FEDERAL TRADE COMMISSION

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WORKSHOP

COMPETITION & CONSUMER PROTECTION ISSUES IN THE PET MEDICATIONS INDUSTRY

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FEDERAL TRADE COMMISSION

601 NEW JERSEY AVENUE, N.W.

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P R O C E E D I N G S

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MS. WILKINSON: Good morning. Welcome to the FTC's Workshop on Competition and Consumer Protection Issues in the Pet Medications Industry. My name is Stephanie Wilkinson and I am an attorney advisor in the FTC's Office of Policy Planning. Before we get started, I need to go over some administrative details.

First, please turn off or place in the silent mode any cell phones, Blackberries or other electronic devices.

Second, if you leave the building for any reason during the day, you will have to go back through security. So, please bear that in mind and plan ahead so that we can stay on schedule.

Third, please try to avoid having conversations in the hallway directly outside the auditorium while panels are in session. The background noise from the hallway carries over into this room and sometimes disrupts the discussions that we're having. Also, the microphones that we have set up are very sensitive. So, some of the conversations that happen in the hallway may be picked up by the court reporters or by the live webcast. So, fair warning on that.

Fourth, the restrooms are located out in the

lobby, behind the elevator banks. There are signs to indicate where they are, but if you go out to the security guard's desk, the restrooms are to your left.

Fifth, in the unlikely event that an emergency occurs and the building alarms go off, please proceed calmly to the main exit in the lobby, and assemble across the street on the sidewalk in front of the steps of Georgetown Law School. Hopefully it won't be raining too hard should that happen. At that point the security guards will let us know when it's safe to return to the building.

Lastly, I would like to remind all presenters and panelists to speak directly into the microphone so that everyone can clearly hear your remarks. If anyone has any questions throughout the day, please feel free to ask the people wearing the FTC staff badges or the people at the registration desk and we will be glad to help you.

We will be conducting moderated panel discussions today. If members of the audience would like to submit questions to the panelists, you will need to obtain a question card. These are located on the table in the hallway and you can pick one up during the breaks.

FTC staff will be live tweeting today's

workshop. Our Twitter handle is @FTC. You may tweet questions and comments to our Twitter handle @FTC with the hashtag #FTCpets. You may also submit questions and comments via the FTC's Facebook page at www.Facebook.com/FederalTradeCommission.

To open today's workshop, I would like to introduce FTC Chairman Jon Leibowitz. During his tenure at the FTC, Chairman Leibowitz has demonstrated leadership in examining complex competition and consumer protection issues in health care markets. Consistent with this interest, Chairman Leibowitz suggested that the Office of Policy Planning conduct research into the pet medications industry. He has been very supportive of our efforts to organize this workshop, and remains committed to protecting the American consumer, including their beloved pets.

Chairman Leibowitz?

CHAIRMAN LEIBOWITZ: Wow, I just want to say how appreciative we are that so many of you got here, despite the inclement weather and difficult traffic patterns this morning. So, thank you.

Welcome, everybody, to the FTC's Workshop on Competition and Consumer Protection Issues in the Market for Pet Medications. I have personally been looking forward to this workshop, because like the majority of

Americans, I own a pet. He is a shelter dog named Tank and he is truly a member of my family, of our family.

When Tank was a puppy, I once brought him here to work with me at the Commission and I thought it was a lot of fun. Now, Tank did, too, and he certainly enjoyed himself barking and running around my office and the adjacent corridors. Later, I learned that there was a deposition taking place just down the hall, and apparently the lawyers thought Tank's barking was annoying. Now, it seems to me that a puppy barking would be preferable to the barking of the objections of the lawyers at a deposition, but --

All right, I'm sorry, I know it's early in the morning, but that was a joke, you're going to have to laugh. Since then, by the way, I have pretty much left Tank at home. I wanted to bring him with me today, but instead I brought a picture of him to show you, and here he is. Is that cute or what? And you can see in the photo, he's in front of the flag, because he holds a position of some importance in the dog world. Anyway, there he is.

Once in a while, we have a consent decree here at the FTC regarding animal medications, for example, in Pfizer's acquisition of Wyeth in 2009. But on most days, it seems that pets and the FTC just don't mix.

Today, however, they do, of course, because we're going to talk about competition and consumer protection issues relating to the distribution of pet medicines, and pet medications.

Judging by the variety of pet products that are now available in any number of retail outlets, pets are very important to American consumers. For example, during a recent visit to a local Costco store, we were able to purchase this box of Frontline Plus for a very competitive price. How many of you know about Frontline Plus? Of course, because you have dogs and hopefully the Frontline Plus has taken care of the flea, flea egg larvae, tick or chewing lice. What is chewing lice? How many of you know what chewing lice is? Because I don't know that and I don't want to know it.

There's a huge convenience, of course, of being able to buy a product like this in the same cost-cutting retail outlet where so many Americans shop.

Among the questions we're going to ask today, are whether consumers benefit from being able to purchase pet medications at retail outlets. In particular, I think the Commission is interested in knowing whether competition from retail outlets results in lower prices for pet medications, as it does for so many other products that we buy. Unlike human medicine,

which is supported by both public and private insurance, and reimbursement, pet medicines are largely paid for by consumers out of their own pocket. So, today, we hope to examine some of the options that are available to consumers to help them manage the cost of pet care and discuss some proposals that have been made to give consumers more choices when buying pet medications.

Here's what we know: And I learned this, actually, as we were preparing for this workshop. Sixty-two percent of U.S. households own a pet, and our national pet population includes more than 78 million dogs and more than 86 million cats, and sometimes they, of course, even live in the same house. American consumers spend more than $50 billion a year on their pets, including nearly $7 billion a year for over-the-counter and prescription pet medications.

And here's something else we know: More and more, consumers are able to purchase pet medications from sources other than their veterinarians. Some pet medications are available over-the-counter without a prescription, and even for prescription medications, consumers may be able to obtain a written prescription from their vet that they can use to buy pet medicines in an online or brick-and-mortar retail pharmacy. But that information isn't always volunteered, by the way.

Still, an increasing array of options for consumers to purchase their pet medications has begun to lead, we believe, to lower prices and increase consumer choice, certainly in a few pet medicines. While this market may be becoming more competitive, it clearly has a way to go. We have heard that many pet medicine manufacturers choose to distribute their products only through veterinarians, so retailers can't purchase these products directly from the manufacturer. As a result, some retailers use secondary distributors.

Take, for example, our box of Frontline. Now, this was purchased, as I said, at a local Costco store. And we don't exactly know how Costco or other retailers acquire Frontline because we do know that the manufacturer publicly denies selling the product directly to non-veterinarians. We also know that this Frontline was priced about 20 percent or more below the prices of some local veterinarians.

Now, this may be so, for example, this three-month supply at Costco costs about $37.99. And the veterinary prices ranged, it was a small sample of five veterinarians, one veterinarian priced it at or below the Costco price, four priced it above, one priced it 20 percent above. So, the prices ranged up to $48.50 for I think that's for a three-month supply. At Costco,

again, $37.99 for a three-month supply.

So, again, this may be competition, or this mystery of gray market distribution may be leading to increased prices for consumers. I think it's a pure distribution system and we just want to learn more about it.

We have also heard that complex, cumbersome, and sometimes antiquated state and federal laws may be restricting competition in the pet medicine market. In fact, a major national retailer has told me that it wants to enter this market, and it would, but for the crazy-quilt patchwork with state licensing and regulatory requirements. Although many or even all of these regulations may have once had sensible health and safety justifications, some now may no longer be in the best interest of Americans and our pets.

Today, our panelists, and it is a terrific, terrific group of panelists, who include veterinarians, animal drug manufacturers, distributors, brick-and-mortar and online retail pharmacies, pharmacists, animal welfare advocates, academics, economists and lawyers, of course this is Washington, so we will have lawyers, will explore the costs and benefits of consumers getting a written prescription from their veterinarian that they can fill wherever they choose,

say at a grocery store pharmacy or an online veterinary pharmacy. We will also explore whether the consumers are able to verify that the products they buy at those retail outlets are the same medicines that they could buy from their veterinarian and whether there are any safety risks with purchasing these products from retail outlets.

We will also hear about restrictions on the distribution of some pet medications by manufacturers or by states, and how these business practices may limit their availability. And by having this dialogue, we hope to educate consumers, and we hope to educate ourselves about changes occurring in the marketplace, ones that may create new opportunities for consumers to obtain high quality, low-cost medical treatment for their pets.

So, let me thank our panelists for coming to Washington to share their experiences with us. I know some of you have come great distances, and let me also thank hundreds of industry participants and consumers who have submitted comments in advance to our workshop, that was really terrific.

For our audience here at the conference center and for those watching on our webcast, we hope you sit, stay, I'm not going to go too far into that, I am not going

to say don't bark at each other, but don't roll over either. I'm just going to say we hope you sit, stay, and enjoy the discussion.

We thank you all for coming here, we really do appreciate it. I am going to turn it over. Stephanie, are you coming up? Great, I'll give this to you.

MS. WILKINSON: Thank you, Chairman Leibowitz.

Many people have asked us why is the FTC interested in the pet medications industry, and why are we conducting this workshop? We have learned over the past many months that the market for pet medications is in flux. Industry stakeholders have noted that consumer demand for pet medications has grown dramatically over the past decade. Manufacturers have introduced many new products to the market.

During this time period, new distribution models have also emerged for pet medications, including online retail pharmacies, such as 1-800-PetMeds and Drs. Foster& Smith, as well as brick-and-mortar retail pharmacies, such as Target, Walgreens and several large grocery store chains. Generic products have also been introduced into the pet medications industry, although perhaps not to the same extent as what we've seen with human medications.

We are interested in exploring the competitive

impact that these changes have had on the market for pet medications, and what this means for consumers. To help us better understand these issues, we are pleased to bring together a broad spectrum of industry experts to serve as presenters and panelists for our workshop who will offer diverse and important perspectives.

We will begin this morning with two introductory presentations that should help set the stage for our panel discussions. During these presentations, we will learn about the veterinary profession, including the importance of the relationship that veterinarians have with pet owners and their pets, particularly within the context of diagnosing the condition of pets, prescribing medications and providing follow-up care. We will also learn about the various options that consumers have for purchasing pet medications, and about how the various distribution models for pet medications work.

During our first panel, we hope to explore two categories of distribution practices that appear to be used in the pet medications industry, the first being exclusive distribution by manufacturers through the veterinary channel, and the second being exclusive dealing arrangements between manufacturers and distributors. Ultimately, we are interested in understanding how both of these distribution practices

affect the choices that consumers have when purchasing pet medications, including the scope of products offered to consumers, where consumers are able to purchase products, and the prices that consumers have to pay. In addition, we are interested in understanding whether there are product safety and dispensing safety issues that consumers should be aware of when making decisions about where to purchase pet medications.

After lunch, there will be a second panel discussion regarding the ability of consumers to obtain written, portable prescriptions from their veterinarians. When a pet dog or cat needs medication that requires a prescription, the pet owner often buys that medicine from the veterinarian at the time of the exam. But consumers also purchase a substantial amount of pet medications from retail pharmacies, particularly long-term maintenance drugs such as heartworm preventatives and diabetes medications. In order to make these purchases, consumers must be able to obtain a written, portable prescription from their veterinarian. Some states require veterinarians to provide portable prescriptions, while other states leave this to the veterinarian's discretion.

Anecdotally, we have heard that many veterinarians give clients prescriptions upon request,

but we've also heard that some veterinarians refuse to provide prescriptions to clients even where state law requires that they do so. There is a bill pending in Congress, H.R. 1406, that is called the Fairness to Pet Owners Act which would require veterinarians in all states to give a written prescription, regardless of whether they request it. We are hoping to discuss the pros and cons of this legislative proposal during this second panel.

We have also heard that there may be safety issues with pharmacists that are untrained in veterinary pharmacology dispensing pet medications, such that veterinarians may be concerned about giving clients portable prescriptions if they believe there is a risk that retail pharmacies do not dispense the medications in a safe and appropriate manner. We are interested in better understanding all of these issues today.

Finally, there will be a third panel discussion about whether we can learn any lessons from the contact lens industry about the effects of restricted distribution practices and prescription portability on consumer markets. We intend to examine the similarities and differences between the contact lens and pet medications industries, and the degree to which the evolution of the contact lens industry provides a

reliable basis for predicting the potential consumer cost savings and non-price benefits that might result from eliminating vertical restrictions for the distribution of pet medications and empowering pet owners with prescription portability.

We are examining the vertical restraints on distribution and prescription portability issues that once characterized the contact lens industry. In 2003, Congress passed legislation to give consumers a federal right to written prescriptions for their contact lenses. Furthermore, vertical restraints on the distribution of contact lenses were eliminated during this time period through litigation efforts by several states attorneys general. As a result of these changes in the market, consumers today have many more choices for buying contact lenses. Some have suggested that requiring prescription portability and addressing restricted distribution practices for pet medications would potentially have similar benefits in terms of more consumer choices and more price competition.

To conclude, I would like to thank everyone for attending today's workshop, including those who are viewing the live webcast. In particular, I would also like to thank our distinguished presenters and panelists for their participation, as they have spent a

significant amount of time preparing for today's workshop.

We also appreciate all of the public comments that we have received so far, and to ensure that everyone has an opportunity to submit comments, we have extended the comment period to November 1st. We strongly encourage everyone to submit written statements if they have not already done so.

Now, I would like to introduce Dr. Douglas Aspros, who will be making the first presentation of the day. Dr. Aspros is the president of the American Veterinary Medical Association, and a companion animal practitioner.

Dr. Aspros?

(Applause.)

DR. ASPROS: If I had realized I could have brought pictures of my animals, I would have done that, but they didn't tell me that was an option.

I am Dr. Doug Aspros, I am the president of the American Veterinary Medical Association, and a companion and exotic animal practitioner in Westchester County, New York, part of the New York City metro area.

AVMA has been asked to set the stage for this discussion today at the workshop to present the ecosystem in which companion animals and their owners

find medical services, including the dispensing of animal drugs. As you shall see, this is a wide, divergent and fragmented system, on all sides, including the client, the patient and the providers.

A little bit about AVMA. AVMA has a little over 82,000 members, which comprises about 83 percent of all the veterinarians in the United States. About 61 percent of them practice on companion animals, that means that at least part of their practice is on companion animals. If you look at this pie chart, some of the companion animal practitioners are in what we call mixed practice, meaning that there are some livestock patients that are being cared for in the practice, as well as companion animals. Remember, these are self-reported numbers. The figures may not quite add up, nearly 25 percent of our members don't list a species affiliation, either because they don't practice clinical medicine, or because they don't like to fill out surveys.

About two-thirds of households in the U.S. owned one or more pets in 2011. Of those pet-only households, almost two-thirds own more than one pet. All of these data come from the AVMA's U.S. Pet and Demographic Survey Book from 2012. It is the largest scale survey of U.S. households conducted every five years and there's some data I'll present a little later on that

comes from the same studies.

These patients, these veterinarians, practice in approximately 25,000 different practices. We said earlier, there are about 50,000, roughly, small animal -- I'm going to switch back and forth between companion and small animal. Companion animals are for our purposes dogs, cats, birds, reptiles, ferrets, rabbits and rodents, but inside of AVMA, when we talk about companion animals, horses that don't work, pleasure horses, are considered companion animals, but for the purpose of today, I don't think we're talking about horses in any way.

These 50,000 veterinarians provide services in 25,000 or more practices, meaning that the average size practice has one veterinarian, since there are multiple practices with multiple veterinarians. These practices are quite diverse. They're diverse in the size of the practice, the number of veterinarians and staff. In the species that are catered to, we talked about how wide the companion animal practice could be, but there are practices that only do cats, there are practices that do just cats and dogs, there are practices that do only birds and exotic species.

These practices are in rural, suburban and urban settings, all of which provide different resources and

opportunities both for the practice and their clientele. Mobile clinics to multi-practice sites. So, veterinarians can be one person in a car or a truck, they can be large, large, large practices. Primary care to specialty care. Veterinarians, by and large, in companion animal practice provide general care, meaning that veterinarians do everything from taking care of happy and well puppies and kittens to major surgeries and, of course, at the end, perhaps to euthanasia.

Specialty care these days is on the rise. There are more and more specialty practices where veterinarians do just what they do, just ophthalmology, just surgery, and not provide general care. And, of course, routine care and emergency care. One of my practices does just after-hours, weekend and emergency care, no primary care at all. And then finally, private to corporate to not-for-profit to university practices.

So, these are the kinds of animals we're talking about, dogs and cats and birds, ferrets, rabbits, rodents and reptiles. The total veterinary visits, and these are every five years, again this is from the AVMA's U.S. Pet Demographic Surveys. The number of veterinary visits for dogs has been going up as dog ownership has as well. The number of cat visits, particularly over the past ten years, has not only peaked, but has been on the

way down, and there are a lot of reasons for that, some of which we don't understand. The total visits for birds has been on the decline, and bird ownership, actually, has been on the decline. This slide shows the mean veterinary visits per year. The average dog visits the veterinarian about one and a half times a year. The average cat doesn't get to the veterinarian every year. Birds get there when they actually have problems. And specialty, meaning all of the other kinds of exotic animals, even less than that, even fewer times than that.

So, we're talking about veterinarians and drugs. So, what do veterinarians know, how do veterinarians get educated to do the services, provide the services that we do? Veterinary education programs are accredited by the AVMA's Council on Education, which is a member of the Council for Higher Education Accreditation, under the authority of the USDE. Most or all college curricula include one or more veterinary pharmacology courses.

While pharmacy is not mentioned by name in the standards for accreditation, the basic and applied principles of pharmacology are covered throughout the four years of the curriculum, in both pre-clinical and, of course, in the clinical years of programs. Students receive a firm foundation in biology, biochemistry, pharmacology, medicine and therapeutics in a wide range

of species. At the end, in the licensing test, the North American Veterinary Licensing Exam covers material on therapeutics in dogs, cats, pigs, horses, cows, birds and exotic pet species.

Veterinarians operate in all jurisdictions under what's called the VCPR, the Veterinarian-Client-Patient-Relationship. The VCPR is a recognized obligation both in the AVMA's Principles of Veterinary Medical Ethics and in state and federal law. The VCPR requires sufficient knowledge of the patient and when we're talking about companion animals, in almost all cases, examination; the veterinarian advising the client; diagnosing and prescribing; the client's election to follow the veterinarian's advice; the veterinarian's obligation to keep written records, and to provide information and options for emergency care and follow-up.

To put this in context, in routine veterinary practice, about 17 percent of revenues -- now we're talking revenues, not bottom line -- in companion animal exclusive practices are Rx drugs, and another five percent are non-Rx drugs and pet products. And this varies to some extent by species. If you look at dogs, it's not that drugs have been over the past 25 years actually a decreasing source of practice revenues, as

physical exams, vaccines and laboratory tests and other diagnostics have become a more important part of veterinary practice. For cats, the same thing holds true. Cats have been vaccinated less often, if you look at the numbers over the past ten years. And so more of what veterinarians do are physical examinations and all of the services there attendant to diagnosing. And for birds, most of what we do is examinations, and when we look at grooming there, it's mostly nail trimming.

How do veterinarians get drugs? Well, they get them two ways: They either get them directly from the manufacturer or through a distributor. The manufacturers may have several distributors that they work with, but we'll go through that later. I think that a number of other presenters will talk about how that works.

Regulation and oversight of the veterinary practitioners, and Adrian Hochstadt will be talking further about this, but just to set the stage for it, licensure requirements for veterinary practices are set by the states. State licensing boards have the authority to suspend or revoke a veterinarian's license for unprofessional conduct or other infractions. The state veterinary medical boards, of course, enforce the

state practice acts, examine prospective licensees, set the requirements, define unprofessional conduct, investigate breaches and, of course, discipline violators.

If consumers have complaints, if clients have complaints, they have many avenues to have their complaints heard. They can take complaints of negligence or other unprofessional conduct to a wide variety of places, including the state licensing board, state veterinary medical associations, the state AGs, departments of consumer affairs, and even to local or state courts.

Veterinarians have, in all states, as part of veterinary practice, the authority to dispense drugs and pharmaceuticals for their patients. And, of course, veterinary prescribing and dispensing are also covered under regulations from FDA and DEA.

Finally, veterinary clinics are just one of many channels for pharmaceuticals sold in the U.S. to companion animals and their owners. Please keep in mind as we go through this day that veterinarians primarily dispense drugs and pharmaceuticals to ensure the health and welfare of their animal patients. We would be wise to remember this dictum as we go through the rest of today's presentations.

Thank you.

(Applause.)

MS. WILKINSON: Thank you, Dr. Aspros.

Our next presentation will be given by Dr. Paul Pion, president and co-founder of the Veterinary Information Network.

Dr. Pion?

DR. PION: Good morning.

So, I have been asked to give an overview of how medications get to consumers, and a look at how the market has evolved. So, the first question I asked was, why me? Probably the least likely person in this room to be giving this presentation. I'm guessing nobody else wanted to give it.

I've never worked in either drug manufacturing or distribution, and I'm actually a former academic and researcher, and currently the co-founder and president of Veterinary Information Network, which is a purely subscription-based information service. You can think of a mixture between Google and Facebook for veterinarians. And we actually accept no advertising and no sponsorship, purely supported by the membership fees of our colleagues.

My background really is and my passions are in medicine and information, the generation, quality and

delivery of that information.

So, VIN, as part of our services we offer our own news service, the VIN News Service, and we did some articles. The Chairman, who I thank for giving my talk before I gave it, alluded to the fact that there is diversion of drugs from the prescribed and official supply chains, and our news service did some investigative reporting into that gray market diversion, and I think that Stephanie and Elizabeth read those articles and contacted us and that's how we got here.

So, my disclosures for conflict of interest, I'm certainly pro-veterinary, pro-pet owner, pro-patient, pro-fairness and pro-informed choice. Most of the lecturing I do is on information, and I look at information as its own economy. It's got manufacturers, distributors and consumers on the wholesale and retail level, and to convert that to a slide for this talk, we just had to look at pet medications certainly have the same players and channels. These are the players that I consider play a part in the information economy of veterinary medicine, and if we look at pet medications, then we would add the drug retailers, both online and big box type.

When we're looking at any economy, we should be looking at in our situation the goals, what's the

currency we use, what are the ethics and what's at stake? And for information, I'm very much interested in what's the quantity of that information, what's causing us to generate more or less, and what's the quality of that information? And when we're talking about pet medications, I hope we also very much consider the safety issues. In any economy, it's simple -- we all learn it's simple supply and demand. And for pet medications, certainly we're here to talk about how that affects pricing.

I had to do some Googling to figure out the size of this market, and if I just look at individual, I've heard between $6 and $10 billion as an estimate of the market. I've heard the human market is up to about $250 billion. So, and if you look at this, looking at a couple of companies, and there's people in the room who can tell us these numbers certainly more accurately than I can. Just looking at Pfizer Animal Health, we're talking a couple of percent. This animal health part also includes livestock and all the other animals that don't include what we're talking about. So, I think we're down in the one to two percent of what the human market would be.

What products are we talking about? Well, for the most part, everybody here is interested about what

we would consider mega products. So, these are the flea and tick preventions, this is the heartworm preventions, and then there's everything else. And the mega products tend to be continual use. So, like any consumer product, people like to get into things that people are going to buy over and over again, whether they are sick or not, and if they're sick on an ongoing basis. They're dealing with things that are over-the-counter. The flea and tick prevention tend to be you don't need a prescription, and the heartworm preventions you do need a prescription and those are FDA-approved.

The "everything else" category includes both categories. They could be short-term things like antibiotics to treat an infection, or they could be chronic use such as pain relief, et cetera, and those tend to be more attractive and profitable for the manufacturers.

One big question in pet drugs is, is it worth seeking registration approval for a specific veterinary product? So, what else do we need to know to answer that question? A large percentage of the medications prescribed by veterinarians are not labeled for the patient species they're targeted for. They're the same medications and formulations that you and your grandmother are taking. There are several differences:

the indications, the safety, the dosing, the drug interactions, many of them differ from grandma and between species. You know? A dog is not a little person, and a cat is not a little dog. The physiology and the pharmacology are very different, and that's what a lot of the veterinary education is focused upon.

As we've seen, it's a much smaller market, and the research possibilities and NIH funding for veterinary research are much less than in human medicine. So, the information sources -- a lot of these things are figured out by colleagues in academia, in practice, and shared through literature, conferences and other media that are generally not explored by typical medical education or a pharmacy education.

I mean, I am by training a veterinary cardiologist and I can't tell you how many times I run into colleagues, physicians in all trades of life who look at me and go, snakes have hearts? So, I think it's a whole different world for them. Some of my best patients were snakes.

So, one of the questions that Stephanie and Elizabeth put to me to think about was the growth trends and future projections. I've got no idea. So, an honest answer.

So, like any supply chain, we'll start looking

at the supply chain and how I think we've gotten to the current situation. We've got manufacturers. The manufacturers sell to the veterinarian, as Doug talked about, either through distributors or directly, through distributor reps or manufacturer reps. And classically, as I said before, most consumers and their pets got their medications from the veterinarian.

One thing to really make clear is that the local pharmacist has always been a big part of this chain. It's not new for veterinarians to be writing prescriptions. And when I was in practice full-time, the relationship with a local pharmacist was a big, important thing because a lot of the formulations we use are different, and the pills and the solutions need to be cut up and diluted down into concentrations and sizes that a cat and dog or a bird or a snake can take. These are not easily available unless you're producing them yourself within your practice, or dealing with a good compounding pharmacy or a local pharmacist that you have a good relationship with.

In the '90s, with the advent of the Internet, we started to see the appearance of the online pharmacies. And the question that arose was, how were they getting products? Because the manufacturers and the distributors had -- for reasons we'll get into -- stated that these

products, many of them would only be sold into the veterinary channel, because they believed -- and there's many reasons we'll talk about -- that the veterinarian was the most educated to be able to decide when they should be used and which should be used, and to detect problems. And so, they wanted their products to get a good reputation and be used properly.

So, there appears the gray market. And the question arises, how did those middlemen within the gray market, who are aggregating product, get the product? And that's the investigative reporting that the VIN News Service did, and it turns out, from everywhere. I'm embarrassed to say that there were veterinarians who buy product beyond their personal needs, aggregate it and sell it to these middlemen for not much profit we found out. We did that by creating our own diverter of only over-the-counter products, so to keep it legal.

Manufacturer and distributor reps, it turns out, are a big part of this. How high it goes up that they're encouraged to do this, to make their numbers, and to increase their income, we don't know. But we know that they're a big part of this. And there's a lot of indications that manufacturers, despite saying that they don't want to sell into these channels, and distributors, are doing so directly as well.

The latest players would be the big box stores, such as the Walmarts and Targets, and the big chain pharmacies, like CVS and Walgreens, who have recognized that there is a good market in these products, although we recognize very tiny. So why would they be interested in this? And as you'll see, they're probably getting the product by the same mechanisms, and the reason that they're interested is because I think for them, it's the latest milk in the back of the supermarket. It's the way to get more consumers in the store rather than a true interest in pursuing pet health.

So, there's another part of this chain. Recently, in the last decade, manufacturers, distributors and other providers have come in to provide technologies to veterinary practice to give them their own online pharmacy presence, and be able to compete with some of the other markets. There is kind of a second gray zone that came in, it's not really a gray market. And this involves, it started with a company called VetCentric, who is now owned by Vets First Choice, and they had to change their model, because what they were doing was they would make an online store for the veterinarian, and the veterinarian's client would purchase from there, and then VetCentric could pay them a

commission. And several pharmacy boards saw this as a kickback, so they had to change that model. There's another group today, VetSource, who is doing something similar. But both of these involve kind of phantom inventories and virtual transactions to make it the veterinarian's product actually, so it looks like on paper actually they're paying for the product and getting their mark-up above it. So, this is just another market out there.

So, a big question is, what has this change and this gray market and being able to get product through other outlets done to consumer purchasing patterns? Well, obviously, if most of it was going through veterinary practices before, and then these markets are emerging, things have moved in the direction towards the right, and the market has moved over. How much, I don't have an idea for, maybe somebody else on the panels will give us an idea of where they think that split is today.

I can give you a better idea of sort of the veterinary thoughts and reactions to this evolution. Manufacturers now come in two flavors. So, Bayer, a couple of years ago, decided to come out of the closet and openly sell to the other chains, and admit that they were selling to the big box stores and the online pharmacies directly. The remainder of the manufacturers have remained in the closet and still claim to be

selling only through veterinary channels.

So, manufacturers are a big, important part of this market. We need them to be developing new products. We need them to be our partners, and to work with veterinarians. But I think due to distrust that has grown over the years and disbelief in the honesty of their statements, there is a strained relationship between the veterinary profession and the manufacturers.

Distributors, for the most part, I think have remained in the good stead of the veterinary profession and trusted. The distributor reps, although I think many are trying to squeeze them out of the market, they still are seen by the veterinarian as their friend and a big source of drug and new product information. And I think that the realization that they're involved in the diversion of product has given them a little bit of a black eye in the profession.

The local pharmacist is still a very important part of the veterinary practice and relationship locally. Obviously the gray market diverters are not viewed as very ethical, or the veterinarian's friend.

The online pharmacies, I would believe, and I think most veterinarians believe that the convenience of purchasing product in the Costcos and Walmarts will diminish their market, and they will not go into oblivion, but

probably are the ones greatly threatened by the big box stores and the big pharmacy chains becoming interested. And although I think that there's a mixed relationship with the pharmacist within those chains, I think there is a great fear that they're coming to this market purely for financial reasons, without true concern for the health of pets and properly educating consumers.

There's lots of issues, I'm sure we'll get into today, as far as being able to advise. We all go to the pharmacy, and what do we fear? Getting called into the counseling booth, and being told how to swallow that pill. But for a pet, that's a very big issue. There's no sense in giving a pet -- especially a cat, for example -- a medication if the pet owner can't get the medication in. That's classically been a lot of why a veterinary practice has been the best place for administration, at least getting the first dosing, because the pet owner needs a lot of help. And then afterwards they're calling and they can't get it in and the medication is no good if it doesn't get to the patient.

The other thing that is a concern is that pharmacists are not traditionally trained in veterinary pharmacology, and all the nuances that I referred to before. And in the panel we can talk to many examples

where this becomes a very important issue. So, there is a danger to the pet health if the person dispensing can't recognize problems, can't inform about interactions, and even doesn't understand the proper dosing and is trying to make a dog a little person, or if there are no dogs, a cat a little dog.

So, how did we get here? Well, I think there's a very logical reason as to how we got here. We said it's a much smaller market, and so we have a manufacturer who has high costs in getting a product to market. So, how can they effectively market it? Well, you turn to the veterinarian and you make him feel like a hero. And I have been to many releases of new products at big conferences that go exactly this way in that we believe the manufacturer saying that the only way that this medication can be used properly is being sold through veterinary clinic, with your expertise. And, of course, there's the carrot for the veterinarian of feeling important, and having a new product to truly treat. Some of these were wonderful new advents. If anybody has been hurt by the new flea medications, it's the fleas of the world. They're just, they're under attack. The veterinarians were not immune from seeing that this was extra revenue coming into their practice.

The manufacturers also had control over the

distributors in which they would look at the major distributors and say, if you handle our mega product, you can't handle our competitor's mega product, and I think this did a lot to artificially inhibit competition.

The other players, just as happens in our free market society, is if there's money to be made, others are going to try to get into the market. So, I think it really was kind of a predictable reaction down the chain that all these things would happen. How much the manufacturers planned this and how much it happened as unintended consequences, I don't know. But to look at kind of the chain of events, the manufacturers would look at it as advertising new products and pharmaceuticals for pets as too expensive to do direct to consumers. And I think if we don't keep that in mind and that cost gets added to the manufacturer's costs, we may actually see the opposite effect of what we're intending here in that we will see prices go up from the manufacturer, who is truly the one who sets the bottom line on pricing. They set the floor.

