do for other products.

We understand the financial burdens facing many of our clients, and we all want what is best for a pet's well-being, but we do not believe that this legislation would advance those goals. We are honored by the ongoing confidence and trust of pet owners, and we look forward to maintaining that trust. Thank you.

[The statement of Dr. De Jong follows:]

# U.S. House of Representatives

Committee on Energy and Commerce

Subcommittee on Commerce, Manufacturing, and Trade

# Hearing

"The Pet Medication Industry: Issues and Perspectives"

April 29, 2016

Testimony of

John de Jong, DVM

On Behalf of the

American Veterinary Medical Association

#### Main Points:

- Veterinarians understand that their clients must make financial decisions when planning and
  paying for services and medications, which is exactly why we support policies that give our
  clients the flexibility to choose where they fill their prescriptions. However, the "Fairness to
  Pet Owners Act" will require veterinarians to provide a written copy of every prescription
  for a companion animal, whether or not the client needs or even wants it. This is
  unnecessary and will place undue regulatory and administrative burdens on veterinarians and
  small businesses.
- Though not required by federal law, the AVMA's Principles of Veterinary Medical Ethics and its policy on Client Requests for Prescriptions call on veterinarians to write a prescription in lieu of dispensing a medication when desired by a client, and a majority of states have similar laws or policies.
- In some cases, veterinary medications are only available through a veterinarian, negating the need for a written prescription. In other situations, the client might choose to have the medication dispensed by their veterinarian for a variety of reasons, including convenience and timeliness. But if this bill were to pass, veterinarians would still be required to provide the written prescription to these clients, take the piece of paper back, and then dispense the medication. This creates an administrative burden for veterinarians who should be spending their time and resources taking care of their animal patients.
- Although some of the bill's advocates claim that veterinarians are only interested in profiting
  from filling prescriptions in-house, that is not the case. A report issued by Federal Trade
  Commission staff in 2015 did not find evidence of veterinarians withholding written
  prescriptions from their clients. Until we have real evidence showing that a problem actually
  exists, it is premature to consider such a sweeping federal mandate.
- Thirty-six states have laws, regulations, or policies that require veterinarians to provide their clients with a written prescription upon request. If clients feel these requirements are not met, they can file a complaint for unprofessional conduct with any state's veterinary licensing board. And even in states that have not adopted formal laws or regulations in this area, state boards of veterinary medicine could find that failure to honor a client's request for a prescription constitutes unprofessional conduct, leading to discipline against a veterinarian.
- In addition to the threat of discipline, veterinarians have other incentives to honor clients'
  requests for prescriptions. A veterinarian who denies such a request risks alienating clients
  and harming his or her practice. In cases where the patient's condition may worsen quickly
  without medication and the client wishes to fill the prescription at a pharmacy, denial of a
  written prescription may place the veterinarian at legal risk.
- The FTC report concluded that more study is needed on whether competition in the pet
  medication industry is affected by consumer knowledge of and access to portable
  prescriptions. There is no evidence that consumers in states without a requirement are
  adversely affected as to price or quality of pet medication services. In addition, the consumer
  outcry that would demand such a dramatic remedy simply does not exist.
- If pharmacies believe consumers are unaware of the option to obtain products from them, then they are free to market and advertise their services, much like they do for other products.

## Testimony:

Thank you, Chairman Burgess, and distinguished members of the subcommittee. My name is Dr.

John de Jong, Chair of the Board of Directors for the American Veterinary Medical Association, and

I am a companion animal practitioner in Massachusetts.

The AVMA is one of the oldest and largest veterinary medical organizations in the world, with more than 88,000 member veterinarians worldwide engaged in a wide variety of professional activities, and dedicated to the art and science of veterinary medicine.

As an association, the AVMA is dedicated to protecting, promoting and advancing the veterinary profession and the veterinarians whose duty it is to serve both animals and people.

The AVMA is opposed to federally mandated prescription writing for veterinarians and believes such an act is unwarranted. Veterinarians are already writing prescriptions for clients, and this practice is supported by a majority of state laws and the Principles of Veterinary Medical Ethics of the AVMA. These ethical principles call on veterinarians to honor client requests for written prescriptions when the decision is made to treat a patient with a particular prescription drug.

The AVMA fervently supports a client's right to have their prescription filled by the veterinarian's office or a licensed pharmacy. But our utmost concern is the well-being of our patients.

The AVMA is taking several steps to promote optimal outcomes for consumers who choose to obtain prescription drugs for their pets from independent pharmacies.

We are collaborating with pharmacy stakeholders to help ensure that licensed pharmacists understand their roles and responsibilities for counseling and educating clients when filling a veterinary prescription, including verification with the prescribing veterinarian should the pharmacist have any questions about the medication or dosage.

We educate veterinarians through various communication channels about prescription drug rules and the importance of following the AVMA's Principles of Veterinary Medical Ethics and state rules. And we are interacting with pharmacy stakeholders to determine how best to train licensed pharmacists in basic veterinary pharmacology so that the prescriptions provided to those pharmacists are filled as intended.

Animal drugs are under the jurisdiction of the U.S. Food and Drug Administration and are defined under the Federal Food, Drug, and Cosmetic Act as being substances "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."

Veterinarians generally obtain their inventory of medications directly from manufacturers and distributors.

Historically, veterinary prescription products were only available through a veterinarian and were almost exclusively filled on-site, thus providing a written copy of a prescription was unnecessary. While some veterinary products remain available only at a veterinary clinic, there are now many brick and mortar and online pharmacies that carry veterinary prescription products.

Additionally the Animal Medicinal Drug Use Clarification Act of 1994 allows veterinarians to prescribe certain FDA-approved human drugs for use in animal patients. The AVMA was

instrumental in advocating for passage of this critical piece of legislation, and today veterinarians readily write prescriptions for these products to be dispensed, often exclusively from a pharmacy.

When a veterinarian has determined that a patient needs a prescription drug, the drug can be dispensed in several ways:

- · directly from the clinic inventory
- · from the clinic's online store, where inventory is supplied by a third-party distributor
- by providing a written prescription to the client
- by prescribing via telephone or electronically to a pharmacy
- or by signing a faxed prescription from a pharmacy upon request, as allowable under individual state veterinary medical and pharmacy rules.

Assuming that pharmacies acquire FDA-approved drug products through legal channels and store and ship them in the appropriate manner per manufacturer guidelines and state pharmacy rules, there should not be a concern with product safety or quality.

That said, wide availability of drugs through various retailers appears to be associated with quality concerns in some situations. In the online article *Purchasing pet drugs online: buyer beware*, the FDA reports, "Some of the Internet sites that sell pet drugs represent legitimate, reputable pharmacies..., but others are fronts for unscrupulous businesses operating against the law. The FDA has found companies that sell unapproved pet drugs and counterfeit pet products, make fraudulent claims, dispense prescription drugs without requiring a prescription, and sell expired drugs."<sup>3</sup>

As I'm sure you can understand, these types of FDA warnings create a tremendous level of concern among veterinarians for the health, safety and welfare of our patients.

The AVMA has observed foreign prescription drugs available on nonpharmacy retail websites. For example, the AVMA submitted a letter<sup>4</sup> to eBay in response to our observation of foreign-source heartworm preventive drugs made available for purchase by the public without a prescription. This would create an animal health concern if, for example, the drug were stored inappropriately or used in a heartworm-positive dog.

The availability of animal drug products from various retailers creates risks and benefits for both veterinarians and pet owners. Given that not all veterinarians, particularly mobile practitioners, are able to stock or choose to stock every prescription product they might prescribe for their patients, there is a benefit to pharmacies carrying certain prescription products.

For these situations, pet owners will have to have their prescriptions filled elsewhere, requiring an additional step in obtaining the medication. Of course, treatment with medications dispensed directly from a veterinary clinic can be started promptly and there are no anticipated concerns associated with the quality of the drug product.

On the other hand, if a prescription drug is not obtained from a pharmacy immediately or at all, or if it is later realized that the pharmacy does not stock the needed medication, then treatment may be delayed to the detriment of the animal's health.

In addition, we understand that pharmacists are not required to have training in animal pharmacology. Whereas veterinarians have been educated to recognize unique pharmacological needs across species, including the idiosyncrasies of different animal species – take, for example, feline sensitivity to acetaminophen and rabbits' sensitivity to certain antimicrobials – pharmacists might not have this awareness.

As a matter of fact, we have learned that this lack of awareness has resulted in incorrect counseling, wrong dosages, or unauthorized drug substitutions, which could harm animal patients and create the need for additional treatment that would have been unnecessary had the correct medication or information been provided initially.

Other factors should also be considered when analyzing the competition and consumer protection issues related to the distribution of pet medications.

State authorities need to enforce rules with regard to prescription drug sales. Almost all states require a valid veterinarian-client-patient relationship (VCPR) for a veterinarian to prescribe or dispense medications for their patients.<sup>5</sup> This ensures that the veterinarian is familiar with the patient's condition and history and can make the proper diagnosis and decide on treatment, including prescribing veterinary drugs in appropriate circumstances.

