Dear Donald S. Clark and the Workshop for Pet Medications Issues,

My name is Martin Watkins and I am submitting this comment as a law student and current pet owner. This comment specifically focuses on distribution of pet medications from providers other than the veterinarians that examine pets, the regulation of such an industry, the constitutional issues that surround this issue, and suggestions for regulations that could be implemented to ensure that the marketplace is competitive, that the medicine is of an adequate quality, and that the integrity of the industry is maintained at the highest possible level.

According to the American Pet Products Association Industry Statistics & Trends cited in the Request for Comments, the American pet industry accounted for over \$50 billion in the year 2011. This statistic includes \$6.7 billion spent on pet medications, a number that is expected to grow to over \$9 billion by 2015. Additionally, the survey cited found that close to 100 million households in the United States owned pets.

Due to the size of this industry and the vast amount of households owning pets, the implications of restricting access to pet medications are significant. Limiting pet owners to purchase medicine from one source, their veterinarians, stymies competition and directly affects consumers' ability to purchase goods for their pets. Furthermore, such regulation is fundamentally at odds with the foundation of the United States.

In the Federalist Number 42, one of the founding fathers, James Madison, contemplated the importance of the federal government regulating interstate commerce. The significance of this concept is found in Article I, Section 8, Clause 3 of the Constitution, more commonly known as the "Commerce Clause," that states that the United States Congress has the power "To regulate Commerce with foreign Nations, and among the several states."

The importance of protecting interstate commerce has not diminished as the years have passed. With the advent of the internet and the decrease in costs for shipping, interstate commerce may be more important to the United States and its citizens than ever before. Allowing individual states to restrict such commerce would be to undermine the basic principals of the United States.

This power has been discussed and interpreted for hundreds of years, with many scholarly works and courts, both state and federal, finding in favor of the federal government's ability to regulate interstate commerce. This concept was examined in fine detail in the Supreme Court of the United State's decision in *H. P. Hood & Sons, Inc. v. Du Mond*, where the Court recognized the significance of protecting the federal government's ability to regulate such commerce.

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¹ The Library of Congress, The Federalist Papers, *Federalist No. 42*, *available at* http://thomas.loc.gov/home/histdox/fed_42.html (last visited Oct. 29, 2012).

² U.S. Const. art. I, §8, cl. 3.

In this case, the Court found that producers of consumer products should be "encouraged to produce by the certainty that he will have free access to every market in the Nation... Likewise, every consumer may look to the free competition from every producing area in the Nation to protect him from exploitation by any. Such was the vision of the Founders; such has been the doctrine of this Court which has given it reality."³

Opponents to such a concept with regard to pet medications and their state regulations would likely point to the state's power to regulate the health, welfare, and safety of its citizens granted by the 10th Amendment to the Constitution. However, this argument may fail to survive judicial review. Even if it were to survive such judicial review, federal law would likely be able to supplant such regulations.

First, in the eyes of all fifty states, animals are considered to be property.⁵ A state could not properly call upon its reserved police powers to protect animals, as they do not consider them people whose health, welfare, or safety should be regulated by the state.

Secondly, a state may argue that, by regulating and limiting the pet prescription medication industry, it is attempting to protect its citizens' welfare by protecting their pets from medication that might harm the animal. This is a stretch of the reserved power given to the states by the 10th Amendment. Limiting pet medications for these reasons would be to protect citizens from emotional harm caused by damage to their private property. This restricts individuals from controlling their personal property as they see fit and in a manner that likely would not affect the health, welfare, or safety of other individuals. Currently, almost every state does not allow for any recovery of emotional damages when an individual's pet is harmed, so it would be contrary to the current state of the law to claim that such regulation would be to protect a citizen in this way.

Thirdly, expanding the law to protect an individual from potential damage to their property in a manner that would not be protecting the individual from physical harm possibly exceeds a state's rights in protecting its citizens, and it would conceivably violate the 14th Amendment to the Constitution. The 14th Amendment states "No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law..."

³ <u>H. P. Hood & Sons, Inc. v. Du Mond,</u> 336 U.S. 525, 539, 69 S. Ct. 657, 665, 93 L. Ed. 865 (1949)

⁴ U.S. Const. amend. X.

⁵See Kim Eileen Bell, <u>Nelson v. State Board of Veterinary Medicine: The Commonwealth Court Carves a Sharper Definition of Veterinary Malpractice, 16 WIDENER L.J. 473, 474 (2007)</u> (in all fifty states animals are still considered property in the eyes of the law) (citations omitted); BRUCE A. WAGMAN, ET AL., ANIMAL LAW: CASES AND MATERIALS 74 (4th ed. 2010)).

⁶ U.S. Const. amend XIV, §1.

Typically, most regulations on individuals concerning their ability to act freely receive rational basis review at the judicial level, resulting in many regulations being upheld by the court so long as the regulation is related to a legitimate state interest. However, when a state infringes upon the fundamental right of an individual, a court may use strict scrutiny, a much more rigorous standard than that of rational basis review. Arguably, a state requiring a citizen to fill prescriptions with their veterinarian would limit that person's fundamental right to liberty and could limit their ability to freely travel between states if they could not fill prescriptions in other states. This would invoke a strict scrutiny basis for judicial review, and a court could find that such a state regulation violates the 14th Amendment of the Constitution.

Lastly, the federal government likely has a right to make a law regarding the regulation of pet medications that would be enforceable over the states under the Commerce Clause and the Supremacy Clause of the Constitution. As stated earlier, the right for the federal government to regulate interstate commerce is one of the most basic principles of the United States, being preserved in the constitution under the Commerce Clause. The regulation of pet medications would fall under this clause because the sale of such medication often involves the sale of products, produced either foreign or domestically, between individuals and business across state lines.