They promise veterinarians exclusivity because they were the only ones who were qualified for these products to be sold through. They would demand distributor exclusivity, and that would also keep the

price up. And they made happy, feeling-like-hero veterinarians, but they also made dependent veterinarians, because we saw how much of their gross revenues have come to be seen as drawing on these products. To be honest, I think veterinarians should focus a lot more on service, because product is not what we were trained to sell. And it made happy clients.

But once the brand was established, the gray market starts to appear, and what this did was expand the market. It reached consumers who didn't go to veterinary clinics. It didn't really lower prices much, because it was still all mostly coming through veterinary chains, and so there wasn't much of a margin, because veterinarians weren't marking them up as much as people believe, in general. The big box entry, I don't know if manufacturers predicted this. So was this an end game for them, they were waiting for it, or is this a note on their case?

For the veterinary profession, I see it as a big detriment, overall, this evolution, because I think it's damaged the public's trust in the veterinary profession. The veterinary profession has a need to supplement the inability to charge adequately for services. It costs veterinarians equivalent to what it costs a human hospital to maintain that hospital, in many cases, and

to provide those services across. And yes, they have sustained the ability to charge affordable pricing for services by supplementing with product fees. But I think when you have a situation where you're advertising to the public that veterinarians are overcharging you for these products, the public is going to start to ask what else are they overcharging me for.

I think also, veterinarians are in trouble now. That's a part of the story that hasn't been told. There's an article that just came out in the New York Times on lawyers, and the oversupply and the educational debt. And the article ended being about lawyers, but it started out saying, don't feel so bad if you're a lawyer, because veterinarians have it much worse. Right now, a veterinarian's educational debt is like 2.3 times their starting salary, and most people will tell you, you don't want to go beyond one time your starting salary. So, if you think lawyers have problems, veterinarians have it worse.

I think that there's a danger here if you stress the veterinary profession too much further here that with the increased competition you'll damage quality of service available to the public. As Doug pointed out, in the end, we're talking about trade, but we can't forget that really the most important players here are the pet

owner and the pet. We really need to look at what we're going to do here and the intended and unintended consequences and what impact it will have upon them.

Thank you.

(Applause.)

MS. WILKINSON: Thank you, Dr. Pion.

We will now take about a ten-minute break, and we will meet back here at 10:00 for the first panel.

(Whereupon, there was a recess in the proceedings.)

PANEL ONE

DISTRIBUTION OF PET MEDICATIONS

MS. WILKINSON: Could everybody please take their seats and we'll go ahead and get started with the first panel discussion.

Welcome back, everyone. I would now like to introduce our first panel. Given our time constraints, I will be keeping these introductions very brief, but you can find detailed information about each panelist in the bios that we have sitting out on the table. Once introduced, each panelist will have approximately five minutes to make remarks. Panelists, we do have a time keeper in the front row who will indicate to you when there's one minute remaining, 30 seconds remaining and when your time has ended. We will then use the remaining time to pose questions to the panel.

I am joined by my colleague Elizabeth Jex, who is the co-moderator of this panel. She is also an attorney with the Office of Policy Planning.

Panelists, if you would like to respond to any of our questions that we pose, please place your name placard on its end, as Elizabeth is demonstrating, and we will do our best to call on you as time permits. For members of the audience who wish to submit questions to the panelists, please fill out a question

card and then hold it up in the air and one of the FTC staff will come by and pick it up and then make sure that the moderators get your questions. For those of you watching our live webcast who wish to submit questions to the panelists, please tweet your questions to our Twitter handle @FTC with the hashtag #FTCpets. You may also submit questions via the FTC's Facebook page www.Facebook.com/FederalTradeCommission.

Our first panelist is Clinton Vranian. He is the vice president and general counsel for Novartis Animal Health.

MR. VRANIAN: Good morning. First I would like to thank the FTC and Chairman Leibowitz for including Novartis Animal Health in this workshop. We are very pleased to be able to participate and to provide information about our business and some perspective as it relates to the issues that we're discussing today.

I'm Clint Vranian, general counsel for Novartis Animal Health US, Inc. We are a division of Novartis AG, the pharmaceutical firm. As you already may be aware, Novartis is a world leader in the research and development of products focused on the health and well-being of patients. Across our organization, our driving force is leveraging innovation to meet unmet medical needs. At Novartis Animal Health, we extend this

innovation to provide solutions which extend and enhance the quality of life of our patients, our veterinary patients, our companion animals, pets and their pet owners.

Today's workshop centers on, as you heard, the companion animal or the small animal side of the veterinary market, those that we use on our pets. Novartis' companion animal portfolio -- and Dr. Pion talked a little bit about this -- like many manufacturers, consists of two categories: parasiticides and therapeutics. Parasiticides, which represent the bulk of the market today, are those medications or solutions that affect internal and external parasites on our pets, things like fleas, ticks, heartworms, chewing lice, as we heard earlier. These can take a variety of forms. Some of them are FDA-regulated, some of them are EPA-regulated. They can be systemic, developed specifically for companion animals or reformulated pesticides from the agricultural field.

Therapeutic medications are products that address medical conditions, they're much more akin to human medications. They will address the medical condition of the pet, such as arthritis, allergic dermatitis, Addison's Disease and other conditions that can challenge the pet's quality of life. These are largely FDA products and they represent treatments that

pets did not enjoy just a decade ago. Although these medications are essential, they represent a minority of the market for animal health products. Animal health therapeutic products, as I've said, are largely FDA-regulated prescription medications.

At Novartis Animal Health, our entire portfolio -- parasiticides and therapeutics -- falls towards the FDA side of the spectrum. As a division of a globally respected health care company, we're a company with a strong FDA prescription pedigree. Consistent with this pedigree, our product portfolio which places the health and well-being of our pets at the center of our mission that is also FDA regulated. While today some of our products, a small subset are indeed non-prescription, we've founded our business on prescription medicine and today our portfolio followed suit. This underscores our primary objective, which is a commitment to and history of delivering innovative medicines through the veterinary channel. We introduced the first commercially successful prescription flea medication in the 1990s. Since then our focus on FDA prescription medicine has not changed.

Now, prescription medications by definition must be administered in the context of their efficacy and their safety. It is essential to ensure that these products are prescribed by trained professionals that

are educated on the risks and benefits of these innovative technologies.

The unique circumstances of a pet, of an individual pet, setting aside its species or breed or things endemic to the specific pet can impact the administration, efficacy and safety of these products. This is why the Veterinarian-Client-Patient-Relationship plays a critical role for an FDA-focused company like ours. Appropriate therapies require familiarity with pharmacology, adequate education and a thorough understanding of the unique circumstances of an individual patient.

The Veterinarian-Client-Patient-Relationship is essential to ensure the optimal application of these innovations that can help prolong and save pets' lives. Accordingly, we bring our products to consumers and their pets exclusively through practicing veterinarians. We consider these highly skilled professionals to be our partners in addressing unmet medical needs. We have found no better way to ensure that innovative science is best leveraged to the benefit of our companion animals.

We understand that the issues presented today during this workshop will go right to the pocketbooks of consumers and that our concerns are to better understand distribution practices and analyze how these may affect

consumer choice and price competition. Questions will be posed here that ask essentially whether all pet medications should be required to be made available to consumers in different ways than they are today. Novartis Animal Health does not have an answer to this question for all companies. Nor can we take a position that would speak for all products and all product portfolios. But as a company with an FDA pedigree and founded on delivering innovation to unmet medical needs for the sole purpose of preserving and enhancing the quality of life for our patients, we believe that doing so through the Veterinarian-Client-Patient-Relationship creates efficiencies that serve this objective.

MS. WILKINSON: Thank you, Mr. Vranian.

Our next panelist is Michael Hinckle. He is a partner with K&L Gates law firm.

MR. HINCKLE: Thank you.

Good morning. I would like to thank the FTC for the opportunity to come and present on behalf of my generic drug clients. I am primarily an FDA regulatory attorney. I serve as outside counsel for a number of pharmaceutical companies. A number of those are generic drug companies, and some of those are in the generic animal drug space. I know now you're thinking, “I didn't even know there was a generic animal drug space.” But

there is, and I think that one thing that we would like to present today is a question and then maybe think about what those answers would be.

The question, I think, on a lot of people's minds, certainly my clients' minds is: Why are consumers of animal drugs, particularly FDA-regulated companion animal drugs, not seeing the same degree of savings through the generic drug process that they see, say, on the human drug side? I'm sure there are a number of reasons. I suspect one of those is not that pet owners are just not price sensitive and don't care how much their drugs cost. I think they probably do. I think certainly in this economy, almost everyone cares. I also think that when you look at our experience with the human drug side, where there has been tremendous pressure to try to contain costs, one of the areas that has certainly been a successful area in that cost-containing effort has been the generic drug industry.

So, why is it that we don't have generic animal drugs in the same way? Well, is it because the FDA doesn't have a way to approve them? Well, that's really not the case. The Federal Food, Drug and Cosmetic Act does set forth a pathway for approving generic animal drugs. In fact, it uses the same bioequivalence

criteria that's used for human drugs, they use the same statistical criteria, the same confidence intervals and the same type of bioequivalent studies. So, certainly the opportunity is there. There are some other reasons why, and I hear these from my clients and see them, as to why they're not entering the market and why you don't see the same cost savings. I congratulate the FTC on addressing these issues quite well with these panels.

With this panel in particular being the distribution panel, there's a couple of things that I would like to comment on. One is that as a generic competitor thinking about entering the market -- the fact that has been mentioned several times -- the veterinary distribution channel, the channel to get right into the veterinary clinics, is often times foreclosed by way of exclusive arrangements that don't allow a generic competitor to easily enter that market.

The second one, and maybe not so obvious, is that you would think, as a generic company, well, if I can't get into the veterinary channels, can't I use sort of the standard prescription drug wholesaler channels that are used on the human side that primarily serve the retail pharmacies and online pharmacies, and mail order pharmacies. The problem there, again, is an access problem, and a bit of a demand problem. In order to, as

a generic company, if I want to try to get my product into a major wholesaler, say a Cardinal or Amerisource Bergen, that services the retail market, I've got to be able to convince them that there's actually a market at the retail market.

One thing that I would say that probably will surprise you as someone representing the generic side is one of the real problems is a lack of brand products at the retail pharmacy level. This may also surprise you, the fact is the generic industry -- and a robust generic industry -- relies on a robust innovator industry. There has to be an innovator product in order for there to be a generic product. A real substitutable generic relies on the brand product being prescribed, and then substituting the generic. Without the brands in the pharmacies, there's no demand. There's no reason for a mainline standard wholesaler to carry the product.

So, I hope what I'll bring a little bit to this discussion is that if we're going to provide real competition and lower prices, like we've seen on the human side, with generic animal drugs, there needs to be a little bit of a leveling of the playing field so that these generic companies can have access, both to veterinary clinics, through the veterinary channels, and also through the retail pharmacies and mail order

pharmacies, through these standard wholesale distribution channels.

So, once again, thank you for your time.

MS. WILKINSON: Thank you, Mr. Hinckle.

Our next panelist is John Powers. He is the executive vice president of Drs. Foster & Smith.

MR. POWERS: Good morning. I would like to thank Stephanie and Elizabeth for moderating this panel this morning, and for inviting us here today.

I have had the good fortune of working in the pet supplies and pet pharmacy industry for over 35 years. My experience includes being vice president of marketing and merchandising, as well as the vice president of operations both in the direct marketing brick-and-mortar business and the Internet business, all on a national scale. I have also taught marketing for several years at the university level. As Stephanie mentioned, I've been now 20 years as vice president of Drs. Foster & Smith.

There are three main points I would like to make here this morning. One, because of our background history, we are uniquely positioned to fill pet prescriptions. Two, there's a real dichotomy between pet prescription portability and restricted distribution. And thirdly, the restricted distribution is both

illogical and untenable.

Drs. Foster & Smith is now in its thirtieth year of providing quality pet products to pet owners. The company was founded by two veterinarians, Dr. Race Foster and Dr. Marty Smith, who continue today to own and operate our business. Our pet pharmacy is an integral part of our operation. The Drs. Foster & Smith pet pharmacy is both Vet-VIPPS and PCAB certified. In addition to Dr. Foster and Dr. Smith, we have staff veterinarians as part of our company. We also have a trained staff of fully licensed, full-time pharmacists, certified pharmacy techs, and veterinary techs. In 29 years, our company has been dispensing over-the-counter and prescription medications, therefore filling thousands of prescriptions. We have never had a single state or federal dispensing violation in our history, and we're proud of that record.

Drs. Foster & Smith, therefore, has all the necessary pharmacy certifications and accreditations, and educated licensed staff of both veterinarians and pharmacists working together, and a stellar record. The question that I would like to ask is, then, what is the justification for restricting pet prescription products from us?

Second, prescription portability is one of the

main subjects of these workshops. Later this afternoon, an entire panel is devoted to that subject. I would like to emphasize the point that true prescription portability cannot exist within the context of restricted distribution. Writing a prescription for a particular drug and having that manufacturer of the drug severely limit where the drug can be sold, to only a veterinarian's office, has the real effect of denying true portability. The result is that consumers have far fewer choices of where to fill that prescription, and the ultimate result is higher prices. The AVMA guidelines state, a veterinarian should honor a client's request for a prescription in lieu of dispensing. The AVMA also talks about using Vet-VIPPS as a way of ensuring a pharmacy's credentials. I would like to remind everyone here this morning that Drs. Foster & Smith is a Vet-VIPPS certified pharmacy.

Third, it is clear that the current method of restricted distribution isn't working for anyone. Not the manufacturers, who spend an inordinate amount of time attempting to police the system and struggle with chain of custody. Not the veterinarians, who deal with conflict among colleagues and act as pharmacists as opposed to practitioners. And not the consumers, who pay higher prices and the result is often poorer pet

health.

There's a tangential issue that should be of concern to all of us, that is the real possibility of product recalls. In the last several years, some of the best known consumer companies in the United States have faced product recalls. Baby toys, medical devices, automotives. In fact, in the third quarter of 2011, there were 35 million units of pharmaceuticals recalled in this country. The only real way of controlling chain of custody is for manufacturers to deal directly with companies like ours. Selling directly to a pharmacy retailer like Foster & Smith rather than being an impediment to safety actually enhances consumer safety when it comes to drug recalls.

The current system of restricted distribution is also illogical. Why should the distribution of pet pharmaceuticals differ from the human model? Our pharmacy has purchased and filled prescriptions from companies like Pfizer for human heart medications like Lipitor. Yet the same manufacturer denies us the ability to purchase drugs like arthritic medication for dogs. Does it make any sense that my pharmacy can dispense heart medication for you, but not arthritis medication for your pet?

Let me relate a personal story. My young

daughter was diagnosed with human growth deficiency. The endocrinologist put her on a growth hormone treatment. That is an injectable prescription drug that is directly shipped to our home. When we need a prescription refilled, that is sent again to our home. We can inject this into my daughter, but I can't buy a refill for pet medication anywhere but a vet's office or through a veterinarian.

To recap, let me make just three quick points: Drs. Foster & Smith is uniquely qualified to fill prescriptions; portability without product availability is a sham; and restricted distribution just doesn't make sense.

Thank you.

MS. WILKINSON: Thank you, Mr. Powers.

Our next panelist is Andrew Bane. He is the chief operations officer for VetSource.

MR. BANE: Thank you, Stephanie, and good morning everyone. Again, my name is Andrew Bane and I am chief operating officer for VetSource. We appreciate the opportunity to participate in this panel today and offer our input and experience as the FTC considers these important issues.

For those of you who do not know, VetSource offers outsourced pharmacy services, as well as

wholesale distribution services, for our contracted veterinary hospital customers. We hold pharmacy licenses in all 50 states, as well as wholesale distribution licenses in all required states. We are Vet-VIPPS accredited, and our outsource pharmacy services enable veterinarians to offer the convenience of home delivery directly to their clients. In essence, we operate a specialized central fill-like pharmacy that gives veterinarians an Internet presence.

We designed our business model similar to other business models that exist in the marketplace to operate as an extension of the veterinarian's pharmacy and to fit within the context of the current veterinary pharmaceutical network. This means that we do not acquire any of our products via the gray market.

Regarding the distribution of pet medications, we believe that veterinary medicine represents a special niche within the practice of pharmacy. As has been stated by other panelists, the medications, their unique dosing, side effect profiles and uses for the veterinary industry are very different from those in human use.

For these reasons, we believe it's a better standard of care, pet health care, to utilize health care professionals that have specific training in this area of medicine. Of course this includes

veterinarians, but it also includes specialists, for example, members of the Society of Veterinary Hospital Pharmacists, as well as other pharmacists who specialize in veterinary medicine and work closely with the prescribing veterinarians.

It's true from a regulatory perspective a pharmacy is a pharmacy. In other words, a pharmacy specializing in veterinary medications is required to operate under the same regulatory statutes as a pharmacy dispensing human medications. However, we know the practice of pharmacy is very broad. For example, human hospital pharmacy is recognized as different than retail. Specialty pharmacy and compounding pharmacy are also recognized specialties within the practice of pharmacy. Specific training is required to properly evaluate, dispense, educate and counsel pet owners on the proper use and administration of medications to different species of pets.

Because not all pharmacists receive this training in the course of their education, we believe veterinary pharmacy is also a specialty within the practice of pharmacy. Just as a DVM degree is not interchangeable with an MD degree, we feel that pharmacists trained only in human medicine is not interchangeable with a pharmacist specializing in

veterinary medicine.

Until this training gap is closed and the pharmacist-DVM relationship more closely models the pharmacist-MD relationship, we believe that some level of selective distribution by manufacturers or additional regulatory standards is warranted to ensure pet safety. I also think it's important to point out that restricted distribution is not unprecedented in human pharmacy. Some human medications requiring specialized knowledge for dispensing, counseling and management are only sold to specialty pharmacies that have demonstrated competency in supporting the proper use of those medications.

On the matter of gray market distribution of veterinary prescription products, we feel that this unregulated product trafficking has the potential to endanger pet health. The lack of regulatory oversight means that the appropriate mechanisms are not in place to ensure that prescription products are stored and shipped under their required conditions. This also means that there's a lack of transparency in the chain of custody of the products for the dispensing pharmacists as well as for the pet owner. Furthermore, this gray market distribution channel creates substantial risk of adulterated or counterfeit compounds being introduced

into the supply chain.

Generally, veterinarians are authorized to dispense prescription products via the respective veterinary practice acts of the states within which they practice. These acts require that the prescription dispensing by the veterinarian is to occur within the context of the valid Veterinarian-Client-Patient-Relationship. This requirement is violated when veterinarians wholesale products outside of the context of this relationship to other businesses.

Additionally, anyone reselling prescription products needs to be properly licensed according to the state boards of pharmacy, just as is required of legitimate wholesale veterinary distributors. We feel that gray market sales are occurring in violation of one or more statutes in nearly every state. Although the state boards are consumed with many pressing issues in their mission to protect the public health, we encourage them to revisit this issue in veterinary medicine and remind veterinarians that this practice is not approved or sanctioned.

Once again, we appreciate the FTC's invitation to participate in this workshop and we look forward to the ensuing discussion.

Thank you.

MS. WILKINSON: Thank you, Mr. Bane. Our next panelist is Brad Dayton. He is the senior director of pharmacy for Ahold USA.

MR. DAYTON: Good morning. Thank you, Chairman Leibowitz and Stephanie for the opportunity to speak this morning.

I am a retail pharmacist, I have been in the retail pharmacy industry for 24 years. I started my career at a local chain that existed in the Washington, D.C. area, Peoples Drug. I worked for CVS Pharmacy and worked for Giant Pharmacy in this area. I am currently the senior director of pharmacy for Ahold USA. Most importantly for this conversation today, I am a pet owner, and I'm glad to learn this morning that I know what percentage I fall into. I am not part of the 47 percent that one of our candidates mentioned, I am not part of the one percent, but I'm part of the seven percent, I have four pets. So, and all my pets are shelter pets, also, and I would love to have brought my animals today.

Ahold USA is a retail grocery-pharmacy combination. We operate stores up and down the east coast and the northeast and mid-Atlantic regions. We operate our stores under the banners of Stop & Shop, Martin's, and in this local market, Giant. Ahold is a

$25 billion company. We're the fifth largest grocer in the United States. We operate 784 grocery stores and 565 pharmacies. Our pharmacies are in 11 states and the District of Columbia, and in 2012, we'll fill approximately 27 million prescriptions.

So, the question is, why is a retail pharmacist interested in pet medications? A couple of points were brought up in presentations this morning, 63 percent of all Americans own pets. Very strange that between 60 and 65 percent of our customers who shop our grocery store also shop our pet aisle. So, it is a natural offering that we can offer our customers more services such as being able to fill their pet medications.

We also -- as Dr. Pion pointed out -- fill many prescriptions today from the human supply chain for pet medications. However, we have limited ability to do that. We have basically three ways to fill prescriptions today for pets. One is from the human supply chain. Secondly, are the products that we do have available to us that are pet medications only. And third, we've had to partner with a mail order type pharmacy, PetCareRx, which is also a Vet-VIPPS certified mail order pharmacy; and our customers are able to drop their prescription off at our store or use our website to order their prescription, and then we deliver that

prescription through the mail to them at home. Obviously, being a brick-and-mortar retail establishment, that is not our preferred method, but it at least allows us to play in the arena.

There have been questions raised this morning as if we are actually qualified to dispense pet medications as retail pharmacists. I would like to thank Dr. Pion for using the picture of the retail pharmacist. That was an Ahold pharmacist. So I was very happy when he said the part about the trusted partner, but then we ended up on the bad side of the equation where there were just dollar signs and the word "danger."

Pharmacists are not 100 percent trained in vet medications. I agree with that completely. However, a pharmacist's experience, knowledge and education -- pharmacists go to school for six years, sometimes take up to two years of post-doctorate work -- you can use your education to develop and work with veterinarians on a regular basis. I've had many opportunities as a pharmacist myself, when I was presented with a prescription for an animal that, I'll be honest, was not quite sure of what that dose was.

A specific example with a horse -- a dose that would have killed a human being -- that I needed to go speak with the vet who wrote the prescription. So, the

relationship does exist, and retail pharmacy wants to play in this space, not only to increase sales -- because let's face it, we are a business -- but we do care for our patients and animals are our patients, also.

What I think the future should look like? I think pet owners should have the right to choose where they get their prescriptions filled, whether it be a retail establishment, a mail order pharmacy or their local vet. I believe that competition will only help prices for pet owners. And I also learned this morning that the average dog only makes it to the vet 1.6 times a year. I need to talk to my wife, because it seems like we go many more times than that.

So, in conclusion, I would like to thank the FTC again for the opportunity to speak here, and just to reiterate, pharmacists are qualified and we would like to play in this space.

Thank you.

MS. WILKINSON: Thank you, Mr. Dayton.

Our next panelist is Gregg Jones. He is the compliance manager for the National Association of Boards of Pharmacy.

MR. JONES: Good morning. Thank you for the opportunity to be here to speak with you about some of the observations that the NABP, National Association of

Boards of Pharmacy, has made. I, too, am a pet owner. I consider myself having five children -- three daughters and a German Shepherd and a Spaniel. I love those dogs more as I get older. They stay home with me and watch ball games and seem to love it, and they don't ask for money or anything.

NABP primarily assists its members, boards of pharmacy, in protecting public health. That's our primary mission. We issue the Vet-VIPPS accreditation to online pharmacies that dispense prescription drugs for companion animals. What we do is offer an assurance to the consumer that they are buying their medications from a licensed pharmacy and a pharmacy that complies with state and federal laws. Our pharmacies that are accredited undergo an extensive application process, and once they're accredited, they undergo an annual compliance review and every three years are re-surveyed to ensure their compliance with the standards.

I would like to touch on a few of the observations that we have made regarding the acquisition of drugs that are, as we've heard, exclusively distributed to veterinarians and how we have seen these entering into pharmacies. Overwhelmingly, the majority of the pharmacies that we see obtain their drugs from wholesale distributors. Included in that process are

wholesale distributors and pharmacies that solicit veterinarians to purchase medications. We see veterinarians who serve as consultants to pharmacies or wholesalers and the drugs are purchased in the name of the veterinarian and then transferred to the wholesaler.

There are situations where veterinarians actually own pharmacies and buy the drugs in the veterinarian's name and then transfer them over to the pharmacy. There are some situations where we have seen veterinary wholesalers that are purchasing directly from manufacturers and we're not sure exactly how they have obtained those relationships, but they are buying directly from the manufacturer certain types of medications that appear to be restricted. We think some of these involve situations where the wholesale distributor license was obtained under the name of possibly a veterinary hospital and then the veterinary hospital went out of business and the wholesaler continued.

We have heard -- I think it was mentioned earlier by one of the veterinarians -- about the relationships that exist between veterinarians and some of the online pharmacies, and the financial arrangements that are made between them. We have confirmed that there are pharmacies that are removing secondary bar coding that

has been placed on certain types of medication to identify the veterinarian that purchased that product. Shortly after we learned of that, the pharmacies moved to removing those medications and placing them into vials and dispensing much like a human drug would be dispensed.

I would like to touch on some of the differences in the human drug distribution supply chain and veterinary drug supply chain. Under the Food, Drug and Cosmetic Act, human drug distributors must be licensed by their resident state in accordance with rules established by the FDA. Those requirements do not exist for veterinary distributors. Under the federal act, human drug sales must be tracked back to a manufacturer or authorized distributor in accordance with FDA rules. And again, this does not apply to veterinary distributors. The licensing of wholesale distributors for veterinary drugs varies widely by the states. Some states do not license veterinary wholesale distributors of drugs and some states do not require veterinarians to have a wholesale license to sell to a pharmacy.

In the human prescription supply chain, we strive for and have the highest confidence in a closed distribution system where drugs move from the manufacturer to the wholesale distributor to the

pharmacy or practitioner, through what is referenced in the wholesale distribution for human drugs as the "normal distribution chain." This type of system is not developed for animal drug distribution.

NABP's accreditation of online pharmacy ensures that they are operating in accordance with the laws and rules of their state and federal requirements, and ultimately ensures that the medication that we give our pets is safe.

Thank you very much.

MS. WILKINSON: Thank you, Mr. Jones.

Our next panelist is David Miller. He is the chief executive officer of the International Academy of Compounding Pharmacists.

MR. MILLER: Thank you, Stephanie.

Good morning, everyone. I am going to cover a few quick points, but before we get into that, pretty much everyone up here has some sort of relationship with the veterinary industry. Some of us are clinicians, some of us are pharmacists, some of us are involved in manufacturing and distributing, but I would say most of us in this room, when we were listening to Dr. Pion's presentation, was thinking about the fur balls that we have at home. How many of you own dogs? Yes. How many of you held out your cell phone to show the person next

to you a picture of your dog? How many of you are owned by cats? Notice how I have phrased that, because up until recently, I had five small ones that ran my life. I'm now down to one, fortunately.

The reason why I tell you this, and I ask this, because we all do share something in common, and that is as pet owners. Sometimes we need medicines for our animals, for our family members, if you will. Compounding pharmacists play a rather unique role in the treatment distribution system. If you think about dogs, we have small Teacup Poodles and then we have Great Danes. And it doesn't require clinical training to understand that the dose of medicine you need for that small Teacup Poodle is probably going to be a little bit less than what you need for the Great Dane.

In the case of a cat -- for those of you who have ever tried to get a pill into a cat -- after you have managed to put the tourniquet on your bleeding arm and come back from the emergency room, you know that there are preferred ways to get things into a cat. And that's usually with a gel that you can apply to their ear or a tuna flavored solution that you can attempt to squirt into their mouth at some point.

What compounding pharmacists do in collaboration with veterinarians is create formulations, modified

doses, and solutions for obtaining and creating drugs that aren't available commercially. Things that aren't in the manufacturer-wholesaler distribution chain.

I know much of our focus this morning is on the mega products. But I want to make sure that you understand how the marketplace and its current economic incentives has created some rather difficult catch-22s for compounding pharmacists and for veterinarians who are trying to treat a wide range of species and a wide range of sizes and types of animals within a given species.

What do compounders do? We create medicines on prescriptions in collaboration with prescribers, both on the human side and the veterinarian side. In the case of veterinary compounding, things are a little bit different. The Food and Drug Administration has something termed a compliance policy guideline that requires that the compounding of medications for veterinary use must, must, be done with commercially-available finished drug products.

Now, when a pharmacist compounds something, we really have two choices. We start with the raw ingredient, the drug that we buy from the same FDA suppliers that many manufacturers do, and that's the same thing for both the human side and the veterinarian

side. We also can use the old-fashioned method of take the tablets off the shelf, grind them up and turn them into something else. Those are the finished drug products that I can buy from a wholesaler, or I can buy directly from a manufacturer. The FDA requires in veterinary compounding that both pharmacists and veterinarians must use the finished drug product.

Now, here's the problem. I receive a prescription from a veterinarian. I have to prepare that and compound it. The only way that I can legally do so is if I use a finished drug product, a commercially-available manufactured product I buy from the manufacturer or the drug supply company. Unfortunately, because of unilateral decisions by manufacturers who have restricted their sales to only veterinarians or veterinary supply houses, a pharmacy cannot buy that finished drug product. So, how do I get it? Well, I have to turn to and eventually begin to develop an unfortunate disruption in our supply chain that challenges the integrity. I have to get that medication not from the manufacturer, not from a veterinary supply house, I have to get it from a veterinarian. And that starts opening up a whole series of potential disruptions in the supply chain. As the pharmacists on this panel and in the room will tell you, the first and foremost thing that we are concerned about

is knowing that when we pull something off of a shelf, preparatory to dispensing to a patient, animal or human, we want to make sure it is what it is.

So, I think we need to address how the manufacturing-wholesaler side of the veterinary business is set up in a manner that restricts pharmacists from being able to obtain medications that they are legally required to have in order to care for patients.

Thank you.

MS. WILKINSON: Thank you, Mr. Miller.

Our next panelist is Nate Smith. He is the vice president of business development at NuSkin Enterprises and a former retail strategist for Walmart.

MR. SMITH: Thank you for having me. I appreciate being on the panel.

I hope today to be able to share comments that I believe reflect the interest of consumers. Because of the distribution practices in this industry, consumers pay more. They are limited as to where they can buy pet medications, and they are, in many cases, denied the chance to buy less expensive alternatives. This is an important issue in this economy, as all Americans are looking to save money, and they're demanding good service and they also want convenience in the way that they buy these drugs.

When it comes to purchasing medication for their pets, consumers are at a severe disadvantage. They can't buy pet medications without a prescription. The prescriber, in this case the veterinarian, chooses the medication, and is free to choose a medication distributed only through veterinarians. But this system, with its inherent conflicts of interest, also puts the veterinarian in a tough spot. It's unfair to both, and the government should step in to assure consumers are treated fairly, their ability to choose is protected, and competition is allowed to flourish.

Allow me to summarize my remarks in five points. First, the distribution practices for pet medications cost consumers money. These practices inflate prices for pet medications and limit competition. They discourage the prescribing of generics, which would save consumers money, in and of itself, and put a downward pressure on prices for the name-brand drugs. And it would serve as a strong incentive for pharmaceutical manufacturers to develop new drugs.

Number two, veterinarians choose the medication and the brand. This makes the marketplace much different than for consumer products. It's fine to limit the channel distribution if you're a manufacturer of a premium brand that you want to associate with a

Nordstrom's and not a Walmart or a Costco. But it's not okay when legally-established prescribing powers are combined with exclusive distribution.

