April 19, 2018

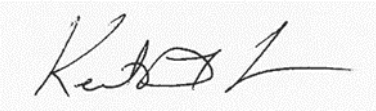
The Honorable Michael Burgess, Chair
The Honorable Gene Green, Ranking Member
U.S. House Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

Answers, Questions for the Record for the March 14, 2018 hearing entitled "Reauthorization of Animal Drug User Fees 2018: ADUFA and AGDUFA" from AVMA President Dr. Mike Topper

Dear Chairman Burgess and Ranking Member Green,

Thank you for the opportunity to testify at the March 14, 2018 hearing entitled "Reauthorization of Animal Drug User Fees 2018: ADUFA and AGDUFA." On behalf of AVMA President Dr. Mike Topper, please find attached the answers to submitted questions for the record. If you have questions or require further information, please do not hesitate to contact Dr. Lauren Stump at lstump@avma.org or 202.289.3211.

Sincerely,



Kent McClure, DVM, JD
Chief Government Relations Officer

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The AVMA is the nation's leading representative of the veterinary profession, speaking for more than 91,000 member veterinarians across the United States who care passionately about protecting animal health, animal welfare and human health. Informed by its members' unique scientific training and knowledge, the AVMA advocates for policies that advance the practice of veterinary medicine and support the crucial work of veterinarians nationwide.

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Answers to Questions for the Record, hearing entitled "Reauthorization of Animal Drug User Fees 2018: ADUFA and AGDUFA" from AVMA President Dr. Mike Topper

The Honorable Gus M. Bilirakis

Question 1: In your testimony, you mentioned the need for new and innovative medicines to fulfil unmet needs for veterinarians. Would you walk us through some of the unmet needs your members see in their practices?

Answer 1: There are numerous examples of unmet animal drug needs in veterinary medicine given the number of different animals that we treat. It is not economically feasible for a drug company to develop a treatment for a disease or condition that occurs uncommonly or in only one species. Further, it is not economically feasible for drug companies to go through the development and approval process for a drug for each of seven major species of animals, much less each of innumerable minor species of animals. Nor is it practical for drug companies to go through the same approval process for different, but similar, indications. Certain diseases are difficult to study due to inherent difficulties in constructing long-term studies, enrolling the required number of patients, and in studying people's pets or other owned animals, among other factors. Specific examples include a lack of commercial eye drops to treat common herpesvirus eye infections in cats, immune-modulating or gene-targeted therapies to decrease the severity of a fatal condition called degenerative myelopathy in dogs, local analgesics for use during procedures such as castration or dehorning in food animal species, and drugs to treat or prevent a fatal infection called blackhead in turkeys. More generally, targeted therapies for immune-mediated conditions would improve treatment outcomes and decrease potential side effects, and the development of more selective anti-inflammatories or other pain medications for arthritis in cats, for which there is no proven safe drug for long-term treatment, would also be a great step forward. Not only is the development of therapies for use for their labeled indication important, but the safety and efficacy data they provide is enormously beneficial when extralabel drug use (ELDU) provisions in the Federal Food, Drug, and Cosmetic Act apply. ELDU allows veterinarians to legally use a drug approved for one species or condition to treat a different species or a different condition in which that therapy is effective, but not labeled. Development of additional therapies and the generation of additional safety and efficacy data will benefit both approved uses and ELDU and are critical for improving the health and well-being of our pets, and through food animals, the quality and safety of our food supply.

Question 2: Would you explain some of the challenges that exist for veterinarians and veterinary therapeutic options in the context of extralabel drug use?

Answer 2: Extralabel drug use (ELDU) is a vital provision in the Federal Food, Drug, and Cosmetic Act that allows veterinarians to effectively treat their patients despite a lack of a drug specifically labeled for that condition. Veterinarians do not enjoy access to the same number of approved therapies as human physicians and practitioners, as there are roughly 25 times the number of approved drugs for use in humans as there are for use in all animal species. Even in human medicine, where there is much greater access to approved drugs, there is often the need to use them in a manner that differs from their approved labeling. In many cases there is no financial incentive for manufacturers to develop animal-specific products or to go through an approval process in each species of animal for which a drug may have use, and an understanding of ELDU becomes critical. Under ELDU provisions, veterinarians may use a drug approved for one animal or purpose in a different animal or for a different purpose when a more appropriate therapy does not exist. For example, many anesthetics and pain medications used daily by veterinarians in hospital or clinic procedures are approved only for use in humans, but they are no less vital to our animal patients for the same purposes. Veterinarians regularly perform the complex task of interpreting multiple sources of data including labeled animal and human drug data, independent studies, foreign research and data, and historically successful clinical endpoints to choose the most appropriate therapy for their patients. Conditional approval is a process through which a manufacturer is able to market their product after proving full safety data and a reasonable expectation of efficacy, but while still gathering final efficacy data. Currently this process is only allowed in the approvals process for minor uses and minor species, and it would be a transformative improvement to the user fee agreements if this were expanded to major uses in major species, and if this improvement included allowing ELDU of these conditionally approved drugs. Allowing ELDU of these drugs, within the current legal and regulatory framework, would further increase options available for treating animal patients, especially for all those species that are not one of the seven major species and for more uncommon conditions. Expanding this under the existing legal and regulatory framework would keep existing prohibitions on uses of antimicrobials and certain other drugs in food producing animals, and continue to prohibit ELDU of medicated animal feed. Allowing for ELDU of conditionally approved products would have no impact to any FDA policy to address antimicrobial resistance.