However, based on information the AVMA and state veterinary medical associations have received from members over the years, pharmacists have allegedly dispensed prescription products without the veterinarian of record's knowledge. The decision for use of a prescription drug in an animal should be made by the veterinarian—not a pharmacist—within the confines of a VCPR.

Thirty-six states<sup>6</sup> have specific laws, agency regulations, or policy statements that require veterinarians to provide their clients with a written prescription upon request. California and Arizona laws additionally require a prescriber to 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.

In these states, consumers may file a complaint for unprofessional conduct with the state's veterinary licensing and disciplinary board. In some states, state veterinary medical associations offer consumers the opportunity to file complaints with ethics or grievance committees. In addition, some states provide consumers a private cause of action for violation of a statutory right. Consumers also may attempt to get assistance from their state's attorney general in enforcing the state's laws.

And even in states that have not adopted formal laws or regulations in this area, state boards of veterinary medicine could find in acting on a complaint that failure to honor a client's request for a prescription constitutes unprofessional conduct, leading to discipline against a veterinarian.

Unprofessional conduct refers to a departure from or failure to conform to the standards of acceptable and prevailing practice of veterinary medicine.

At the same time, all veterinarians who are AVMA members are expected to follow the AVMA Principles of Veterinary Medical Ethics, which state that veterinarians shall honor a client's request for a prescription in lieu of dispensing (Section VII-f-iii).

In addition to the threat of discipline against their licenses, veterinarians have other incentives to honor clients' requests for prescriptions. A veterinarian who denies such a request risks alienating clients and harming his or her practice. In cases where the patient's condition may worsen quickly without medication and the client wishes to purchase the medication at a pharmacy, denial of a written prescription may place the veterinarian at legal risk.

At the heart of the matter – and this is what resides in the heart of each veterinarian – is the health and well-being of our pets.

Whether it's a routine visit to the veterinarian or in the event of an emergency, we all want our pets to receive the best veterinary care. Veterinarians understand that their clients must make financial decisions when planning and paying for services and medications, which is exactly why we support policies that give our clients the flexibility to choose where they fill their prescriptions.

However, the "Fairness to Pet Owners Act" will require veterinarians to provide a written copy of every prescription for a companion animal, whether or not the client needs or even wants it. This will place undue regulatory and administrative burdens on veterinarians and small businesses.

As previously stated, this bill is unnecessary because clients already have the ability to fill a prescription at a pharmacy of their choice. Though not required by federal law, the AVMA's Principles of Veterinary Medical Ethics and its guide on Client Requests for Prescriptions<sup>7</sup> encourage veterinarians to write a prescription in lieu of dispensing a medication when asked by a client, and a majority of states have similar laws or policies.

In some cases, veterinary medications are only available through a veterinarian, negating the need for a written prescription. In many situations, the client wants and prefers to have the medication dispensed by their veterinarian.

But if this bill were to pass, veterinarians would still be required to provide the written prescription, take the piece of paper back, and then dispense the medication. This seems illogical to me, would create confusion among clients and takes time away from our ability as a veterinary team to focus on our patients, and not on paperwork.

Although some of the bill's advocates claim that veterinarians are only interested in profiting from filling prescriptions in-house, that is not the case.

A report issued by Federal Trade Commission (FTC) staff in 2015 did not find evidence of veterinarians withholding written prescriptions from their clients and determined more information would be needed to understand the impact on consumers. Until we have real evidence and data showing that a problem actually exists, it seems premature to consider such a sweeping federal mandate.

The Fairness to Pet Owners Act would usurp the many laws and regulations that states have enacted to address the various aspects of veterinary prescribing and dispensing.

The FTC report concluded that more study is needed on whether competition in the pet medication industry is affected by consumer knowledge of and access to portable prescriptions.

The burden of showing that a federal intervention is required falls on the proponents of the bill. To date, they have not met this burden. In fact, they have produced no evidence that consumers in states without an affirmative law are adversely affected as to price or quality of pet medication services. In addition, the consumer outcry that would demand such a dramatic remedy simply does not exist.

The number of visits to veterinary clinics has declined in recent years. We understand the financial burdens facing many of our clients. We all want what is best for a pet's health and well-being and for our clients, but we do not believe that this legislation would advance those goals.

Thank you very much.

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Mr. Burgess. The Chair thanks the gentleman.

The Chair would first recognize Mr. Mullin from Oklahoma. Five minutes for questions, please.

Mr. MULLIN. Thank you, Mr. Chairman.

And if I come across, you know, I guess badgering, it is not badgering, it is passion and frustration. Because badgering, to me, seems like someone that is trying to pick a fight. I am not someone to pick a fight, but I do have frustration when we have something that is claiming to be needed and it is not needed, but yet the vets themselves and the associations are saying they don't like it, but yet the other side is saying there is a need for it.

And then, Mr. Smith, as you and I spoke in my office yesterday, the day before yesterday, we had, you know, a cordial conversation, and we agree to disagree on the issues. But I have some concerns about one thing that you said a while ago. You said that the system doesn't work, because if it did work, essentially there would be more prescriptions being bought online or from pharmacies? Am I summing up your opening statement and what you said there?

Mr. SMITH. As a part of the consortium of organizations that support this bill, we work with a lot of the leading pharmacies in the country, and we also have online pet pharmacies that are part of it. And every day, they experience thousands of people who weren't able—

Mr. MULLIN. But you said it wasn't working because there wasn't enough prescriptions being bought online and through pharmacies. Is that fair to sum up what your statement said?

Mr. Smith. As a result of people not being able to get their pre-

scriptions and having the intent or the-

Mr. MULLIN. But you are basing that on what, on what data? You are basing that on the fact because there is not enough people buying it, or maybe that is because there is not a problem with it?

Mr. SMITH. I am basing it on the experience of the members of our consortium, who—

Mr. MULLIN. Which are who?

Mr. Smith. Which are the National Community Pharmacists—

Mr. Mullin. But these aren't the vets and these aren't the patients?

Mr. SMITH. These are the licensed pharmacies that have the ability to dispense——

Mr. MULLIN. But they are not the vets and the patients.

Mr. SMITH [continuing]. If someone shows up with a prescription, which—

Mr. Mullin. But, Mr. Smith, I am saying that you are basing your opinion not on the vets or the patients, the consumers. Are they the one asking for it, or is it your clients?

Mr. SMITH. Every day, thousands of pet owners show up to licensed pharmacists—

Mr. Mullin. No. I am asking—

Mr. SMITH. And we are basing it on that, like, the actual experience.

Mr. Mullin. OK. But are they asking for it?

Mr. SMITH. Yes, they are—

Mr. Mullin. Who?

Mr. Smith [continuing]. Asking for it.

Mr. Mullin. Who is asking for it?

Mr. Smith. Pet owners who come into every Walgreens, Walmart. Petcarerx.com.

Mr. MULLIN. They are coming in there because they already have

a prescription, don't they?

Mr. SMITH. No, no. Ten percent of people who show up to petcarerx.com, for instance, have a prescription, despite wanting to buy it because of lower prices.

Mr. Mullin. So did they ask—had they asked their vet for one?

Mr. Smith. Yes. And in many cases—

Mr. Mullin. They had? Because the doctor that just testified said that there is already a system in place, and the letter I submitted earlier for the record specifically stated to two regulations that requires them to do that even outside the States that don't have it. So I don't think you are actually getting the correct information.

Also, I want to get to it before I run out of time. You also mentioned that this doesn't go to large animals, it specifically goes to companion pets. Is that what you told me in my office?

Mr. Smith. Yes.

Mr. Mullin. And yet we had this conversation that, what is considered a companion pet, because pigs are considered a companion pet now. So wouldn't that open the door to large animals? I mean, Shetlands are considered a companion pet now, and lot of people consider those horses. Wouldn't that open the door to large animals too?

Mr. SMITH. As we discussed in your office, our intent—the \$7 billion being spent on pet medications is largely for dogs and cats—

Mr. MULLIN. But what my point was, is that this intent opens the door to larger regulations, it goes into unintended consequences. Once you go down this road, how do you stop it? How do you put it back in a box?

And I am really concerned that we are going after an issue that you are in favor of that isn't needed. It is just undue regulation on

an industry, as I stated earlier, that is already hurting.

I mean, I haven't had anybody to actually give me the numbers of what is causing this support for this to go through, other than assumptions, and that is simply what I am hearing from you too. While I support your position to be able to have an opinion, I do think you are on the wrong side on this.

I yield back, Mr. Chairman.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentlelady from Illinois, Ms. Schakowsky. Five minutes for questions, please.

Ms. Schakowsky. Thank you.

So as we have heard, exclusivity agreements between manufacturers and distributors force some retailers to acquire medications they sell through secondary distributors. As much as 25 percent of all pet medication being sold in the United States may have been acquired through secondary distributors.

Mr. Smith, is this figure consistent with what you are seeing in your experience?

Mr. SMITH. Yes. We are a secondary distributor, so we supply all the leading human pharmacies the pet medications they have available, both Rx medications requiring a prescription and some

of the leading over-the-counter medications.