Number three, pharmaceutical manufacturers can engage in practices with pet medications that they could never do with human medications. There are examples of manufacturers providing sales incentives to veterinarians, protecting them from price competition, and rewarding them with extra product that can be resold. In 2011, Elanco sent a letter to veterinarians highlighting and then condemning the decision by a competing pharmaceutical company to sell its products outside the veterinarian channel. I ask that a copy of this letter be made a part of the record, and I will provide that to you, Stephanie.

Number four, veterinarians can engage in practices which human physicians do not or cannot. Under the American Medical Association Code of Ethics, where there is a potential of conflict of interest between the physician's financial interest and that of the patient, the physician is required to so advise patients and to resolve the conflict to the patient's benefit. The AVMA code recognizes that a patient whose interest is in receiving quality health care is placed in a difficult, if not impossible position when the

health care provider sells products or additional services to that patient. Pet owners are the same. If they ask for a copy of the prescription, it puts them in an uncomfortable position of having to ask their health care provider for permission to purchase elsewhere. This is an unreasonable burden which is why we don't have to ask for our prescriptions from human physicians, or from an eye doctor, for that matter.

Five, finally, consumers have a right to know they are grossly underrepresented in this marketplace and they are the ones with the most at stake. Consumers are unaware of the hostile market power. Pet owners rightfully love their vets for the care they give; however, veterinarians have an identity crisis on the horizon. The system keeps prices high, discourages the use of generics and more affordable or efficient alternative solutions, and blocks more convenient access.

So, I commend the FTC for holding these workshops, and I hope that this becomes the beginning of creating solutions and a means to an end that will help the consumer. When and where that occurs, I believe that everyone will win. I believe that manufacturers, veterinarians and consumers will all enjoy improved economics and benefit from a change in the way we manage and regulate this industry.

MS. WILKINSON: Thank you, Mr. Smith.

Our next panelist is Mark Cushing. He is a partner with Tonkon Torp law firm and he is here today representing the American Veterinary Distributors Association.

MR. CUSHING: Good morning. It's a privilege to represent the AVDA. Let me start with some broad observations, and then I'll tell you a bit more about AVDA and our role in the pet medication chain.

I look around the room and I see a number of colleagues that, like myself, have been involved for the past two years in efforts to defeat the retail support for H.R. 1406 in Congress, which after two years is not proceeding. I share that because what became clear on Capitol Hill, fortunately for those of us who opposed the bill, is that this is a classic solution in search of a problem.

I will tell you that the discussion today and the focus of this workshop is much the same. It is a solution in search of a problem. It's fair in our system to go to Congress, to go to an agency and raise issues, that's great. We're here to have a good discussion, but the very fact that you have the conversation does not mean that you, in fact, do have a problem that requires federal intervention.

Let me expand. For example, every state extensively regulates the veterinarian-client relationship. It is not the subject of a one-paragraph statute buried in state statute books. It is a comprehensive, multi-paged, detailed, administratively enforced scheme to regulate the veterinarian-client relationship. The intent of 1406 was to nationalize that, and for the first time to have the Federal Government, and specifically the FTC, regulate the veterinarian-client relationship. Many of us felt, and I believe the majority of Congress felt, that at this time in our nation's history, that's not necessary and not a good idea.

Second point. We have a vigorous, highly competitive pet medication marketplace. I respect my colleague, whom I have just met to my right, but I couldn't disagree more with his conclusions. The notion that consumers are trapped, that they're prisoners in this simple veterinary-driven pet medication marketplace is just not true. It is a highly competitive marketplace.

My client, AVDA, shared in its comments -- and I encourage you to take a look at this -- a study commissioned by Axiom, an animal health consulting firm, to just get a feel for broadly how competitive is the pet medication

marketplace. Take a look at that. One can only conclude, as consumers understand, you can get pet medications, both prescription and otherwise, OTC, from a host of sources all over this country, online, retail, veterinary and otherwise. It's simply not correct to say that that marketplace is constricted and somehow works against the consumer. Again, it's a solution in search of a problem.

So, to my main point. At the heart of the system, when you strip it down to its essentials, we're talking about the health of a pet and the safety of a pet, period. It is a rational decision. You can debate it, but it is a rational decision for a manufacturer to determine that it wants medical products that depend upon an understanding of the physiology and the pharmacology of a host of species to be placed in the hands of licensed medical professionals who were trained to do that.

Therefore, it's a rational decision for distributors to honor those contracts and provide those medications to veterinarians. And we can spend all day talking about that, and I'm not qualified as a lawyer, doctor of juris prudence, but certainly not a DVM, I am not qualified to enhance the discussion there.

So, do go to the record and read hundreds of

submissions, mainly by veterinarians and many by state veterinary medical associations, an excellent submission by the AVMA, that make that point. It's not a condescending point. It's not a point that in any way attempts to demean pharmacists, of course not. Human pharmacists have impossible jobs. In the current environment, thousands of chemical factors that they have to understand for the human species, and they have to do it right every time.

My point is, don't assume it's a simple thing. I know pharmacists don't assume it's a simple thing after their human pharmacy training to turn around and say, let me see, with a 10-hour course here, a little bit of extra work there, I can figure out how dogs work, how large dogs, small dogs, old dogs, young dogs, cats, go down the line. It's very complicated.

It makes sense that medications are placed in the hands of professionals trained, and frankly, 75 percent of a veterinarian's training in their four years of vet school, in some meaningful way, involves or considers knowledge related to how medications and pharmacology operates in a given species.

I just suggest to all, including, of course, the FTC, take that expertise seriously. Take seriously the concerns that you need to bear in mind as you make a

decision about an individual pet.

I'll say to that end, I'm disappointed that we don't have on any of the three panels today a representative from state veterinary medical associations, many of whom submitted comments, most importantly from Oregon, my home state, documenting a whole series of examples of adverse consequences for pets when there was a decision made by a pharmacist, online or retail, to change dosage, or to swap out the particular prescription for a different drug reflecting a lack of concern or understanding about how the medication would work with a pet when a simple phone call might have made the difference.

Of course, veterinarians, every day, I'm sure by the time, 11:00 on the east coast, there have been a thousand prescriptions written and probably handed to clients that go to human pharmacies. Veterinarians understand that. And what they hope is that a pharmacist who has any questions, or more importantly, gets some independent idea about what to do with that prescription, would get on the phone and call the veterinarian and ask for guidance. Unless that pharmacist was trained to deal with animal-related issues. That's fine, but we're not talking about that in this context. So, I would just urge you to keep that

consideration in mind.

Very briefly, AVDA has 74 members. It is a combination of both distributors and associate members who are manufacturers. It has both generic and pioneer manufacturers in its membership. It services approximately 55,000 veterinarians and 25,000 practices, as well as 10,000 other retail and over-the-counter outlets. It should be obvious just from those figures why distributors exist, from the manufacturer's perspective, right? If you're trying to service that broad of a market, you need the assistance, and distributors provide that, and I think they do a good job. They comply with a whole host of Federal agencies, DEA, FDA, USDA, of course, EPA on the pesticides or insecticides, as well as state boards of pharmacy and so forth. It's a complicated business, and they take it seriously, and I'm happy to answer questions as the day goes on. Thanks.

MS. WILKINSON: Thank you, Mr. Cushing.

Once again, we have Dr. Paul Pion. He is the president and co-founder of the Veterinary Information Network and we wanted to give him an opportunity to provide any additional comments to his presentation earlier.

DR. PION: Thank you.

So, when I gave my presentation, despite the one slide that I tried to show what veterinarians were thinking, I tried to keep it as objective as possible and just tell a story. Last night, when it kind of dawned on me that I had to say more than that, I started to jot down some thoughts to speak more as a veterinarian.

One of the points I realized that I had left out of my presentation was the issue of compounding, so thanks for covering that. The only thing I would add there is one of the patterns we've seen is there's a great partnership between veterinarians and compounders, but sometimes it's gone too far and not been regulated and it's kind of merged into manufacturing when products weren't yet available. So, just one other thing to throw in the mix.

I would agree with the Distributors Association that the market is right now very competitive. I mean, just the fact that the Chairman of the Federal Trade Commission could walk into Costco and buy Frontline and give a product ad in front of this forum was documentation that anybody can buy any product, and if the chains were not open, these big retailers would not be currently providing them if they didn't think they had a sustainable supply chain. So, despite

the fact that what's written down and what's said publicly by manufacturers and distributors, the chain is quite open.

One of the things that really dawned on me is that the focus has been on veterinarians in H.R. 1406, and that kind of says it backwards, since the control here has always been and is in the hands of the manufacturer and distributor and their relationships that are largely dictated by manufacturers.

Veterinarians want to do what is best for their patients and clients. This is not to deny that losing medication income has and will hurt veterinarians, but I think they've already lost much of that. But I do believe there's a real chance that as it increases, there could be an increase, and we're already seeing an increase in service fees that will result. In the end, pet owners will end up paying more for their pet care, or fewer pets will be seen, which will deteriorate the health care of our pets and our population.

One of the things I don't want to see come out of this is animosity between veterinarians and pharmacists, in that there has always been a great relationship between them. They're two very noble professions, and I really see that trying to force it by law will start to create that animosity.

So, yeah, I agree, and I think most colleagues agree that pet owners should be informed, they have the right to a prescription to purchase their medications elsewhere. I think in that regard, all veterinarians are asking is a level playing field, that they be able to not have their clients purchase in other retailers for less than the veterinarian can purchase for themselves, which is often the case. They want to know that the products that their clients purchase have a known pedigree, and they've been handled properly. That's one issue that hasn't come up, I think in all the jiggling that goes on in the supply chain, who knows how long those products sat out on the tarmac in Phoenix at 110 degrees.

We have to remember that dogs are not little people, and that cats are not little dogs. Dispensing for pets is like dispensing for an infant. The client, like a parent, needs the person providing the medication to be able to advise them and caution them about drug interactions and possible side effects, how to administer it safely and effectively and even to spot inappropriate doses due to math or transcription errors.

These can all be overcome by education. I have no doubt that pharmacists can learn this, but is it realistic to believe that the big box stores and

pharmacies who largely see selling pet medications as a way to increase traffic are going to pay adequate attention to these issues?

I've said, most veterinarians agree that pet owners should be informed and have a choice, but it shouldn't be at the expense of ensuring that the medications are dispensed appropriately with appropriate ability to counsel.

So, I agree maybe veterinarians should do more to inform pet owners they can get prescriptions elsewhere, and maybe a sign in a lobby would be enough. Most veterinarians, it just doesn't come up in the conversation. I don't think it's an outright attempt to restrict it. And if pharmacists don't get the proper education and don't respect veterinary prescription directions, meaning consult the prescribing veterinarian before they consider substituting what they consider an equivalent drug, or preparation, or questioning a dose without first consulting the prescribing colleague, then I think we're going to see lots of problems within the market.

I've got hundreds of examples where this has been an issue, just recently about a Dachshund in California who was given 61 units of insulin when it should have been six units, that ended up in the

euthanasia of the animal because of the cost it would have taken to take care of that.

And on a less severe degree, just last night a colleague was telling me about a cat who had a ringworm infection, a simple problem, and they prescribed a systemic medication, Metronidazole, the pharmacist looked at it and said, I would never do that for a person, don't do that. And that delayed the treatment for a couple of months before the person almost gave up and euthanized the cat until they gave it the medication for a few weeks and it was resolved.

Thank you.

MS. WILKINSON: Thank you, Dr. Pion.

So, we've heard in the presentations and in some of the panelist statements what some of the business rationales are for manufacturers to exclusively distribute pet medications through the veterinary channel, and not through the retail channel. It seems namely that veterinarians are the ones who are trained in veterinary pharmacology and that they are in the best position to be able to properly oversee pet medications and the way that they are used for safety reasons.

My question is, although the veterinarian is the one with the VCPR, and is in the best position to properly prescribe pet medications, why is it that the

veterinarian is in the best position to also dispense the medications? In other words, as long as retail pharmacists dispense prescriptions exactly as written by the veterinarian, why should there be concerns about safety if a retail pharmacist dispenses the medications? And I would open this up to the panel.

Okay, Mr. Vranian?

MR. CUSHING: This is Mark Cushing, I'm sorry, did somebody else go first?

MS. WILKINSON: That's okay.

MS. JEX: From now on, if you could put your name card up on end and we'll call folks in order.

MR. CUSHING: It’s always the lawyer that misbehaves.

MR. VRANIAN: You've cited to the VCPR and the importance of preserving that, and again I think it comes to the portfolio of the manufacturer. If you have non-prescription products or ones that have higher safety and efficacy balancing acts to maintain, it's important that the vet maintains these contact points -- and points include treatment, prescription, dispensing, and follow-up. And dispensing is one of these contact points that allows trained professionals to get some feedback from somebody who doesn't speak any human language. They are trained to acquire that feedback.

From a manufacturer's perspective as well, here we are today and there's billions of dollars of market share that people want to get a piece of. That's one of the questions here today. Many of the most effective life-saving products, take our Clomicalm product, considered medically necessary by the FDA. In other words, we are required to make it available.

The market this year for Clomicalm is about $2 million. We are not getting requests from big box stores for Clomicalm. They don't want a piece of that action. But by this model where we educate the vets and they have ownership in the dispensing and prescription and treatment and follow-up, and they know in their community across 25,000 veterinary clinics who needs this drug, a model where we can efficiently provide that on a one or two-box basis across the country I think increases access to medicine.

You also factor that into innovation. We come out with products for diseases that weren't available just a few years ago: Addison's Disease for canines, ectopic dermatitis for cats and dogs, life-threatening and devastating diseases. The vet clinic is a good way to generate awareness and demand for that. All we know, we have a dog that's itching or that seems unhappy, we take our dog or our cat to the vet. That is the point

where these innovations can be made available to the pet owner. By focusing on that channel and training them and giving them those additional contact points where we can keep sacred that Veterinarian-Client-Patient-Relationship just ultimately enhances the quality of pet health.

MS. WILKINSON: Thank you.

Mr. Bane?

MR. BANE: From our perspective, again, the veterinarians are the ones who receive the formal training, so it makes sense, as Clinton just mentioned, that distributing those products to the professionals that they know had experience in monitoring the side effects and being able to get ahold of that group of professionals to be able to train them appropriately, monitor side effects, administer doses, et cetera, makes some sense.

From our perspective, one of our closest allies as a pharmacist -- and having to expend significant time overcoming this training gap and the availability of information for pharmacists -- one of our closest allies is the veterinarian. So, in the case of dispensing, often times our veterinarians, before they send us a prescription they would like us to fulfill and send to their client, they'll administer that first dose in the

hospital, where that one-on-one interaction with that pet owner and that pet allows them to understand how it's dosed and what signs to watch out for is very important.

In fact, I think in some of these other establishments, we can't see the patient, so that's an important thing for us to maintain that very close relationship with the veterinarian in that context where they can explain those things to the client in a way that's much more difficult in other ways.

MS. WILKINSON: Thank you.

Mr. Powers?

MR. POWERS: Thank you. I would like to make a few points. First of all, with all due respect to Dr. Pion, I think there's some clouding of the issue when Chairman Leibowitz showed that product up there, Frontline, that is an OTC product. So I think we have to be careful when we talk about restricted distribution, we separate those products which are OTC products that were registered by the manufacturer to be sold over-the-counter as opposed to prescription drugs.

Secondly, there was a point made about there's plenty of distribution out there because of big box retailers getting some product. That's true, but that's usually as other people have pointed out, often times

through the gray market or through the nefarious ways of getting the product. My question, again, is I've heard the comments of the veterinarian-pharmacist relationship, we're a company who has both veterinarians working in concert with pharmacists, we're still told we can't get the drugs, they're restricted from us.

The third point that I wanted to make was listening to the VCPR relationship, my vet is great, I love my personal vet, but where does that relationship begin and how does it progress? Pfizer in their statement to the board here said that there were six million prescriptions filled outside the veterinary channel for pets. We've heard it again and again that other people fill many of these, the pharmacists fill many of these. Does that mean that each time each of those six million times that somehow the veterinarian-client relationship was diminished?

In my own case, I have a Groenendael that was abandoned that I took in that recently had eye problems. My veterinarian, Allison French, a wonderful woman, decided the dog was coming down with glaucoma. She prescribed a drug, pilocarpine, to reduce the pressure in that dog's eye, but she said, "John, I don't carry it, here's the prescription, you should take it to Walgreens or some place to have it filled." Does that mean that once she

gave me that prescription for my dog that it diminished the Veterinarian-Client-Patient-Relationship between Allison and I? I don't think so.

MS. WILKINSON: Okay, thank you.

Mr. Miller?

MR. MILLER: Thank you, Stephanie.

I know we're the distribution panel, and it's always a struggle sometimes for the clinicians in the room. I think there's a lot of discussion today about stuff. Stuff -- the things that we can buy, sell, what's in the marketplace, what's in the chain. But to the clinicians in the room, the veterinarians and the pharmacists, this is not stuff. This is now we treat and cure disease. Whether it's for an animal or for a human.

Stephanie, your question was should we, considering the VCPR, ensure that veterinarians still have the ability to obtain and dispense medications, even in an environment or a marketplace that's changing and expanding so that other types of distribution points, retail pharmacies, online pharmacies, whatever it might be, evolve. The answer to that is so simple, I guess, from a pharmacist's perspective, and I would think from a vet's as well. Absolutely. Because we know as clinicians that there are instances when a patient

presents, when a client presents, that they're going to need that medication to be available immediately, and that's going to be from the veterinarian. There are specialty medications, as we've heard, that are only appropriate for dispensing by veterinarians. And that needs to remain with them.

At the same time, we also have to recognize that just as in the human side of the world, that there are instances where the medication isn't available and approved by the FDA CVM, that it is a human version, and that probably the retail pharmacy, be it a Walgreens or Dave's Independent Drugstore, is the place to go get that.

We need to ensure for consumers that they have as many options to get the medications and therapies they need, but we also have to balance that with the very simple fact that this is not the marketplace of widgets. This is the marketplace of patient care that just happens to have a product associated with it.

We cannot let that be forgotten in this discussion.

MS. WILKINSON: Thank you.

Mr. Cushing?

MR. CUSHING: Thanks. Two points that haven't been made. The question, again, is the role of the

veterinarian in the actual dispensing, not just in the writing of a prescription. There's a simple practical value. Many pet owners in the real world, at the end of a workday, stop by their veterinarian, their pet may have been examined during the day or treated, and they pick up their pet to take them home, and it's extremely convenient and it's very consumer friendly for the veterinarian to play that role, just as a practical matter.

More complex, and I would encourage you all if you haven't read it to see the submission by the Animal Health Institute, which had an excellent description from the Bureau of Labor Statistics that just summarized six or seven of the services, if you will, that pharmacists typically provide to their customers, and we've all experienced that in the human context.

If you go down that list, we don't just go to a pharmacist and get something back. There's a conversation, there's advice given, there's questions asked. It's expected. It's part of the pharmacist view of their own profession. That's appropriate.

The veterinarian, uniquely, that is unique meaning there may be a veterinary-trained pharmacist in a pharmacy, but for the most part, the veterinarian is in that position to have that conversation with the client

as to how this works, what to do, what problems to expect, what frustration you're going to meet in about 35 minutes when you get home and try to administer it, how to respond to that and so forth.

That's much more than a pure prescription writing service and I think it's appropriate.

MS. WILKINSON: Thank you.

Dr. Pion?

DR. PION: Well, you may be surprised that I'll probably be the least likely to try to defend keeping the status quo. I think most colleagues have accepted that product medication sales has to become less a part of their practice. I don't think we're here trying to stop that.

I think that we are here to try to see it done rationally. I think there are issues that relate to convenience. I mean, we all go to the physician now, and what happens? You might get a physical exam, you get sent here for blood work, you get sent there for a radiograph, you're sent there to pick up medication, and that's not been classically what people are going to put effort into for their pet's care, and I don't think that's what the public wants to see.

So, physicians handle that. Manufacturers handle, since physicians can't dispense, they handle

directing what physicians are likely to dispense by providing them with samples. So, they tend to prescribe what they can give you: here, here's a few doses and you can go fill it in a couple of days when it's convenient. So, the same still does go on in the human market.

I think veterinarians are all in favor of choice and helping their clients, because veterinarians are faced every day with the choice as opposed to humans, where insurance covers costs. We're not able to apply our healing arts because it's limited by money. I think most of us would be happy if the medications were available elsewhere, free, cheap, but in the end, the client is going to look at the cost of that health care, as what they spent at the veterinarian, and what they paid for the medication.

If we take out efficiencies of the system, and I talked about how, and I think Novartis and a few others have addressed how it's just not efficient for them to try to introduce these products and will it reduce the incentive for innovation and introduction of great products into pet health care if the unintended consequences of the outcome here is that it actually ultimately increases pet health care cost.

So, I think there's lots of conflicting issues here, but I don't think you're going to find

veterinarians wanting to say I think that this should be restricted in that way. I think most veterinarians, they're good, honest, open people, and they would just like the shenanigans to stop. And if these things are going to be sold in the open chain, then that should be fine and the public should have a choice and maintain their relationship with their veterinarian.

MS. WILKINSON: Okay, thank you.

And finally, Mr. Hinckle?

MR. HINCKLE: Thanks. Stephanie, to get kind of back to your question of why do we believe that a pharmacist can't consistently follow directions on a prescription and dispense the drug, I think the obvious answer to that is that they can, and the reason why I say it's obvious is because they do in a large number of cases already.

As I think has already been mentioned, pharmacists already dispense a lot of drugs for animal patients. Many times it's off-label human drugs that are being dispensed for the animal use. And bear in mind in that case, the pharmacist doesn't even have an FDA-approved package insert that discusses animal uses. We're talking here about higher priced animal-only prescription drugs where there is an FDA package insert that a pharmacist can at least refer, aside from the

obvious question that they can call the veterinarian with any questions as well.

The idea that a pharmacist really can't dispense these, surely there are some exceptions, as there are in the human context, where you have some drugs that are under restricted distribution, restrictive or risk evaluation mitigation strategy, or REMs they're called on the human side, that says you can only dispense this drug after a physician has gone through a certain amount of training or they've had certain lab tests for that particular patient, for safety reasons.

Are there examples like that on the animal side? Yeah, I expect there probably are, and I think most of the veterinarians here would probably know that there are some, but I think the concern here, and as far as this workshop goes is, are we going to let those exceptions drive the rule? Are we going to open the market up to allow generic competitors in the retail space, and then carve out the exceptions where necessary to ensure animal safety?

MS. WILKINSON: Thank you.

I would like to move on and talk about the fact that we've heard today that as a result of exclusive distribution practices, that many retailers currently obtain at least some portion of their product supply

through the secondary distribution system. What I'm interested in understanding is whether there are any inefficiencies associated with this secondary distribution system for both prescription and over-the-counter pet medications and how do these inefficiencies impact consumers?

Mr. Hinckle?

MR. HINCKLE: Okay, I'll just pick back up again. Again, speaking from somebody who represents generic drug companies, one of the things that I've heard that's a problem for getting generic companies' products into, in this case a chain retail drugstore, was the chain said, look, we can't really carry your generic if we can't also carry the brand.

From a corporate perspective they said, look, we're not comfortable buying product outside of what in the human side is considered the normal distribution chain. We don't want to get it outside. They deal in a PDMA world, the Prescription Drug Marketing Act, where everything is very controlled on the human side. I think Gregg talked about that from that perspective.

So, they are very uncomfortable getting out of that chain, and so the impact is that the generic products can't get into the retail market either because the brand products aren't there. That clearly has an

impact on consumers.

MS. WILKINSON: Thank you.

Mr. Dayton?

MR. DAYTON: You asked a question on inefficiency, I think the largest inefficiency is time. For products we cannot obtain, we go to a secondary supplier, which takes longer to get the medication to our patients. So, I think time is the biggest inefficiency.

MS. WILKINSON: Thank you.

Mr. Smith?

MR. SMITH: I think just in classic supply chain consideration, you're always going to look at how many players are there in a supply chain, how many times is a product received, touched, reaped, distributed, shipped somewhere else. And so when you think about the chart Dr. Pion put up with all the arrows, and all the additional touches that are occurring all across the supply chain, it inevitably has to cost more money when you have more people making a profit along the chain, more people touching it, more freight miles, it can't be cheaper.

The other thing that I would add is, at some level, when you think through that chart, and then you think about the average end prices that are being

offered to consumers, it also makes no sense that the product that gets tortured along the longest supply chain with the most touches is generally showing up to the market right now with the lowest price. It makes no sense.

I think it demonstrates where margins must be taken by certain players and the rate at which they're taking those margins. It's not an efficient market. I think the notion of convenience needs to be treated carefully, because convenience at a cost is a certain question. If I don't want to drive somewhere, because I just want to have it prescribed and I want to take it, fine. I think it's very well documented that prices are much lower and if price becomes an important issue to the consumer, then you can't claim that convenience at a prescribe-and-fill location is better than how often do they go to a supermarket or a place where a pharmacy is, that's also convenient. We don't shop in a meat shop, a bakery, and a sporting goods store. In our world today, consumers need access and convenience to product, and the obvious preference is they like to be able to buy more than one thing in one place.

So, there's obviously inefficiencies for the consumer as well. I don't think it's more convenient to have to go to the vet every time I want my Heartgard

refilled.

MS. WILKINSON: Thank you.

Mr. Powers, did you have a comment you would like to make?

MR. POWERS: I was going to echo his comments. Any product, whether it's hardware or housewares, where you include another step in the distribution channel, is going to raise prices for the consumer ultimately. Most companies have a minimum mark-up they can work on and still be profitable. Cost enters into that equation. So, every incremental cost you add, from the time the product is manufactured until it gets to the ultimate retailer, will definitely affect the price of that product to the consumer.

MS. WILKINSON: Thank you.

Dr. Pion?

DR. PION: I think it's important to remember there's many different sides to the answer. So, from a cost basis, to me, the one who has the most to lose by opening the supply chain is the manufacturer. The Walmarts, et cetera of the world push back on them and buy on consignment, as they do with all others, and it will bring lesser prices. There's other dangers in that even if they're over-the-counter products, it doesn't mean they're without harm.

The EPA has been looking into the registration of many of the spot-on products and if they're actually causing problems. There are questions about lack of efficacy, because of inappropriate use and overuse and the species of insects or parasites that they're aimed against becoming resistant to them. These are all questions that are coming up.

So, again, I'll reiterate, I don't think it's the veterinarians who are arguing strongly about this. All the veterinarians really want is a level playing field. I don't think they would mind at all if their clients could purchase this for their patients for less money, they just want to have an equal footing in there and to give the consumer an option.

MS. WILKINSON: Thank you.

Finally, Mr. Vranian?

MR. VRANIAN: I think that certainly I defer to many of the points that were made, but we have to realize that this market is very dynamic and it's evolving and these inefficiencies are resolving themselves. Manufacturers that were cited in an earlier presentation have embraced the non-veterinary channel, voluntarily. We have seen innovations such as home delivery services that embrace the Veterinarian-Client-Patient-Relationship that leverage both of those.

You've got mobile clinics.

So, to the extent there are inefficiencies in the market, I would just put out there that the market appears to be addressing them as well.

MS. WILKINSON: Thank you.

MR. POWERS: Excuse me, I would disagree with that.

MS. WILKINSON: Okay.

MR. POWERS: Let me tell you why I disagree with that. Some of the same manufacturers who are restricting distribution to us today up until a year and a half ago were encouraging us to carry their prescription products and soliciting us to do more business with those prescription drugs.

An arbitrary decision made by a manufacturer to no longer sell to us without even informing us, left us with a case of we have lots of prescriptions on file with customers needing refills and the drugs aren't available to us.

So, I would disagree that it's an open channel, and I would disagree that it's an arbitrary relationship. It's an arbitrary decision on many manufacturers' parts to turn off and turn on the spigot of their prescription drugs.

MS. WILKINSON: Thank you.

How do manufacturers typically respond when veterinarians resell products to retail pharmacies or to secondary distributors?

Mr. Vranian?

MR. VRANIAN: As the manufacturer on the panel, I can only speak from experience at Novartis Animal Health and only conjecture about what others might do. There appears to be a range across the industry. Some might leverage the secondary market to obtain sales they might not have obtained through the veterinary channel. We've seen, over the past two decades, companies claim to try and be able to control that, claim to be able to police it and implement measures that they say can stop it, but even those products tend to wind up in the veterinary market.

I think in both cases, it can be a distraction for both the manufacturer and the veterinarian when our primary purpose is ensuring the safe, quality health care of our pets. So, we've been in this industry for two decades. We started before the Internet, it was before my time, but my sense is that this really started happening with the advent of online retailing. We had a history of trying to stop it. It was impossible. It's clear that this is an economic force and where there's sufficient demand for a product, the consumer or the

market is going to find a way.

It's not our place, and there are many illegitimate secondary markets, but a secondary supply can be done legally and it's not our place to prevent a legal business from operating in any way.

So, we refocus on controlling what we can control and that's focusing on the health and well-being of our patients. To the extent that we see a counterfeit or unapproved product, that is aggressively pursued and reported. Let me put that out there. We ask our contractual customers to guarantee what they are going to do in the context of the Veterinarian-Client-Patient-Relationship. We don't incentivize our sales force to somehow look for opportunities to create a secondary market. They are not incentivized if those things are found. And if we learn of somebody that has represented to us that they're going to sell in the context of the Veterinarian-Client-Patient-Relationship and breaches that representation, we have terminated supply relationships with those clients.

We don't publish this to other customers, we don't use it as a marketing tactic at all. I think that's part of the distraction we're talking about. Instead, we consider it our job to focus on what we can control. Does that mean that some of our product leaks

through to the market? We know it does. Our best estimate is between two and five percent maybe on an annual basis winds up in the secondary market. The cost of trying to stop that, setting aside competitive issues, is just cost prohibitive.

We focus on bringing clients back to the veterinarian and controlling what we can control. In the end, our objective through these measures is to protect the quality and health and life of animals. It's not to protect the channel, control distribution, limit competition or support inefficient businesses. Rather, our driving goal is to meet our medical needs through the innovation and ensure the health and quality and life of our companion animals.

MS. WILKINSON: Thank you.

I don't know if anybody would have a response to this, but how do veterinarians view the practice of their colleagues reselling products to retail pharmacies or to secondary distributors?

Dr. Pion?

DR. PION: They certainly are not looked upon kindly, but also, I think it makes us sad that colleagues can't support themselves by providing services and need to look for other ways. I talk to veterinarians every day now who are going bankrupt, and that makes me

worry about the future of our profession and the ability to provide the services and the relationship that everybody here seems to value so highly.

So, in some ways, I can understand the desperation of some, and I don't understand those who purely get into it when they don't need that. I'm not justifying it in any way. I see it outside the way things are supposed to be, but I see that a lot in the world.

MS. WILKINSON: Thank you.

MS. JEX: I want to thank everyone for submitting so many questions, I'm having a little trouble figuring out how to ask them all. So, bear with me.

There are several questions from the audience that relate directly or indirectly to the issue of the term "diversion" or "gray market." Many people are familiar with the term "diversion" as used in the human pharmaceutical market, which typically involves counterfeit, adulterated or the illegal trade in narcotics. In our workshop, we've been using the term "secondary distribution," but the terms "diversion" and "gray market" have also come up in the context of our workshop today.

Could any panelist address the issue of how is

diversion different in the animal pet medicines market as opposed to the human pharmaceuticals market, and with regard to the issue of secondary distribution, what is the legality, the status of the legality of, for example, a veterinarian who has a valid wholesaler distributor's license, reselling prescription products into the secondary distribution channel?

I apologize for the complexity of the question.

MS. WILKINSON: Yes, Mr. Jones?

MR. JONES: As you mentioned, the term "diversion" in the human side of prescription drug distribution generally always implies something illegal occurring such as the diversion of controlled substances, the diversion of complex special priced medications within that system.

