United States House of Representatives
Energy and Commerce Committee
Health Subcommittee Legislative Hearing: Reauthorization of the Animal Drug User Fee Programs

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The Honorable Michael Burgess

In the last ADUFA reauthorization, Congress created more flexibility for the expanded conditional approval pathway.

1. Dr. Teller, are you aware of any difficulties with implementation of this policy?

We do not have visibility to the implementation of this agreement within FDA, but we do continue to have a need for more new and innovative animal drugs and more generic animal drugs. We would like to see additional conditionally approved drugs to provide an option to meet a previously unmet clinical need.

2. What more can Congress do to ensure expanded conditional approval pathway runs smoothly?

The AVMA supported establishing conditional approvals in the last animal drug fee reauthorization. Conditionally approved drugs provide an option to meet a previously unmet clinical need and are preferred over alternatives, such as compounded drugs. There have been a few conditionally approved drugs and we would like to see more. On May 1, 2023, the FDA announced conditional approval of the first drug for anemia in cats with chronic kidney disease.

We urge the FDA to work with the drug sponsors to achieve full approval. Additionally, allowing extra-label drug use of conditionally approved drugs would provide veterinarians with additional tools for the animals under our care.

The Honorable Earl L. "Buddy" Carter

1. Dr. Teller - 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?

In the last year there have been two drugs approved fulfilling longstanding needs in small animal medicine. One is for long-term pain management in cats, often associated with arthritis, and the other is for management of pancreatitis in dogs. Prior to these approvals, management of diseases required symptomatic care and/or extralabel drug use (EDLU).

There are innumerable examples of still unmet animal drug needs in veterinary medicine that include therapies for a multitude of conditions across animal species. Given that there are seven major species and innumerable minor species, it is a challenge for drug companies to develop therapies for the various

diseases and conditions that might affect all of them. Certain diseases are challenging 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. For example, therapies for cancer, such as ocular squamous cell carcinoma in beef and dairy cattle, and a multitude of cancers affecting companion animals are areas where improvements could be made. Various autoimmune conditions could benefit from targeted therapies with fewer side effects, and the development of more selective anti-inflammatory medications could decrease detrimental side effects sometimes seen when using these medications in certain species. The development of additional therapies and the generation of additional safety and efficacy data that can benefit both approved uses and ELDU only stand to improve the health and quality of life of veterinary patients.

2. Dr. Teller - Can you explain how the animal drug user fee agreements have improved animal health, both for pets and food-producing animals?

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 address their patient's needs. In recent years, the veterinary community has seen the approval of several new animal drugs, partly 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. These user fee agreements have also contributed to the approval of many companion animal products that allow us to live more closely and comfortably with our pets than ever before.

The Honorable Tony Cárdenas

1. Dr. Teller - in your testimony you note that you believe there should be more similarity between the US drug approval process and approval processes used in other developed countries. You note that, "When reviewing the same data, our understanding is US approvals lag behind Europe and Canada by up to a year." What are some of the key factors contributing to this lag?

Our understanding is a shorter review process allows manufacturers to bring more products to market that otherwise would not be developed. We need more FDA approved products available to treat the animals under our care.

Whether the user fee programs actually bring products to market sooner is a question best answered by the manufacturers and FDA, but our understanding is applications to FDA have up to a one-year lag time compared to approval in similar markets such as the EU and Canada. Increasing the efficiency of the animal drug approval process results in potentially expedited review and more predictable paths to market for some new animal drug applications. If the review of a new animal drug application were to result in approval, that drug would then be available for use in animal patients sooner than if these user fee agreements were not in place. Alternatively, if the review process were to result in denial of approval, that may lead to the development of other therapies by manufacturers. In both scenarios, animal health may be improved through the timely approval or denial of new animal drug applications through the eventual approval of a new product. ADUFA and AGDUFA have helped bring innovative products to market in order to help treat animal patients, and there are improvements that can be made to the conditional approval process to further increase the number of approved drugs for both major species and minor species under the existing legal and regulatory framework surrounding ELDU.

2. How can FDA balance moving faster while still being the gold standard of safety and efficacy?

The Animal Drug User Fee Act and the Animal Generic Drug User Fee Act provide the Food and Drug Administration Center for Veterinary Medicine with additional financial resources that enhance the review of pioneer and generic drugs. The intent of the program is to provide manufacturers with a predictable pathway to market for new and innovative drugs. The predictable pathway allows the FDA to expeditiously review the safety and efficacy of the drug with more FTEs supported by user fees so that the manufacturer may bring an approved drug to market sooner than they would if they lacked the additional resources.

3. Why is it so critical that we bring these products to market so quickly?

Veterinarians need more, innovative animal drugs and more generic animal drugs are also needed. These programs are intended to expedite the review process necessary for potential new products to make it to the marketplace.

The intent for the programs is to stimulate innovation in the pioneer drug market and then have a robust generic industry. There are far fewer approvals for animal drugs than human drugs; specifically, there are approximately 1,600 drugs that are FDA-approved, conditionally approved, or indexed for use in animals, compared to approximately 20,000 FDA-approved human drugs. We support efforts to improve the efficiency of the process.

4. To what extent do these agreements bring us closer to a more timely process?

This question is better answered by the FDA and manufacturers. As part of their agreement with the manufacturers, the FDA has performance goals that must be met. According to Director Forfa, they "have also agreed to report certain programmatic metrics, as well as engage an independent third-party to assess first cycle reviews and other review processes, as part of the program's objective of expediting the animal drug development process."