In terms of attempts to supply our generics, for instance, to veterinary clinics, the leading distributors for drugs going to veterinary clinics oftentimes have blocking agreements that won't allow our generic medications to go to the veterinarian so long as the brand from the pharmaceutical company is being offered through that distributor.

Ms. Schakowsky. So to obtain the medications they sell, secondary distributors have to buy products that are diverted from the traditional supply chain. In some cases, secondary distributors acquire medications by purchasing overstock from veterinarians. Is that correct?

Mr. SMITH. Yes, that is correct. We source in a couple of different ways. Sometimes, just as you mentioned, we will buy excess inventory from veterinarians, sometimes we buy straight from distributors, and at other times we have been able to source direct from manufacturers. Different drugs travel in different ways. We carry a wide range of medications, but we have a broad array of ways that we get the product to then sell on to human pharmacies.

Ms. Schakowsky. OK. So, Dr. De Jong, has the American Veterinary Medical Association surveyed veterinarians to find out how widespread the practice of reselling to secondary distributors is,

and if so, what was the result?

Dr. DE JONG. We have never surveyed our members as far as that specifically. We do find out from our veterinarians all over the country that they are strongly opposed to this legislation. But as far as what percentage of veterinarians are actually buying and selling to secondary distributors, I could not tell you that.

Ms. Schakowsky. So let's consider a branded flea and tick overthe-counter medication that is being sold at a big box store. The manufacturer has made the medication, sold it to a distributor, who sold it to a veterinarian, who sold it to a secondary distributor, who sold it to an alternative retailer, who then sells it to a consumer.

So, Mr. Smith, it is not uncommon for pet medications to be sold three or four times within the distribution network before they are ever sold to an actual pet owner, correct?

Mr. SMITH. That is correct. The supply chain is longer. There are more players in it, more expense of moving things, additional profits being taken by each player. But despite that, on the example you mentioned, Frontline, Frontline Plus, generally speaking, those clubs will still, despite the additional costs, have a 20 percent lower price than the price offered—

Ms. Schakowsky. But isn't it fair to say that everybody in the supply chain is hoping to make a profit from these transactions, or at least to recoup their administrative costs? Isn't that right?

Mr. SMITH. For sure.

Ms. Schakowsky. And most of them aren't selling the product at a loss, right?

Mr. SMITH. No.

Ms. Schakowsky. So, therefore, it is possible that the price of these pet medications has been marked up multiple times long before they are sold to consumers, right?

Mr. SMITH. That is correct.

Ms. Schakowsky. So in your experience, how much does this affect the prices that pet owners end up paying out of pocket for pet medications? I heard you say that there still, at the end of the day, can be a lower price for consumers, but this does not seem to be an efficient supply chain, to me, in terms of best buy for the consumer.

Mr. SMITH. Prevailing prices, and we don't know exactly, but you would imagine prices could fall an additional 15 to 30 percent, based on the elimination of those extra steps in the supply chain.

Ms. Schakowsky. Thank you. And I yield back.

Mr. Burgess. The Chair thanks the gentlelady. The gentlelady

yields back.

And the Chair would like to exercise the chairman's prerogative and ask Mr. Schrader if he would like to go next in the questioning. And I will yield to you. Five minutes, sir.
Mr. Schrader. Thank you very much, Mr. Chairman. I appre-

ciate it.

Mr. Smith, where are you from?

Mr. SMITH. Utah.

Mr. SCHRADER. Utah. Do you know where the sponsor of the bill, pet fairness medication, is from?

Mr. SMITH. Yes, I do.

Mr. Schrader. And where is that?

Mr. SMITH. Utah.

Mr. Schrader. OK. OK. Could you tell me a little bit about how you distribute your two products that you manufacture? How do you distribute them? And what do you manufacture?

Mr. Smith. We manufacture generic versions of all patent medication. We also manufacture pet treats and pet wellness products, including a medicinal line for hip and joint, dental products. So we have a wide range of things that we manufacture and sell our-

selves. Mr. Schrader. You also manufacture, as I understand it, Carprofen and-

Mr. SMITH. We do.

Mr. Schrader [continuing]. Your version of ivermectin/pyrantel?

Mr. SMITH. We do. It is called TruProfen.

Mr. Schrader. Very good. Good commercial. That is fine. I am OK with that. Good businessman.

So it is my understanding you sell only direct to pharmacies, is that correct, for at least those last two medications?

Mr. Smith. Yes, we sell to human pharmacies.

Mr. Schrader. Just to pharmacies. Isn't that correct?

Mr. SMITH. We have attempted to sell through the leading distributors of all the medications to veterinary clinics, but because of the blocking agreements, we have been told that they are unable to carry substantially similar generics to the brands without losing their ability to distribute the brands.

Mr. Schrader. That certainly hasn't been my experience.

Dr. De Jong, do you want to comment on that, please?

Dr. DE JONG. Not necessarily.

Mr. Schrader. Yes. I mean, what we have seen here is that there are usually a lot of opportunities. Now, the fact that you are prescribing and distributing only to pharmacies as opposed to direct to the patients, direct to other distributors, the secondary market that Congresswoman Schakowsky talked about, why aren't you distributing direct to them?

Mr. SMITH. We are a 6-year-old business, so our initial start was dealing with the big pharmacies. Our whole infrastructure is set up to work in large quantities sufficient to meet the needs of the coun-

try's biggest pharmacies in the country.

Mr. Schrader. So what you have done is made a business choice to limit the distribution of your products to make money, and I get that. Doesn't this fly in the face of your argument a moment ago about increased competition and making sure it is available through all different outlets?

Mr. SMITH. As our company has grown, our intent actually is to expand to more direct to veterinary opportunities. We have started the process of trying to figure out a way to sufficiently distribute

broadly.

Mr. Schrader. But currently the bottom line is you restrict ac-

cess to your medications.

So to be honest with you, Mr. Chairman, I think that flies in the face of what we are talking about. I don't know too many businesses that are advocating for more Federal involvement, particularly in an area that is not a problem, I think it has been clearly stated.

Just a last comment if I may, Mr. Chair. I am very concerned about what we are trying to do with this type of approach to distribution of prescription medications and other things that, frankly, need some sort of doctor-patient, you know, relationship on an ongoing basis. It flies in the face of a lot of what we passed yesterday out of our full committee.

We are very concerned about overprescription, overuse of opioids. And here we are going down a track of trying to make these medications, many of which are very dangerous to our pet populations, more widely distributed, more subject to potential abuse. I think that, you know, based on what this committee has been working

on, this sort of flies in the exact opposite direction.

I would also argue, respectfully, that the administration has made it a point to be very concerned about the overuse of antimicrobials and other medications in livestock operations. And, again, you know, we are trying to pull it back from some of the over-the-counter use, not because we don't want the farmers or ranch communities to be successful; we are worried about, you know, inadvertent circumstances and problems without direct veterinary supervision.

So, Mr. Chairman, with all due respect, I think that this whole approach to the distribution and, frankly, the impugning of the veterinary community is exactly the opposite of where this committee has been going. And I hope that this is the first and last hearing

we have on this sort of bill, with all due respect.

I appreciate everyone's time. Thank you.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman for his forthright testimony.

And Dr. Schrader touched on something, Dr. De Jong, that I was going to ask, and I will anyway because it is now my time. And

I yield to myself 5 minutes for questions.

You know, a lot of parallels to the contact lens legislation from 2003 have been drawn. And one of the concerns that has come up now several years later is that a contact lens prescription is written and then it is refilled. Yes, the prescribing physician has an opportunity to interject some professional opinion when it is presented for a refill to the online contact lens dispenser, but there is also a fairly finite period of time in which the prescriber can reply, and if they don't, by default, it was approved.

So you get into these situations where the office was queried, but perhaps if it was the wrong time of day, the time frame was short, nobody responded, so I guess it is, "OK, here is your stuff, we will

ship it this afternoon."

Dr. Schrader brought up the question, or an observation with a medication like Prednisone. And Prednisone is something that you want to be thinking about. You just would never want to write an indefinite prescription for Prednisone to take forever, even though we recognize there are some conditions where a patient, in this case a pet or an animal, is going to require the medication over a long period of time, still there needs to be some real physician or veterinarian interaction and some questions asked.

So is that something which you are in general agreement about, that there would be a hazard just by these indefinite refillings of prescriptions if we followed the same pathway as the contact lens

legislation?

Dr. DE Jong. Absolutely. I think it is important that we have to monitor our patients on a regular basis if they are being given any medication that has side effects, and just about every medication out there potentially does have side effects. If you were to give an indefinite prescription without monitoring the patient, you could do real harm to the patient.

Mr. BURGESS. You know, and everybody else has talked about their pet today. I didn't as I started my opening statement. Now I am regretting that I didn't, because if my dog is watching, I am

sure he feels left out.

Ms. Schakowsky. Go for it.

Mr. Burgess. But February a year ago, our little dog Sammy, who at that time was 15 years old, developed signs and symptoms of congestive heart failure. And my wife took him to the vet and said, "Please, what can you do? We would miss our little friend." And he said, "Well, I can't do much, but I will give you some stuff, and we might get 1, 2, or 3 months out of it." Well, doggone it, that little dog is still going strong today. But every month, basically, my wife goes back to the vet to get the medications.