As far as the diversion of the veterinary prescription drugs, as we've touched on here on the panel, there are some very widely varying regulations that deal with veterinary drug distribution, and some states actually allow veterinarians to have a wholesale license, and it's not illegal for the veterinarian to wholesale their products. Some are allowed to actually obtain a veterinary wholesale distribution license and there are no specific audit trail requirements in whether they buy under their veterinary license and sell

under their wholesale license.

So, these terms "diversion" may not be as negative in the veterinary industry related to the legality of them as they are on the human side.

MS. WILKINSON: Thank you.

Mr. Smith?

MR. SMITH: So, just maybe a quick point of clarification. First, I used to work for Walmart two years ago, I no longer do. So, at some point I'm reflecting back on some of the things that we were working on and considering then.

As it relates to the way Walmart, and I presume other retailers, work, when a product comes into Walmart, vendors are required to indemnify the retailer as to the integrity of the product, to the efficacy, the safety of the product, that the product is what it claims to be, and that's the requirement of the vendor who delivers the product into Walmart.

The challenge a retailer has with diversion from a legal perspective is that our preference is not to divert product, because the chain of custody becomes really problematic. We would prefer sourcing the product from the manufacturer to know that that supply chain has had all the integrity, all the controls. So, diversion is something that creates this legal gray area

as well, and it's not good for anybody when that legal uncertainty exists.

I know Walmart, for one, would prefer to do business with all these great manufacturers who provide products to their human pharmacy. That's safer for everyone involved, if that were the case.

MS. WILKINSON: Thank you.

I would like to move on now and discuss the exclusive dealing arrangements that may exist between some manufacturers and distributors. In particular, I'm interested in understanding what are the business rationales for these types of exclusive dealing arrangements?

Mr. Vranian?

MR. VRANIAN: We don't have them. Novartis, on behalf of Novartis, we don't use them, but we know they exist out there. I would be interested in the distribution perspective on this, but some context as to the role of distribution within animal health is helpful and we received some good context in the opening comments. But it's absolutely essential in the veterinary medication industry, if you have 25,000 customers out there -- so distributors have a sales force that has a huge share of voice with these customers -- they're one-stop shopping for the veterinarian.

Everything from Novartis products to syringes to latex gloves, they can rely on their distributor for.

We have one of the most highly qualified or highly respected sales forces in the industry, about 300 folks out in the field. But for every one visit that one of our guys or one of our sales representatives has in the field, they get five to seven from a distributor rep. There's just a share of voice out there.

Most distributors deal with all manufacturers. I think they pride themselves on the ability to carry everything, to be one-stop shopping for everybody.

It's particularly relevant today, and that's because distributors can be very effective when you're launching a product, with that voice. What I referenced earlier, the ability to launch the new information, the science to a veterinarian, having that presence within the clinic is very valuable. As our industry shifts into more generics and we're seeing a rise in generics, each generic in and of itself is a launch, so to speak. So, the ability to leverage distribution to that is a useful thing.

We've seen both sides of it. We've had competing molecules to ours that have gone off patent launch and become part of differentiated generics and they've, through savvy use of distribution and certainly

merits of the product, achieved extraordinary penetration within a year. It's been good.

We've also been on the other end of it. We recently launched a generic version of a blockbuster product, and a differentiated generic, the one that had the off-patent molecule with a compound that provided superior efficacy. This product was well adopted by the vets that adopted it, but we were unable to access distributors. We presume that was due to an exclusive dealing arrangement. Obviously we don't know the details of it, but we achieved one, two percent penetration on that product in a launch. You had a superior, lower-priced product that was just not getting that share of voice out there.

So, to the extent exclusive arrangements can be done in a pro-competitive manner that may facilitate lower prices or access to medicines, but to the extent that they're done to protect from market forces, I think that they're anti-competitive.

MS. WILKINSON: Thank you.

Mr. Cushing?

MR. CUSHING: Thank you. I appreciate the explanation from Novartis.

First of all, it's much less common than you might think, and the line between generics and pioneer

of course changes. Bayer just announced it acquired Teva on the animal side. So, our members of the AVDA typically have between 20 and 50 generic products in their portfolio. As counsel for Novartis said, it's a very competitive business, multiple distributors carry multiple manufacturers' products and that happens all the time out there in the marketplace. Some distributors are regional, a handful are national, and the instances are very few. You can count on one hand, I believe, you don't need all five digits to count to my understanding the cases where there would be an exclusivity only as to a specific generic tied to a specific pioneer product. And there's a couple of those instances, but this is not a typical practice and certainly not one on a scale that would, I think, concern the FTC. It's also not unlawful, to state that up front, but it's just not a common practice. So, I think it's much less of a concern.

MS. WILKINSON: Thank you.

Mr. Bane?

MR. BANE: It's become less of a concern, it's actually changed over the last handful of years or so, and there are fewer of these instances. I think it's becoming less and less of a problem. In addition, because of some of the newer business approaches, not

everybody is under those same restrictions. In fact, we've never signed an exclusivity contract with anyone. We feel as though from a pharmacist's perspective, we need to be able to provide those medications that we're being requested to fulfill, so I have never signed an exclusive arrangement with any manufacturer.

MS. WILKINSON: Thank you.

Mr. Smith?

MR. SMITH: I'm kind of confused by that because I don't understand how access is being made available to all pharmacists, it's just not true. A pharmacist can, like a Walmart pharmacy, for instance, can secure the drug if we're willing to work with a diverter, but there is an exclusive distribution reality in terms of who the product is going to and it's to certain distributors who then in turn will not deliver it to Walmart.

I think it's important here to kind of talk about exclusive distribution and what I think it effectively does. From the manufacturer's perspective, they're very happy to have brands that are effectively supported by that recommendation of the veterinarian. And as long as they can preserve a place where theirs is the exclusive product that's being recommended, that's a tremendous place to be when every consumer is interested in following the advice and the counsel of their trusted

veterinarian. The brand value associated with that vet recommendation is I can charge higher prices, I can have higher margins, because it's what the veterinarian has established from a brand perspective as the most efficacious, the most optimal medical treatment.

From the veterinarian's side, if they can avoid a brand or a competing product, they have a challenge as well, because they have a conflict of interest, because their recommendation creates a lot of sway with the consumer.

To the comment earlier -- “this is a solution looking for a problem” -- I think there's a real problem that needs a solution. And I think when you look at the American Medical Association, and this is a quote from the American Medical Association, I think I referenced it, "Under no circumstances may physicians place their own financial interest above the welfare of their patients. If a conflict develops between the physician's financial interest and the physician's responsibility to the patient, the conflict must be resolved to the patient's benefit." So, to me, the problem here is when an exclusive distribution is connected to the legal right to also prescribe, and it's in a limited number of places where that product can be dispensed, you have a problem with a conflict of interest.

We don't dislike our human physicians, but we expect our human physicians to be completely objective and independent in the things that they prescribe to us, the medical direction they give us. And as long as there's a personal interest in there, that can be really challenged. I think that's the problem that needs the solution.

MS. WILKINSON: Thank you.

Dr. Pion?

DR. PION: So, a couple of points. One, I think when you look at 1406 and you look at the prior comment, I don't think the focus really needs to be on the veterinarian. I think if you look historically -- and your question was more about manufacturer-distributor relationships than it was to pharmacists, but of course they're down the chain -- it is true that it's less of an issue today. But I don't think that was as much a voluntary choice as just the reality that as is happening in many industries, very much in the veterinary industry, consolidation is taking place. The number of distributors who came together and were bought up and gobbled up, it just created confusion. Because now you had to actually -- when the consolidation began, actually that discussion happened, okay? You sell this manufacturer and this manufacturer. When you consolidate, you're going to have to choose. I think

eventually it got down to so few that that conversation didn't make sense anymore.

I don't think it's in anybody's best interest, other than the manufacturers, to have those type of exclusive relationships; not to the consumer, not to the veterinarian, both for price, convenience and other reasons. I think that it did lead to some predatory practices. I mean, I think the place it still occurs in our industry is in the veterinary lab sector and especially in-house. I know that the FTC is investigating that as well within our industry.

That involves distributor relationships as well, where there are some of the larger lab providers are playing unfairly and making it impossible for others to compete.

So, I think the answer to your basic question is that the restricted practices are in nobody's best interest, other than the manufacturers.

MS. WILKINSON: Thank you.

Mr. Hinckle?

MR. HINCKLE: I'm not able to really comment on the pervasiveness of these types of agreements, and it may be that they're rare, I don't know. But what I can say from my personal knowledge, what I've heard from my clients, I've had at least one client tell me that

they were considering launching what I would consider more of a branded generic, much like Novartis was talking about. So, these are generics in the sense that they're approved through a pathway that relies somewhat on a prior product, but the fact is they are sold as a branded product through the veterinary channels directly to vets. They opted to discontinue their R&D program, because they felt like because of the exclusive arrangements that were there, they were not going to be able to get market penetration. That's one anecdotal thing from my experience.

I would also say that there's a difference when we're talking about generic products because those branded generics that compete with the brands as a brand product with a sales force through the veterinary channels versus what one would consider on the human side a more typical straight generic that's sold maybe even without a brand name in a retail pharmacy and relies on pharmacy substitution or drug selection depending on the state laws where the pharmacist actually makes the switch in the pharmacy.

That's what I've pointed out before is really missing in the animal drug market now.

MS. WILKINSON: Thank you.

Finally, Mr. Cushing?

MR. CUSHING: Yes, just two points to respond to my colleague. First, we were talking, there's two types of exclusivity, and I think you may have been thinking this statement was made that there's not a number of exclusive relationships vis-a-vis veterinarians. Yes, there are exclusive vet channels. We were discussing, I thought, the issue of exclusivity in terms of very limited practices where a manufacturer would say to a distributor, if you carry X, you can't carry Y, that was the comment made there, and that was quite limited.

However, having the microphone, I do want to comment that I think, and I'll just be blunt, I think it's superficially appealing, but I think it's unfair to veterinarians to create this drama around a so-called conflict of interest that they have and that they're somehow placing pricing burdens on their clients.

Number one, I just don't think that factually describes what happens. And secondly, veterinarians, all day long, utilize a whole host of medications, many of which are human, many of which are prescribed through pharmacies, to address their clients' pets' needs, and I don't think there's this calculation going on that somehow they're attempting to maximize their revenue via some preferred branded product. I think that theory sounds attractive and would get people excited. I hate to

disappoint folks, I don't think that's the reality of the U.S. veterinary practice. I think if it was, you would have seen consumers storming Congress when there were efforts made by parties supporting 1406, there was a broad social media effort to get consumers to go to Congress and show your concern about this practice. Hence my solution in search of a problem, because guess what, the phones didn't ring, the emails didn't fly. You didn't see pet owners perceiving that they were in the sort of vise that's been described, and I just don't think that's the factual case and for that reason Congress hasn't taken any interest after two years.

MS. WILKINSON: Thank you.

Mr. Hinckle, would you like to briefly respond?

MR. HINCKLE: No, I'm sorry.

MS. WILKINSON: I saw your placard up. So, we are technically --

MR. POWERS: I have a response.

MS. WILKINSON: Brief response, Mr. Powers?

MR. POWERS: I disagree once again with Mr. Cushing down there. I do believe there's a problem. I believe that 1406 may or may not be a bad bill, we can discuss that this afternoon, but I don't think as many consumers, pet consumers knew about that or were able to be as reactive to that as Mr. Cushing stated. I do

think there is a distribution problem. Again, Dr. Pion said that veterinarians shouldn't care whether the channels of distribution are open or not, and he laid the blame at the feet of the manufacturers. I agree with him. And for the life of me, with all due respect to Mr. Vranian, I don't understand why companies like his or Pfizer restrict distribution to a company like ours who has both veterinarians and pharmacists on staff. Thank you.

MS. WILKINSON: Thank you.

We are technically at the stopping point for this panel, but I think it would be important to try to go into some of the safety issues that we were planning to get to. If people on the panel are willing to spend another maybe five to ten minutes discussing, I think it might be worthwhile to extend our time a bit. Is that all right with everyone? Okay. We'll try to move through this very quickly.

What product safety issues exist with respect to the secondary distribution system that people feel haven't already been addressed?

MR. BANE: I'm not sure that they haven't already been addressed. As Gregg said, from the NABP, the regulations vary from state to state. I'm no JD, but have read more than I care to remember about the

distribution requirements from state to state, and there are concerns that when we have what's called a normal distribution supply chain on the human side that's regulated by pedigree, that was put in place for a reason. There were tremendous abuses going on. If anybody wants a good read, Dangerous Doses is a fantastic historical account of exactly why those rules were put in place.

I think that some of the practices today create these loopholes whereby it's just a matter of time before there's some adulterated or counterfeit product that's going to be placed in the marketplace. Arguments are that maybe these compounds aren't that important and the criminals will focus their efforts elsewhere. But certain shortages in the marketplace and existing demand by consumers I think will ultimately lead to some places whereby these products can enter through a non-regulated mechanism into the channel and there's potential dangers there.

MS. WILKINSON: Thank you.

Mr. Miller?

MR. MILLER: A very interesting question given some recent discussions on the FDA side, specifically as they pertain to human drug shortage issues. And what has cropped up in response to that with gray market, where

pharmacies purchase then sell back to other wholesalers, who sell to other tertiary wholesalers, who sell to other pharmacies. And what you see is this massive churn in the system. And where the safety issues start to come in, as those of us, the pharmacists on the panel, my preference is to always purchase either directly from the manufacturer, or through a wholesaler who has a direct relationship that is licensed and regulated.

The minute we start, as I mentioned before in my own presentation, when I have to obtain a product from a veterinarian because I can't buy it through my regular channel, two types of safety start to play a part of it. Number one is, how is that medication handled? Was it stored appropriately? Did it go through the appropriate environmental handling methods that we expect?

The second is, is it what it is? Because the minute that you start introducing an additional player -- a veterinarian who sells to a pharmacy, a pharmacy that sells to a secondary supplier, a veterinarian that sells to a wholesaler -- you give the opportunity, as you were just saying, to have diversion in the truest sense, which is the introduction of false or counterfeit medications into the system. The minute I don't know where this came from, as a pharmacist, as a

practitioner, as a veterinarian, then there is a safety issue.

The unfortunate thing -- and we see this on the human side, it's even worse on the veterinarian side -- is if we have treatment failure because of a medication, we don't know because of the current marketplace whether that medication didn't work or it's not what it says it was. Because I don't have that assurance of the supply chain integrity that I should have, but has unfortunately been manipulated by relationships between manufacturers and the terms that they place on the wholesale distribution system or veterinarians themselves.

We need to open the marketplace up so that legitimate, licensed pharmacies can purchase the same way that a veterinarian can purchase from either directly a manufacturer or wholesaler. Then there will be no need for a secondary market.

MS. WILKINSON: Thank you.

Finally, Dr. Pion?

DR. PION: I think just for completeness, since I think we've covered most of the issues, there's one indicator that I think the market has gotten much more open but a source of question of how deep the diversion definition went in this market is in years past there was a significant amount of the online pharmacies, et

cetera, that would deliver products that were registered for outside this country coming in, Australian products and other countries. And I think it speaks to how open the market currently is that I really don't hear that from colleagues that clients aren't coming in with those products anymore. So, it seems like there is adequate openness to the chain at this moment.

MS. WILKINSON: Thank you.

Moving quickly through this, there have been a number of concerns raised today about pharmacists who may be untrained in veterinary pharmacology dispensing pet medications. I have a few questions about that. One is could manufacturers of pet medications provide product training to retail pharmacists similar to the types of training they provide to veterinarians? If anybody would like to respond to that.

Mr. Vranian, you're the manufacturer on the panel, so you might be the obvious place to start.

MR. VRANIAN: To the extent that doing so would enhance the quality of pet care, absolutely. But as I mentioned earlier, we have a $2 million market product and -- I don't know how many -- 60,000 pharmacists around the country. It may wind up increasing the price of certain products. But our primary goal is the quality of life for the animal.

MS. WILKINSON: Thank you.

Mr. Dayton?

MR. DAYTON: As I said in my presentation, a pharmacist might not always know the answer to every question. But it was mentioned earlier that if you have a package insert that is the way a pharmacist, when they do not know information, gathers information and uses it. So, if we have the package insert coming from a manufacturer, we have a better chance to answer questions and dispense medication properly. So, I think that it addresses the safety. Dr. Pion in his presentation addressed that pharmacists are already a trusted partner in the medications that we do dispense. If the market is opened up, we have access to that information. I feel that pharmacists can continue to be that trusted partner.

MS. WILKINSON: Thank you.

Mr. Miller?

MR. MILLER: The question was whether the manufacturing industry has a responsibility to educate the pharmacy profession. I would say absolutely not. That is ultimately our responsibility. It needs to fall within our curriculum, it needs to fall within the continuing professional education, our board certification processes, the specialty that pharmacy has, just as any other health care profession does.

Having come from the pharmaceutical industry and having worked in education, the objective of a manufacturer is not to teach how to, but rather to teach about the product that they are bringing to market, the particular therapeutic class, where it fits, new diagnosis, new trends.

So, I think we have an obligation as pharmacists to train ourselves. We need to do that collaboratively through our professional organizations, with AVMA, but most especially, and I want to re-emphasize this, because it's been mentioned a few times and I find it personally very disturbing as a practitioner. You know what, if a pharmacist is making an error or making a judgment call that is inappropriate, there is a way to handle that. And that is actually through our boards of pharmacy. If a pharmacist changed a human prescription, without calling the doctor, that's illegal. It's like pharmacy 101. It's illegal. We're not allowed to do that. And you guys will come and get me.

It should never happen in the veterinary industry either. I will tell you right now, AVMA, if you know of instances, you need to get that in front of our boards of pharmacy because that is not the way practice is done. This is collaboration. Ultimately, pharmacists, vets, need to train each other on how best

to work together, not the manufacturers.

MS. WILKINSON: Thank you.

I'm going to give Mr. Cushing and Dr. Pion a chance to respond, but just in follow-up to what Mr. Miller just raised, should retail pharmacies or pharmacy schools be offering veterinary pharmacology training to pharmacists?

Mr. Miller?

MR. MILLER: Yeah, that's a no-brainer, sorry, Stephanie. Yeah, of course, we should.

MS. WILKINSON: I wondered if anybody else wanted to respond to that.

Okay, Mr. Cushing?

MR. CUSHING: Thank you. I think, first of all, the key is for pharmacists, which most do, to understand that if they are inclined to change and not deliver the product that was prescribed by the veterinarian, pick up the phone and call. I mean, that's the most basic idea here. I will say, had we had state VMA officials participate, you would have heard it is not an easy thing. And there have been many efforts in many states to work with state boards of pharmacy. And as you may expect, some are easier to work with than others. Some are more successful than others. It's to get the pet owner, the veterinarian may hear about it much later to

get in and make sure you've got all the evidence to go to a state board of pharmacy and begin a proceeding. It's complicated. People can decide it may or may not be worth their effort to do. There's a lot of ongoing discussion. I know in the case of Oregon, the Oregon VMA and the State Board of Pharmacy talk all the time. And unfortunately, it's not as simple -- and I'm sure you don't think that -- but it's not as simple as it may sound and there's a lot of ongoing effort to try to do that.

You're right, that's what should ultimately happen, because the state board of pharmacy should say, don't do that, and stop that practice.

MS. WILKINSON: Thank you.

Dr. Pion?

DR. PION: So, I think in theory it sounds easy, and that label is clear and confusing. But the reality is, in our profession, off-label usage, whether a veterinary product or non-veterinary product, is the majority of usage. And much of that information is generated after the product's released. It costs the manufacturer a huge amount to go back for another indication, another label. They don't want to change that label. If the product is out there, and the profession is learning how to use it and evolving and finding other uses, that's what they want. It's not

even just off-label at indication, it's moving it into other species. Most of the time a product gets into another market just for one species or two species and then they're looking to refine where we can use it in other species. There's many indications where the label dose is wrong, and it doesn't go back and get changed. But it's through collegial communication that it gets communicated that this is a better dose, and you can follow that in many ways.

Just to address the simplicity of reporting things to the boards, I know in our work, we have called many veterinary boards, many pharmacy boards, on pharmacy issues, and often there's confusion in the states about who's responsible. We call the pharmacy board, they say, why are you calling us, call the veterinary board. We call the veterinary board, they say, why are you calling us, call the pharmacy board. And they don't even know if diversion, as we've defined it here, is legal or illegal. They don't know if in their states veterinarians can resell prescription drugs. So, I think there's many levels here that contribute to the situation where we're at.

MS. WILKINSON: Thank you.

One final question that I will probably pose to Mr. Vranian, what position do manufacturers take on

whether to guarantee products that are distributed through the secondary distribution system, and do manufacturers have concerns about product liability issues in the event that consumers purchase either expired or adulterated products from retailers?

MR. VRANIAN: We certainly have those issues with adulterated products, which underscores some of our distribution practices that we've discussed earlier. On the product support, I think you need to differentiate between technical medical support and perhaps commercial premiums or premium support, for lack of a better term.

We provide technical support irrespective of origin. Everything, no matter where somebody bought a product, is reported to the FDA as an adverse event and that adverse event is logged and becomes part of the technical support record.

Where a veterinarian is involved, one of our voluntary policies is to provide reimbursed diagnostic costs where our product may have failed or where efficacy could be an issue or have caused an adverse event. Necessarily a veterinarian needs to be involved in that equation. There's patient records, there's a history of that patient. So where that's initiated by the veterinarian, which is who we usually get the call

from, the origin of the call does not make the determination.

Now, if somebody calls us from the street and they've purchased it from the secondary market and demands free product, that will probably be the end of the discussion right there and that's just not something we do. Each of these is honestly looked at on a case-by-case basis, but that diagnostic reimbursement guarantee is what I would call our premium level support, and honestly, where a veterinarian is involved, where they initiate, it is not determined by product origin.

MS. WILKINSON: Mr. Powers, if you would like to briefly respond?

MR. POWERS: The second part of that you asked, Stephanie, what about expired product, et cetera. I think as David Miller suggested, the easiest way to solve the distribution channel issue in secondary distribution in gray markets is for the manufacturer to have direct relationships through themselves or through authorized distributors with companies like ours. When you talk about old or outdated product, ironically -- and I don't mean to cast any aspersions on the veterinary profession, some of my best friends are veterinarians -- an article this summer in DVM Magazine reported when in

Massachusetts they inspected veterinary clinics, 20 percent of those clinics had misused, expired or poorly handled products. In some cases it was the second or third offense of those clinics.

So, the issue of product viability, efficacy, and whether outdated or not, extends throughout the channel, and I think it needs to be policed at every level. One of the things that companies like ours and other people here who are Vet-VIPPS certified do is they have a prescribed policy for handling product and how the product is stored and they have to follow it or they lose certification.

MS. WILKINSON: We have definitely gone way over our time and I think in order for people to have enough time to eat lunch before our afternoon sessions we do probably need to end the discussion.

I would like to thank all of our panelists for their participation. I think this has been a really interesting and informative discussion. If everyone would please join me in a round of applause for our panelists.

(Applause.)

MS. WILKINSON: So, we'll now take a short lunch break and meet back here at 1:00 for our afternoon panels. There are hand-outs out in the

hallway about lunch venues that are nearby and many of them move very quickly. Thank you.

(Whereupon, at 12:04 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(1:02 p.m.)

PANEL TWO

PORTABILITY OF PRESCRIPTION PET MEDICATIONS

MS. KOSLOV: I think we will go ahead and get started with our afternoon session, if everyone could please take their seats.

Good afternoon, everyone, thanks for coming back from lunch. My name is Tara Koslov. I am the deputy director of the FTC's Office of Policy Planning, and on behalf of all of us, I would like to thank you again for coming to our workshop. I would especially like to thank this morning's panelists and presenters for their excellent presentations and discussion.

In our first panel this afternoon, which focuses on prescription portability, we hope to really build on some of the topics we heard about this morning and see where we can go from there.

One thing that's become clear from what we've heard so far is that any discussion of what's best for consumers and their pets has to start by recognizing the importance of the Veterinarian-Client-Patient-Relationship. Of course, pets should be properly examined and diagnosed by a veterinarian so that the vet can determine the appropriate course of treatment and that might include

the prescription of medication.

So, with that context and framing in mind, what we hope to focus on in the next session today is what's the best way to handle the dispensing of pet medications, assuming that there is a prescription for medication.

Historically, vets have done most of the dispensing and selling of pet medications, not just the providing of the medication, but also providing important information and counseling to ensure proper administration of drugs. But as we heard this morning, there are other alternatives that have become more prevalent in the pet meds marketplace, in particular over the last ten years, as we've heard, there has been a larger presence not only by brick-and-mortar, but also online retail pharmacies. And it seems that more consumers are, indeed, asking their vets for portable prescriptions so that they can shop around among alternative sources.

The issue of prescription portability clearly implicates a very complex network of state-by-state laws and regulations. So, to start our afternoon's discussion, in order to provide us with a foundation for the subsequent panel discussion, we are going to begin with an overview presentation by Adrian Hochstadt. He

is the director of the AVMA's State Legislative and Regulatory Affairs Division. He is going to explain some of the basic issues and applicable state and federal policies on prescribing and dispensing pet medications. He will also provide us with a brief summary of H.R. 1406, the legislation that we heard a little bit about this morning which would mandate, among other things, that vets provide written prescriptions.

After Mr. Hochstadt's presentation, we will ask our panelists to quickly yet gracefully get themselves to the table, and we will explore a variety of factual and policy questions relating to the provision of prescriptions to pet owners following a similar format to this morning.

So, Mr. Hochstadt, you are welcome to come up. Thanks.

MR. HOCHSTADT: Thank you, Ms. Koslov. It's a pleasure to be here. So, I'm going to introduce the second panel. We'll try to keep the flow going after lunch. Hopefully everybody is back.

I'm going to cover quickly some of the basic tenets of prescription writing and dispensing. I want to touch on the AVMA Principles of Veterinary Medical Ethics, talk a little bit about state regulation in this area, and also go over the basic elements of H.R.

1406.

So, let's get right to it. The basic tenets of prescription writing. Pet medications are either dispensed by a veterinarian as medically indicated, or the veterinarian provides a written prescription to a client who may then have the prescription dispensed at the pharmacy of his or her choice, either retail or online.

Prescriptions sometimes are provided by fax or telephone, although that's subject to state rules, and also DEA rules on controlled substances.

Traditionally, we've heard that veterinarians stock and dispense pet medications due to his or her specialized knowledge and training, and the fact that pharmacies didn't stock many animal drugs years and years ago. It was seen, and I think it still is, as one product of a larger service provided by that veterinarian.

In the last 30 years or so, we have seen more pharmacies, especially online, selling pet medications and prescriptions are being written. What caught my attention is a study referenced in the AVDA comments submitted to the FTC. During a 12-month period, in 2010-2011, more than 45,000 veterinarians provided more than four million prescriptions to be filled through a retail pharmacy location. So, these prescriptions are

being written. Under state laws and FDA rules, however, a pharmacy may only dispense a pet drug, pet medication to the client with a prescription from a veterinarian.

You heard a little bit about the Veterinarian-Client-Patient-Relationship, the VCPR. This is a critical piece at arriving at a decision that a prescription drug is needed. It's based on the lifestyle of the client, the needs of the animal, and the specific needs based on the situation.

A veterinarian may fulfill pharmacy-initiated requests, but only if medically appropriate, and in most states, within a VCPR that I mentioned.

Let me touch on the AVMA Principles of Veterinary Medical Ethics. Something was brought up during the first panel a little bit. This is a code of ethics. Like all the other code of ethics, they're basically the defining rules of what's right and what's wrong within a given profession. They were developed in the 19th Century in the learned professions, law and medicine primarily, and the essence of veterinary medical ethics was captured by one of the founders of veterinary medicine in the U.S., Alexandre Liautard, not for ourselves alone, or *non nobis solum*. And this is probably the last time that you will hear a Latin phrase today.

The AVMA approved the Principles of Veterinary Medical Ethics for the first time in 1867 to promote exemplary professional conduct and uphold the dignity of the profession. The document, of course, is revised as need be, to assure relevance to current professional practices and expectations.

The AVMA Principles address professional behavior in a number of areas, ranging from what's appropriate in consulting and referring clients, what are improper influences on judgment, keeping appropriate medical records, inappropriate fee arrangements, advertising, and the topic under examination today, the prescribing and dispensing of products to clients for use on their animals.

As explained previously, state governments license, regulate, and discipline veterinarians. So, while the AVMA Principles on their own are not enforceable, keep in mind that 12 states have incorporated these Principles into their disciplinary standards. And in the other states, certainly the AVMA Principles are a guiding tool to help those state veterinary boards determine what is unprofessional conduct.

Section III(c) of the AVMA Principles state that dispensing or prescribing a prescription product

requires a VCPR. Now, almost every state has adopted this language in some form. The VCPR is required for treating a patient, but also for prescribing or dispensing.

The VCPR requirement is also specifically incorporated into the federal rules in three places, which I'm going to show briefly. I don't plan on going into too much depth here. I wanted you to have the Code of Federal Regulations citation if anyone wants to do some follow-up on this, but autogenous biologics is one area, extra label drug use, VCPR definition was incorporated in this FDA rule, and veterinary fee directive, which applies more to food animals, but I did want to mention that the VCPR is also mentioned in those requirements.

Another AVMA Principles provision that is of interest here is paragraph III(c), a veterinarian should honor a client's request for a prescription in lieu of dispensing. Now, let's take a look at how states have addressed this provision. We have the 17 states that you see in green, that have a specific law or regulation or policy statement that basically mirrors that provision of the AVMA Principles that clients, when they request a prescription, the veterinarian should honor that client's request.

So, we have these 17 states. In an additional ten states, the AVMA Principles of Veterinary Medical Ethics, which again, incorporate that provision, officially is part of the disciplinary rules. There's some overlap. There are two states with both a specific law and which have incorporated the Principles. But the total, if you take the two groups, you're looking at 27 states with something specific in writing on the books that require a veterinarian to honor that client's request.

So, what happens in the other 23 states? I'm sorry, let me mention a couple of unique regulations that have to do more with notice, providing notice. Arizona, for example, has a law -- it's actually an administrative regulation -- that requires a dispensing veterinarian to notify the owner that some prescription drugs and controlled substances may be available at a pharmacy, and there are three ways of providing this notice. Note that under paragraph (B), however, a dispensing veterinarian may -- and it's permissive, not mandatory -- may provide a written prescription to the owner if requested.

Well, California has a slightly different statute there. The prescriber also must offer notice, but also the prescriber in California, prior to

dispensing, must offer to give a written prescription to the patient that the patient can then elect to have filled with a pharmacy, or with a prescriber. So, California has a notice requirement, and in addition to that, also a requirement that the prescriber must offer to write a prescription.

Before we leave California, though, I did want to talk a little bit about the other 23 states, because I don't want to leave you with the wrong impression. It's important to note that even in states without specific laws or regulations, the state boards of veterinary medicine, as we heard before, regulate the profession. They could easily find in acting on a complaint that failure to honor a client's request for a prescription constitutes unprofessional conduct, which can lead to discipline.

Unprofessional conduct generally refers to a departure from or failure to conform to the standards of acceptable and prevailing practice of veterinary medicine. State boards do routinely look at the AVMA Principles of Veterinary Medical Ethics as a guiding tool or principle in how to define unprofessional conduct.

In addition to the threat of disciplinary action, veterinarians also have some other practical

disincentives for not honoring a client's request, whether those are business reasons; alienating the client is probably not a real good idea; or even the threat of legal exposure when that particular pet needs medication on a timely basis, and failure to honor that request for prescription could actually expose the veterinarian to some liability.

