

Risks Associated With Prescriptions and Purchases of Pet Medications From Sources Other Than Veterinarians

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Let me start by saying that after sixteen years as a full time veterinary practitioner and twenty four as a full time author, speaker and consultant regarding veterinary legal issues, it is my opinion that the risks to the nation's "domesticated household animals" and costs of business related to implementation of HR 1406 far outweigh the benefits. In my opinion, a better name for this piece of legislation would be the "Unfairness to Pets Act."

1. **Knowing What Is In the Drug.** Anytime veterinarians deal with prescription drugs, the first thing they must know when prescribing them is, "What ingredient(s) are in the product being prescribed."
 - a. When they administer, dispense or prescribe a drug, they must at least know the source from which that drug was obtained or the pharmacy from which the prescription was filled.
 - b. That way if it doesn't work as prescribed or expected, or there is an adverse reaction, they can contact the company from which it was purchased. This would become impossible, or at the least very difficult, when veterinary prescriptions are provided *en masse* for clients and filled by outside pharmacies or other sources.
 - c. To know what produced the success or failure of a drug, when patients fail to respond to prescribed medications, veterinarians must consider whether it was the client's lack of compliance with its purchase from an outside source or delivery to the patient, the patient's rejection of the client's efforts to administer it or a resistant disease.
 - i. If they know nothing about the drug or ingredients in the one dispensed by an offsite pharmacy, there is no way veterinarians can make such a determination.
2. **Liability Issues.** When a treatment regimen goes wrong and the drug was obtained from a veterinary practice, clients have a cause of action against the veterinarian and/or the practice for product liability or negligence in selecting or dispensing the drug that was prescribed. They also are communicating with a full staff of people who treat and care for animals as the key to their daily passion and livelihood.
 - a. HR 1406 prohibits veterinary practices from allowing or requiring that pet owners sign waivers of liability in order to obtain the prescriptions that are mandated by the Act. [HR 1406 (2) (A) (iii)]
 - b. This protects pharmacies that fill veterinary prescriptions with unapproved, fraudulent or ineffective drugs, while making it more difficult for prescribing veterinarians to get dismissed from litigation arising from circumstances that were completely outside their control.
 - c. The public relations, time and financial costs of defending a suit constitute a huge risk and burden for small businesses, such as individual veterinary practices, as opposed to billion dollar ones such as Wal-Mart, Walgreens, Target and/or Amazon.com.
3. **Knowledge of Veterinary Pharmacology.** Very few human or internet pharmacies that fill veterinary prescriptions use pharmacists who are trained in veterinary pharmacology. None have

people educated in veterinary medicine. Although only a select few veterinary practitioners have advanced degrees in pharmacology, at least they have had years of course material and training in this subject matter prior to obtaining their degrees and state licenses to practice veterinary medicine. Thus, the pharmacies and pharmacists filling these prescriptions who have had no education on this subject are more likely to dispense drugs that are ineffective or, perhaps, even dangerous for the species.

- a. Whereas humans are only one species, veterinarians treat a multitude of species that qualify as domesticated household animals. To do so, they must have knowledge of the pharmacodynamics, routes of administration, dosages, withdrawal time and efficacy of drugs for this wide array of species, each of which differs one from another in the way drugs are metabolized and/or work in the species.
- b. Just because one or more internet pharmacy or pharmacy chain HAS an FDA approved human drug counterpart with an active ingredient that could be substituted for the veterinary drug that has been prescribed does NOT mean that that drug will be effective in the species for which it was prescribed.
 - i. Variations and concerns by species include the fact that changes in excipients, pH, molecule or molecule size can change the bioavailability, metabolism and/or excretion of the ingredients in the “generic” drug substituted by the outside pharmacist.

4. **Rising Risks for Illegal Drugs Entering the Market.** The rising number of internet pharmacies and/or an increase in the number of pharmacies that can sell veterinary drugs will boost the likelihood that veterinary prescriptions will be filled by pharmacies with 1) unapproved FDA drugs, 2) what they term “generic” drugs, 3) pirated drugs, 4) fraudulent drugs or 5) ones that are ineffective for patients that cannot speak and, thus, cannot tell their owners or veterinarians what it is they are feeling or experiencing.

- a. Although the original, 2003 legislation upon which HR 1406 is patterned required the provision of prescriptions for contact lenses may have worked for humans, at least humans can communicate with the providers of the lenses. Moreover, that law pertained to VISION, not the far less visible aspects of drugs acting upon multiple basic body organ systems other than vision.
- b. In veterinary medicine, our patients have no ability to communicate their mental or physical responses to the drugs they receive. Instead, they rely totally on their owners’ observations of their responses to treatment to relay information about the alleged medication’s side or adverse effects or efficacy or lack of it to the doctors that care for them.
- c. The absence of regulatory oversight and limited risks of liability for injuries to animals serves as an open invitation for “fly by night” pharmacies to enter the veterinary pharmacy arena to sell any and/or all of the above five categories of drugs.

5. **Sizes Shapes, Forms and Concentrations of Products.** As a practicing veterinarian, I am forced to make daily decisions about the drugs we dispense or prescribe.