Sure, we could get them from an on—if I had had any idea he was going to live this long, maybe I would have. But I always thought it was a short-term venture, but it is also helpful, because there is an interaction that takes place of how's little Sammy doing, and is he looking good, you know, does he need to come in for a recheck? And several times, in fact, that recommendation has

been made and followed and a medication adjustment has been made, which you wouldn't have had the opportunity to do, while I guess you could have taken a picture with your iPhone and sent it in to the 1–800 number and gotten some advice back, but let's face it, we are not to that level of sophistication.

So I realize that is anecdotal, and the plural of anecdote is not data, and I get that, but at the same time, I think there is some value in the pet owner-veterinarian interaction that takes place, and I think that brings value to the transaction. I think that is something that I would be uncomfortable about just saying that it—I would discount that and that is not important. Sure, people should be able to make their own decisions.

Have you ever denied a patient or an animal owner a written

prescription if they asked you for one?

Dr. DE JONG. Never. And I can't think of any veterinarians or

colleagues that I know that have.

I can tell you that in my almost 31 years in practice next month, I have had plenty of clients ask, can you give me a written pre-scription, or can I call online and have it sent in? We get them in our office every day. But I have never, ever experienced a client say, is that an option?

I think the knowledge base of the consumer, of the general public is well aware. The amount of commercials for online pharmaceuticals are on every TV station in America, and the consumers today are educated. With the advent of the Internet and commer-

cial advertising, they know it is out there.

Mr. Burgess. I am sure there are Facebook ads. And I agree with Dr. Schrader. I think that is a positive thing that consumers do know that they have more choices.

I just have to make one other editorial comment. Many people have said today that, you know, we spend a lot of money on pet medications, true enough, we do, and should we not have the same

options for our pets that we do for our families?

I would just caution people to be careful what you wish for. I know my dog wouldn't want to go to an HMO. And the fact that my dog is taken care of by a veterinarian where it is a cash transaction, I recognize they may get a little bit better attention than I get when I go to my HMO. And there is nothing like a cash business. People ought to be careful what they wish for, because, after all, our pets are pretty darn important.

Is there anyone on the panel that wishes a followup or additional

or redirected question?

Seeing no additional members wishing to ask questions for this

panel, I do want to thank our witnesses for being here today.

Before we conclude, I would like to submit the following documents for the record by unanimous consent: a letter from the Animal Health Institute, a letter from Consumers Union, a letter from Oklahoma State University.

[The information appears at the conclusion of the hearing.]

Mr. Burgess. Pursuant to committee rules, I remind members that they have 10 business days to submit additional questions for the record, and ask the witnesses that they submit their responses within 10 business days upon receipt of those questions.

So without objection, the subcommittee is adjourned. And thank you all for being here.

Dr. DE JONG. Thank you.

[Whereupon, at 11:56 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

#### 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 horse 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.

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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 online 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

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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

# Animal Health Institute Statement Page 4

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.

### ConsumersUnion

POLICY & ACTION FROM CONSUMER REPORTS

April 28, 2016

The Honorable Michael Burgess, Chairman
The Honorable Janice Schakowsky, Ranking Member
Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Burgess and Ranking Member Schakowsky:

Consumers Union, the public policy and advocacy division of Consumer Reports, <sup>1</sup> appreciates the attention the Subcommittee is bringing to the issue of how consumers obtain prescription medications for their pets.

We are familiar with the workshop held by the staff of the Federal Trade Commission in 2012, and its continuing examination of the issue, leading to the report published last May. We believe this is an important consumer issue, warranting the Subcommittee's consideration.<sup>2</sup>

According to one estimate, Americans spend \$5.2 billion each year on prescription pet medications.<sup>3</sup> This is a significant household expense for consumers.

Unlike with prescription medications for family members, which are obtained from a retail pharmacy that typically has no affiliation with the prescribing doctor, prescription medications for pets are often obtained directly from the prescribing

<sup>&</sup>lt;sup>1</sup> Consumers Union is the public policy and advocacy division of Consumer Reports. Consumers Union is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. It conducts this work in the areas of telecommunications reform, health care reform, food and product safety, financial reform, and other areas. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit organization rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications.

<sup>2</sup> "Competition in the Pet Medications Industry: Prescription Portability and Distribution Practices,"

<sup>&</sup>lt;sup>2</sup> "Competition in the Pet Medications Industry: Prescription Portability and Distribution Practices," Federal Trade Commission Staff Report, May 2015,

https://www.ftc.gov/system/files/documents/reports/competition-pet-medications-industry-prescription-portability-distribution-practices/150526-pet-meds-report.pdf

George Puro, Packaged Facts: Pet Medication in the U.S. (4th Edition, October 2015), at 17.

veterinarian. As of 2012, roughly two-thirds of prescription pet medications were obtained in this way.<sup>4</sup>

We recognize that many consumers appreciate the convenience of having the option of obtaining the medications directly from the veterinarian. But when that is their *only* option – when their veterinarian refuses to give the consumer a copy of the prescription, or fails to make the consumer aware of the option to get a copy, or will only write it for a shorter period of time, or imposes other costs or restrictions on consumers who want to obtain their pet medications elsewhere, or when manufacturers refuse to market pet medications through alternative distribution channels – consumers lose the benefits of competition.

First and foremost, they lose the benefit of obtaining more affordable pricing. When consumers cannot comparison shop, veterinarians feel less competitive pressure to hold down costs on what is a major profit center for them.

But the effects of less competition go beyond the immediate effect felt by the veterinarian. A veterinarian who is protected from price competition has more incentive to develop cozy relationships with pet medication manufacturers, and to support manufacturer efforts to resist competitive market entry by lower-cost generic alternatives. This closed marketing chain also has the effect of dampening incentives for innovation of better, more effective medications.

These kinds of adverse effects are hallmarks of a marketplace where competition is not permitted to work.

But there is another characteristic of the pet medication/veterinary marketing chain that creates further risk to consumer satisfaction. The veterinarian is the professional gatekeeper for deciding which medication is appropriate in a given situation. If the veterinarian is also able to profit by selling the medication, that can create a conflict of interest. Manufacturers have an incentive to court veterinarians by offering them a higher suggested retail markup, and to offer additional bonuses to veterinarians who prescribe their medications to the exclusion of rival medications.

That risk inherently stems from having the provision of professional veterinary services tied to the sale of prescription medications. This tie is generally not present for physicians and the medications they prescribe for pet owners and their families. That separation between the prescriber and the seller is one of the safeguards in helping ensure physicians exercise independent medical judgment.

This same kind of tie, between prescribing and sale, was once prevalent in the prescribing and sale of contact lenses. As with many veterinarians now, many eye doctors sold the contact lenses right out of their offices, and many refused to give their

<sup>&</sup>lt;sup>4</sup> TheBark.com: "Making Pet Meds More Affordable," 2012, http://thebark.com/content/making-pet-meds-more-affordable. More recent estimates suggest the veterinarians' share of the overall prescription pet medications market may be slightly lower, in the range of 60 percent.

patients a copy of the prescription. Or they discouraged patients from taking it, by requiring them to sign a liability release before they could get it. Consumer complaints led to investigations in a number of states, and ultimately to enactment in Congress of the Fairness to Contact Lens Consumers Act of 2003. This legislation requires eye doctors to give their patients a copy of the contact lens prescription, at no charge, without the patient having to request it. This requirement is supplemented by an established expedited procedure for an outside retailer to verify the prescription and address any issues.

And this same kind of tie was once prevalent in the prescribing and sale of eyeglasses, and was addressed by the FTC in a rulemaking 40 years ago.

The Fairness to Pet Owners Act is modeled on the 2003 Act. It requires the veterinarian to give the pet owner a copy of the prescription – including electronically – whether or not requested, and at no extra charge.

At Consumers Union, our mission is to work for a fair, just, and safe marketplace for consumers, and to empower consumers to protect themselves. Safety is thus a cornerstone concern for our work, along with square dealing, and competitive alternative choices for consumers. And we do not see any reason why any of those goals should be compromised in the name of pursuing any of the others. All are critically important.

Veterinarians have a strong and legitimate interest – indeed, a professional responsibility – in overseeing the prescription medications given to the pets in their care, to ensure the safety of their animal patients. But that responsibility can be exercised without controlling who sells those prescriptions to the pet owners. Many veterinarians are accustomed to having the in-office dispensary as an additional means of monitoring. But physicians are able to do quite well in partnering with pharmacists, whether at "brick and mortar" stores or on-line – and with appropriate regulatory oversight – to ensure the safety of their human patients.

The FTC staff report documents a number of situations where veterinarians and manufacturers have successfully adjusted to a more open distribution system, bringing greater choice and lower prices to consumers without compromising pet safety.

Consumer Reports wrote about the benefits of shopping around for pet medications a few years ago. 5 Obviously, being able to shop around is dependent on having a copy of the prescription in hand.