So, let me touch on the pending Federal bill, H.R. 1406, titled Fairness to Pet Owners Act. This is legislation that was introduced in the U.S. House of Representatives in April 2011 by Representative Jim Matheson from Utah and Representative Lee Terry from Nebraska. Congressional co-sponsors include Representatives Phil Gingrey, Walter Jones, Jim Moran and Jim Sensenbrenner.

H.R. 1406 would require veterinarians to provide pet owners with a copy of the prescription, regardless of whether the client requests a prescription; and provide a written disclosure that the pet owner may fill the prescription through the prescriber or through a pharmacy determined by the pet owner; and finally, it would require that the veterinarian must provide or verify the prescription by electronic or other means to any person designated to act on behalf of the owner.

The legislation also would prohibit

veterinarians from requiring owners to purchase a prescribed drug as a condition for providing that prescription; would prohibit requiring payment for providing or verifying a prescription; and would prohibit requiring an owner to sign a waiver or disclaim liability as a condition of providing or verifying a prescription.

H.R. 1406 would also require the FTC to promulgate rules implementing and enforcing the act within 180 days of its enactment and violations of the rule would be treated as unfair or deceptive practice under the Federal Trade Commission Act.

While the AVMA is supportive of a client's ability to have a copy of the written prescription should they request it, AVMA, as you've heard earlier today, strongly opposes this federal mandate every time a written prescription is prescribed, and we look forward to explaining our rationale the rest of today.

I want to mention, there are other organizations opposed to this legislation, including some in the pharmacy community, such as the American Veterinary Distributors Association and the Society of Veterinary Hospital Pharmacists, and they are also opposed to federal mandates when the states are governing this issue adequately.

That's my presentation, and thank you for your attention.

(Applause.)

MS. KOSLOV: While we have all of our panelists coming up and taking their seats, I will remind, especially those who are watching via webcast, that you are welcome to submit questions at the hash tag #FTCpets. We will also be taking questions here on comment cards if anyone in the audience wants to pass them along.

I would also like to take this opportunity to introduce my co-moderator, my colleague Christopher Grengs, also from the Office of Policy Planning.

So, we will follow a similar format here. We're going to have each of the panelists make brief introductory presentations and then we will move to a panel discussion.

We are going to start with Dr. Race Foster. He is a licensed veterinarian and co-owner of Drs. Foster & Smith Pet Supplies.

DR. FOSTER: I would like to thank the FTC for inviting me to come participate. My name is Dr. Race Foster. I have had the privilege of serving the pet supply and pharmacy needs of American pet owners for 29 years through our company, Drs. Foster & Smith.

In addition to being a licensed and practicing

veterinarian, we have three other veterinarians on staff and have a full team of pharmacists to sell prescriptions in all 50 states. Our pharmacy is both Vet-VIPPS and PCAB certified. For 29 years, we have dispensed thousands of prescriptions each year and have never had a single state or federal dispensing violation or even a reprimand. That is a record I am very proud of.

It is our sterling pharmacy record that is one of the frustrating touch points regarding the subjects being discussed at this workshop, namely restricted distribution and prescription portability. In my definition, portability ends with filling the prescription, not just obtaining it. What I mean is that you cannot have true prescription portability without medication availability. So, while this panel is discussing prescription portability, written prescriptions are worthless without a product supply.

Today, in our pharmacy, we have more prescriptions on file than we are allowed drugs to fill. And I hope you don't forget that point, because I heard in this morning's session that drugs were freely available. Not.

The reason I suggest that our sterling record is a frustrating touch point regarding prescription

portability, is the false impression some drug manufacturers create as they suggest to the public or clients that all online pharmacies are not trustworthy. We have a proven track record and the appropriate accreditations showing that we are trustworthy.

The AVMA suggests that Vet-VIPPS certification is something a veterinarian and their client should look for when evaluating an Internet pharmacy. We have that certification. And just so you know, to be Vet-VIPPS certified, pharmacists have to do the dispensing. So, I'm not sure why sometimes we question that. It's if you want to be Vet-VIPPS certified, which is what the AVMA suggested, you have to have pharmacists do the dispensing.

When it comes to compounding of medications, it is PCAB accreditation that matters. We have that accreditation. When it comes to pharmaceutical qualifications, we have a pharmacy license to fill prescriptions, even human prescriptions, in all 50 states. When it comes to the question of understanding how medications affect animals, we are a company owned by veterinarians, which has veterinarians on staff. I am a veterinarian. We have both veterinary and pharmacy qualifications. You can imagine our frustration when the very drug companies that will sell us human medications refuse to sell us pet medications, implying

that such medications should only be dispensed through veterinarians. I am a veterinarian. Moreover, do they really mean to say that we are qualified to dispense medication for a child but we are not qualified to dispense medications for a dog or cat?

Now, in closing, let me get that straight. Our pharmacy has veterinarians and pharmacists on staff every day. We have over 80 years combined experience amongst the veterinarians, thirty right here. We have over 150 years combined experience in our pharmacists. We are FDA-inspected, DEA-inspected, Vet-VIPPS certified, PCAB certified, and have never had a single violation in 29 years.

We can buy all human drugs from companies such as Pfizer, Merial and Lilly to fill your prescriptions for you and your kids. But somehow I'm not qualified to buy their medications to fill prescriptions for your cat or even your pet rat? I mean, does it make sense to any pet owner in the audience? Really?

And while this may sound like a subject for the previous panel on restricted distribution, it is not. Prescription portability cannot exist without medication availability. I think pet owners deserve better.

Thank you.

MS. KOSLOV: Thank you, Dr. Foster.

Next, we welcome back Nate Smith, previously a retail product strategist at Walmart.

MR. SMITH: Thanks for having me back, and thanks for the workshop.

I commend the Federal Trade Commission for starting into this, and as I mentioned before, I think this needs to be the start of a process of creating a solution.

As Dr. Foster has pointed out, right now, if your child needs medication, you as a consumer have protection. The doctor gives you a copy of the prescription, without you having to ask, sign a waiver or pay a fee. You can take that prescription to the pharmacy of your choosing. Once you get there, you frequently have the option of a generic alternative. Alternatively, if your dog needs medication, you have no right to automatically receive a copy of the prescription. Once you get the prescription, you are limited as to where you can go to get it filled. When you do get it filled, odds are it will be with a name brand pharmaceutical as opposed to a generic.

So, when your child needs an antibiotic, you can go to a pharmacy and pay $4 or $5 for a full series of antibiotics. When your dog needs the same antibiotic, your vet will charge you $30 or $40 for the same

treatment. Something is obviously amiss and we need to change how this practice is working.

I have five points that I would like to make: First, this is an issue which affects most Americans. As was pointed out this morning, two-thirds of Americans own a companion animal. We spend about $7 billion a year on medicines and health-related products for our pets. Many Americans, if not most, view their pets as members of the family. They want the right to comparison shop for their pet's medication, just like they do for their own meds and for the meds of their children. They do not understand why they cannot.

Number two, 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 set rules to assure consumer choice and competition, just as the government has done with eyeglasses 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 veterinarians 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.

Number three, and I think potentially the most important, 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.

Number four, pet care is a discretionary expense. If a 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, to the pet owner, to the manufacturers, to the veterinarian communities, everyone.

Number five, we must not lose sight of the big picture. This is a very tough economy. Every indication is that it will stay tough for the foreseeable future, and 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. The Internet and purchasing using the Internet has become the norm rather than the exception. So, while a couple of decades ago,

buying pet medication only from your vet may have been the only practical choice, the world is much different today.

The Federal Government is already in this marketplace It bars pet owners from buying most medications without a prescription. I hope the government will step in again to allow this marketplace to operate like those for other prescription items, whether that is a prescription drug, eyeglasses, or contact lenses. Doing so will allow consumers to reap the full benefit of technological advancement and have the freedom to purchase their pet meds where they want, based on the best price, service and convenience.

It was a decade ago that the FTC, in issuing the Eyeglass Rule, recognized that automatic prescription release is essential to letting consumers know they have a choice. As the FTC stated in its 1997 review of the rule it issued, this automatic release requirement, based on finding of consumers' lack of awareness that eyeglasses could be purchased separate from the exam. Automatic release is still the most effective and efficient means of letting consumers know they have a choice.

As the FTC stated in its 2004 review of the Eyeglass Rule, "Release might not occur in the absence

of a federal release requirement" and "release of prescriptions enhances consumer choice at minimal compliance cost to eye care practitioners. . ."

I urge the Commission to apply these same principles and rules to pet meds.

MS. KOSLOV: Thank you, Mr. Smith.

Next we have Dr. Wendy Hauser. She's managing DVM of Coal Creek Veterinary Hospital in Centennial, Colorado.

DR. HAUSER: I am honored to participate in this workshop examining the very complex issues surrounding pet medications.

I am Dr. Wendy Hauser, I'm a small animal practitioner, from Centennial, Colorado, which is in the Denver metro area. I graduated in 1988 from Oklahoma State University's College of Veterinary Medicine. I practiced as a small animal veterinarian in New Jersey, Pennsylvania, and Parker, Colorado, prior to starting a start-up veterinary hospital, Coal Creek Veterinary Hospital, in 1998.

In 2008, I successfully transitioned from practice ownership when I sold my hospital to a national corporation. I continue to practice at Coal Creek where I do serve as the managing DVM.

I am a veterinarian because I love helping

people by helping their beloved pets. By forming strong partnerships with my clients, my patients benefit. During the course of a patient visit, client concerns are identified, an examination occurs, and clinical recommendations are presented. Those recommendations may include diagnostics, lifestyle modifications, and medications.

In prescribing medications to a pet, the best medication for the disease process is the reason that I select a drug. Additional considerations include: species, age, size, breed, existing medical conditions, potential for adverse drug reactions, and client input. Client education and communication is critical for satisfactory outcomes.

If there are several good options that exist, dialogue with a client occurs, and that includes the drug differences, also discussing cost. I routinely offer to write prescriptions if I'm aware that there are significant cost savings at human pharmacies. I acknowledge that health care for pets is expensive, or can be expensive, and I feel it's my obligation to lessen those costs when possible.

Today we're examining pet medications, specifically, and you haven't heard a lot about this, but specifically in regard to H.R. 1406. There are

significant concerns regarding this proposed legislation. Those concerns include compliance and safety.

I feel confident that when I dispense a medication to a client directly, that there's a high likelihood that my patient is going to receive the medication, cautionary adverse drug reaction statements are printed on the label, and the client is directly counseled regarding potential complications. When I provide a written prescription to a client, I don't know if that prescription gets filled, I don't know how it's filled, and I don't know what my client's told. Furthermore, default human adverse cautionary statements are usually attached to those prescriptions, which often times are not applicable to our veterinary patients and create confusion.

I fail to see how my client and their pet benefit from the latter scenario. I feel a tremendous sense of responsibility for my patients' well-being. Our veterinary oath dictates, and you've seen it once already today, above all, do no harm. I believe if H.R. 1406 is enacted, that drug-induced adverse events will occur and will cause harm.

MS. KOSLOV: Thank you, Dr. Hauser.

Next we welcome back Dr. Aspros, a practicing

veterinarian and also president of the American Veterinary Medical Association.

DR. ASPROS: Thank you. I am still Dr. Doug Aspros, president of the American Veterinary Medical Association, and represent the interests of more than 82,000 veterinarians, approximately 83 percent of the profession. We're dedicated to the science and the art of veterinary medicine.

I've practiced companion animal medicine in New York since my graduation in 1975 from Cornell University's College of Veterinary Medicine. I'm a partner at Bond Animal Hospital in White Plains, New York, and in Pound Ridge Veterinary Center in Pound Ridge, New York. I'm also the managing partner of the Veterinary Emergency Group in White Plains.

Every day, my staff and I strive to serve the best interests of both our animal patients and, as Wendy said, their human owners. Whether we're seeing a dog or a cat, a bird or a lizard, a ferret or a rabbit, our focus is on optimal care for that patient, and that care often includes the prescribing or dispensing of an animal product.

As we gather together to examine competition and consumer protection issues in the pet medication industry, I want to assure you that our utmost concern

is with the well-being of our patients. The AVMA does, therefore, have concerns with proposed federal legislation and the underlying premise that there's a need for such legislation. We stand behind AVMA's Principles of Veterinary Medical Ethics, which encourage veterinarians to honor a client's request for written prescriptions, and we continue to educate veterinarians about prescription drug rules and the importance of following these Principles.

The proposed federal legislation, as written, leaves veterinarians open to potential ethical and legal liabilities and would negatively affect the strong bond of trust that veterinarians have earned with their clients. Pet owners may encounter misinformation or inappropriate substitution from pharmacists who are not trained in veterinary pharmacology, who are prepared to discharge all of the responsibilities of a pharmacist when dispensing to a pet. Even worse, it increases the likelihood that pet owners will obtain counterfeit product online. The AVMA believes that veterinarians are uniquely qualified to provide professional guidance, support and education to pet owners when it comes to dispensing and administering prescription products to pets.

While we are not supportive of a federal mandate on veterinary prescription writing, the AVMA is

supportive of clients' right to choose where they have their prescriptions filled. We are, therefore, taking several steps to promote optimal outcomes for consumers who obtain prescription products for their pets from independent pharmacies. We are interacting with pharmacy stakeholders to help ensure that licensed pharmacists better understand their roles and responsibilities when it comes to counseling and educating pet owners when filling veterinary prescriptions. We are also collaborating with pharmacy industry to help determine how best to train licensed pharmacists on basic veterinary pharmacy issues.

We're honored by the ongoing confidence and trust of pet owners and to be a part of this important workshop, and we look forward to maintaining that trust.

Thanks.

MS. KOSLOV: Thank you, Dr. Aspros.

Next we'll hear from Dr. Elaine Blythe. She is a pharmacist, PharmD and an associate professor at St. Matthew's School of Veterinary Medicine on Grand Cayman Island.

DR. BLYTHE: Thank you.

I appreciate the invitation today from Chris and his team. I have come here today to participate and share some view points as a pharmacist educator. My contributions to the panel discussion are focused on the

educational offerings in veterinary pharmacy for practicing pharmacists, as well as pharmacy students.

As a licensed pharmacist, I may also be able to offer some insight into the changes that have occurred to the practice of pharmacy via the advent of third party payers, that is very common in the managed health care market that we all experience today.

I'm a firm believer in the development of close working relationships between pharmacists and veterinarians. I think there is a tremendous amount of opportunity for the two professions to work together here for the betterment of animal health. I am an absolute and firm believer in that.

But about some of the educational offerings that are available out there today, with the support of the University of Florida College of Pharmacy, I have offered a two-credit hour online course in veterinary pharmacy to any interested pharmacy student in the nation -- and I also get students from outside the United States -- that is open and available to, like I said, any interested pharmacy student in the nation. The same course materials are also available and open to any interested practicing pharmacist in the United States in a continuing education format.

So, to add some numbers to these, since the

inception of the course in about 2003, I've educated over 1,800 pharmacy students through this online course offering, and I've educated over 200 practicing pharmacists through the continuing education offering of the same course materials.

In addition to this, I can also speak to, perhaps later in the discussion, individual offerings that are made at individual schools of pharmacy in veterinary pharmacology, veterinary pharmacy in face-to-face teaching formats, as well as advanced pharmacy practice experiences typically called clinical rotations.

To kind of give you an idea of the content of these classes, for the most part, they certainly focus on the most common, chronic and preventative medications used in dogs and cats. They may be FDA-approved medications, they may be compounded therapies that are used to treat some of the most common conditions and disease states that we see in dogs and cats, such as heartworm preventatives, nonsteroidals for progressive musculoskeletal disorders, drugs for diabetes, for other endocrine type disorders, urinary incontinence, as well as seizure control. Also a fair amount of space is given to legal regulatory issues, as well as veterinary informatics.

Now, someone coming from academia, I can tell you it is absolutely impossible to teach a student absolutely everything they need to know about every topic. One of the most important things that you can equip students with is the knowledge of where to look their questions up and how to research them, and where to go for guidance and verification and additional information.

In a full-time position, I teach seven credit hours of pharmacology to vet students at one of the off-shore vet schools in the Caribbean, St. Matthew's University School of Veterinary Medicine located on Grand Cayman Island. So, I am a pharmacist who is actively educating veterinary students on a daily basis in vet pharmacology.

I can also bring the perspective of someone who has 15 years of experience in regulatory affairs and regulatory compliance for several large veterinary drug distributors. So, I have actively participated in acquiring Vet-VIPPS accreditation for some pharmacies, as well as VAWD accreditation, Verified Accredited Wholesale Distributors, which is also a program offered through NABP.

I can also offer the perspective of the pharmacist. I have for going on eight, nine years

now on a weekly basis, I provide consulting services to Midwest Vet Specialty Referral Hospital in Omaha, Nebraska, as well as the Nebraska Humane Society. I help them with their compounding therapy needs, obtaining drug vendor sources, client education and compounding on a weekly basis, as well as all of their controlled substance recordkeeping.

If you will allow me, I am running short on time, so I will simply close by saying, I have devoted my career to academia, pharmacy academia, veterinary academia, it is close to my heart. I believe there are opportunities out there to educate pharmacists to fill some of the prescriptions that we have been discussing today.

I hope I have the opportunity to further differentiate some of the pharmacists who have training versus those who don't, because I think that's an important concept to discuss, and where the current educational efforts are focused. I am absolutely a firm supporter of collaborative working relationships between pharmacists and veterinarians for the betterment of animal health.

MS. KOSLOV: Thank you, Dr. Blythe.

Next we'll hear from Deborah Press. She is the regulatory affairs manager in the Government Relations

Office of the American Society for the Prevention of Cruelty to Animals.

MS. PRESS: Thank you for the opportunity to participate and for organizing this panel.

I'm here to speak on behalf of pet owners, and really on behalf of our nation's pets and our shelter animals. The ASPCA supports the concept of prescription portability, because it will make pet care more affordable. More choice encourages competitive pricing, and competitive pricing makes it more affordable to be a pet owner.

Our support for prescription portability and for the Fairness to Pet Owners Act comes down to two basic points, both related to the affordability of pet care. The first point is that making vet care more affordable is good for animal health. It means that more animals who need medical care will get it, and more animals can avoid medical intervention by access to affordable preventative treatments.

The second point is that making pet care more affordable encourages pet ownership, and that means getting more animals out of shelters. Making quality pet care more affordable is really the broad goal here, and giving the pet owners the choice to take advantage of less expensive sources of medicine is a small but

logical step toward that goal.

A little bit of background about the ASPCA. Animal health is a cornerstone of our mission. The Bergh Memorial Animal Hospital was founded in New York City in 1912. We serve 20,000 patients a year. We have 22 vets on staff, and we provide general and specialized veterinary services to pets. Our hospital also treats our shelter animals. We run a large adoption center in New York City. We have 300 animals at any given time, and last year we adopted between 3,500 and 4,000 animals out to the public. Our hospital also treats victims of animal cruelty. The ASPCA has a humane law enforcement division that investigates thousands of animal cruelty cases every year. We treat those victims at our hospital as well. At our hospital, we do release prescriptions when it would benefit the client and patient. Vets at Bergh provide either written prescriptions or they will call prescriptions in to retail pharmacies. Our vets will affirmatively suggest the clients fill prescriptions elsewhere if they know that doing so will be significantly less expensive. I'm going to go back to those two main points that I mentioned to elaborate a little.

The first point was that affordable vet care is good for animal health because it means wider access to

health services. Shelter-related euthanasia is the number one preventable cause of death of dogs and cats in the United States, and the highest euthanasia rates are associated with the neighborhoods of highest poverty. Studies have shown that cat mortality rates in shelters were three-and-a half-times higher in poor neighborhoods than in wealthy ones. So, one's ability to afford pet care really does impact health outcomes. We also know that affordable access to preventative meds impacts animal health in the poorest communities. In some poor areas of the South, the majority of dogs entering shelters test positive for heartworm, and it's a disease that is difficult and expensive to treat, but easy to prevent. What all this together tells us is that the most at-risk animals belong to the most at-risk people, and for the sake of the health and welfare of these pets, it's important to take steps that make their care more affordable. We think that prescription portability is one way to do that.

The second point is that making pet care more affordable encourages pet ownership. We want pet care to be more affordable, to encourage adoption and get pets out of shelters. Costs are a real issue. Vet care costs and general care costs are cited as prohibitive factors to pet ownership. Survey data shows that vet

care costs are the number one reason people who previously owned dogs currently don't have them. 30 percent of previous dog owners, and 25 percent of previous cat owners, cited vet care cost as the reason they don't currently have pets. Budgets are tight today and pet ownership is down for the first time in 20 years. So, if we can take steps to keep pet care costs down, we'll encourage pet ownership and hopefully that will occur through adoption so we can get more animals out of shelters. Prescription release will be a helpful step towards keeping costs down.

To sum up, the ASPCA does support the Fairness to Pet Owners Act and we support prescription portability. For pets requiring ongoing medication for chronic conditions, the cost savings could be significant. Costs are also significant for pet owners with limited financial resources. These are the pets and pet owners for whom prescription portability is especially important.

MS. KOSLOV: Thank you, Ms. Press.

Finally, we will hear once again from Michael Hinckle, he is a partner at K&L Gates where his practice focuses on FDA regulatory matters.

MR. HINCKLE: Thank you, Tara, and thanks to the FTC again, and it's me again. I'm back up on my stump

on the generic drug issue again.

Let me just say, starting out, that we talked earlier in the last panel about how distribution issues affect the ability of real substitutable generics to get in the market and provide that competition and low priced, affordable products that we see on the human side. But I will say that the lack of prescription portability is probably the primary reason why consumers are currently denied access to affordable generic drugs.

When I say generic drugs in this context, I'm talking about substitutable generics. We see branded generics that are sold as a generic that's approved through the abbreviated new animal drug process, so it is a generic drug in the FDA sense, but they're sold with a brand name.

So, when we think about what makes a generic drug affordable to consumers, it's really two things. It's one, you don't have to repeat all the R&D work. There's still an expense to doing the bio studies that's necessary to get a generic approved, generic animal drug, but you don't have to repeat all that R&D work, because you get to piggy-back off the pioneer drug.

But there's also the cost of branding and marketing a product -- selling the product out to veterinarians, paying through the distributors to have

their reps sell the product, all those marketing costs. You don't pay those on human generic drugs, because of generic drug substitutability. That is, on the human side, when the physician writes for the drug, he or she writes for the brand drug, it goes to the pharmacy, and the pharmacist then dispenses the generic if he has the generic available. In many states, that's required by law to make that substitution if Medicaid is paying for it. If state Medicaid is paying for it, it's required to make the change. You say, well, why is that the case? Well, if the government or insurance companies are paying for drugs, they're going to demand that they pay for the low-cost generic. We don't have that market pressure on the animal drug side, so we don't see these animal drug generic substitutable products available at the pharmacy.

But for all this to work, for all this to work at the animal drug side and provide these kind of savings, there has to be a prescription. If that client walks out of the vet's office and has been dispensed a drug instead of the prescription, this whole generic drug substitutability process and the savings that can flow from that just aren't going to happen.

Now, there are some challenges besides the prescription issue, that's for sure. The state laws

present some issues with regards to substitution. FDA presents some issues. They published the approval of generic drugs in a different book. The states haven't caught up sometimes. The state pharmacy laws aren't clear as to when you can substitute -- there's probably 15 states that aren't sure when a pharmacist can substitute a generic animal drug.

But those are things that can be overcome, as I think the distribution side can be, too, if there's a demand. Right now, there is no demand for these products at the retail pharmacy level because those prescriptions aren't there.

Now, we talked about ethical veterinarians, and I expect everybody that's sitting here is an ethical veterinarian, you're taking the time to be here. Most, if not all, ethical veterinarians do provide prescriptions when they're requested. I expect that's true even in states where it's not required by law, regulation, or board policy. The problem really comes to this, that just as a matter of historical business practice, they're just not offered. The drug was just dispensed and given, and the bill was given. There are incentives for veterinarians to dispense more drugs, the pioneer drug companies provide those incentives. But even that, I think it's more just a sort of historical practice that people don't

question.

I think Nate talked on that, they sort of white coat the idea that people just don't question and they pay for it and they don't realize that maybe the savings that they receive on their generic drug, or actually the government or their third party payer receives on their human generic drugs, could be available to them if they had a prescription and if there was a distribution process that would allow the substitutable generics to get into the retail pharmacies.

Let me just close by saying, on behalf of my clients, that generic drug companies are not anti-veterinarian, any more than human generic drug companies are anti-physician. They're supplying a product that is able to be sold at a very affordable price, because they don't have to expend the resources on extensive R&D and marketing. At some point, pet owners should not be paying brand drug monopoly prices for a drug that's been off patent for ten years. At some point, there should be a generic that's available, and the only way that's going to happen is if we get prescriptions from veterinarians that can then be dispensed at the retail pharmacy.

Thank you.

MS. KOSLOV: Thank you, Mr. Hinckle.

Well, obviously we have a tremendous amount of expertise on this panel and they have raised a wide variety of issues. Chris and I are going to do our best to unpack some of those a little bit and explicate them some more.

So, the way we thought we would begin is framing this by looking first at what we would call, as antitrust lawyers, the demand side, and then looking at the supply side. So, on the demand side, looking at situations where pet owners are likely to seek portable prescriptions, and then look from the supply side at how veterinarians tend to respond when they get those requests.

So, let's start with the idea of when pet owners seek portable prescriptions. Are there instances where clients are more or less likely to seek a written prescription and also looking at how often that's happening?

So, Dr. Hauser, do you want to start us off on that?

DR. HAUSER: Sure, that would be great. Thank you.

There are several times that prescriptions are either requested or provided by the veterinarian, and some of the times that that would be would be if the

drug is not stocked in the hospital. And that may be due to a low demand or perhaps due to human abuse potential. It's sometimes a little bit better for our veterinary hospitals not to keep those things readily in stock.

When there's a need for compounding, we've heard a lot about compounding this morning. I think you need to look at there are cost variations, especially with chronic medications, and I would say that of the prescriptions that are requested in my practice, it tends to be mainly for the chronic anti-inflammatory drugs and the heartworm medications.

I also think you have to take a look at the type of the practice that you're in, the setting. I'm limiting my comments today to small animal medicine, because I'm a small animal practitioner. But in talking to some friends that are mixed animal practitioners and large animal practitioners, they'll tell you, this ship has already sailed for them. Large animal lost that prescribing, dispensing, or I should say the dispensing aspect years and years ago when the drugs went into the feed stores.

So, what you're looking at is this, is an issue that's going to impact primarily small animal veterinarians. I believe, I don't have proof, but I believe it's going to impact veterinarians that are in

more suburban and urban areas. I used to live very rurally. My husband still thinks we live rurally, but I don't quite think ten miles out from town is rural. And quite frankly, if you live in a very rural area, it's more convenient for you to get the drug from the vet than to drive 25 or 30 miles, like my parents would have to go, to a Walmart.

So, I think that the location also plays a role, and I do think that the types of clinical settings play a role. I spoke with a lot of stakeholders to make sure that I was fairly representing as broad of a spectrum of veterinarians as I could, and I wanted to keep my own biases out of this. Certainly my experience will come in, but I think it's their voices you need to hear.

I have a friend that owns an emergency and specialty practice, he sees this as a very minimal consequence for him for the number of prescriptions will actually not be filled at his facility. When we get into some of the other issues, it's going to have impacts of huge magnitude on his operational efficiency. But right now, he says, no, people need it, it's an urgent situation. It's not a low-grade chronic pain medication where the owner isn't even sure that they fully believe you that their dog is in pain, it’s that their dog is seizing and they need to take the medications home.

So, those are some of my thoughts.

MS. KOSLOV: Did anyone else have anything to add on those points? I don't know if Dr. Foster, did you have anything else you wanted to add to that?

DR. FOSTER: No, but I agree pretty much with what she said. I mean, it's the long-term therapeutics and the preventatives where the pet owner is getting gouged. That's where the prescriptions are going to come in. Compare the prices, you'll see.

MS. PRESS: I'll briefly highlight the convenience issue, but I want to highlight a slightly different aspect, and that is just access. Most neighborhoods have access to a pharmacy, not all neighborhoods are served by veterinarians. I live in a city and I don't have a car, so getting to the veterinarian is always a little bit of a problem. If I need to refill my prescription every month, it's just a lot easier to do at a local pharmacy. So, access to veterinarians is another issue that affects neighborhoods differently.

MS. KOSLOV: Dr. Aspros?

DR. ASPROS: I was going to say that we really have very little data, maybe no data to really answer this question. It's really anecdotal, and some of these things sort of make sense, but whether or not there's

any truth in any of them is hard to say.

MS. KOSLOV: Do any of the panelists have any sense of whether there are differences based on client socioeconomic status in terms of whether they are more or less likely to seek a portable prescription?

DR. HAUSER: Not in my practice. In my practice, I certainly have clients that are very cost sensitive, and you can bet those are always the ones that I offer the prescriptions to. And I am surprised that probably about 50 percent of them will look at me and say, you know what, I would just rather get it from you. I would just rather get it while I'm here, I want to get him started on the medication.

So, I cannot see a lot of socioeconomic variations, but I should also reference that by the fact that I am in a very stable neighborhood from a socioeconomic point of view.

MS. KOSLOV: Did anyone else have any perspectives on that question?

MS. PRESS: I'll just say that I don't know if we can link it to socioeconomic status, but some people are savvier shoppers than others. Some people are more assertive than others when it comes to speaking out and being advocates for themselves. So, some people just may be more comfortable asking questions of their

veterinarian than others. We like making prescription release automatic, because it just does away with that information disparity, that disparity and comfort.

So, again, I can't say it's necessarily linked to socioeconomic status, but there are certainly differences across the board in people's comfort.

DR. FOSTER: Can I add something to that? Are we supposed to put our cards up?

MS. KOSLOV: Ideally, yes. We're a smaller group and Chris and I placed ourselves in the middle, so we could try and keep track of all of you.

DR. FOSTER: I think we're talking about the comfort level of pet owners when they go ask a veterinarian for a prescription. Sometimes that's intimidating, and it's especially intimidating when they say something like, well, you can do it, but we'll have you sign this waiver. Has anybody here ever signed a waiver when they went to their physician?

Dr. HAUSER: I have.

DR. FOSTER: Is it part of routine?

Dr. HAUSER: Um-hmm.

DR. FOSTER: How about when you transfer a prescription from a pharmacy to another pharmacy? Does that pharmacist say, well, you've got to sign that waiver or I'm not going to transfer your prescription?

My son is a physician, and has never had a client sign a waiver, by the way.

I realize that the AVMA's position is it should be up to the practicing veterinarian to determine that, at least I shouldn't say it's the AVMA's position, I saw that in the Texas association in their letter they wrote to the FTC. What I'm trying to tell you is it can be very intimidating for a consumer to have to do that.

We have a file this deep of waivers and complaints, and for routine medications I'm talking about, not chemotherapeutics that are unapproved. Waivers are common then. But there is this intimidating factor, and it ties to the socioeconomic factor because typically the more educated the consumer the more likely they are to question it. If you're a lawyer, or you're a nurse, you're educated, a doctor. Like why do I have to sign this to get Amoxicillin for my dog? Geez, I just filled my prescription for my child and I didn't have to sign anything.

I think we've got to clean that up. I'm on the side of the veterinary profession, but I'm also on the side of the pet owner. We just have to clean it up and act like physicians do and other professionals that are involved in animal health care. When we charge an

extra fee for a prescription, or we have you sign a waiver and make statements like, well, maybe it's going to be counterfeit. Well, yeah, that can be counterfeit. There's lots of counterfeit products in human medicine, too, but there's still Medco, CVS, and others that we don't throw the pharmacies out because there might be a counterfeit.

And, you know, the most likely thing to cause counterfeit is restricted distribution, because if the real product's there, they're not going to make much money on counterfeit. We've just got to think logically as a profession.