Here, as it is the federal government regulating interstate commerce, such regulation will be upheld in court so long as Congress has a "rational basis" for making the regulation. In this situation, there are numerous reasons for the federal government to establish a regulation on pet medications, such as protecting the integrity of interstate commerce. As such, a regulation would likely survive any judicial review.

Additionally, federal regulation regarding the sale of pet medications would be enforceable over state regulations due to the power given to the federal government in Article VI, Clause 2 of the Constitution, known colloquially as the Supremacy Clause. This clause states that the laws made by the United States shall be the "supreme law of the land." The Supreme Court of the United States has interpreted this to clause create the effect that "[a] state statute is void to the extent it actually conflicts with a valid Federal statute."

The result of these concepts is that the federal government has a right to regulate the sale of pet medications and should do so in order to protect its citizens from harsh and overbearing local and state laws. In the case here, some states do not allow prescription pet medications to be dispensed from anyone other than their veterinarian. Other states have regulations allowing for prescriptions to be dispensed from other sources, such as

¹⁰ Edgar v. MITE Corp., 457 U.S. 624, 631, 102 S. Ct. 2629, 2635, 73 L. Ed. 2d 269 (1982)

⁷ Washington v. Glucksberg, 521 U.S. 702, 719-20, 117 S. Ct. 2258, 2267, 138 L. Ed. 2d 772 (1997)

⁸ <u>Heart of Atlanta Motel, Inc. v. U. S.</u>, 379 U.S. 241, 258, 85 S. Ct. 348, 358, 13 L. Ed. 2d 258 (1964)

⁹ U.S. Const. art. VI, cl. 2.

pharmacies, but do not require the veterinarians to provide for prescriptions that may be filled with these alternative and legal sources. The end result is inconsistent, and sometimes unconstitutional, state regulations on products that should be freely available to pet owners who get prescriptions from their veterinarians.

To resolve this issue, the federal government, with assistance from the Federal Trade Commission's workshop on pet medications, should create regulations that allow for pet owners to take advantage of the free market by requiring veterinarians inform their clients of certified alternative vendors and to write prescriptions for pet medications that can be filled with any certified vendor. These regulations should cover numerous concepts in order to protect individuals, their property, the veterinary practice, and the pet medication industry.

In order to account for these interests, the regulation on prescription pet medications must ensure that medications sold in pharmacies, by veterinarians, through a certified online marketplace, or by other means meet a sufficient quality as required by the veterinarians. This could be achieved with minimal overhead by allowing pharmacies and veterinarians that comply with requirements of the National Association of Boards of Pharmacy, an association recommended by the Food and Drug Administration¹¹, and the American Veterinary Medical Association, an organization accredited by the Department of Education¹², to continue to sell prescribed medications in the manner in which they currently sell such items. Additionally, the regulation could require online dispensaries to become "Vet-VIPPS" certified, a certification currently available and recommended by the Food and Drug Administration, in order to legally sell pet medications.¹³

These regulations should also include punishments significant enough to deter those who do not comply with the regulations of National Association of Boards of Pharmacy or of the American Veterinary Medical Association. Additionally, certified distributors of pet medications would be required to get the prescriptions directly from the certified veterinarian or through a medium by which the validity could be ascertained, such as in the manner physicians currently use to prescribe people medicines that are filled in pharmacies.

Such regulation would benefit pet owners as a whole in numerous ways. First, it would increase competition among distributors of pet medications. This would push

http://www.fda.gov/forconsumers/consumerupdates/ucm048164.htm (Last visited October 29, 2012).

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¹¹ Food and Drug Administration, Consumer Updates, *Purchasing Pet Drugs Online: Buyer Beware, available at*

¹² U.S. Department of Education, *College Accreditation, available at* http://www2.ed.gov/admins/finaid/accred/accreditation_pg8.html (Last visited October 29, 2012)

¹³ Food and Drug Administration, Consumer Updates, *Purchasing Pet Drugs Online: Buyer Beware, available at*

 $http://www.fda.gov/forconsumers/consumerupdates/ucm048164.htm \ (Last\ visited\ October\ 29,\ 2012).$

pharmaceutical companies to develop medications more efficiently and pass the savings along to the pet owners filling prescriptions. The result would be cheaper medicine available from more sources that would allow more pet owners to pay for medicine they may not otherwise be able to purchase from legitimate and certified providers.

Secondly, it would ensure that distributors are providing safe and effective medicine for pets. If a pharmaceutical company does not comply with the required regulations of the associations, they could be stripped of their certifications or face other penalties that would deter such actions. Doing this would protect pet owners from giving their pets medication that would harm them, as the distributors would have to abide by certain guidelines that would ensure quality medicine.

Finally, the regulation put in place would keep the current veterinarian-pet owner relationship intact. Such relationships ensure that the medications prescribed are appropriate for the animal to which it will be prescribed. Additionally, requiring prescriptions from certified veterinarians would allow for medication to be properly administered, as the veterinarian should be able to adequately describe such a process.

The distribution of pet medications is an important issue that affects millions of Americans. It is a part of a multi-billion dollar industry that, in part, affects our country's economy as a whole. The regulation of this process by the federal government would allow for a uniform approach to the distribution of medicine that would ensure quality and competitiveness in a marketplace that is currently unbalanced and irregular. A federal regulation that calls for certified veterinarians to allow pet owners to fill prescriptions for their pets from certified vendors nationwide, eliminating potential monopolies by local veterinarians or other outlets, would keep prices of medicines low through competition, increase innovation and efficiency of the industry, and keep more pets healthier by allowing for more pet owners to have access to pet medications they would otherwise not have been able to buy.

Thank you for allowing me the opportunity to comment on this topic for your proposed workshop.

Respectfully submitted,

Martin Watkins