This simple step – requiring that the consumer be given a copy of the prescription, to enable the consumer to choose where to purchase – has been of tremendous benefit to consumers in shopping for a variety of contact lenses and eyeglasses at the most affordable prices. Similarly, the separation of prescription writing and prescription filling

<sup>&</sup>lt;sup>5</sup> "Don't automatically get pet medicines from the vet," Consumer Reports, Aug. 2011, http://www.consumerreports.org/cro/magazine-archive/2011/august/money/pet-costs/dont-automatically-get-pet-medicines-from-the-vet/index.htm

for human medications has helped bring lower prices for consumers at the pharmacy or through the mail, while also giving them confidence in the independence of their doctor's recommendations.

We believe the benefits of consumer choice are likewise an important consideration for the prescribing and sale of pet medications. The FTC report notes that a number of states have already enacted laws to require veterinarians to offer pet owners this choice. And that in other instances, some veterinarians voluntarily take the initiative to offer it. We hope the Subcommittee will keep those benefits in mind as it considers the Fairness in Pet Medications Act.

We respectfully request that this letter be included in the official record of the hearing.

Sincerely,

George P. Slover Senior Policy Counsel Consumers Union



#### CENTER FOR VETERINARY HEALTH SCIENCES Healthy Animals - Healthy People

April 28, 2016

Congressman Markwayne Mullin 113 Longworth Washington DC 20515

Dear Sir:

College of Veterinary Medicine Office of the Dean 205 McEiroy Hall Stillwater, Oklahoma 74078-2005 Phone: (405) 744-8648 Fax: (405) 744-8633

I write to you today to provide input on the Commerce, Manufacturing, and Trade hearing titled "The Pet Medication Industry: Issues and Perspectives". I believe the intent of this hearing is to review the pet owning public's ability to shop around for their pet's medications. I strongly oppose requiring veterinarians to provide a prescription regardless of whether or not it is requested for the following reasons:

- Any client of a veterinary practitioner already has the right to have any medication prescribed in such a
  way as to allow the client to take the prescription and shop around for the best price if they choose to.
  - a. The Federal Trade Commission did not find evidence that veterinarians were withholding prescriptions from their clients. To do so would violate the AVMA Medical Ethics on Clients Request for Prescriptions. Also, this would be a violation of the Practice Act in many states including Oklahoma.
  - In addition, many medications prescribed for these pets are only available through a veterinarian.
- The implementation of this requirement would place an unnecessary burden on the veterinary practitioner by requiring all drugs prescribed to have written prescription which would add time and costs which could be at the expense of the pets care.
- 3. Having a prescription pad available during working hours, if veterinarians were required that all such prescriptions be written, could increase the risk of misuse by staff who might have access to the prescription pad during those working hours. Because it is unusual for this request to be made, prescription pads are often kept under lock and key along with controlled substances.

Therefore, the reason for which this requirement has been proposed is already in place. Also, requiring a prescription be written would add an unnecessary step to dispensing these medications to owners who most often would hand it back to the same clinic to be filled. This service is offered as a convenience to the clients. It is the opinion of the leadership within the Oklahoma State University, Center for Veterinary Health Sciences, that such a requirement would not resolve a problem as one does not exists. It also will create an undo documentation burden on veterinary practitioners. This opinion is in alignment with the Oklahoma Veterinary Medical Association and The American Veterinary Medical Association.

A better solution would be for the pet owning public to be better educated about existing practices that are available to them upon request.

Jean E. Sander

Dean, Center for Veterinary Health Sciences Oklahoma State University Stillwater, OK 74078 FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

# Congress of the United States

### House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115 Majority (202) 225-2927 Minority (202) 225-3641

May 17, 2016

Ms. Tara Koslov Deputy Director, Office of Policy Planning Federal Trade Commission 600 Pennsylvania Avenue, N.W. Washington, DC 20580

Dear Ms. Koslov,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Friday, April 29, 2016, to testify at the hearing entitled "The Pet Medication Industry: Issues and Perspectives."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, May 31, 2016. Your responses should be mailed to Giulia Giannangeli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to <a href="mailto:Giulia.Giannangeli@mail.house.gov.">Giulia.Giannangeli@mail.house.gov.</a>

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Michael C. Burgess, M.D. Chairman Subcommittee on Commerce, Manufacturing, and Trade

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade

Attachment

Questions for the Record for Tara Koslov
Hearing on "The Pet Medication Industry: Issues and Perspectives"
House Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing and Trade
April 29, 2016

#### The Honorable Michael C. Burgess, M.D.

 Ms. Koslov, please detail the number of complaints the FTC has received where a consumer asked for a prescription from their veterinarian and it was not given to them.

In preparation for the October 2012 public workshop, <sup>1</sup> FTC staff interviewed numerous industry stakeholders. We repeatedly heard that while many veterinarians provide portable prescriptions to their clients under at least some circumstances, some veterinarians refuse to provide portable prescriptions or are reluctant to do so. Several public comments received in conjunction with the workshop, as well as a few recent emails from consumers, noted difficulties in obtaining portable prescriptions.

Furthermore, since 2011, the FTC has received 37 non-public consumer complaints regarding veterinary prescription practices through our Consumer Sentinel website. Most of these complaints concerned veterinarians refusing to honor client requests for prescriptions, with many originating in states that require veterinarians to provide prescriptions upon request. Some of the complaints concerned veterinarians reluctantly providing prescriptions after being pressed by consumers, and charging fees for the prescriptions or making disparaging statements about online veterinary pharmacies. A few of the complaints concerned veterinarians requiring additional examinations or diagnostic tests as a condition for providing prescriptions, some of which may not have been necessary. For example, some veterinarians allegedly wanted to conduct multiple heartworm tests in an annual period as a condition for providing a portable prescription, even though best practices indicate that typically this test is only necessary once annually.

2. Ms. Koslov, are there other sources of complaints against veterinarians outside of the FTC's complaint system? If so, please detail those sources. Do you have any data from those sources about the number of instances, or complaints from individuals, where a client asked their veterinarian for a prescription and the request was denied?

<sup>&</sup>lt;sup>1</sup> Information about the workshop is available on the workshop's webpage. *Pet Medications Workshop*, FED. TRADE COMM'N (Oct. 2, 2012), <a href="http://www.fic.gov/news-events/events-calendar/2012/10/pet-medicationsworkshop">http://www.fic.gov/news-events/events-calendar/2012/10/pet-medicationsworkshop</a>. A transcript of the proceedings is also available. Transcript of Pet Medications Workshop, Fed. Trade Comm'n (Oct. 2, 2012), <a href="http://www.fic.gov/sites/default/files/documents/public\_events/pet-medicationsworkshop/pet-meditanscript-1.pdf">http://www.fic.gov/sites/default/files/documents/public\_events/pet-medicationsworkshop/pet-meditanscript-1.pdf</a>.

As stated in our 2015 report, FTC staff did not identify any comprehensive data sources that quantify the extent to which veterinarians provide portable prescriptions. We are aware that some state veterinary medical associations have surveyed veterinarians on this issue; our understanding is that survey responses indicate that some veterinarians refuse to provide prescriptions to clients when requested, even in states with laws, regulations, or policies requiring them to do so. As explained above, FTC staff also received anecdotal evidence in written public comments and emails, and reviewed other publicly available sources, indicating that some veterinarians refuse to provide prescriptions to clients when requested.<sup>3</sup>

Based on informal conversations with some state veterinary boards, it is FTC staff's understanding that boards receive few consumer complaints about this issue. The complaints they do receive are usually informal (e.g., a telephone call) and resolved on an informal basis (e.g., via a follow-up telephone call to a veterinarian, informing her that she should comply with the client's request), typically without official written documentation. Therefore, it is difficult to ascertain the actual number of complaints that these boards have received. Based on FTC staff's understanding of consumer behavior in this industry, we also believe it is unlikely that a significant number of consumers would know how, or expend the time and effort necessary, to file a formal written complaint with a state veterinary board.

3. Ms. Koslov, are there any provisions of law, or industry codes, which bar pharmaceutical manufacturers from providing physicians with payments, gifts, or other benefits as an inducement to prescribe their products? If so, please explain the impact of such restrictions.

FTC staff are unaware of any laws or regulations barring pharmaceutical manufacturers from providing veterinarians with payments, gifts, or other benefits as an inducement to prescribe their pet medication products. Although such practices have been banned in the human medications industry with respect to physicians, it is our understanding that these restrictions have not been extended to the pet medications industry and veterinarians.

Some observers have suggested that there is an inherent conflict of interest associated with veterinarians recommending and prescribing medications that they also sell, and that the conflict may be exacerbated when pharmaceutical companies offer financial incentives to veterinarians for recommending or dispensing their products. For example, economic self-interest could lead some veterinarians to be biased toward over-prescribing medications, or recommending more expensive categories of medications, in an effort to generate greater revenues. Many veterinarians, however, strongly deny that these financial incentives affect their decisions regarding the products they recommend or prescribe to their patients.<sup>4</sup>

<sup>&</sup>lt;sup>2</sup> FED, TRADE COMM'N STAFF REPORT, COMPETITION IN THE PET MEDICATIONS INDUSTRY: PRESCRIPTION PORTABILITY AND DISTRIBUTION PRACTICES (May 2015),

https://www.ftc.gov/system/files/documents/reports/competition-pet-medications-industry-prescription-portability-distribution-practices/150526-pet-meds-report.pdf [hereinafter "FTC Staff Report"].