- a. Some of our household pets weigh nearly two hundred pounds, others a mere two ounces.
- b. This entails decisions as to whether the client can administer a round or oblong tablet or a capsule to the individual patient being treating. In some cases it entails cutting the pill into fourths, sixths or eighths to arrive at the safe and effective dose.
- c. All too often I will suggest one form and the client will say, “I just can’t get that into my dog, cat (or other household pet).” This, then, entails a discussion of how to mask the essential medication in cheese, peanut butter, cream cheese or another food the pet loves. When that won’t work we discuss and/or demonstrate the use of a “pet

- pillers” devise or a “Greenies Pet Pocket.” Among the “pet pockets” we may have to choose from a beef, chicken or allergy free pocket.
- d. When clients cannot administer the correct dosage in a tablet or capsule form, we have to come up with a properly dosed liquid for them.
 - e. I find it hard to believe that an offsite pharmacy or pharmacist who knows nothing about the “practice of veterinary medicine” will have the patience or skill to assist clients in the effort to arrive at a palatable drug for them to purchase.
 - f. One or more of the above scenarios occurs daily or hourly in veterinary practices. Providing written prescriptions for these clients is a waste of time and effort that will serve only to drive the costs for pet care higher, not lower their cost as the authors of HR 1406 undoubtedly expect and desire.
6. **Issues with Compounded Drugs.** A growing number of veterinary prescriptions are unavailable from FDA approved sources and, thus, are compounded, in most cases, by human compounding pharmacies or the veterinary practices themselves. If veterinarians are required to provide prescriptions for these drugs, clients will struggle to find credible compounding pharmacies that can legally fill these prescriptions.
- a. This means that requiring prescriptions for owners of pets that need compounded drugs would be an exercise in futility that does nothing more than create work and expense for veterinary practices while adding confusion to the prescription process.
 - b. The status of the “legality” of compounded drugs and FDA compliance guidelines regarding their use is currently in flux because of the legal battles involving the *FDA vs. Franck’s Pharmacy*, which is now on appeal. Imposing the requirements of HR 1406 on these already “muddy” and “unadjudicated waters” will further confuse the public and veterinarians, harming both in the process.
7. **Unclear or Nonexistent Definitions for Animals Covered.** Another serious flaw in HR 1406 pertains to its Section 5 (2) definition of “domesticated household animal.” Massive legal research illustrates that this term is either nonexistent in many states or varies remarkably from one jurisdiction to another. My own legal research on state laws turns up many definitions for “domesticated animals” but rarely “domesticated *household* animals.” Many jurisdictions do not define either term, leaving uncertain which animals would fit within the scope of HR 1406.
- a. Although most states have no definition for “domesticated *household* animal,” some local jurisdictions may. Thus, even within a particular state, HR 1406 could be enforced differently within local jurisdictions of a given state without ever provoking a violation of state law.
 - b. Thus, enforcement of federal legislation on a subject where the definition of the affected animal that is defined only by state or local jurisdiction will bring forth nothing but massive confusion and inconsistencies from state to state.
 - c. In fact the hodge-podge of variant definitions for animals governed by HR 1406 might well be considered an interference of interstate commerce.
 - d. If the word *household* is omitted from this definition, one ends up with “domesticated animals.” State statutes and local ordinances are replete with varying definitions here. In most cases domesticated animals include horses, cattle, sheep, pigs, poultry, rabbits, rats, guinea pigs, hamsters and other species.
 - e. For HR 1406 to have any consistent application and enforcement would require rewriting thousands of federal, state and local laws, an impractical and impossible task.
 - f. Alternatively, HR 1406 could try to limit its application to “companion animals” or “pets.” I have researched and worked on various definitions for the word “pet” for the past decade and never come up with one that seems to meet societal needs nor the clarity needed by the legal profession.

8. **Limited or No Government Regulation.** Many incidents have occurred where prescription drugs provided to clients via nonveterinary sources have consisted of counterfeit or unapproved FDA drugs. With reduced governmental funding and, thus, oversight of drugs for humans and no or very limited state pharmacy board oversight of veterinary drug vendors, this could easily recur or, worse yet, grow. The problem already has occurred often with unapproved EPA topical pesticides.
9. **Medical Records Issues.** As the provider of pet care, veterinary medical records must keep track of all drugs prescribed and/or dispensed. When the drugs are purchased elsewhere, the practice's computer tracking system is not activated to print instructions for use, risks of adverse effects. Equally problematic, the attending veterinary practices lose the opportunity to send reminders for follow-up exams and/or lab tests that are needed to monitor results or adverse reactions. This means that the attending veterinarians are no longer inside the loop of care for the nonvocal patients they treat.
10. **Timely Availability of Initial Drug Doses.** When medications are not dispensed at the time patients are discharged from a veterinarian's care, it is likely that clients will not have the prescription drug(s) available soon enough to start their pet's medications at the optimal time to provide relief for their condition. Thus, staff time is wasted drafting and printing prescriptions for medications that will not be purchased and received by clients in time to properly maintain the blood levels required for these drugs to be effective.
11. **Teaching Clients How to Administer the Drugs.** When prescription products are purchased elsewhere from internet or human pharmacies, veterinary staff members there are unavailable to teach clients how to administer them.
 - a. Even more problematic, when clients come back to the veterinary practice to have staff members show them how to administer these drugs acquired elsewhere, clients will expect this to be at no charge.
 - b. Moreover, it is likely that the drugs obtained elsewhere will not be usable in the form that was dispensed by the offsite pharmacy. That means the veterinary practice will have to replace the drug with one that can be used, rendering the purchase a time wasting, useless, and costly effort on everyone's part.
 - c. This creates a serious administrative and financial burden for veterinary practices and is likely to increase the cost of veterinary care for the pets this bill is supposed to help.
 - d. It also generates major problems for clients who are now required to administer the drugs purchased at offsite human pharmacies after their veterinarian's office has closed for the day, week end or holiday.

As indicated in the opening paragraph, it is my opinion that the risks to the nation's "domesticated household animals" and costs of business related to implementation of HR 1406 far outweigh the benefits. With that background, I continue to believe that a better name for it would be the "Unfairness to Pets Act."