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Hearing

"Reauthorization of Animal Drug User Fees 2018:

ADUFA and AGDUFA"

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Testimony of

Michael J. Topper, DVM, PhD, DACVP

President, American Veterinary Medical Association

Introduction

Thank you, and good morning Chairman Burgess, Ranking Member Green, and Members of the Subcommittee. I am Dr. Mike Topper, President of the American Veterinary Medical Association. On behalf of the AVMA, I appreciate the opportunity to discuss the importance of reauthorizing the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

Founded in 1863, the AVMA represents over 91,000 individual member veterinarians engaged in the many segments of professional veterinary medicine, including private practice, public health, biomedical research, and more. As an association, we are devoted to advancing the science and art of veterinary medicine and advocating on behalf of the veterinary profession.

Background and Support

The U.S. Food and Drug Administration Center for Veterinary Medicine's (FDA CVM) collection and effective utilization of drug sponsor user fees are important to veterinarians. By providing new animal drugs with a predictable pathway to market, these fees provide veterinarians with access to new and additional tools that can potentially improve treatment outcomes, provide alternatives to existing therapies, fill unmet medical needs in veterinary medicine, and ultimately improve patient care, which is the center of veterinary practice.

A drug that is approved by the FDA has been shown through rigorous studies to be safe and effective for its labeled indication. This gives the veterinarian confidence when selecting the drug for use in their patients. Unfortunately, there simply are not enough FDA approved drugs for use in animals. In fact, there are far fewer than there are approved for use in human medicine. With seven major species and innumerable minor species, all of which have many varied diseases and conditions to treat, veterinary access to FDA-approved medications for use in numerous diverse species is critical.

Each animal is different, and therapeutics that are used to treat dogs do not act exactly the same in cats, nor in horses, cattle, turkeys, parakeets, koi fish, or any other animal species. The inherent pharmacokinetic and pharmacodynamic differences in each species

provide very real hurdles to overcome in the treatment of our patients when there are few options with which to help them. Our veterinary medical education, clinical training, and understanding of the pharmaceutical products we use enable us to navigate these uncertain waters, but driving innovation and increasing the number of approved medications will ultimately lead to better patient care, especially in instances where extralabel drug use (ELDU) is prohibited.

The FDA defines “major species” as horses, dogs, cats, cattle, pigs, turkeys, and chickens. “Minor species” are all remaining animal species. A “minor use” in a major species is defined by FDA in regulation as a drug for a condition that occurs infrequently or in a limited geographic area and in only a small number of animals each year.

A small number of animals is defined by FDA in regulation as fewer than 50,000 horses; 70,000 dogs; 120,000 cats; 310,000 cattle; 1,450,000 pigs; 14,000,000 turkeys; and 72,000,000 chickens. These numbers translate to very small populations, and the availability of animal drugs to treat rare diseases in these limited populations is low.

A January 2018 review of FDA CVM’s Green Book and Orange Book that list approvals of animal drug products and human drug products, respectively, revealed the difference between the two is staggering. In fact, comparisons show there are twenty-three times as many approved labeled indications for human use than there are for animal use. The picture is equally dire for animal drug products approved for Minor Use and Minor Species (MUMS), a program modeled after the Orphan drug program. There have been approximately twenty-six times the number of approved label indications through the Orphan Drugs process as through the MUMS program. For all species treated by a veterinarian, most approved indications are for use in one of the seven major species, but these disparities highlight the need for more approved drug products for major uses, minor uses, and minor species. The lack of approved animal drug products limits treatment options in these patients.

Thankfully, through the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) and its ELDU provision, veterinarians with a valid existing veterinarian-client-patient relationship (VCPR) are provided with greater prescribing options so that animals may receive treatment with therapeutics that are not labeled for that indication.

However, this is not a panacea for the lack of options that are labeled for use in animals. Veterinarians must use the safety and efficacy data available to them from veterinary literature, alternate sources, and extrapolate data from other studies, data from other medications, and data from human medicine.