<sup>&</sup>lt;sup>3</sup> See FTC Staff Report, supra note 2, at 38.

<sup>&</sup>lt;sup>4</sup> See FTC Staff Report, supra note 2, at 72-73.

Notably, the American Veterinary Medical Association (AVMA) Principles of Veterinary Medical Ethics advise veterinarians not to accept financial incentives from pharmaceutical companies. This guidance is generally only prescriptive unless states have adopted it via statute or regulation.

4. Ms. Koslov, in its 2015 report, the FTC discussed the practice of pet owners being required to sign a waiver of liability prior to receiving the copy of a prescription. Does the FTC have any data about the terms of these waivers? Are veterinarians liable for any damages which occur as a result of a pharmacy incorrectly filling a prescription or any other pharmacy performance failures?

Based on the workshop record and additional research, FTC staff believe such liability concerns are unfounded. Some veterinarians have expressed concerns about possible liability if a pharmacist dispenses an incorrect, counterfeit, or otherwise adulterated pet medication. FTC staff are unaware of any instances where a veterinarian has been held liable for a pharmacist's dispensing error. Some pharmacy boards have expressly indicated that pharmacists, not veterinarians, are responsible for any prescription misfills. As long as an animal is properly examined and diagnosed, and a prescription is written properly, it is unlikely that liability would attach to a veterinarian in the event a retail pharmacist incorrectly dispensed a medication.<sup>5</sup>

As stated in our 2015 report, FTC staff are aware that some veterinarians nevertheless require clients to sign a waiver of liability before providing them with a portable prescription, and would be concerned by proposals to prohibit the use of such waivers. FTC staff have collected some examples of liability waivers, and there are numerous examples available online. These waivers typically state that the prescribing veterinarian is released from any liability potentially stemming from the purchase and administration of medications from alternative retail sources, or from any complications that may arise from the use of these medications. Often, these waivers recite purported safety concerns associated with purchasing pet medications from retail sources other than the prescribing veterinarian, including risks of improper storage and handling procedures, questionable sourcing (*i.e.*, products not purchased directly from manufacturers, which allegedly might negate product guarantees), incorrect or mislabled products, and compromised product integrity (*e.g.*, products that are expired, counterfeit, or unapproved by the U.S. Food and Drug Administration).

<sup>&</sup>lt;sup>5</sup> See FTC Staff Report, supra note 2, at 62-64.

See, e.g., http://www.wsvh.net/wp-content/uploads/2014/02/prescription\_policy.pdf; http://aplusanimalhospital.com/doc/Internet-Pharmacy-Waiver.pdf; http://www.ublitesburganimalhospital.com/forms/pharmacy-waiver-form.pdf; http://www.alpinehospitalforanimals.com/files/2014/03/Online-Waiver.pdf; http://nmah.com/faqs/can-i-fill-my-pets-prescription-at-an-online-pharmacy.

#### The Honorable Susan Brooks

1. In regards to pet owners filing complaints claiming their veterinarian would not provide a prescription upon request (i.e. withholding the prescription), what specific practices by veterinarians have complaints been filed about? What specific types of complaints have been filed? How many complaints have been filed? Which state(s) do the complainant(s) live in? Do the state(s) in which complaints have been filed already have state-level legislation or regulation in regards to issuing pet medication prescriptions?

In preparation for the October 2012 public workshop, FTC staff interviewed numerous industry stakeholders. We repeatedly heard that while many veterinarians provide portable prescriptions to their clients under at least some circumstances, some veterinarians refuse to provide portable prescriptions or are reluctant to do so. Several public comments received in conjunction with the workshop, as well as a few recent emails from consumers, noted difficulties in obtaining portable prescriptions.

Specifically, the following types of concerns have been expressed about veterinarians: refusing to provide prescriptions to clients upon request; actively discouraging clients from requesting prescriptions and filling them them elsewhere; providing misleading information about non-veterinary retailers; requiring waivers of liability that exaggerate the purported dangers of purchasing from non-veterinary retailers; and requiring extra fees for portable prescriptions.

Furthermore, since 2011, the FTC has received 37 non-public consumer complaints regarding veterinary prescription practices through our Consumer Sentinel website. Most of these complaints concerned veterinarians refusing to honor client requests for prescriptions, with many originating in states that require veterinarians to provide prescriptions upon request. Some of the complaints concerned veterinarians reluctantly providing prescriptions after being pressed by consumers, and charging fees for the prescriptions or making disparaging statements about online veterinary pharmacies. A few of the complaints concerned veterinarians requiring additional examinations or diagnostic tests as a condition for providing prescriptions, some of which may not have been necessary. For example, some veterinarians allegedly wanted to conduct multiple heartworm tests in an annual period as a condition for providing a portable prescription, even though best practices indicate that typically this test is only necessary once annually.

As stated in our 2015 report, FTC staff did not identify any comprehensive data sources that quantify the extent to which veterinarians provide portable prescriptions. We are aware that some state veterinary medical associations have surveyed veterinarians on this issue; our understanding is that survey responses indicate that some veterinarians refuse to provide prescriptions to clients when requested, even in states with laws, regulations, or policies requiring them to do so. As explained above, FTC staff also received anecdotal evidence in written public comments and emails, and reviewed other publicly available sources, indicating that some veterinarians refuse to provide prescriptions to clients when requested.

In addition, FTC staff have been informed that retail pharmacies selling pet medications regularly receive denials from veterinary practices in response to prescription authorization requests. We have some examples of these denials on file.

Based on informal conversations with some state veterinary boards, it is FTC staff's understanding that boards receive few consumer complaints about this issue. The complaints they do receive are usually informal (e.g., a telephone call) and resolved on an informal basis (e.g., via a follow-up telephone call to a veterinarian, informing her that she should comply with the client's request), typically without official written documentation. Therefore, it is difficult to ascertain the actual number of complaints that these boards have received. Based on FTC staff's understanding of consumer behavior in this industry, we also believe it is unlikely that a significant number of consumers would know how, or expend the time and effort necessary, to file a formal written complaint with a state veterinary board.

FTC staff are unaware of any state-by-state comparison data that might demonstrate variation in the number of consumer complaints depending on state laws, regulations, or policies.

#### The Honorable Kurt Schrader

1. During the hearing, you referenced veterinarians generating 20% of their revenue coming from pet medication sales. Please provide your reference for such data.

In our 2015 report, FTC staff stated that veterinarians have long relied upon pet medication sales as a source of revenue, and that pet medication sales comprise approximately 20 percent of the total income for a typical primary care veterinary practice. Our sources for these statements include the FTC workshop transcript, public comments, publications by the American Animal Hospital Association and American Veterinary Medical Association, presentations by veterinary consultants, and interviews with veterinarians and other industry participants.<sup>7</sup>

2. During the hearing, you stated that the FTC had received a number of complaints about veterinarians failing to honor a request for the written prescription or not being aware that they could have a prescription filled outside of the veterinarian's office. How many complaints have you received, what are the nature of the complaints, and are these complaints from states with or without laws, policies, or regulations requiring veterinarians to honor a client's request? Additionally, how do complaints received from states compare – those from Arizona and California (which require veterinarians to notify clients of their option to fill the prescription elsewhere and then honor the request) versus those from states where veterinarians simply must honor a request versus those states with no laws, policies or regulations?

In preparation for the October 2012 public workshop, FTC staff interviewed numerous industry stakeholders. We repeatedly heard that while many veterinarians provide portable prescriptions to their clients under at least some circumstances, some veterinarians refuse to provide portable prescriptions or are reluctant to do so. Several public comments received in conjunction with the workshop, as well as a few recent emails from consumers, noted difficulties in obtaining portable prescriptions.

Specifically, the following types of concerns have been expressed about veterinarians: refusing to provide prescriptions to clients upon request; actively discouraging clients from requesting prescriptions and filling them them elsewhere; providing misleading information about non-veterinary retailers; requiring waivers of liability that exaggerate the purported dangers of purchasing from non-veterinary retailers; and requiring extra fees for portable prescriptions.

Furthermore, since 2011, the FTC has received 37 non-public consumer complaints regarding veterinary prescription practices through our Consumer Sentinel website. Most of these complaints concerned veterinarians refusing to honor client requests for prescriptions, with many originating in states that require veterinarians to provide prescriptions upon request. Some of the complaints concerned veterinarians reluctantly providing prescriptions after being pressed by consumers, and charging fees for the prescriptions or making disparaging statements about online veterinary pharmacies. A few of the complaints concerned veterinarians requiring additional examinations or diagnostic tests as a condition for providing prescriptions, some of

<sup>&</sup>lt;sup>7</sup> See FTC Staff Report, supra note 2, at 66, fn. 262 and 263.

which may not have been necessary. For example, some veterinarians allegedly wanted to conduct multiple heartworm tests in an annual period as a condition for providing a portable prescription, even though best practices indicate that typically this test is only necessary once annually.