Thank you.

MS. KOSLOV: So, are any of the panelists aware of whether or would you characterize that there have been any trends in the relative number of requests for portable prescriptions over time?

DR. FOSTER: I can answer that. I've been taking prescriptions since 1983. There's no question that the veterinary profession today is more likely to give out a prescription. I think the American Veterinary Medical Association has done an excellent job of talking to their constituents and educating them. And again, it only makes sense, if you would get one for yourself. Remember, you've already had the

client-patient relationship, that's at the point where the drug is prescribed. Now we just have to count the pills and fill it.

Yes, pharmacists have some other roles, and in our pharmacy, veterinarians serve some of those roles, too, to speak with a client. But it's not like we're this far apart. Guys, I served some time on the board at Michigan State University. To the best of my knowledge, of the 25 colleges that have pharmacies in their veterinary school, 24 of them have pharmacists in charge, not veterinarians. It's a common thing. Just think about that. Michigan State is one of them.

MS. KOSLOV: So, I think with that answer, we have transitioned to what I had called the supply side, I'm talking about how veterinarians respond when clients seek a portable prescription. So, to paraphrase what I think we heard from Adrian Hochstadt's introductory presentation and what we just heard from Dr. Foster, and some of the presentations this morning, it seems as though what we're hearing is that most vets do supply prescriptions upon request. I just wanted to see, would anyone on this panel disagree with that statement or want to clarify that statement?

DR. ASPROS: No, I would absolutely agree that AVMA's Principles of Veterinary Medical Ethics requires

veterinarians to honor clients' requests. AVMA supports client choice, and I think veterinarians have done a very good job. If they had not done that, I don't think Race Foster would be here, because he wouldn't have a business to represent.

DR. FOSTER: I would be selling more live fish.

MS. KOSLOV: Looking at it from the vet perspective, one of the other issues we wanted to explore is are there situations where vets proactively might offer prescriptions to their clients on their own initiative as opposed to waiting for a client to request a prescription?

Dr. Hauser, is that something that you do?

DR. HAUSER: I absolutely do. I would say that 95 percent of the medications that I dispense on a daily basis are human generic drugs. So, if I'm aware of significant cost savings, I will absolutely let that client know that there is a cost saving, and do they want to go pick that prescription up. And again, I would say it's about a 50/50 split with my clients.

MS. KOSLOV: Dr. Aspros?

DR. ASPROS: Yeah, there are drugs that -- and again, I'm speaking for myself, not for AVMA, as a practitioner -- there are drugs that we can't easily stock, because there's just not enough demand for

them, and yet there's a need for them on the part of our patients. Those we assertively write prescriptions for our patients.

MS. KOSLOV: Ms. Press, do you have any perspectives from the ASPCA's animal hospital perspective?

MS. PRESS: Yeah, I mean, our policy is very similar to Dr. Hauser's. When we know that it will result in significant cost savings, we will affirmatively suggest that the prescription be filled elsewhere, and when it will benefit the client and the patient, that's what we do.

Certain medicines, we can't do this for. They're not available at retail pharmacies. But yeah, when we know it will help, when we know that there will be a significant cost difference, we will suggest it.

MS. KOSLOV: So, go ahead.

DR. ASPROS: I also am the managing partner of an emergency clinic and I would say that that's one situation where we don't do that because of the time frame. These are emergent conditions -- it's frequently the middle of the night, on holidays, on weekends. It's important that the patient begin treatment as soon as possible. It's often not easy for the client, or even possible for the client, to fill that prescription in a

convenient or timely way.

MR. SMITH: Could I make one comment? I think that one of the main issues is does the customer really have the right to choose? The comments of the panelists, who I think have an outstanding position of being fast and immediate to release a prescription upon request, I think Dr. Foster's sense of there's a pile of veterinarians who don't behave that way. And the FTC recognizing in the past that release might not occur unless a federal requirement is there for a release of the prescription, needs to be factored in. The voices here I don't think represent all practices or the ways veterinarians work.

I also want to just stress that point that if I'm dependent on my vet to continue to take care of my family member and I feel like I'm taking something away from them when I ask for the prescription to go fill it somewhere else, and the vet clearly has an economic interest of wanting to sell that product to me and make money, what happens the next time I come in to get my routine service, like the real practice of medicine? Do I feel like I've somehow degraded or compromised that relationship? No customer wants that.

I think that what a customer wants is the real right to choose. And as I mentioned in my opening

remarks, every person knows that when I'm handed a piece of paper from my human physician, that gives me the chance to go where I want to fill it where I think is the best for me, whether it be for convenience or economics or whatever the case is. And I don't think anyone will argue that the prices online are generally much lower than in a veterinary clinic.

So, if I'm given a prescription every time, my mind changes in the way that I think about how I can access these medications, and I'm now more conscious of the fact that I have different options of where I can go to get a medication filled. I think that change in the consumer mentality will cause a significant shift in where products are being sold when consumers start to be more aware of the market condition they live in.

One final point, I do acknowledge and I have sympathy for the fact that if we leave it the way it is, the veterinarian has a stronger influence in the way that a treatment is administered and the way that people get their medications. But it comes with an expense, an expense that will limit the number of pet owners who can seek out -- this is the ASPCA's point of view -- who can seek out and get those medications in the first place.

So, is the additional therapeutic value of

having your vet so closely administer the release of Heartgard worth the fact that the inefficiencies are keeping the prices so high that far fewer consumers can avail themselves to those treatments?

I think we'll discover in the next panel about how that worked with contact lenses, that when prices came down, more consumers started to use contact lenses as prescribed and wouldn't wear them longer and created kind of a better patient health and safety outcome. The same thing will happen here. More dogs will get the treatments they need when they become more affordable, and the value of that oversight I think diminishes the total gain or the total benefit of consumers.

MS. KOSLOV: So, we don't want to steal too much thunder from the next panel, which will be discussing the contact lens issue in more detail. I did want to pick up, Nate, on one point that you raised and just open this specific point up in case other panelists have any thoughts on it.

So, what economic incentives or other incentives might affect the perspectives that vets might have on providing a written prescription? So, Nate raised the idea of the vet's economic interest. Are there any other points anybody wants to raise on that topic?

DR. FOSTER: As I mentioned before, I think the

veterinary profession has to get smarter. Guys, we have a profession where drug companies dictate what we do. We take kickbacks, we take incentives, we take free trips, we get free drugs. Do you know what that really means? Does every veterinarian prescribe the drug that's right for your dog or where he makes the most money?

Think about that question. Now, I don't think most veterinarians do that. But you know they took that away in human medicine by not letting the physicians charge for the drugs, for the most part. The drug companies are driving this with their incentives. Their 12/12/12 programs. What does that look like to the consumer? I don't think it looks very good. I don't think it passes the smell test.

Guys, I know 90 percent of the veterinarians don't do that, but why do we have restricted distribution and incentives, if it's not about money? Why do we have it? Why don't we just let vets do the therapeutics, do their treatments, sell the medications when they need to, especially in the acute cases, that's what they do, allow the portability, and any qualified place can fill them?

As the Iowa Veterinary Medical Association said in their submission to the FTC, that would let normal market

forces dictate. Why don't we just do that?

MS. KOSLOV: Dr. Hauser, I think you're anxious to respond.

DR. HAUSER: Certainly I am. I have a lot of responses, I am going to hope that more pertinent points will come up a little bit later in the conversation. We have about a half hour left.

I have a lot of responses back to what Dr. Foster just said, but I'm going to limit them to the question that was actually asked. What are our concerns that would affect vet perspectives? As a veterinarian that's practiced for 25 years, as a veterinarian that has been I would say 99 percent responsible for deciding, with input from my associates, what goes in my pharmacy, those drugs are selected not based on buyback programs or buy-in programs, and percentage discounts. They're selected because they're the best medications that I can offer my patients, period. So, that was actually very offensive to me, and you can tell.

So, to get back to the question at hand, compliance is a huge issue. Safety, especially with diverted drugs. You bet I have my clients sign a waiver if they want to order online, and the reason that I do is because I can't guarantee the safety of those drugs. I love my patients. And I love my clients, and if I

wouldn't give that drug to my pet, why in the world would I have them give it to theirs? I'm happy to write the prescription. They're never just handed a waiver and said, hey, fill this out. It's explained to them. I look at that waiver as informed client consent, period.

I do like the fact that I feel it releases me from some liability. Misfilling the scripts, yes, it's happened and it's happened to me, as well as illegal substitutions. Those tend to be more in the brick-and-mortar pharmacies that that's occurred, as opposed to the online.

I think the big issue here is that when that client comes in to pick up a refill on medications, every veterinarian here will tell you that their team loves seeing those clients. They love that touch point, and that's a very informal way to make sure that George the Bulldog is still doing okay. Hey, Mrs. Smith, how's he doing?

We have had so much fragmentation within our industry, that this is one more way that we're going to lose touch with our patients. I think inappropriate drug requests are another reason that we have concerns. If the blood work isn't accurate, if the drug isn't safe and appropriate for the patient.

MS. KOSLOV: I'm going to transition us to the next topic, and I have a feeling you'll have an opportunity to raise some other points here. As we were preparing for this panel, we realized that the bottom line question we're really trying to get at with this panel is: how is this pet medications marketplace working right now from the perspective of pet welfare and from the perspective of consumer choice?

So, with the particular emphasis on the role that the portability issues play in that, because obviously this morning we talked a lot about the distribution issues come into play. But the bottom line question really is: is the market functioning well today?

I would open up that question to anyone here on the panel who wants to try to get at that bottom line question.

DR. ASPROS: I would submit that the market is functioning quite well today. It's diverse, there's new products coming on to the market all the time, consumers have choices like never before. The Internet and transparency and pricing has probably been a part of that, but we believe, I believe it's a very, very vigorous and well functioning marketplace. Maybe not for quite everybody on the end of the table here, but I believe for consumers and for our patients.

MR. HINCKLE: Can I comment on that one?

MS. KOSLOV: Mr. Hinckle?

MR. HINCKLE: I think I probably disagree. It's not necessarily well functioning right now and it's probably going to get worse if there's not prescription portability and some true interchangeable generics. Because as we see more and more, as the companion animal market becomes more lucrative and new drugs come out that are wonderful drugs to help with the quality of life for our pets, but those drugs are going to go off patent sooner or later. When those drugs go off patent, the question is going to be, are consumers going to continue to pay those patent monopoly prices or are they going to get generics?

One of the problems we see, I have here this question, why don't you just sell generics through the veterinary channels? That goes to some of the distribution issues we talked about in the last panel. But we also face the same issues that we faced with the medical physicians 15, 20 years ago, where I still have clients telling me that they hear from veterinarians that are disparaging the quality of generic drugs, the FDA approval process, whether these products really are equivalent to their pioneer counterparts.

So, it's an educational issue that’s

going to take time to get through, but without the prescription portability, we're just not going to have those interchangeable generics. And as more brand products go off patent, people are going to continue to pay the high prices.

MS. KOSLOV: So, just to refine the question a little bit, we had talked a little bit about this chicken and egg perspective on the question. Do we have a situation where either the market is fine the way it is? Do we have a situation where we need greater prescription portability which might spur the development of a more robust marketplace? Do we need the market to expand first which would then drive consumers to demand more prescription portability? What do we think about that?

DR. FOSTER: The problem is not the veterinarian. The problem is supply of product. Again, it was brought up this morning that superficially it seems all happy and hunky-dory because catalogers and Internet sites have product. Guys, we're charging you five to ten percent more than we have to because the availability is not there. I submitted that to Stephanie, in writing, showed her receipts of products, we paid the mark-ups that are on there throughout the various distribution things. The pet owner is suffering

the price game. They're not suffering because veterinarians are not issuing prescriptions.

And it looks like there's a supply out there, but guys, they've tightened up. Pfizer has cut us off after 25 years. There will be no supply of chewable Rimadyl in the next few weeks. That's a fact, if it doesn't loosen up. Which means the only place you can buy it is at a veterinary clinic or one of the central fills, because they can buy direct and I cannot, even though I'm a veterinarian.

But remember, this isn't about me. We need a supply of product. We do need veterinarians to have portability, and I think they're working in that direction. I think it's getting better. I think we've thrown up some obstacles that are not logical. But I do think there's a big issue facing the pet owners. They are paying more today than they should be for things like Heartgard preventatives, flea and tick preventatives. That's a fact.

MS. KOSLOV: Nate, did you want to respond?

MR. SMITH: Real fast, if I ask the question is the market working well today from the consumer's perspective, I would look at the prices available and say, Amazon.com is selling Frontline for $10 a dose, and a vet clinic is selling it for $16. So, I walk into my

vet and I say, hey, why are you $16 and they're $10? And it's a bad example.

I should use Heartgard, because Heartgard is an Rx drug. But if I see the price of Heartgard and I see the price of Heartgard in a vet clinic and I say to my vet, I would like the prescription because I would like to go get Heartgard for much less money. Well, okay, then you need to sign this waiver and this consent because all hell is breaking loose out there, this could be bad product, it could be degraded.

So, then there's no generics in the market. So, from the consumer perspective, is the market working efficiently when I see the price differences and I'm told by my trusted vet that this is dangerous territory, you've got to sign this consent if I'm going to release a prescription. That doesn't sound like a well-tuned market to me.

I think we've all talked about the diversion issue, and have largely vilified it as if it's evidence of it not working correctly. So, this idea that the market is robust and competitive when distribution is limited, that just makes no sense.

MS. KOSLOV: Dr. Aspros or Dr. Hauser, does either of you have a perspective on whether veterinarians are responding on price based on any

additional competition in the marketplace?

DR. ASPROS: I think AVMA does not have data on that. I don't think anybody collects data on that. I can speak from my perspective as a companion animal practitioner, and I would tell you that most of the time, unlike what Nate Smith said, most of the time we're actually cheaper. We're not in business to sell drugs, we're in business to serve clients and our patients, and a lot of the pharmaceuticals that we carry, we carry because it's convenient for clients.

We know we need to put patients on medications in order to keep them safe and living longer, and we are aware of the fact that there are lots of other opportunities for clients to obtain prescription medications, and I think most of the time we are more than competitive, because it's easy to check.

I mean, there is pretty much price transparency these days. My clients are as smart as I am, I'm no smarter, but I can go on Amazon, so I know what pricing is, and should be, and so does anybody else who's connected to the Internet. Pricing, by and large, is competitive. If it's not competitive, then the clients are going to ask for a prescription and we're not going to sell the product because we can't do that or we're going to write them a prescription.

DR. FOSTER: I would encourage you to do your own study on the pricing. Sorry to interrupt. Some are, some aren't.

MS. KOSLOV: So, we have two other topics that we're going to try and address in the remaining 20 minutes of this program. I'm going to turn it over to Chris to migrate over to those.

MR. GRENGS: This morning we heard the topic of qualifications for pharmacists to fill animal medications prescriptions, and this is a topic that's also come up in some of the written comments that we have received and I thought I would ask Professor Blythe if she can give us a quick summary of the types of education and training opportunities that are available to pharmacists during their formal education, and after, when they're practicing, and any other types of supplementary information or training that they might receive.

MS. BLYTHE: You bet, Chris.

I think in the context of today's discussion, you can take pharmacists and all licensed pharmacists within the continental United States and you can almost divide those out into three different groups. The vast majority, the large majority are pharmacists who do not have any training in veterinary pharmacology or

veterinary pharmacy and they typically do not feel comfortable filling those types of prescriptions and frequently they will self-identify as, boy, I don't know on this, I'm not comfortable.

You then have kind of a second group of pharmacists who have had access to elective courses within the pharmacy curriculum. They could have been in the form of didactic electives or clinical electives via rotations. So, those types of pharmacists have had opportunities via education while they're in the PharmD program, after they exit the PharmD program, whether it be continuing education courses or other courses that are offered by veterinary organizations, or even more commonly, pharmacy organizations.

So, there's a subset of pharmacists who have sought additional training and education. They have an interest in veterinary pharmacy and they are motivated to self-educate, and typically will seek avenues to shadow, consult a veterinarian, and they are typically very proactive in developing positive working relationships with veterinarians within their community.

Even a third subset is some highly specialized pharmacists who have had a great deal of post-graduate training. Perhaps they've had anywhere from five to ten to 20 years of hands-on clinical experience in a

veterinary teaching hospital, an online pharmacy, a brick-and-mortar pharmacy that specializes in veterinary pharmaceuticals only or in teaching academia. So, that's an even smaller subset of pharmacists out there.

So, certainly groups two and three, I think with education and training and on-the-job training, peer training, can educate each other and they can get to the point where they can safely and confidently field some of your most common chronic and preventative medications used in companion animals, and by that I say largely cats and dogs, much as Dr. Hauser has referenced.

So, those are kind of the three, how they shake out.

With regards to specific numbers, let me start by saying there is no requirement that a pharmacy student take any type of course in veterinary pharmacy. If they are available, they are entirely elective. So it could be a didactic course in a face-to-face environment, it could be an online course, or it could be a clinical course that they take typically in the fourth year of their pharmacy education and we call it a clinical rotation or an advanced pharmacy practice experience.

So, those are the types of educational offerings that occur today within the doctor of pharmacy

curriculum. Of those, of the schools that are currently accredited by ACPE, and that is the Accreditation Council of Pharmacy Education, there are 127 accredited pharmacy schools in the United States, of those 102 have full accreditation, 17 have partial accreditation, so they are the newer schools, and then there are two that have pre-accreditation status. But collectively, we have 127 schools that are taking pharmacy students in today in the United States.

Of those, to the best of my ability to collect data and knowledge of my peers from being in pharmacy academia for so long, roughly 20 to 25 percent of those schools will have a faculty member on staff who is offering a face-to-face didactic elective in veterinary pharmacy and/or a clinical rotation in veterinary pharmacy for those students.

If that is not an option, which is the case for the majority of pharmacy schools in the United States, there is always the option to take online courses in veterinary pharmacy. They are available to everyone within the continental United States, for interested students as well as a continuing education course for practicing pharmacists.

So, that's kind of how it shakes out with regards to numbers, what is currently available, and so

perhaps that will give some data for a framework to reference here.

I can confidently say that the number of courses in veterinary pharmacy within the schools, whether they be didactic or clinical education experience, has been on the increase in the past ten years. Without question, more schools are recognizing the need to train pharmacists in those types of medications, more schools are embracing faculty to offer those specialty services or have knowledge in that area or their area of expertise. More pharmacy schools are actively working with other stakeholders within the pharmacy profession to somehow make educational opportunities available for their students or for practicing pharmacists within their state.

So, definitely I think the increase in educational offerings is reflective of the increase in prescriptions that are being outsourced to community pharmacies, in your typical retail community settings, by veterinarians for your chronic and preventative medications in dogs and cats.

MR. GRENGS: Anybody else on the panel have any follow-up thoughts about the training that pharmacists receive?

DR. FOSTER: I would like to add something.

First of all, I think ongoing continuing education is absolutely essential. At our place, at Foster & Smith, we use University of Wisconsin. They have some continuing education classes. The pharmacist's letter also has some that they have taken for CE. I am not going to ever sit here and say that the pharmacists are trained as well as the veterinarians right now, but remember, they're not prescribing, they're dispensing. And there's room for improvement.

I think what Elaine said, if pharmacists want to participate in the field of veterinary medicine, it should be mandatory that they have CE, I think, in this field. Just my opinion.

MR. GRENGS: And to follow up on that point, are there any other types of best practices that you feel are important in running a pharmacy?

DR. FOSTER: I think that the AVMA already has established some of that by their recommendation of a VIPPS-certified pharmacy. And there's I believe 16 VIPPS, there might even be more today, certified pharmacies. That's some assurance.

That's the best standard that we go by today. Other than that, remember, we're governed by the Board of Pharmacy. And in my case, our pharmacy is licensed by the Board of Pharmacy. The veterinarians work under

the Board of Veterinary Medicine. You don't just mess up for the heck of it, you lose your license. I mean, we do have severe guidelines and punishment if we don't go by the letter of the law. Thank you.

MR. GRENGS: And with that, I thought we would turn to some interesting policy questions, including legislative approaches to prescription portability, among them H.R. 1406. And just to follow up on Adrian Hochstadt's introductory presentation, H.R. 1406 was a bill that has been introduced in Congress, but the FTC, to be clear, had no role in developing that legislation, and FTC staff don't have any particular position on it, and to my knowledge, none of our five commissioners have any current positions on the bill either, but it has obviously raised a number of interesting policy issues.

So, I will start off with a basic question, is H.R. 1406 or other legislation needed? Is there a problem, or is this a solution in search of a problem?

MS. KOSLOV: If I could just embellish that question a little bit, only because in the interest of time I want to make sure we get this point out as well. So, to the extent that H.R. 1406 might impose some burdens in the name of notice, if you have ideas for alternative approaches or less burdensome approaches for those of you who might oppose the legislation, in

particular, you can maybe address those as well.

DR. ASPROS: Well, I will start out repeating something that we said earlier today, this looks like a solution looking for a problem, in search of a problem.

AVMA is unaware of any data, any data, that suggests that there's a problem associated with veterinarians providing written prescriptions that this is a problem that requires a solution, a legislative solution in Congress.

If there is any issue, there's certainly no federal recourse required to resolve it. State boards of pharmacy and state boards of veterinary medicine certainly have the tools they need to identify and solve this problem if they decide that there is one.

MS. KOSLOV: Ms. Press?

MS. PRESS: Yes. So, the ASPCA does support this bill, and we think that there is a federal problem. We think it's also a problem of consumer education. We think both are issues here. Right now, there's no uniform framework to guide consumer expectation, and the benefit of a federal solution is that consumers know what to expect every time that they go to the vet. They're going to walk out with a prescription in hand and they can choose to fill that with a vet or fill that elsewhere. So, there's going to be certainty.

So, we do see benefits to a federal solution to this issue.

MR. GRENGS: Mr. Hinckle?

MR. HINCKLE: Yeah. There definitely is a problem that needs a solution, and again, coming back to American consumers, when Congress passed the Generic Drug Act for animal drugs, it had a reason to believe that eventually they were going to get affordable generic drugs. That's not happening, and I think it's in large part because there's not enough demand because people just don't ask for the prescriptions many times. For whatever their reason may be.

That lack of demand means that there's not a market for the generic drugs. We talked about prices are competitive. Well, prices are too high. Prices should be lower. Prices would be lower if we had a robust, generic industry, and it would also be helpful for everyone in the sense that a robust generic industry drives the innovator companies to develop the new generation of products instead of using marketing techniques to continue to evergreen their existing products.

So, I kind of keep tooting the horn here, but that's what this industry is missing is a real robust, substitutable generic business.

MR. GRENGS: Nate Smith?

MR. SMITH: I think it depends on who you ask. If you ask the consumer is there a need or a problem, I think a consumer would quickly tell you that they believe that this is something that would border on a right, just like it is in a human situation. If someone is going to prescribe me something, isn't it my right to be able to take that prescription and go to somewhere where we all can create a safe place to have it filled? We talk a lot about what the manufacturer, the pharmacy or the veterinarian thinks. As a consumer myself, I feel like I should have the right when a prescription is granted for my dog, why don't I have the right to the piece of paper? It seems reasonable.

MR. GRENGS: Dr. Foster?

DR. FOSTER: I think there's a problem, but I don't believe it's the veterinarians. It's the drug companies. We've just got to say it. When they restrict distribution, that's the problem. When there's no drugs to fill your prescription, that's the problem. It doesn't mean we can't improve as a veterinary profession or as a pharmacy profession. It doesn't mean we don't have some bumps in the roads, but I've been in it since I was a kid, and I've seen a lot of positive changes in the profession. I think Dr. Aspros and the

rest of the AVMA members have done a good job. Do I agree with everything they do? No, I don't. But I think it's improving. I don't believe the problem is the veterinarian. It's not going to be in the future, either. It's the drug companies. It's got to be dealt with.

It doesn't matter how many prescriptions we issue where you walk out with or are sent to Foster & Smith. They won't be filled. Or if they do, they will be done at a higher price because we have to protect our supply, for refills. You just can't -- the consumer is losing in this. And it's real. But guys, it's not the veterinarians.

MS. KOSLOV: So, I would like to make sure that we do get a veterinarian perspective specifically on the question of H.R. 1406, and from your perspective, the burdens that it might impose and whether there are better alternatives if, in fact, there is some value. My question presumes that there may be some value in educating consumers and giving them more notice that they have options out in the marketplace. If you disagree with that, by all means, go ahead.

DR. ASPROS: I would say that there are significant unresolved issues with the specific legislation 1406. One is, as we had mentioned earlier, veterinarians are allowed to, under state law, to

dispense for their own patients under a VCPR. That doesn't make a veterinarian a pharmacist.

Veterinarians in at least every state that I know of may not act as a pharmacist and fill prescriptions for other pet owners for which they're not the veterinarian who's established a VCPR.

If, in fact, under 1406 we are writing prescriptions for every potential dispensed product, it's really unclear to me what we're supposed to do and under whose authority are we filling those prescriptions, even for our own patients for whom we've just written the prescription to, and I'm not sure that 1406 makes that clear at all.

My license as a veterinarian is governed under state law. Pharmacy is governed under state law. And suddenly we have this overlay of Federal legislation over both of those licensed professions, and it's not clear how that's going to be managed. It's clearly not a zero sum game in terms of the very small businesses that veterinary practices represent. As I said earlier, the typical veterinarian practice has one veterinarian and six staff working at the practice. These are burdensome regulations that 1406 would apply.

MS. KOSLOV: If I could follow up on one point that you raised, and Dr. Hauser, I know this is

something you have thought of as well and this also responds to one of the many questions that we received, but I do want to pick up this one in particular. If there is greater prescription portability, how does this affect the financial viability of veterinarian practices? Is this something that you've thought about and would we see a situation where perhaps the price of the medication goes down but the price of services goes up?

DR. HAUSER: So, before I answer that, I want to further a little along what Dr. Aspros just said in relation to what Dr. Pion also said this morning. Veterinarians want an equal playing field. The point that needs to be perfectly clear is, at least in Colorado, I am happy to write those prescriptions for my clients. When I have other clients bring in prescriptions from other hospitals, I can't fill them. So, it's not an equal playing field under 1406. Any retail pharmacy, any online pharmacy, and obviously, the VCPR veterinarian will be able to fill those prescriptions. So, I just wanted to clarify that.

As far as the economics, they're significant, and make no mistake about it. I love listening to Ms. Press say how lovely it's going to be in this ideal world when pet prescriptions drop and the cost of

veterinary care drops. If you own a small animal business -- not small animal business, just a small business -- and you look at losing 17 percent, which is the number we heard today, and that by some accounts is a conservative number, 17 percent of your total gross revenue, how are you going to keep the doors open? You're going to have to increase costs somewhere else. The most likely place is going to be through service-based increases.

I had a dialogue with a gentleman earlier this morning. When I sold my practice in 2008, it cost me $3.75 a minute turnkey cost. I think that was the last time I calculated it. But $3.75 a minute. So, for every minute that I was open, that's what it cost me, without compensating my doctors. So, that was just the fixed costs, not variable costs like pharmacy.

So, if I have a 30-minute office visit, the true cost to have that client in the building is over $120, and I charged, at that time, actually $55.

So, there's a sharing perspective that goes along to keeping those doors open, and I would love to be seeing a client every single minute that I am in that hospital, but that does not work either. So, you talk about the economics of it, you can't have it both ways. I do not predict -- my personal opinion -- that you will

see veterinary prices go down. The veterinarians, we have the fragmentation in the industry, actually for the first time in 20 years, a 2012 AVMA study just showed a decrease in pet ownership. We know since 2003, we've had decreasing patient visits. This is a really scary time to own a business or to run a business.

MS. KOSLOV: Ms. Press?

MS. PRESS: So, I'm not a vet, so I can't really speak to how vets decide to set their prices in their practices. I can speak about responsible pet ownership, and I think pet owners appreciate vets who provide good value, and we tell the public that they should shop around for caring, quality, affordable vet care and pet meds. Part of being a responsible pet owner is being a smart consumer, and I know that Dr. Hauser appreciates that. I think that's something that vets understand and appreciate.

We want affordable prices for pet meds and it doesn't matter to us where those affordable meds come from. If the vet can offer the lowest price on those pet meds, that's great, that offers a lot of advantages. We just want the competitive environment to be there so that those prices are available.

MR. GRENGS: I would just ask one follow-up question. To what extent is prescription portability a

legal or policy issue that requires a particular formal solution, if it does, or to what extent is this really a consumer education and awareness issue about their ability to get a prescription and take it elsewhere to be filled outside of a veterinary clinic? Are there any thoughts on the state of consumer awareness about their ability to get a prescription?

Dr. Hauser?

DR. HAUSER: I do believe portability exists. I write prescriptions not infrequently in my hospital. I think that client education would help to maybe breach part of this divide. Again, looking at the clients that I serve, they're very well-educated. They're very consumer savvy. And I would be very surprised if very many of them think that you can't get your prescriptions filled elsewhere. I mean, they do. They know that we use a lot of the same medications.

DR. ASPROS: I would say that just one company, 1-800-PetMeds, has spent more than $200 million in the past ten years letting the pet owners know that they can ask for prescriptions and fill them online. I don't think that this is something that consumers are unaware of.

Again, I think this is a solution looking for a problem. This is a very robust marketplace with I think

pretty fine margins and veterinarians are doing the best thing possible for their patients, and consumers I think have many options that they're aware of.

MS. KOSLOV: So, in the interest of time, I think we'll have to let that be the final word for now. I do want to note that we've gotten a ton of great questions from the audience, as well as from the Twitter feed. Some of the questions I think got answered implicitly or explicitly during the discussion.

As for some of the other questions, we will definitely take note of those and staff will do our best to follow up on those as we decide what our next steps will be.

I would like to thank our panelists for an extremely productive conversation, and I hope you'll all stick around for the next panel where we'll try and apply some of what we've been hearing about over the course of the day and look at the contact lens experience and see what, if any, lessons we can draw from that.

Please join me in thanking our panelists.

(Applause.)

MS. KOSLOV: We will reconvene at 3:00.

(Whereupon, there was a recess in the proceedings.)

PANEL THREE

LESSONS LEARNED FROM THE CONTACT LENS INDUSTRY

MR. GILMAN: Hi, I wonder if people could start to make their way to their seats.

So, let's get started. A couple of preliminaries. So, I would like to welcome you all back to this, our third and final panel of the day. I hope it's been an interesting and fruitful day for everyone here. I would like to introduce our panelists to Erin Flynn, who is sitting in front of me, for two reasons: One is Erin is an honors paralegal here at the FTC, she has been terrifically helpful to us in preparing for this workshop, and it's sort of unsung work, and so I would just like to say thank you.

(Applause.)

MR. GILMAN: For our panelists, I just want to say that Erin will be the timekeeper and enforcer on your brief presentations. She will hold up a little sign warning you when you've got one minute to go, 30 seconds to go, and no time whatsoever, and I'll just ask that you sort of look her way as you're going through your presentations. No need to be mindful of her six black belts in different martial arts.

So, here we go. This panel could have been titled, "And now for something completely different."

We're not going to talk so much directly about animal medicines. We're going to talk about the FTC's experience with and learning about the contact lens industry. The reason for that is that this isn't something wholly different, although there are differences and we want to keep them in mind and ask when and to what extent they're important.

So, there are some salient similarities here. This is part of the FTC's general interest in e-commerce, and it's an area where we've got considerable experience in optical goods and contact lenses. There are some common issues. The common prescriber/vendor model, some common competition and consumer protection issues, questions have been raised about restrictions on distribution or what might be seen as private vertical restraints. Prescription release and portability questions have been raised. Consumer credence issues for established and new markets have been raised. Quite a lot of flux in the market is also true.