The Honorable Frank Pallone, Jr.
I'm interested in your perspective on how the ADUFA and AGDUFA programs have improved animal health, as well as the nation's food supply. Animal drug development and approvals are critical to ensuring that our companion pets lead longer and healthier lives and that our foodproducing animals are safe for human consumption.

Question 1: Can you explain how the animal drug user fee agreements have improved animal health, both for pets and food-producing animals?

Answer 1: Animal drug user fee agreements and animal generic drug user fee agreements have improved animal health for pets and food-producing animals by providing veterinarians with additional tools with which to treat their patients. In recent years, the veterinary community has seen the approval of several new animal drugs, partly in thanks to the streamlined and predictable pathway provided by ADUFA and AGDUFA. Examples of improvements include a transdermal solution for cattle to treat pain in cases of a debilitating and painful disease called footrot, and which also treats the fever associated with pneumonia. In pigs, a first-in-class, animal-only antimicrobial that is not considered medically important in human medicine, Avilamycin, was developed to reduce a disease called scours that causes devastating diarrhea in weaned pigs. We have seen approval of a drug for use in horses to relieve certain types of a condition called colic, which can cause significant pain in the gastrointestinal tract and be fatal. These user fee agreements have also contributed to the approval of many therapies that improve the comfort and well-being of our pets. For example, a new drug was developed to target and inhibit a step in the pathway in a dog's response to allergens, and provides them more effective relief from allergies. An insulin product approved for use in both dogs and cats also allows for improved management of diabetes mellitus in many instances. In addition to these, there are many other examples of improvements that have been made, leading to improved animal health for pets and livestock.

Question 2: As a veterinarian, what are the benefits of increasing the efficiency of the animal drug approval process? Does ADUFA and AGDUFA help bring new and innovative products to the market faster in order to help treat animal patients?

Answer 2: By increasing the efficiency of the animal drug approval process and providing a predictable path to market, veterinarians have been provided with new and more efficacious therapies for some conditions in animals. This would not have been possible without user fee agreements. In an ideal scenario, there would be both robust pioneer and generic industries providing veterinarians and their patients with approved products for multiple uses and all species. However, the costs associated with developing this number of approved products and the every-day realities of veterinary practice that require cost-efficiencies and effectiveness make this unlikely. ADUFA and AGDUFA have helped bring new and state-of-the-art products to market, and there are improvements that can be made to the conditional approval process to further increase the number of approved drugs to both major species and minor species under the existing legal and regulatory framework surrounding extralabel drug use.

Question 3: Can you discuss why the FDA gold standard of safety and efficacy is so critical when treating animal patients?

Answer 3: The FDA review process provides veterinarians and animal owners with assurances in regard to the use of drug products in animal patients. It provides veterinarians with safety and efficacy data that would not otherwise be available to them. When an animal drug is FDA-approved to treat a specific condition, a veterinarian must choose that drug to treat the patient unless circumstances that warrant extralabel drug use (ELDU) apply, as defined in statute in the Animal Medicinal Drug Use Clarification Act of 1994 and in FDA regulations. However, for the majority of conditions that veterinarians must treat in numerous animal species, there are no drugs specifically labeled for that use. ELDU is a vital provision within the Federal Food, Drug, and Cosmetic Act that allows veterinarians to treat their patients despite a lack of a labeled therapy, protecting both animal and human health. For example, many analgesics and other drugs used daily by veterinarians are approved only for use in humans, but they are no less vital to our animal patients in those instances. Even in human medicine, where there is much greater access to approved drugs, there is often the need to use them in a manner that differs from their approved labeling. Legal restrictions on use in food animals are in place to safeguard human health, such as banning ELDU of medicated animal feed, and appropriate restrictions on the use of medically-important antimicrobials and certain other drugs. In both food and companion animals, veterinarians regularly perform the complex task of interpreting multiple sources of data including drug labels, independent studies, foreign research data, and historically successful clinical endpoints while applying their medical knowledge of unique pharmacokinetic and pharmacodynamic principles for many drugs and species in order to choose the most appropriate therapy for each specific patient. To determine the best course of action when ELDU is required, as in cases when no appropriate labeled therapy exists, veterinarians use their medical knowledge and training to analyze existing sources of safety and efficacy data, including data from FDA-approved animal drugs. When full approval is possible, feasible, and practical, a fully approved-drug can yield an abundance of information to veterinarians for both its labeled indication and in cases when ELDU is required. Drugs conditionally approved for use in animals provide full safety data and preliminary efficacy data in at least one animal species, and that data can be translated to other uses in that same species and across species as well. FDA safety and efficacy data is the gold standard, and ADUFA and AGDUFA's capability to provide veterinarians with an increase in this data can improve the health of animals regardless of the labeled indication when ELDU is legally allowed. Improving both the conditional approvals process through expansion to major species and allowing ELDU of conditionally approved drugs would be a transformative improvement to the user fee agreements. Allowing for ELDU of conditionally approved products would have no impact to any FDA policy to address antimicrobial resistance.