As stated in our 2015 report, FTC staff did not identify any comprehensive data sources that quantify the extent to which veterinarians provide portable prescriptions. We are aware that some state veterinary medical associations have surveyed veterinarians on this issue; our understanding is that survey responses indicate that some veterinarians refuse to provide prescriptions to clients when requested, even in states with laws, regulations, or policies requiring them to do so. As explained above, FTC staff also received anecdotal evidence in written public comments and emails, and reviewed other publicly available sources, indicating that some veterinarians refuse to provide prescriptions to clients when requested.

In addition, FTC staff have been informed that retail pharmacies selling pet medications regularly receive denials from veterinary practices in response to prescription authorization requests. We have some examples of these denials on file.

Based on informal conversations with some state veterinary boards, it is FTC staff's understanding that boards receive few consumer complaints about this issue. The complaints they do receive are usually informal (e.g., a telephone call) and resolved on an informal basis (e.g., via a follow-up telephone call to a veterinarian, informing her that she should comply with the client's request), typically without official written documentation. Therefore, it is difficult to ascertain the actual number of complaints that these boards have received. Based on FTC staff's understanding of consumer behavior in this industry, we also believe it is unlikely that a significant number of consumers would know how, or expend the time and effort necessary, to file a formal written complaint with a state veterinary board.

FTC staff are unaware of any state-by-state comparison data that might demonstrate variation in the number of consumer complaints depending on state laws, regulations, or policies.

3. The FTC report acknowledges veterinarians face increased price competition from other retail distribution channels and have responded by lowering prices on some medications. Pet owners, the report says, have many more choices for purchasing pet medications than a decade ago. Pet Med Express claims to have 2.5 million customers with 50 percent of its business being prescription medications. So lots of people are using portable prescriptions and competition is increasing. Why does the government need to create a new mandate in this environment?

Many consumers of pet medications already appear to have benefitted from price competition between veterinarians and non-veterinary retail pharmacies, and many veterinarians already provide portable prescriptions to their clients under at least some circumstances. Nevertheless, greater prescription portability is likely to further enhance competition, with the potential to yield additional procompetitive benefits for consumers, including lower prices, improved service, more choices, and greater convenience.

As discussed extensively in the FTC staff report, it appears that some consumers do not always receive a portable pet medications prescription from their veterinarians, or are uncomfortable requesting one. Likewise, despite the marketing efforts of non-veterinary retailers, it appears that some consumers are not aware that they can request portable prescriptions and comparison-shop. Federal legislation requiring automatic prescription release may be an effective way to raise consumer awareness about this option and ensure that consumers actually receive portable prescriptions when they want them, especially in comparison to the current patchwork of state statutes, rules, and policy statements that require veterinarians to provide prescriptions only upon request, and the many states with no such requirements.

4. The FTC report says the traditional distribution model of pet owners purchasing medications directly from veterinarians has been challenged by the expansion of retail businesses, both on-line and brick-and-mortar. How could this expansion be taking place if owners are not aware of their opportunity to fill prescriptions outside of the veterinary office?

Many pet owners are aware of the option to fill prescriptions outside of the veterinary office, and many veterinarians provide portable prescriptions to clients in at least some circumstances. FTC staff believe this has resulted in greater competition between veterinarians and non-veterinary retailers, and that consumers have benefitted from this competition. It appears, however, that many pet owners remain unaware of this option, or may be uncomfortable requesting prescriptions from their veterinarians, which means the benefits of competition are not yet being fully realized. Therefore, FTC staff support policies that would enhance prescription portability and increase consumer awareness of non-veterinary retail options.

5. During the hearing you stated that FTC staff reviewed and considered 700 public comments the FTC received in response to the 2012 workshop that was conducted by the FTC. You stated that "complaints persist" that "not all requests [for a written prescription] are honored." Can you provide additional information on these complaints and the nature of the complaints and with whom they were filed? Also, how many of the 700 public comments indicated that requests for a written prescription were not being honored and how many of these were from states that already have state laws on the books requiring veterinarians to provide the written prescription?

Of the more than 700 public comments received in connection with the 2012 workshop, approximately 70 came from consumers and consumer advocate organizations and approximately 14 came from non-veterinary retailers and pharmacies that sell pet medications. Many of these comments included allegations that consumer requests for written prescriptions are not always honored by veterinarians, or that veterinarians try to discourage clients from requesting prescriptions by providing misleading information about non-veterinary retailers, requiring waivers of liability that exaggerate the dangers of purchasing from non-veterinary retailers, or requiring extra fees for portable prescriptions. Some of these comments originated in

<sup>&</sup>lt;sup>8</sup> The FTC held a public comment period from June 29 to November 1, 2012. All comments received are posted on the FTC website. *List of Public Comments Regarding Pet Medications*, FED. TRADE COMM'N, <a href="http://www.ftc.gov/policy/public-comments/initiative-433">http://www.ftc.gov/policy/public-comments/initiative-433</a>.

states that already have regulations, statutes, or policies requiring veterinarians to provide written prescriptions upon request.

In addition, we received over 580 comments from veterinarians and veterinary hospitals. A small portion of these included statements from veterinarians indicating that they refuse to provide clients with portable prescriptions or actively try to discourage clients from requesting prescriptions.

In addition to these written public comments, FTC staff heard anecdotally from numerous stakeholders that while most veterinarians are willing to provide portable prescriptions to clients upon request, some refuse to provide portable prescriptions or are reluctant to do so. Also, we are aware that some state veterinary medical associations have surveyed veterinarians on this issue; our understanding is that survey responses indicate that some veterinarians refuse to provide prescriptions to clients when requested, even in states with laws, regulations, or policies requiring them to do so.

Since the workshop, FTC staff have continued to receive anecdotal information from pet owners indicating that requests for prescriptions were not being honored by veterinarians. For example, we recently received emails from two different pet owners in Michigan whose veterinarians refused to provide prescriptions to Vet-VIPPS-accredited online veterinary pharmacies so the pet owners could purchase less expensive heartworm medications. Michigan does require veterinarians to honor a client's request for a portable prescription. We also received a phone call and emails from a pet owner in Washington whose veterinarian refused to provide a portable prescription upon request. Washington does not currently require veterinarians to release portable prescriptions to clients, but the Washington veterinary board has proposed to adopt a new rule that would require veterinarians to provide clients with a prescription upon request.

6. There have been documented incidences of pet harm from pharmacy mistakes in filling prescriptions, including such things as not recognizing different doses of insulin, thyroid medication, nonsteroidal anti-inflammatory medication, or confusing cc's with tablespoons. Are incidents like this expected to increase if more consumers obtain their pet medications from pharmacies? And have there been any developments since the 2012 workshop to improve training of pharmacists on animal pharmacology so that they reduce errors related to correct dosages, contraindications, side effects, and drug interactions for animal patients?

As discussed extensively in our report, we believe that the safety concerns expressed by veterinarians regarding pharmacists are exaggerated to some degree. FTC staff are unaware of any data indicating that pharmacists routinely alter pet medication prescriptions, and both the AVMA and state pharmacy boards encourage pharmacists to always contact the prescribing veterinarian if they have questions regarding pet medication prescriptions. Therefore, we do not expect that increased prescription portability would lead to more pharmacy mistakes. Even if this were to occur, inaccurate dispensing of pet medications would violate existing pharmacy laws, which means there is already a regulatory mechanism to address this hypothetical problem.<sup>9</sup>

<sup>&</sup>lt;sup>9</sup> See FTC Staff Report, supra note 2, at 52-59.

FTC staff are aware that in 2012-2013 some state veterinary medical associations attempted to collect information regarding alleged instances of pharmacist errors when dispensing pet medications. It does not appear that this information resulted in any substantiated claims or formal actions taken by state pharmacy boards. We are aware that the Oregon Board of Pharmacy subsequently received and investigated additional reports of pharmacist error, and that some have resulted in disciplinary fines being imposed, but most of these reported incidents were related to accidental changes rather than deliberate substitutions.<sup>10</sup>

Notably, some stakeholders have suggested that veterinarians may be just as likely to make prescribing and dispensing errors as medical doctors and pharmacists. The FDA Center for Veterinary Medicine has learned that errors may occur in veterinary clinics, pharmacies, and households when pet owners administer medications to their pets. The FDA has stated that it has not received specific adverse events reports involving intentional alteration of prescriptions by pharmacists without verification from prescribing veterinarians.<sup>11</sup>

With respect to the training of retail pharmacists in veterinary pharmacology, we note that many retail pharmacies that sell pet medications are owned and operated by veterinarians who have adequate training, particularly online pharmacies that are Vet-VIPPS certified. In addition, many retail pharmacies now offer additional pet medications training to their employees, and several pharmacy schools now offer courses in basic veterinary pharmacology. If consumer demand for purchasing pet medications from non-veterinary retail pharmacists were to increase, so might the level and extent of training in veterinary pharmacology.

7. Given legislation related to prescription writing mirrors that for contact lens prescribers, can you tell us how well the contact lens rule is working? Are you having to take enforcement action against prescribers for failing to provide the written prescription, and what does that action look like?