So, we want to explore the basic question, what we've learned about our experience with the contact lens industry and enforcing the FCLCA and the Contact Lens Rule, and whether or to what extent that learning might inform our thinking about issues in this new space.

So, to sort of kick this off and to provide some background, we're fortunate to have our colleague Sydney Knight. Sydney is an attorney in the Division of Advertising Practices here at the Federal Trade Commission, that's in our Bureau of Consumer Protection, which is actually charged with the enforcement of the Contact Lens Rule, which is the FTC's implementation of the Fairness to Contact Lens Consumers Act. So, I would like to introduce Sydney and give him an opportunity to provide some framing remarks for our discussion.

MR. KNIGHT: Thank you very much, Dan.

Good afternoon, everyone. My name is Sydney Knight, and as Dan said, I'm an attorney in the Federal Trade Commission's Division of Advertising Practices here in the Bureau of Consumer Protection.

Today, I would like to provide you with a brief overview of the Fairness to Contact Lens Consumers Act, and the FTC's implementing regulation known as the Contact Lens Rule.

Now, obviously this is mainly background to the main focus of your discussions here today; however, we believe that these measures set forth in this statute could provide some guidance for your consideration. But before I go any further, let me state our usual disclaimer, that my comments today reflect my own views,

they do not necessarily reflect the views of the Federal Trade Commission or any individual commissioner.

The Fairness to Contact Lens Consumers Act was passed by Congress in 2003. Now, it turns out that during the decade that preceded the enactment of that statute, the use of contact lenses had seen a tremendous growth throughout the United States. In fact, in 2003, it was estimated that American consumers were spending approximately $3.5 billion annually on replacement contact lenses.

However, along with this phenomenal growth in the industry, concerns were raised about the lack of competition in the industry. Particularly in light of the prevailing practice at that time where various state laws permitted a prescriber to be the only entity that could fill the prescription.

So, to address these concerns, Congress held a series of hearings. Congress then determined that the practice of contact lens prescriptions being filled only by a prescriber resulted in an unnecessary limitation on the consumer’s ability to shop for the best price for their contact lenses. So it was that Congress passed the Fairness to Contact Lens Consumers Act to increase competition in the sale of contact lenses and to bring substantial savings to America's consumers and contact

lens wearers.

So, let's take a look at the specifics of the statute itself. At the very heart of the Fairness to Contact Lens Consumers Act is the requirement that prescribers must give their patients a copy of their contact lens prescriptions at the end of the contact lens fitting, even if the patient doesn't ask for it.

Now, in giving the consumer this right to a copy of their prescription, Congress clearly understood that this right would be meaningless unless the consumer could also fill the prescription at the business of their choice.

So, the statute states that once the consumer receives a copy of their prescription, the consumer could then take the prescription to any seller of contact lenses, either in person, by mail, or by facsimile to be filled. However, as we know, it is not always possible for a patient to present a copy of the prescription in person, by mail or by facsimile as required. For example, Internet sites. So, in these situations, the act also imposes a requirement that prescribers provide verification of contact lens prescriptions that were written by the prescriber.

Now, it should be noted that this requirement is one that was filled with some element of controversy at

the time, due obviously in part to the inherent competitive tug of war between third party sellers and doctors who also sold contact lenses. However, Congress resolved these issues by setting up a system that allows for the contact lens prescription to be verified in one of three ways. The statute provides that the prescription can be verified if the prescriber confirms the accuracy of the prescription by direct communication with the seller. In this instance, a seller seeking to verify a prescription would simply contact the prescriber, by phone, often times, and provide the prescriber with certain information about the consumer as well as the prescription that was provided by the consumer. Now, once that prescription is verified by the prescriber, the seller can go ahead and fill the prescription.

The second method for verification of prescriptions is where the prescriber verifies the prescription by correcting any inaccuracy in the prescription. This would cover such things as incorrect name spelling or incorrect address, things of that sort.

The third method of verification occurs when the prescriber fails to respond to the seller within eight business hours after receiving the request

for verification. In this instance, if the prescriber does not respond, the statute says that the prescription is deemed verified. Thus, this is clearly a passive verification method whereby the prescriber simply cannot ignore the request for verification and thereby frustrate the wishes of the consumer.

Moreover, the act also provides a few other provisions designed to ensure that prescribers do not impose other requirements as a condition of providing or verifying the contact lens prescription. For example, the act also mandates that prescribers may not require the purchase of contact lenses from the prescriber as a condition of release of verification of the prescription. So, obviously the prescriber cannot say, well, you've got to purchase additional lenses in order for me to verify the one that you would like to have filled by another seller. Secondly, the prescriber may not require the patient to pay additional fees as a condition of release of verification of a prescription. And third, prescribers may not require the patient to sign a waiver or release in exchange for the release of verification of the prescription.

Now, as far as the implementation and enforcement of the act is concerned, Congress turned to the FTC by mandating that the FTC exercise its authority

under the Federal Trade Commission Act and that the FTC also undertake enforcement responsibility for the rule.

Well, it turns out that the FTC did have some previous involvement with other rules regarding eyewear. In fact, in 1978, the FTC issued the Prescription Release Rule, otherwise known as the Eyeglass Rule. Under that rule, an optometrist or ophthalmologist must provide the patient, at no extra cost, a copy of the patient's eyeglass prescription upon completion of an eye exam.

Now, prior to the rule, the FTC conducted a number of comprehensive surveys of state licensing laws and of private associations' codes. Based upon these surveys, it was found that more than 50 percent of optometrists imposed some restriction on the patient's ability to obtain a copy of their prescription.

So, with that background in mind, the FTC was called upon, by Congress, to issue its own rules to enforce the Fairness to Contact Lens Consumers Act, and that the FTC did in 2004. Although the act as passed by Congress did set forth a number of specifics, as we discussed above, it was the FTC's Contact Lens Rule that filled in a number of other specific requirements. For example, the Contact Lens Rule sets forth the manner in which the eight business hours required for verification

of a prescription would be calculated.

So, according to the Contact Lens Rule, a business hour is defined as one hour between 9:00 a.m. and 5:00 p.m., Monday through Friday, excluding holidays. So, essentially, if a verification request is received at 4:00 p.m., the clock stops running at 5:00 p.m., and then will continue running at 9:00 a.m. the next business day. Therefore, it's not 24 hours, eight hours whenever. It has to be within those business hours, 9:00 to 5:00, except the FTC also allowed a business hour to include a prescriber's regular business hours on Saturdays, if the seller has actual knowledge that the prescriber has Saturday hours. So, if the prescription comes in at 4:00 p.m. on Friday, and the prescriber has Saturday hours, then those hours count towards the eight hours.

Another important provision of the Contact Lens Rule specifies that sellers of contact lenses maintain certain types of records, including the seller's verification requests. Such recordkeeping provisions provide the FTC with an opportunity to investigate whether there has been a rule violation by the seller, and in some instances to seek civil penalties for such violations.

Pursuant to the FTC's enforcement authority,

the FTC has investigated and brought a number of cases under the Contact Lens Rule. In fact, since the issuance of the Contact Lens Rule in 2004, the FTC has brought ten different enforcement actions against various individuals and entities. Here's a list of those cases, and they can all be found on the FTC's website.

Now, I won't go into the details of every individual case, but just to give you a sense, our settlement orders have generally provided injunctive relief which, for example, would prohibit the seller from selling contact lenses without obtaining a prescription from a consumer. It would also prohibit the seller from selling contact lenses without verifying the prescriptions first, by communicating directly with the prescriber. It would also prohibit the seller from failing to maintain records of prescriptions and verifications. As I said, in some instances, we have actually obtained civil penalties from some of these sellers.

Finally, I would like to point out to you some additional resources about the Contact Lens Rule that are available from the FTC. The FTC has some online resources available, one publication known as The Contact Lens Rule: A Guide for Prescribers and Sellers,

and as you can see, it's available on the FTC's website. We also have another very important brochure that provides Qs and As for how do you comply with the Contact Lens Rule.

Now, these are just some of the materials that you can find on the FTC's website. You can also contact individuals at the FTC. We have a number there that is the Division of Advertising Practices number, and you can call that number to get additional information if you need to do so.

Thank you.

(Applause.)

MR. GILMAN: Thanks very much, Sydney.

My colleague, Joel Schrag, and I look forward to discussion with this very fine panel that we've been fortunate to assemble here. I commend to you their biographies, which are on the workshop webpage. We'll just go down in sequence as before, introducing people by name and title.

First off, we are glad to have with us Joe Zeidner, who is the chief legal officer and general counsel and corporate secretary for 1-800-Contacts.

Joe?

MR. ZEIDNER: Thank you, Dan.

As you mentioned, my name is Joe Zeidner, I'm

general counsel of 1-800-Contacts, our country's largest direct seller of replacement contact lenses. I thank the Commission for allowing me to participate in today's workshop on pet medications.

The marketplace for pet meds looks a lot like the contact lens marketplace looked before the Federal Government stepped in to promote competition and consumer choice. I am here to talk about three things that we learned from our experience.

First, when the government decides to require a prescription for a good, they also have to give consumers the freedom of choice and allow them to benefit from competition on filling that prescription.

Second, by-request laws do not work. And by request, which you heard about in the other panels, are when a consumer has to ask for a copy of the prescription instead of getting it automatically. These are unenforceable, they're discriminatory, they put consumers in the middle of a conflict of interest, and they create an unfair playing field between doctors who freely release prescriptions and those who don't. They discourage choice, since doctors can ask for a fee or a waiver.

Number three, giving consumers their prescriptions and the right to choose where they fill

them will save consumers money, assure them better service, meet their needs for convenience, and promote health.

Twenty years ago, consumers had no right under federal law to a copy of their own contact lens prescription. Even if they could get a copy, they were limited in their ability to shop around. There was evidence that contact lens manufacturers and optometrists were colluding to lock in consumers. Today, contact lens consumers have a right to a copy of their contact lens prescription automatically, without having to ask, without having to pay and without having to sign a waiver. They can fill that prescription at the retailer of their choice. When that retailer is someone other than their prescriber, they have a right to have that prescription verified.

How did we get here? There are a number of touch points. First off, as Sydney talked about, there was the Eyeglass Rule that gave eyeglass wearers a right to their eyeglass prescription. Second, in 1996, attorneys general from 32 states had a national class action of consumers brought an action against the American Optometric Association and the major contact lens manufacturers for conspiring to impede competition from contact lens sellers. Bob Hubbard, who is on this panel,

will speak a lot more about that.

What's important is in that settlement, the parties eventually settled with the manufacturers, agreeing to abandon their restrictive policies on distribution, and the AOA agreed that it shall not make claims that ocular health is impacted by the channel from which consumers purchase their replacement lenses.

Also in 2002, the FTC staff testified in a regulatory proceeding in Connecticut. The FTC suggested that passive verification was the correct system to settle the conflict of interest between an eye doctor who also sells what he prescribes, and an outside seller. The FTC also documented how the cost to a consumer in time and travel in picking up their lenses from a brick-and-mortar store could exceed the dollar cost of the contact lenses themselves.

What has been the impact on consumers? They're saving money, they're buying more lenses, they have more choices, they go and have more exams, and they are benefitting from technological advances.

I am hopeful that for the FTC's workshop today, this is the beginning of a process, and in the end, all Americans who own pets, and that's most of us, can have the chance to benefit the same way that contact lens consumers have.

Thank you.

MR. GILMAN: Thanks, Joe.

Our next panelist is Dr. Clarke Newman, a fellow in the American Academy of Optometry, and a long-time member of the American Optometric Association.

DR. NEWMAN: Thank you for allowing me to attend and to address the FTC workshop.

I am a doctor of optometry and I have been a contact lens specialist in private practice in Dallas, Texas for 27 years. I have been asked by the American Optometric Association, or the AOA, to address the optometric experience with the Fairness to Contact Lens Consumers Act, and I'll call it the Lens Act for short.

I also cite the official position of the AOA is contained in the letter to the FTC by Dr. Robert Jordan, chair of the AOA Federal Relations Committee, and I incorporate those comments here as I expand on some key points. I have provided expanded written remarks, since time is short.

Our experience with the Lens Act, I think, is quite instructive for all pet medication stakeholders, legislators and regulators as they consider the passage and the promulgation of rules under the Fairness to Pet Owners Act of 2011, which I'll refer to as the Pet Act.

The Lens Act was a very good thing for the

consumer by creating a framework for prescription acquisition that enabled the patient to shop for the best deal on lens prices. The Lens Act was also a very bad thing for the consumer because the process of passive verification, in particular, created significant opportunity for abuse by the suppliers and a nearly impossible enforcement burden which, due to the limited resources of those charged with enforcing the act, often failed -- as witnessed by the fact that a Shell Station down on I-35 south of Dallas has a wider selection of tinted lenses than I do in my practice.

Without the full enforcement of the Lens Act, lenses are frequently purchased without prescriptions or with expired prescriptions. When a patient's ability to purchase a medical device that is worn on the eye is not well controlled, the public is harmed.

The claim has been made that optometrists and now veterinarians are unique in that what we sell we prescribe. That view is foundationally wrong. In the fee-for-service health care paradigm, all doctors profit from their recommendations that they make, whether they're surgeons or dentists or whoever. That's a failed assumption.

It has been suggested that health care claims about contact lens distribution should be viewed

skeptically unless one can provide substantive evidence of health care issues related to sale of prescription products by alternative sellers, and I certainly agree with that.

We now have that evidence and it is compelling. In a 2008 study, a large prospective population surveillance study was published in one of the most respected peer-reviewed ophthalmological journals by a group of highly respected researchers in eye care, led by Dr. Fiona Stapleton. Since the annualized incidents of microbial keratitis is small, the rare disease assumption can be applied and the odds ratios approximate the relative risk, and therefore one sees a fourfold increase in the risk of the most severe complication, microbial keratitis, by those who purchase their lenses on the Internet or through the mail order.

Let me state that again. The multivariate isolated relative risk of developing the worst contact lens complication is just about four times greater for alternative distribution channels.

In an email exchange between Dr. Stapleton and myself yesterday, she states that there has been an increase in Internet and mail order purchases and we are currently seeing about 18 percent of orderers obtaining lenses in that way. These original conclusions are

based on multivariate analysis controlled for wearer demographics and lens wearer modality. We have found these findings to be fairly robust.

Further, in 2010, Yvonne Wu, Nicole Carnt and Dr. Stapleton published data that shows a significant difference in the after care awareness of those who purchase their lenses from alternative channels of distribution. We find that compliance with contact lens care recommendations is low, ranging from 59 percent down to nine percent.

In 2008, Fogel and Zidile found that Internet purchasers were more likely to engage in harmful eye care practices and to trust non-evidence-based information found on the Internet rather than seeking out the best practices as recommended by their prescriber. Only two-thirds of the sellers ask for prescriptions. Three out of four ordered lenses even though they knew their prescription was expired. Three out of four Internet purchasers did not have annual eye exams, while three out of four who purchased them from their provider did have annual eye exams.

I really don't have a dog in the pet fight, that's a bad pun, I know, but I think it's important not to make the same mistakes when contemplating what to do with the Pet Act. Since we are dealings with drugs that have

significant potential harm, even when used correctly, and since the end-consumers of these medications cannot advocate for themselves, it would be far better to err on the side of patient protection than consumer protection. That is the lesson one should take from the Lens Act experience.

Knowing what we know now about the increased risk of alternative channels of distribution for disposable contact lenses, more respect should be given to preventing needless injury to the public while crafting any law or regulation aimed at protecting consumer rights.

Thank you very much.

MR. GILMAN: Thanks.

So, our next speaker is Bob Hubbard. Bob is assistant attorney general in the Antitrust Bureau of the New York State Attorney General's Office, a position he has held since 1987.

MR. HUBBARD: Hi, good afternoon, pleased to be here. I was pleased that Sydney finally said the disclaimer that I thought always was here, I speak only for myself and not for any state.

I had the opportunity to prepare a statement and it goes into a lot more detail about the history of how states dealt with contact lenses. I had the pleasure of

being the chair of the Plaintiff States Steering Committee in the contact lens litigation that consumed about eight years of my life. So, this is somewhat like going to a high school reunion for me, you know, these themes coming back that I thought I had moved beyond.

But it is very interesting and I found this very thought-provoking and I appreciate the invitation and the opportunity.

Now, the Disposable Contact Lens Antirust Litigation was an antitrust claim. I think that what we're talking about here is a legislative fix that if it were an antitrust violation, we wouldn't be talking about this. We would be talking about whether there was enough enforcement and stuff. But in contact lens, they did a whole lot more than what you've heard about here.

The AOA and the practitioners had something we call the supply restraint that go to the contact lens manufacturers. They say: "We know how to write prescriptions, we know that we can limit the prescriptions so that only J&J lenses are sold. We can limit them to only Bausch & Lomb lenses if you'd like. So, because you know we have that power, we don't want you to sell to 1-800 anymore." And they reached an agreement. They were pretty blatant about those kind of things.

In addition to that, they had something that we

labeled the demand restraint. The optometrists knew that the power over prescriptions gave them a competitive advantage. They knew that as soon as a consumer had a prescription, there were things that that consumer could do with that prescription. And so they did things to prevent, as some of the documents talked about, the prescription from walking out the door. So, they had training films about how to prevent the consumers from asking. They had these forms that if you signed it you thought that your firstborn was going to be committed for the rest of your life. There were all sorts of very burdensome requirements and the disclaimers and other things that restricted the demand for using alternatives that we challenged in the disposable contact lens litigation. We went all the way to five weeks of trial. We settled. We got the kind of stuff that Joe mentioned, sort of in passing, and I go through in more detail in my statement, more of that information.

But even after we had finished all of that, we didn't think we were done, because one of the things that happened was that the prescription gave a power to the prescriber that you usually don't have in competitive markets. They had the ability to restrict the access to competitive alternatives. That didn't necessarily happen through collusion, but it could

happen individually within an individual optometrist or an individual ophthalmologist.

So, we thought that it was important to make sure that the prescriptions got released. We urged the FTC in 1997, just after we had filed, in December of '96, to extend the Eyeglass Rule to contact lenses. We thought that contact lenses had become manufactured in an easy, replicable way. No longer did you individually fit the lens on the eye. They were a replacement, you replaced them much more frequently than otherwise. We argued that the rule ought to be extended to contact lenses. We were happy that the FTC didn't rescind the Eyeglass Rule, but they did not extend it to contact lenses.

So, the effort went to legislation, and we wrote letters in support of separating the power of prescription from the power of selling. There were three AG letters in support of that. There were also provisions that we supported that tried to prevent the restricted distribution practices that were built on the power of prescription, where the manufacturers would limit to whom they would sell. I had the pleasure of testifying in support of that legislation that was passed.

I do have to add but one additional point. The problem here was not with state law. State law allowed

that prescribing and dispensing were two separate things. In the litigation, they argued that -- like usual, they tried to blame the victim -- it was the state law problem. It wasn't the state law problem, and we fought that. But we passed that legislation. That legislation got passed, I'm happy it did. It separated the prescription power from the sale of the prescribed products, and I think that that was all quite useful. I think that it promotes healthy results, and it brings value to consumers.

MR. GILMAN: Thanks, Bob.

Our next speaker is Rob Atkinson. Rob is the president of the Information Technology and Innovation Foundation, a non-partisan research and educational institute that deals with issues in technology policy in electronic commerce.

Rob?

MR. ATKINSON: Thank you. It's a pleasure to be here.

I've been writing and speaking about this issue of intermediary resistance to e-commerce since 2000, and it's been amazing to watch the proliferation of industries and professions that fight back against consumer choice. They all use exactly the same logic and argumentation. This is car dealers, wine

wholesalers, lawyers, realtors, undertakers, optometrists, and now veterinarians.

My favorite of all time was when I debated the head of the Texas Car Dealers Association at the National Conference of State Legislators who told me if you bought a car over the Internet from a producer, that you would get ripped off, unlike when you buy it from a car dealer.

They engage in this through three principal ways. One is collusion with producers. Bob talked eloquently about that. The second is limiting access to key resources. We've heard about that with prescriptions, and that's in theory what the 2003 Contact Lens Rule was designed to do. But I say designed because as late as 2007 in Contact Lens Spectrum Magazine, a professional magazine for optometrists who surveyed optometrists and found that in 2007, "Despite this federal legislation, only half of the respondents replied yes to every patient when asked if they release contact lens prescriptions, even though they're required by law," which makes you wonder not only their ethics, but their intelligence for why they would answer a question that is illegal to take in a professional survey. So, clearly even when the law passed, you had optometrists who would resist this. And the third is they passed an array or supported the passage

of an array of laws, including state laws requiring face-to-face transactions, limited sales, et cetera.

So, what can we learn from FCLCA? I think several things. One is that we learned that optometrists would oppose any threat to their business model and do virtually anything and say anything to keep their business model intact. We can also learn that ultimately optometrists benefitted from this law because of the change in the examination rule. Third, we can learn that really despite what you've heard, there's very little evidence of adverse health impacts.

The study that was cited here earlier, the Fogel and the Zidile study, which we have an article in there rebutting, is really a study when you look at it, that it's just chock full of methodological errors. It's not a study that would pass a rigorous statistical journal for peer review. I'm not going to go into detail on that.

The other one that we heard about, the Australian study that had multivariate analysis, which if you look at that, that fourfold increase, what that is a fourfold increase of has two problems. One is that the increase is very, very small. So, it might be a fourfold increase, but it's off of a base that is incredibly minute. The biggest risk in that study is

sleeping with your contact lenses on all night, that's the giant risk. The teeny little risk is this other one.

Secondly, I'll just mention this Australian study, which the AOA representative cited, the study says, "The risks associated with Internet mail order purchase may be related to contact lens care attitudes and behavior, not Internet sales." So, in other words, they haven't controlled for that and they admit that in the study.

Now, the other argument you will hear is that we don't, and James may make this argument, that even with the passage of this law, we haven't seen significant consumer benefits, that essentially the market is the same way it was, and that the contact lens providers have not lowered their prices. James Cooper has written a study on this, which he may talk about, but let me just comment on the study.

One of the things that James did in his study, he looked at 2004 as the base year, and 2007 as the final year. The big problem with that is in 2004, the act was already in existence. So what he was trying to look at is did optometry prices, getting your lenses from optometrists, did they actually go down relative to online over this period? But it was actually after the law was

passed, so you would expect a price impact right away, not later.

The second problem is that the base year, the end year, 2007, which we haven't talked about, was still right around the time that the CooperVision restrictions were in place, and CooperVision was not under this AG restraint. They were able to sell and basically sell lenses to optometrists that were doctors only. So, they would prescribe this lens, you simply couldn't buy it anywhere else. Luckily, they've been stopped, they have stopped doing that.

Just anecdotally, by the way, a sample of one, if you go out to Montgomery Mall and you go to LensCrafters, I took this picture last night, I'm sure you can all see it, but basically what it says, and I'm happy to give you a copy, basically it's a doctor there providing a little price description, and it says his prices or her prices are lower than 1-800 and Walmart. So, actually what it says is 1-800 and Walmart prices, and then Dr. Solomon's prices. It appears to me that that doctor is competing on the basis of price with Walmart and 1-800-Contacts and is trying to tell his or her customers, yeah, I'm going to compete on price and you should buy here.

Now, let's just say hypothetically that that's

what's going on. That, to me, is pro-consumer and suggests that consumers have benefitted from the law, and I would suggest that consumers would benefit from a pet meds law as well.

Thank you.

MR. GILMAN: Thanks, Rob.

I would like to welcome back to the FTC James Cooper, who depending on his perspective is either an alumnus of or a refugee from the Office of Policy Planning, where he has served both as deputy director and as acting director. These days he's at George Mason University Law School where he is director of research and policy at the Law and Economics Center and a lecturer in law.

James?

MR. COOPER: Thanks, Dan.

It's great to be back here. It does feel like old times. I'm here, I think, I don't know, because they couldn't find anyone else, but I did some work on this Contact Lens Rule. It was one of the first things I did here as an attorney advisor in the Office of Policy Planning. I worked on the Contact Lens Rule and the study that was mandated by Congress, and it's the gift that keeps on giving, right? I'm back here. I've been asked to I don't know how many panels I've been on

because of this, really not very many, to be honest, this is it.

In my very limited time, what I want to talk about here is I have done some empirical work. Some of it comes off of the Contact Lens Report, where we did gather some data, and then on my own, after that, I gathered some more data. So, one paper that I have right now, it's
currently a working paper, it's under review at a journal, we'll see what happens, I'll keep you posted if you're interested, but it is to see if the prescription release requirement, how that affected prices.

I'll go forward with the punchline is I don't really find any evidence, but my takeaway from that isn't that it was a bad idea or that consumers didn't benefit. So, the methodology of the study is I did look at prices, we collected for the contact lens study in 2004, that was about a month after the Contact Lens Rule, the act passed, but it didn't go into effect until the Contact Lens Rule. It's a weakness in the study and it's front and center in the report. I devote about three pages discussing it in the caveats of the data.

However, then we go back in 2007 and collect data. So, the idea that if about a month after the Contact Lens Rule went into effect requiring

prescription release, you wouldn't see all the effects right away, and so you go back three, three-and-a-half years later, see how the market has changed. I won't go into the pretty rigorous methodology, and what I find is really no effect on price. On average, there isn't any effect on price.

If there's anything that you can tease out of the data, it's one, that when places like LensCrafters and Pearl Vision, the optical chains, their prices actually rose over the time period, vis-a-vis online, the gap. So, what I'm measuring is the gap between online and offline. If prescription portability worked and the idea was that they would compete more vigorously, you would expect to see the price gaps narrow. The gap between warehouse clubs and online maybe shrunk a little.

So, but overall, you don't see much of a change.

I'm quickly running out of time. So, I will skip through to another little bit of empirical work I did in 2007 looking at the limited distribution strategies, and as alluded to already through Coopervision, lenses that have limited distribution, I did some empirical work there. I didn't really find that the margins or prices of those limited distributed lenses were statistically distinguishable from other lenses

like Acuvue, et cetera, that were not limitedly distributed.

So, I hope we talk more about this in the panel, is prescription release, why do we not see a market effect? Maybe doctors aren't obeying the rule, that's one possibility. The other is something called ordered search, where search is costly and consumers are already there, and they think, okay, I'm going to buy from the first price draw I have, and doctors take advantage of that. They know it's costly to go and find something, so they charge a premium for that.

Limited distribution, I would just make the point here that there is a presumption in the antitrust laws that vertical restraints, both price and non-price, are efficient. The burden is on the moving party to show why they're inefficient. So, I think that's a pretty high burden. We should make sure to distinguish between horizontal collusion, which is going on in Bob's case, and unilateral vertical restraints, I think that's important when we think about policy.

Thanks a lot.

MR. GILMAN: Thanks, James.

Next we have Dr. Link Welborn of the American Veterinary Medical Association.

DR. WELBORN: Thank you. I would also like to

thank the Federal Trade Commission for this opportunity.

I have been asked to speak to the similarities and differences between the contact lens and pet medications industries from my perspective as a practicing veterinarian. Both eye care professionals and veterinarians prescribe and dispense products for long-term use in their patients.

These products, contact lenses for people, and parasite control medications for pets, are typically sold in six-month supplies. However, these medications represent a minority of those prescribed by veterinarians. Most medications are acute short-term care medications and are much more varied in form, function and efficacy than contact lenses.

In addition, the potential for and severity of side effects associated with pet medications is much greater than with contact lenses. For example, the most commonly prescribed oral flea control medication and the most commonly prescribed treatment for mange will often cause a life-threatening side effect if administered to a dog within days of each other.

Further, some medications can be life-saving in one species and life-threatening for another, or even another breed within the same species.

While both large and small animal practice

entities exist among eye care professionals and small animal veterinarians, the vast majority of pet practices are very small businesses and tend to be less profitable and less sophisticated from a business perspective than eye care professionals. Accordingly, veterinary practices are less able to absorb the expense and management effort associated with any additional regulatory burden without passing the additional costs on to consumers.

The veterinary profession is currently experiencing numerous economic challenges. While these challenges intensify during the recession, they certainly predate the downturn in the U.S. economy and will persist even as the overall economy improves. Included among these are the progressive margin compression on veterinary medications that spans more than a decade. While this has reduced the profitability of veterinary practices, it has been beneficial to consumers in that it has reduced the cost of pet medications and it is an example of successful function of the free market.

Today, the mark-up for the most commonly prescribed parasite control medication in my practice is about half of what it was ten years ago, even though there is still no generic competition for that medication.

As I understand it, the price competition among

sellers of contact lenses has intensified significantly since the Fairness to Contact Lens Consumers Act was passed by Congress in 2003. Even though it is impossible to determine how much has been the result of this law and how much occurred independent of it, the competitive landscape has obviously changed greatly within many industries, including pet medications, over the last nine years, because of increased consumer utilization of online merchants and large discount retailers.

Consumer awareness of a large number of online and discount retail sources of pet medications has increased greatly since 2003, as a result of millions of dollars of advertising. As a result, virtually every pet owner that I see in my practice is aware of these options. Just as Ms. Press indicated relative to the ASPCA veterinarians and tens of thousands of other veterinarians across the country, the other veterinarians in my practice and I write prescriptions for pet medications daily. Some at the request of clients and some at the suggestion of the veterinarian.

Clients commonly request prescriptions for the parasite control medications with the expectation that the cost of these medications will be less from another source. Once again, free market forces have been very

effective in the pricing of these medications within most veterinary practices as set based on the prices available through online outlets.

In our practice, clients are often surprised to find that the pricing in our hospital is slightly less than that available from online sources. The reality is that most practices set prices at, slightly above or slightly below the prices of online outlets with many practices matching the lowest price available online. This price parity exists because practices want to serve the needs of their clients and patients, but also because we want our clients to have the impression that we are fairly priced throughout the products and services that we offer.

Unlike eye care professionals, third-party payment for veterinary care is rarely available. Further, pet owners rarely budget for this care. For these reasons, virtually every veterinary visit includes two conversations: One about care, and another about cost.

Since many local pharmacies advertise the availability of low or no-cost medications for both pets and people, it is common for veterinarians to suggest that they write a prescription for a medication in order to help clients afford recommended diagnostics or

treatment procedures.

If I have a patient with a fever of undetermined origin, I would rather write a prescription for a free antibiotic from a local grocery store or pharmacy and utilize the pet owner's funds to perform blood tests to learn more about the nature and severity of the underlying disease than dispense an antibiotic without being able to perform the tests.

The bottom line is that veterinarians help pet-owning consumers spend their money wisely every day.

Thank you.

MR. GILMAN: Thanks, Dr. Welborn.

Finally, and by no means least, we are glad to have Dr. Kent McClure, who is general counsel for the Animal Health Institute. The AHI represents research-based manufacturers of animal health products.

MR. McCLURE: Thank you.

I see my role here today, as we talked about leading up to this panel, as helping to identify some of the differences between the animal health products industry and the contact lens industry. A major difference is the scope and complexity. Unlike products intended for human use, animal health products are labeled for use across a wide variety of species and indications.

Importantly, veterinarians may appropriately use them in a manner that differs from their approved labeling. They are regulated by three different Federal agencies, drugs and devices by FDA, biological products by USDA, and pesticides by the EPA. The intended species for these products may range from dogs and cats, livestocks and horses, to an extremely diverse range of minor species. There are many dosage forms, including oral, it could be liquid or solid, injectable, topical, pet food, aerosol, intranasal, or they may utilize sophisticated and specialized delivery devices. The intended uses for these products impact every conceivable animal system.

Contact lenses for human use represent a single subcategory of medical devices that are used topically on a single organ system primarily for vision correction. The distinction among soft contact lenses primarily involves differing plastic polymers and shape. It's our understanding that the Contact Lens Rule generally relates to the ability of a consumer to order standardized contact lenses that are dispensed for use in accordance with their labeling by a dispenser who must only be familiar with one species, and when it's not an eye care professional, they are essentially just matching the correct box to the correct person.