To understand the unique needs of veterinarians and complicated nature of veterinary therapeutic options when there is no labeled drug available, an understanding of extralabel drug use is beneficial. Under the Federal Food, Drug, and Cosmetics Act, the FDA has the authority to regulate human and animal drugs. If a use is not indicated on the animal drug label, it is deemed unsafe by the FDCA unless it meets specific criteria for use under AMDUCA. ELDU is the term that describes the use of an approved drug in a manner that differs in any way from the drug's approved labeling. This includes deviations from FDA-approved labeling such as:

- In a species not listed on the label;
- For an indication not listed on the label;
- At a different dose or frequency than listed on the label; or
- Via a different route of administration than listed on the label.

It is easy to see that drug labels provide essential information to veterinarians.

AMDUCA appropriately allows ELDU only on the lawful order of a licensed veterinarian in the context of a valid VCPR. ELDU is also limited to circumstances when the health of the animal is threatened, or suffering or death may result from failure to treat. Further, many drugs are prohibited from ELDU for food-producing animals, and ELDU is prohibited in the feed of food-producing animals.

Because of the relative lack of approved animal drug products, ELDU as allowed under AMDUCA is a vital tool in veterinary medicine. It allows veterinarians to use medications that are approved for use in one species in another, or to use the treatment for one disease to treat a different or similar disease. Veterinarians often look to ELDU of approved animal drug products or approved human drug products to fill a void where there is no appropriate medication approved for that indication.

Understandably, there are necessary and appropriate restrictions on ELDU in food-producing animals that further limit treatment options. The production of safe and wholesome food from healthy animals raised in a healthful environment is part of a science-based food safety system, and some drugs are prohibited from use in these species entirely. In non-food animals, veterinarians are understandably allowed more flexibility and ELDU is permitted if there is no appropriate approved animal drug labeled for that indication. However, in these circumstances, veterinarians are still often left with minimal options to choose an appropriate medication.

For instance, there are few drugs approved for use in cats. In some circumstances, medicines that may be used freely in dogs cannot be used in cats because they are metabolized differently. Non-steroidal anti-inflammatory pain medications are one example. These medicines, while approved and commonly used in long-term treatment of our canine patients for osteoarthritis and other conditions, may have dire consequences when given long-term to our feline patients due to potentially harmful side effects. Theoretically, human pain medications could be used for pain management in an extralabel manner, except this is often medically inappropriate due to toxicity in both feline and canine species. This leaves many feline patients with no approved medication, and limited options for treatment via ELDU due to the dangerous side effects of these medications.

Many diseases and conditions, due to the extended course of disease, difficult nature of study, or difficulty in enrolling patients in clinical studies, also lack treatment options. There are many examples in which human drugs are used in an extralabel manner in animals, including treatments for heart disease, pain management, gastrointestinal disorders, diabetes, behavioral conditions, immune-mediated diseases and disorders, and neoplasia. While university studies, anecdotal evidence gathering, and other alternative information all assist in selecting appropriate extralabel therapies, the knowledge that a drug used for therapy has been evaluated by the FDA and shown to be safe and effective is invaluable.

For these reasons, the AVMA supports user fees for new animal drug applications when the fees are directed toward expediting the review and approval process for animal drug

products. The bipartisan and bicameral discussion draft text circulated by the Committee would accomplish this objective.

To ensure adequate availability of veterinary drugs, the AVMA prefers to see Congressional funding of the FDA Center for Veterinary Medicine for the New Animal Drug Application approval process indexed to keep pace with cost increases. However, we recognize that user fees are a valuable tool to expedite the review of new animal drug applications, which ultimately puts new animal drugs in the hands of veterinary practitioners to apply to their daily practice.

We appreciate the attention Congress is giving to this legislation to reauthorize user fees and provide veterinarians with more important tools with which to treat their patients. We feel that more work is needed to attain the program's ultimate goal of more and expedited drug approvals.

Further, we have been encouraged by recent attention given to the topic of expanding Conditional Approval beyond minor uses and minor species. Extending its applicability to major uses and major species would increase the number of tools in a veterinarian's pharmaceutical toolbox. A greater number of approved animal drugs helps to ensure that veterinary patients receive the best care, which is the ultimate goal of clinical veterinarians across the country.

Conclusion

Thank you for the opportunity to provide testimony on this important topic today. We appreciate the attention the Subcommittee is giving to this issue and the commitment to addressing the unmet needs in veterinary medicine. We look forward to working with the Committee and FDA CVM to increase the number of approved animal drugs for the benefit of our patients, their owners, and our communities. Thank you again, and I am happy to answer any questions.