The Fairness to Contact Lens Consumers Act ("FCLCA") and the Contact Lens Rule ("Rule") have helped to promote competition in the contact lens industry by requiring eye care prescribers to (1) provide a copy of a consumer's prescription to the consumer after a contact lens fitting and (2) provide the prescription to, or verify it with, authorized contact lens sellers. The Commission currently is conducting its periodic review of the Rule. FTC staff are reviewing all comments and evidence submitted to evaluate how well the Rule is working and to determine if any modifications are warranted. In particular, staff are considering whether the Rule's automatic prescription release framework is operating as intended to promote competition or, conversely, whether consumers' lack of access to their prescriptions may frustrate their ability to comparison-shop and, ultimately, dampen sellers' incentives to compete on price and quality aspects of contact lens sales and service.

While we believe the FCLCA and Rule have been successful in promoting competition, the Commission remains vigilant against noncompliance. In April 2016, the Commission issued forty-five warning letters to contact lens prescribers that potentially violated the Rule and statute by failing to comply with automatic prescription release requirements, thus impeding consumers'

<sup>10</sup> See FTC Staff Report, supra note 2, at 55, fn. 218.

<sup>11</sup> See FTC Staff Report, supra note 2, at 31-32.

ability to shop in a competitive market. 12 These letters reminded prescribers of their obligations under the Rule and statute and warned them that violations of the Rule and statute may result in legal action, including civil penalties of up to \$16,000 per violation. Along with the letters, FTC staff also provided copies of the Rule, as well as guidance regarding obligations under the Rule. We will continue to monitor the marketplace and take action against violations of the Rule and statute, as appropriate.

8. You're likely aware of concerns by the FDA regarding medications obtained for pets. We're also aware of some safety issues related to contact lenses obtained online. Has the FTC taken any steps to educate consumers about safe sources of contact lenses and would similar action be taken regarding pet medications?

FTC staff are aware that the FDA has issued warnings to consumers about purchasing pet medications from unscrupulous online pharmacies that operate illegally. In consumer guidance documents, the FDA has specifically noted that reputable online pharmacies also sell pet medications. The FDA recommends that consumers purchase pet medications only from Vet-VIPPS accredited pharmacies, or from pharmacies recommended by veterinarians, to ensure product quality. 13 FTC staff agree with the FDA recommendation that consumers should purchase pet medications only from accredited pharmacies that operate legally. Vet-VIPPS accreditation appears to be an easy way for consumers to identify safe retail sources for pet medications, and the FTC has issued its own consumer guidance to this effect.<sup>14</sup> FTC staff will continue to monitor the marketplace to determine whether additional consumer guidance is warranted regarding safe sources of pet medications. As you note, FTC staff have relevant experience relating to contact lenses and other prescription products. FTC staff have issued numerous consumer guidance pieces about identifying safe sources for contact lenses, glasses, and other health products and services.11

9. We are aware of a number of states without laws, regulations or policies requiring that veterinarians honor a client's request for the written prescription. Have you seen consumers in these states adversely affected as to price and quality of pet medication services? Or for those states with a requirement, are you finding consumer complaints or veterinarians not in compliance?

<sup>12</sup> The Commission issued ten similar letters to contact lens retailers that potentially violated the Rule by dispensing contact lenses without a valid prescription. See FTC Press Release (Apr. 7, 2016), https://www.ftc.gov/newsevents/press-releases/2016/04/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule. The FTC also has taken enforcement actions against ten contact lens sellers. Our settlement orders have provided injunctive relief that, among other things, prohibits the defendants from selling contact lenses without obtaining a prescription from a consumer; from selling contact lenses without verifying prescriptions by communicating directly with the prescriber; and from failing to maintain records of prescriptions and verifications.

13 See FTC Staff Report, supra note 2, at 15-16, 59.

<sup>&</sup>lt;sup>14</sup> See Consumer Information Blog Post by Pablo Zylberglait (May 27, 2016),

https://www.consumer.ftc.gov/blog/your-best-bet-pet-meds. See Consumer Information Guidance (Apr. 2016),

https://www.consumer.ftc.gov/articles/0116-prescription-glasses-and-contact-lenses; Consumer Information Blog Post by Colleen Tressler (Apr. 7, 2016), https://www.consumer.ftc.gov/blog/buying-contacts-you-should-seeprescription-first; Consumer Information Guidance (Oct. 2011), https://www.consumer.ftc.gov/articles/0088buying-cosmetic-contact-lenses; Consumer Information Guidance (Sept. 2011),

https://www.consumer.ftc.gov/articles/0023-buying-health-products-and-services-online.

FTC staff are unaware of any state-by-state comparison data that might demonstrate variation in the number of consumer complaints depending on state laws, regulations, or policies. Similarly, FTC staff are unaware of empirical evidence regarding the degree of price variation among different retail distribution channels, or of data comparing the price and quality of pet medication services across states. As discussed in our report, however, FTC staff believe that greater prescription portability is likely to enhance competition, and that the procompetitive benefits to consumers may include lower prices, improved services, more choices, and greater convenience.

10. Have you investigated the bigger health threat to animals posed by online prescription retailers refilling a prescription outside of the veterinarians' recommendations causing preventable harm and pain not to mention death of a person's pet?

As discussed in our 2015 report, FTC staff carefully examined claims of health and safety concerns when pet medication prescriptions are filled by retailers other than the prescribing veterinarian. FTC staff are unaware of any data indicating that pharmacists, including online prescription retailers (many of which are owned and managed by veterinarians), routinely alter pet medication prescriptions or provide information contrary to the prescribing veterinarians' recommendations. If this were to occur, inaccurate dispensing of pet medications would violate existing pharmacy laws and could be addressed via available regulatory mechanisms.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

## Congress of the United States

### House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515–6115 Majority (202) 225–2927 Minority (202) 225–3641

May 17, 2016

Mr. Nathan Smith True Science Vice President 500 East Shore Drive; Suite 120 Eagle, ID 83616

Dear Mr. Smith,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Friday, April 29, 2016, to testify at the hearing entitled "The Pet Medication Industry: Issues and Perspectives."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, May 31, 2016. Your responses should be mailed to Giulia Giannangeli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to <a href="Giulia.Giannangeli@mail.house.gov">Giulia.Giannangeli@mail.house.gov</a>.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Michael C. Burgess, M.D. Chairman Subcommittee on Commerce,

Manufacturing, and Trade

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade

Attachment

Mr. Smith's replies to submitted questions for the record have been retained in committee files and also are available at <a href="http://docs.house.gov/meetings/IF/IF17/20160429/104877/HHRG-114-IF17-Wstate-SmithN-20160429-SD054.pdf">http://docs.house.gov/meetings/IF/IF17/20160429/104877/HHRG-114-IF17-Wstate-SmithN-20160429-SD054.pdf</a>.

FRED UPTON, MICHIGAN CHAIRMAN

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2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115 Majority (202) 225-2927 Minority (202) 225-3641

May 17, 2016

Dr. John H. de Jong Chair, Board of Directors American Veterinary Medical Association 1931 North Meacham Road; Suite 100 Schaumburg, IL 60173

Dear Dr. de Jong,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Friday, April 29, 2016, to testify at the hearing entitled "The Pet Medication Industry: Issues and Perspectives."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade

Subcommittee on Commerce,

Michael C. Burgess

Manufacturing, and Trade

Attachment



May 23, 2016

Representative Michael Burgess, M.D. Chairman, Subcommittee on Commerce, Manufacturing, and Trade Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, DC 20515

Dear Chairman Burgess,

Thank you for the opportunity to appear before the Subcommittee on Commerce, Manufacturing and Trade on Friday, April 29, 2016, and testify at the hearing entitled "The Pet Medication Industry: Issues and Perspectives." In response to an additional question submitted for the record, please find our reply below.

The Honorable Michael C. Burgess, M.D.

- During the hearing, the question was raised as to waivers of liability a veterinarian may require a client to sign before receiving a copy of the prescription.
  - a. Under the AVMA's Principles of Medical Ethics, may a veterinarian require a client to sign a waiver of liability prior to fulfilling that client's request for a copy of the prescription?

The AVMA's <u>Principles of Veterinary Medical Ethics</u> (PVME) do not speak specifically to waivers of liability. Section VII.f.iii. of the PVME states "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." We are also not aware of any state laws, regulations, or policies which allow or prohibit use of waivers. When we unofficially polled veterinarians following the first introduction of the Fairness to Pet Owners Act (2011), we heard from very few veterinarians who ask clients to sign a waiver and these were often for those seeking medications online.

b. What liability does a veterinarian have for medications incorrectly filled by a pharmacy or other alternative retailer?

It is our understanding that the prescribing veterinarian is not liable for errors made by the pharmacy or alternative retailer dispensing the medication as the negligent party carries the liability.

We welcome the opportunity to further discuss the pet medications industry and hope you will utilize the American Veterinary Medical Association as a resource. Please contact Ashley Morgan (amorgan@avma.org; 202-289-3210) with any additional questions or concerns.

Respectfully,

Mark T. Lutschaunig VMD MBA Director Governmental Relations Division

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