The scope and practice of companion animal

medicine, however, is very large, includes the diagnosis, prevention, control and treatment of all animal diseases and conditions. In the course of such practice, most companion animal veterinary hospitals are analogous to human hospitals, providing inpatient, outpatient and emergency care, surgical, medical imaging and clinical laboratory services. In this context, a very wide variety of animal health products will be utilized for many different purposes.

On the other hand, according to the contact lens study, the interaction of eye care professionals with their patients relative to the fitting of contact lenses, is on an outpatient basis, and is typically limited to an examination of the eye to determine eye health, lens power and contact lens curvature and diameter.

With respect to pharmacists, they are an integral part of the delivery of human health care and their training is primarily oriented to human health. However, as we heard on several panels earlier today, pharmacists are not trained in the physiology and pharmacology of companion animals in a manner similar to veterinarians, and as such their participation in the delivery of veterinary health care has been limited.

In our industry, the veterinarian plays a

critical role, matching the correct product with the correct patient is important for many products and extends beyond just prescription products to encompass other types of animal health products, particularly as veterinarians frequently and appropriately use them in a manner that differs from their approved labeling, such as treating a different species, using a different dosage regimen or a different indication for use.

In this environment, the veterinarian is the primary source of information about animal health products for pet owners. Veterinarians have typically counseled clients regarding the use of products, and many manufacturers have invested tremendous resources to educate veterinarians about their products.

Veterinarians also have ongoing close interaction with their clients and have been the primary monitors of patient use of medication, including evaluation for interactions in adverse events. These roles for the veterinarian are understandable due to their unique training.

As was mentioned earlier, products in one species may not be safe for another, combinations in one species may not be safe in another. Involvement of the veterinarian should not be discounted as many in our industry believe that the safety and efficacy profiles

for many of their products are positively impacted by the comprehensive role of the veterinarian.

MR. GILMAN: Well, thank you.

So, we are going to hope to kick off a discussion here. I'm going to let my colleague, Joel Schrag, start things off.

MR. SCHRAG: Thank you very much, Dan, and I think these opening presentations have put a lot of issues out on the table that hopefully we will be able to address.

During the panel discussion, if any panelist in particular wants to respond to something that I raise, please raise your table tent, as Dr. Newman has already done, perhaps he anticipated my first question.

Dr. Newman, was there something specific from the opening presentations that you wanted to respond to?

DR. NEWMAN: Yes, there was.

MR. SCHRAG: Okay, why don't we take a minute, then, for that.

DR. NEWMAN: A couple of things. It was proffered to you all that this information that were in the three studies that I presented was somehow suspect and that's simply not the case. These are all published in peer-reviewed journals that went through vigorous vetting, and again, these numbers do say what they say.

You said that there was an increase in eye exams and that's not true. Among those that purchased their lenses, three out of four don't have annual exams, whereas three out of four who purchased lenses from the provider do have annual exams. Okay.

MR. SCHRAG: If the moderator can break in, it sounds as though we maybe should start under the broad overarching question that people will have a reaction to, which is have consumers benefitted from the FCLCA, Fairness to Contact Lens Consumers Act, the associated Contact Lens Rule and the distribution changes that were brought about by the state attorneys general lawsuit. So, why don't we just open with a general round table on have consumers benefitted.

Dr. Newman?

DR. NEWMAN: I'm surprised to hear the data about the lens cost because I thought it went down, and see that's the neat thing about research is we can think whatever we want, but the data tells us otherwise, and provides us with inconvenient truths.

One other thing: We're not required to release every prescription. There are a lot of us that prescribe rigid contact lenses that are custom prescribed, and so those numbers are not ever going to be 100 percent on the surveys of whether we release

prescriptions or not.

But if you say that, I mean, I think that patients have their prescriptions, but if the cost isn't going down, and we're seeing morbidity that's isolated on a multivariate analysis to this particular group that purchase lenses from alternative distribution channels, have we helped the public or not? That's a good question.

MR. SCHRAG: Well, thank you for your comment.

Why don't we just move down the line. First, Joe Zeidner, please.

MR. ZEIDNER: Thank you. I know from our point of view, the passage of a law, we did a test in Texas and in California. In California, people were able to purchase through passive verification. There was a law that passed in California before the Federal law passed, and passive verification means you don't have to get a copy of your prescription from your doctor, that the seller will contact the doctor and verify if the information is correct. Then the doctor can choose if he wants to get back to us or not. If there's a problem, we hope he gets back to us and lets us know.

In Texas, we had an agreement with the Texas Optometric Association, and they said that if we would agree to wait to get a copy of the prescription, they

would make sure that all the doctors gave us a copy of the prescription when we requested. They didn't. There are over 60,000 complaints filed with the Texas Optometric Board and they said, we're sorry, we told our doctors to. So, there is definitely a problem.

When you said that all doctors profit from their recommendations, it's very interesting, because I thought that was a kickback. And I know that if you recommend someone to go down to get an MRI, you're not allowed to profit from that. But even if that were correct, and it's not.

DR. NEWMAN: It is correct.

MR. ZEIDNER: You get paid for a recommendation when you do a contact lens fitting. That is your payment for the exam. Paying for a product is something separate. You weren't there during the hearings when the bill was first heard by Congress, but the optometrists were asked if they would rather have a bill that said you don't sell what you prescribe, because that would definitely fix it. There wouldn't be any conflict of interest, and there was, and AOA said, no, actually we would rather have the FCLCA, they signed on to support it. So, I don't know at this point what the difference is.

DR. NEWMAN: I'm not speaking against that.

What I'm saying is that when a surgeon recommends a surgery, there is still a profit motive in place and there are a lot of people, in fact there was a whole thing, a whole study about this just released recently about this whole health care paradigm being a fee-for-service. You know, we don't want you to die, we don't want you to get well, we need a whole new system.

MR. ZEIDNER: But they don't sell prescriptions to the people.

DR. NEWMAN: Well, let's take an example. Ophthalmologist says you need cataract surgery. Well, the intraocular lens comes in a box, it's packaged in a commodity way. Why are we not requiring the ophthalmologist to allow the patient to shop for their intraocular lens before they have their cataract surgery? Heart stents are the same way. This notion that because it's packaged and can be put at the front desk of a Walmart or Walgreens for sale somehow changes the ethics of the whole thing is not true.

That was my point, is that we have an ethical construct to prescribe and to dispense products, whether they're eyeglasses, contact lenses or whatever, in an ethical manner, just like the veterinarians do, and just like general physicians do, just like dentists do. There's really no distinction.

What I objected to was the false distinction that we are somehow different from everybody else, and we're not. That's what the point I was trying to make.

MR. SCHRAG: So, now maybe Bob Hubbard would like to react.

MR. HUBBARD: Yeah. No, I mean, this really does bring back memories for me and I remember when the testimony on the legislation was going on, similar fights were going on, and I was sort of sitting in the middle, and I tried to represent consumers as best I can.

So, I want to give as many alternatives as I can to consumers, and the portability of the prescription is one thing that that does. If there is an adverse health consequence, that's something that the regulatory system should address, and that should be discussed with evidence, and we should go forward from there.

So, I think that the better alternatives available to consumers are what's better, and in terms of like if everything is broken, so let's not fix what we can see that's broken, I've never particularly liked that idea. When people come in and say that everybody in the industry is doing it, I say, I'm open to evidence about your competitors. I'm willing to name them as a defendant, also, if you'd like.

So, from my perspective, if the financial incentives are screwed up, and if there's a potential for abuse of power over the prescription, we ought to fix that. If there are problems elsewhere, then we can address those problems when they're articulated and we can go forward from there.

MR. SCHRAG: Rob Atkinson I believe wanted to weigh in.

MR. ATKINSON: Yeah, just a couple of things. On the claim that, again, one of the studies that AOA cites is this Optometry Journal study. I wouldn't call that a peer-reviewed study. This is a journal for the industry by the industry that accepted an article that said everything is fine and if you get your lenses online, you're going to have eye health issues.

So, I think before we make any claims about the health studies, we really need independent, objective experts to review the studies that have been put forward. Because I can just tell you from a statistical point of view, there are serious problems in at least one of them.

The second point about this is we need to understand risk. So, again, if you read the Australian study, the risk is very, very low. So, without stipulating that there's any risk, because who knows,

the study could be right, could be wrong, it looks like there are some problems, but we don't know. That's the key point, we don't know.

But let's just say hypothetically there is a risk of instead of one in 10,000 it goes to one in 8,000, but at the same time, consumers have saved $8 billion. Is that worth it? Any federal cost benefit analysis would tell you that is definitely worth it.

So, the notion that there may be risk, and again, I don't claim that there is, we don't know if there's any risk. To say that that is the objective standard for whether this is a good thing or a bad thing, you cannot look at risk without looking at benefit.

Now, to get to the benefit point, just a couple of points on James' study. One of the things that James did is he looked at basically the control group in his study was online sellers. So, he looked at the ratio of the changes with a various group of different sellers -- ECPs, Walmarts of the world to online -- and saw that it didn't change. As I noted, I think there's one problem, which is that both that first year and the last year were problematic years, and I'll bet if the study were done again, we would have seen something different.

Secondly, that doesn't tell you very much,

because what if competition, because of the law, forced the 1-800s of the world to reduce their prices even more, and as a result optometrists had to just keep up. Well, that would be a huge consumer benefit, and you can't tell which of those is right from the study.

Last point, one of the nice things that James' study -- if you read it, I encourage you to read it -- he does state, "offline sellers clearly offer the highest prices in distribution, the 25 highest priced stores are independent ECPs." Everybody knows who studies it, ECPs have the highest prices, but what's interesting is if you look in the last ten years, the share of sales online has doubled, which means by definition, consumers have saved an enormous amount of money, and you would expect that share to keep going up as more people have broadband.

So, just by definition, even if the people who keep going to their optometrist to buy lenses, let's just say there hasn't been a price change, which I don't agree with, all the people who switched over to online have had big benefits, and that's a benefit that we can't just dismiss out of hand.

MR. SCHRAG: Thank you.

James, did you want to comment?

MR. COOPER: I have to. Anyway, I would just

say that I think Rob and I actually agree in general. I mean, again, I went into this online, off, looking at the 2004 to 2007 comparison, completely agnostic, not to prove a point one way or the other, just what happened. We did this, let's see what happened to the prices. I think I do a pretty good study.

Again the caveat with the 2004, I admit that, I wish we could go back in time, but I didn't have RAs or anyone in the FTC willing to collect data for me until the fall of 2004. So, again, the Contact Lens Rule is what was the triggering event and that went into effect in October or September of 2004, and we collected data starting in October.

So, we did miss a month. I'm doubtful that all the price change, if there were increased competition, occurred in that one month. We came back three-and-a-half years later with the exact same lenses, exact same eye care practitioners. So it's a matched sample from both.

So, I think to the extent, given the caveats, the data is pretty well done. With respect to the 2007 end date, I know this is kind of getting into the weeds, but the Proclear compatible. Number one, the econometrics I use, I have what's called a lens-specific, it's fixed effects. So, I have a little

dummy variable that takes into account any idiosyncratic effect of any lens. So, Proclear wouldn't be driving the effects. Number two, Proclear is a tiny share anyway. So, the 2007 end date is not likely to make an effect, but again, I will completely own the caveat of the 2004, I don't try to hide it. Read the paper. Go to SSRN and download it, so I can up my downloads.

But I guess what I would say is again, back to agreeing with Rob, is that my punchline here isn't the prescription release requirement was bad, you need to know the cost side of this, too. I mean, more choice is unambiguously good, even if consumers don't use it.

So, let's say that my results suggest that, well, to get this, but we're not seeing a huge effect, they're not using this choice. But we have to know the cost. And that's something I don't pretend to know.

We've heard debate back and forth here on the panel of whether the study suggests that there are costs to this, or there are not, but I would not want these findings to suggest that the contact lens prescription release requirement was a bad thing and I think talking about in the pet meds context, I think we would also have to know the costs and benefits. I mean, there are likely benefits from release, you get more choice. More choice I think is unambiguously good, but at the same

time, there could be costs to that.

If, as Rob has pointed out, back to the contact lens, if the costs were minuscule and increased the risk of this micro -- this eye disease, compare that to what consumers may have saved, then I think that that cost benefit analysis, if those numbers are right, stand up, but again, I don't pretend to know the other side of the equation here.

MR. SCHRAG: Thank you.

So, I see that Kent McClure and Dr. Newman and Joe Zeidner all have their tents up. I would like to just ask that I think it would be useful for us to add a little bit more color to exactly how the distribution and retailing of contacts has changed since the promulgation of the Contact Lens Rule.

So, we've heard a lot about some of the potential benefits and costs to consumers, I think it would be useful to hear more about how things have changed and the degree to which that can be tied to the Contact Lens Rule as opposed to other things that were happening in the marketplace.

I want to give Kent McClure a chance to weigh in.

MR. McCLURE: I will let you get to that in just a second, I just want to make a couple of points, because

in listening to this discussion, I can tell you that our industry is about providing useful tools that can be used by veterinarians in the delivery of health care. A cost benefit analysis for us to say, well, gee, we only had a little bit of increase in adverse events, but we saved some money, those aren't the types of analysis that are important to veterinary practitioners. We're about providing patient care, not worrying about just, oh, there's only a small amount of the increase of adverse events that could be prevented.

The other part of this that I heard that I wanted to comment on is there's a lot of touting of the online outlet for these products. To contrast that with the pharmaceutical world or the animal health products world, concurrent with the planning and preparation for this workshop, the Food and Drug Administration has undertaken a consumer awareness program warning them that approximately 97 percent of online pharmacies don't comply with state or federal law.

So, it's not like this is just an innocuous alternative way to provide product to the consumer, and there's just a lot of differences, I think, in a very standardized product that's being dispensed versus products being used in a myriad of different ways.

MR. SCHRAG: Thank you, Mr. McClure.

Dr. Newman?

DR. NEWMAN: Just a couple of things, I don't want to get off in a ditch on this thing, but the Journal of the American Optometric Association is a peer-reviewed journal, all three of these articles were written by academics, reviewed by academics and corrected by academics, and the comment that this is a very rare finding and that a four, almost five times increase among this one group that has been controlled in multivariate analysis, I think is a disservice to the public when we're bean counting relative to the cost savings.

Ford bean counters did that with the Pinto and it didn't work. If your kid was one of the 13 percent that had permanent vision loss associated with microbial keratitis, how many billions of dollars would you be willing to trade for that? It ain't rare if it's in your chair. Yes, these are not widespread events, but they're catastrophic events when they do occur.

MR. SCHRAG: Thank you, Dr. Newman.

Joe Zeidner?

MR. ZEIDNER: Yeah. Just to answer your question about how things have changed, I have a slide, a couple of slides I was going to add to my presentation but ran out of time, but it talks a little bit about the

price comparison in today's dollars, and since we sell more contact lenses than anyone, it might be instructive, but really, prices have gone down quite a bit.

If you want to put it up, just for an example, the most popular, Acuvue 2 in 2004 in the FTC study was $19.95, our price to consumers. In constant dollars in 2012, it's now $24.83. Our current pricing is $18.99 or $20.99 if you buy just one box. So, prices have definitely gone down.

The most important area, I think, is in 2003, as indicated in our product brochure, we sold 37 different brands and types of disposable lenses. Today there are 91 different types and brands, and there has been a lot of manufacturer research and development. There's all kinds of new polymers, more safe polymers that people can sleep in, silicon hydrogels that are more comfortable and have a higher oxygen permeability, and that's what happens in the competitive marketplace when manufacturers have to market the products based on what the products do instead of who sells it. So, we think that there have been some very big differences.

MR. SCHRAG: Thank you.

DR. NEWMAN: One quick comment?

MR. SCHRAG: Yes, Dr. Newman?

DR. NEWMAN: Yes, real quick. That may be true that you guys are selling a lot more lenses, but a lot of that owes to the fact that a lot of those lenses weren't available when the Lens Act first came up.

One other point is in the Stapleton study, there was no difference in the rates of problems with the silicon hydrogels versus the regular hydrogels.

MR. ZEIDNER: No, I think that's why there are more lenses, because of the act, and that's right. They did not exist then, and I believe it's because of the competition that we have more now.

MR. GILMAN: Thank you.

We're having a very useful discussion, I would like to make time for a couple of the questions that we've gotten from the audience. One of them from a couple of sources really sort of has two components, and I think points both to similarities and differences here.

It's a question both about the full range of pharmaceutical products that might be prescribed to non-human animals, to pets, but also highlights, I think, and how much more complex maybe that is than the contact lens issue, but we talk not just about prescription release here, but about restrictions on distribution, and the question also asks whether we

would really want the same treatment for EPA-regulated products, for over-the-counter products.

So, I guess I would like to ask panelists, now I know we have a very few vets here, but we do have veterinarian representation on the panel, and I guess if we could circle back, I would like to ask whether, on behalf of some others, whether that might be a decent fit and whether we can think of a good medical or business reasons for restrictions on distribution, not on the full range of animal medicines, but for EPA-regulated, over-the-counter products.

Dr. Welborn?

DR. WELBORN: I'll weigh in on that. Actually, this was a subject that I wanted to bring up, based on some of the comments that Mr. Zeidner made. He mentioned that there were 60,000 complaints to the Texas Optometric Board about individuals' eye care professionals that were not releasing prescriptions, and my question was, how many complaints have been received from consumers about veterinarians not releasing prescriptions, but that's sort of the corollary. The number that sort of struck me that's somewhere close to 60,000 was 44,000, that was the number of complaints that the EPA received in one year related to consumer concerns about adverse events related to

over-the-counter flea and tick control products that at one point in time were distributed predominantly through veterinarians, and now are to a large degree distributed through other outlets.

One questions whether or not that number of complaints about side effects for those medications would have occurred had those products been continued to be distributed predominantly through veterinarians. The most common adverse event was related to applying a dog product on a cat, which can be life-threatening for cats. That is very unlikely to happen if the veterinarian is dispensing the product because the instruction on the use of the product is fairly straightforward in that regard, whereas if it's purchased from another outlet, there's typically no guidance in the use of the product at all.

MR. GILMAN: Doctor, can I ask just a follow-up question? I mean, one thing we know from the human side is that highly trained professionals -- for instance in a hospital setting, physicians, pharmacists, nurses -- dispensing human medicines all within the building have certain incidents -- maybe some find it alarming; the Institute of Medicine has found it alarming -- of medication errors leading to serious adverse events.

I guess that raises the question, these all seem

to be serious safety concerns we might have about one or another channel of distribution, but I guess one question I would ask is how good is the information, how good are the data, what do we really know about the incidence of adverse events or medication errors associated with sort of the traditional what's sometimes called ethical channel of distribution?

DR. WELBORN: All right. I don't think I have any numbers about the adverse events that are occurring. I think one difference relative to veterinary medicine from human medicine is that veterinarians and their staff members spend a lot more time with their clients, with pet owners. I mean, the reality is that we have the luxury to do that. We are not nearly as busy as human health care providers. We don't have the same time pressures to be able to move patients through the system as quickly as those pressures that occur in the human health care system.

So, I think that type of thing is much less likely to occur in the veterinary field because we simply have more time to spend with our patients and our clients.

MR. GILMAN: One more question from the audience, this is written for one of our participants, but I think I would like to pose it to the panel or at

least to Dr. Newman, to James Cooper and to Rob Atkinson. Sometimes we have the data we have, and we make do, when we can treat it more carefully or less carefully.

I think one of the things we have seen in the discussion here is that both with regard to optical goods and with regard to pet medicines, that sometimes we don't have all the data that we would like to have. So, we have an Australian study, it's not completely different, but it does raise the question, what do we know about risk in the United States, and parsing different categories of alternative vendors, so to translate into the pet medicine space, would we treat Drs. Foster & Smith the same, lump them for data purposes in with bogus websites where there are no pharmacists or vets or checking for prescriptions? A study asking, for instance, 151 Brooklyn college students what their habits are for return check-ups, where they have to do regression analysis on insignificant correlations might not be ideal.

James has an extensive discussion in his paper on limitations on his data, I guess I just ask all of you if there are some key data you would like to have and key studies you would like to see done that would both or either teach us more about the effects of the Contact Lens Rule or about what we want, should want to

know for considering policy interventions in the veterinary space.

Dr. Newman?

DR. NEWMAN: First off to address the differences between Australia and the United States. In Dr. Stapleton's paper, she addresses that up front. There are several large-scale epidemiological studies regarding the incidence of this one thing that we focus on, microbial keratitis, which is the worst of things that can happen with contact lenses, but there are a whole bunch of other minor complications that can happen across the board, and I would like to see data done on those elements relative to the mode of distribution and controlled well in multivariate analysis.

In the Stapleton study, her data was very, very consistent and correlated very well with the Poggio and Schein studies relative to the risk of microbial keratitis. So, the inference from that was that things are not that different in Australia versus the United States.

So, I think we can compare those studies, but it would be nice to see that exact same study done in the United States as well. I would like to see the same type of multivariate analysis that parses out these defects in large scale studies done for not only

microbial keratitis, but also for some of the minor complications that we see in eye care.

MR. GILMAN: James?

MR. COOPER: First I would like to have a time machine and go back to, say, August of 2004. So, that's wish number one. But leaving us and staying in the realm of reality, I think one thing that's unclear, my results suggest that I have to look indirectly. I'm looking at competition, so I'm looking at price. The price gap between online and offline, but it would be interesting to have direct evidence on kind of microdata, what are consumers actually doing at prescribers, have a sample of prescribers that you follow the prices they're charging.

One thing I can't rule out is I don't find an effect. I kind of assume that there's a law and people are following it, but listening to this panel, it sounds like maybe some people aren't. So, maybe the no effect is because eye doctors aren't giving away their prescriptions. I can't rule that out, that would be a piece of data that would be interesting to know to what extent is the choice to stick with your prescriber one you already have it in your hands and you just decide to stay there.

One of my hypotheses and a possible explanation

for this data is this thing called ordered search that I never really got to, but if you're going to search in a predetermined order, and everybody knows that. So, the eye doctor knows that he is going to give you the prescription and he also sells the lens that he prescribes, he is going to be the first draw in your price distribution.

So, if you're going to search for prices, he knows he's always going to be, he or she knows that they are always going to be first. Knowing that, and knowing that search is expensive, even if I want to go somewhere else and look on 1-800-Contacts, or go and check with Walmart, it costs something. It's not free. So, that allows that first person in the queue of search to extract a premium. Maybe that explains this persistent prescriber premium we see, or at least some extent of it.

One thing that would be interesting, and this came in the conversations I had with Dan and Joel leading up to this conference, is nowadays we all have one of these *(cell phone in hand)*, right, so my doctor says I'm going to give you Acuvue 2, and you can pick it up in the lobby. Okay, well how much is it? Hold on, let me check 1-800-Contacts. I say it half jokingly, but there's a large literature on how online and offline, how having

price search engines has perhaps reduced search costs and led to more competition among sellers. I mean, here you go, you can find prices.

DR. NEWMAN: Practically, that's true. I have a large-scale long sample of one doctor over years. There is no question that I am not that first in the chain. In this day and age. Maybe ten years ago, I was the first guy in that distribution chain. Now, practically every patient I come in contact with already knows how much they're selling them for, Coastal and Walmart and Costco, when they walk into my office. So, I'm usually like the fifth guy in the chain.

MR. COOPER: And I guess that's assuming that they already know what you're going to prescribe. Are these return customers in the sense that they have been wearing Acuvue forever?

DR. NEWMAN: Most of them, yeah, most of them are already wearing them.

MR. COOPER: And I think that's going back to the data, the sort of fine data to figure out. Because there are different incentives with respect to each consumer.

DR. NEWMAN: One way you could parse that out is look at neophyte wearers versus existing wearers, because the doctor is almost always the first guy in the

chain.

MR. COOPER: And you're exactly right, that's a way to tease out that ordered search effect.

Let me say one more thing and then I'll shut up, but you gave me the floor to talk about the data I want. The last thing, this is a theory that let's say that there's this lock-in. Let's say that it's right, that you can still take advantage, that the eye docs can still take advantage of their consumers by locking in, they'll say limited distribution lenses or somehow get a premium out of that. There's a theory that, well, since you're bundling the eye care exam with the lens, the eye care, there is a lot of competition to write prescriptions.

So, if you know once you get a customer in the door to write a prescription, you're going to be able to screw them over with the high price at the end. Well, there's going to be competition up front to get that after-market lock-in.

So, that leads to a slight inefficiency, a distribution inefficiency or allocation inefficiency between the price. So, what happens is the price of the exam gets driven down below the competitive level, to compensate for the price of the lens being above the competitive level.

It would be interesting to see, again, I didn't have the resources or the ability to get prices of eye exams in 2004, and then go back in 2007, but that's, again, a theory that would be very interesting to test. It may be ripe in the pet meds area as I understand the legal landscape is there's a lot of state variation in laws, and there's also no federal law at the time. So, you could take advantage of that state variation to do a much more rich econometrics potentially to look at how states vary and you could maybe get vet exam prices in different states with different legal regimes. So, I'll be quiet now.

DR. NEWMAN: One quick comment.

MR. GILMAN: Actually, I'm sorry to interrupt, but I do want to give Rob Atkinson a chance in case he has some thoughts on this.

MR. ATKINSON: Just a couple of quick thoughts. I actually think that Dr. Newman made my case for me, which is that consumers now are coming in and saying here's what I can buy, the repeat consumers coming in, I can get it from this price and they're demanding and expecting that price in return. That to me is an unalloyed, direct consumer benefit from having more competition from prescription release.

I think one of the interesting things that a

couple of people have alluded to in the studies, which don't ask, is online really a gross measure? Online from Fred the gas station who happens to run a little website or online from 1-800-Contacts or online from your eye care provider. Nobody asked that question.

So, that's my other question. If online is so bad, why do optometrists run websites? You can buy from many optometrists, you can go and get your lenses from their website. If online is really the problem, where it's leading to ocular health, then why are optometrists even prescribing online? So, I think that would be useful to put in a study.

The other thing I think we need is we need, if I were ever king, my first rule would be Congress would create the Office of the Federal Statistician, and we would send these studies to the Office of the Federal Statistician and they would say, these are legitimate studies. Simply saying they're multivariate, if you know statistics, is essentially saying they're a study. I mean, that's a meaningless term. It could be a good multivariate study and it could be a bad multivariate study. When I took Ph.D. statistics, you learned that pretty early in the first couple of classes.

So, I think what we really need if we're going

to look at these health effects, we need a legitimate objective understanding from people who understand rigorous statistics and research methods to look at these studies and say they stand up or not, because right now we don't really have that.

MR. GILMAN: And only inside the beltway can we find people who can honestly say that would be their first act as king.

MR. ATKINSON: I readily admit that.

MR. GILMAN: So, I do want to get to Joe Zeidner and Dr. Newman before we turn things over for the conclusion.

MR. ZEIDNER: Yeah, I think one really good study that we would like to see done deals with prescription release. We know that the FTC found that that was a problem with the Eyeglass Rule after the Eyeglass Rule was passed. It's been a problem with the Contact Lens Rule, even as late as 2007, by admission of doctors.

We believe that there has been a lot of scrutiny of our industry, and we have had a lot of complaints to deal with, and we have talked with FTC, Congressmen, optometrists. But there has not been a study done on whether or not optometrists are releasing prescriptions, which could account for some of the lack of data in your

study, James, and we think that that would be something that would be a good follow-up is to see if doctors really are releasing prescriptions.

MR. GILMAN: Thanks, Joe.

Dr. Newman?

DR. NEWMAN: A couple of comments. I don't think that's the problem. Sure, we could do that study. The state boards hammer anybody that gets a complaint, and so if a patient is not getting a prescription, they complain to the state board and they get hammered almost immediately. So, I think it's a pretty good --

MR. ZEIDNER: Not in Texas.

DR. NEWMAN: Yeah, in Texas.

MR. ZEIDNER: No, not with the 60,000 complaints.

DR. NEWMAN: Okay, that happened before the act was passed. Don't conflate that.

MR. ZEIDNER: That's why the act was passed.

DR. NEWMAN: Don't conflate that with what's happened since the act passed.

MR. ZEIDNER: But they didn't give prescriptions when the board told them they were going to.

DR. NEWMAN: Okay. Last point. With regard to the allocation of access between exams and lens cost, and I think the vets in this room would agree with me.

There's an old poker adage that you can sheer a sheep many times but only skin them once, and we find that out very quickly in private practice. Whether we're talking about Medicare, with Physician Compare that's coming online, comparing the quality outcomes and costs, this is something that's huge in the health care reform industry, it's something that we're all feeling pressures, whether you're a physician, an optometrist, a podiatrist or a doctor of veterinary medicine. If you don't toe those lines, then you're going to be out of the system, and I think that's something that would factor into the cost analysis between exams and lenses.

MR. ATKINSON: You shouldn't forget, by the way, that in 2007 there was a study done by your professional association that says that half their doctors don't release their prescription. That to me is pretty obvious that there's a potential problem. It may not be a problem, there may be a reason, but the fact that half report they don't give a prescription.

DR. NEWMAN: Well, I mean we need to look at that data with your statistician, as we go down the line, but it is something that's worth looking at. Again, you'll never have 100 percent on contact lens prescription release because we're not required to release every contact lens prescription.

MR. GILMAN: Thank you.

So, I think this has been an excellent and animated discussion, and I would like to thank all our panelists for participating, and I would also, we can see the light at the end of the tunnel, but I would like to turn the floor over to Andy Gavil, the director of the FTC's Office of Policy Planning, for some wrap-up and concluding remarks.

(Applause.)

MR. GAVIL: Fear not, they are really brief. Thank you all for joining us. Obviously we've had a very informative and thought-provoking day. We would especially like to thank our many panelists who shared their thoughts with us on a range of important issues affecting the pet medications industry and the millions of American pet-owning consumers.

Obviously today's panels have left us with a lot to chew on in the coming months and a number of ideas have been identified that might warrant further research and study, and I look forward to working with our staff to digest all that we have learned.

A few closing points. All slides presented by our speakers today will be posted on the pet meds workshop webpage. In addition, there will be an archived webcast of today's proceeding and a complete

transcript will be forthcoming in the near future, also on the webpage.

Also, just a reminder that the Commission has extended the public comment period to November 1st, so please feel free to submit any additional comments or responses to today's presentations and discussion.

In closing, I would like to thank all of the members of the Pet Meds Workshop team, especially our panel moderators and co-moderators who have worked very hard to prepare for and conduct today's workshop. From the Office of Policy Planning: Dan Gilman, Christopher Grengs, Elizabeth Jex, Tara Koslov, Susan DeSanti and Stephanie Wilkinson; from the Bureau of Economics: Joel Schrag; and from the Bureau of Competition: Kelly Signs, Erin Flynn and Lauren Rine.

A special thanks to Stephanie Wilkinson from OPP, who spear-headed our efforts, kept us focused and moving forward, as always with good cheer. Well done. It's over, Stephanie, where are you? There she is.

(Applause.)

MR. GAVIL: And our appreciation to the Office of Public Affairs for help with publicity and social media, and the staff of the Office of the Executive Director for event planning and technical support. Yes, it takes a village to put on a workshop.

Finally, I would like to thank Chairman Leibowitz for joining us this morning and for the support of his office. For those of you who have been obediently sitting and staying as he requested, you are now released, but please do heel as you leave the building. As a relative newcomer to the Commission, I feel reassured by his participation today that we haven't been barking up the wrong tree, which might have landed me in the doghouse. Yes, I couldn't resist. Thank you all for joining us, bye-bye.

(Applause.)

(Whereupon, at 4:38 p.m., the workshop was concluded.)

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Sally Jo Quade