Written Testimony of Dr. Rachel Cumberbatch
Animal Health Institute

Subcommittee on Health, Energy and Commerce Committee

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Mr. Chairman and members of the Committee:

Thank you for holding a hearing on this important piece of legislation, and for the opportunity to speak to you today about the important human and animal health benefits that result from using medicines to keep animals healthy.

My name is Dr. Rachel Cumberbatch and I am a veterinarian here today on behalf of the Animal Health Institute, a trade association that represents companies that make medicines for animals. I am here today to ask Congress to reauthorize the Animal Drug User Fee (ADUFA) program and provide a pathway for sponsors to meet unmet medical needs by enhancing opportunities for innovation.

The animal health industry makes important contributions to the American economy both through direct economic activity and by supporting and fueling economic activity in other industries, including agricultural production, veterinary services and pet services. We directly employ over 24,000 workers and indirectly contribute to 1.5 million jobs. Our U.S. sales of nearly $14 billion spurs another $594 billion in the sales of industries we supply. The $1.6 billion we pay in direct wages fuels another $73 billion in indirect wages. These contributions extend to every state, and every Congressional district, where people own pets and rely on food to be safe.

Even more important than these economic contributions are the social benefits of the animal health industry. Some 70 percent of U.S. households own at least one pet and there are some 397 million pets in the country. Animal health products ensure the health and welfare of companion animals which improve the mental and physical wellbeing of their human caretakers, serve as aides, and assist with therapy for those in need. These needs substantially increased during the COVID-19 pandemic, which contributed to a rise in the prevalence of mental health issues and the desire for companionship.

Animal health products protect food-producing animals from diseases that can affect food availability and safety for consumers. Animal health products also give veterinarians, and livestock and poultry producers, the necessary tools to treat, control and prevent disease in order to protect the health and well-being of 9 billion food producing animals annually. A vital first step in producing safe meat, milk and eggs is keeping animals healthy. Veterinarians work hard to prevent disease in animals, but it is important for them to have medicines available when needed to treat a disease or disease threat.

Animal medicines also help farmers operate more sustainably and profitably. Healthy animals are simply more productive, since animals that struggle with disease require more resources, and may never produce as much as if they had never fallen ill. For example, a dairy cow that receives medication to prevent an infection by parasitic roundworms produces more milk, enabling the farmer to meet production needs with fewer animals.

Passage of ADUFA is needed not only to capture these benefits but also to address the many unmet medical needs that exist in animal health.

The CVM Drug Review Process

The statutory standard for Food and Drug Administration (FDA) approval of animal drugs under the Federal Food, Drug and Cosmetic Act is the same as that for human drugs: they must be proven to be safe and effective. As a result, the animal drug approval process looks much like the human drug approval process: animal drug companies submit data packages to demonstrate safety, efficacy, and the ability to meet the same stringent FDA manufacturing standards. While the standards are the same, the process is different: rather than submit a complete application package at once, as is done with human drugs, animal drugs have a phased review process in which data packages are submitted at different times. It is a costly process, requiring as much as $100 million and 7-10 years to bring an animal drug to market. In the case of food animals, the standard to ensure that meat, milk, and eggs are safe for human consumption adds an additional set of requirements that increases the cost and time to market.

The market for animal drugs, however, is nothing like the market for human drugs. Our products are used to treat seven different major species of animals and many more minor species. A blockbuster animal drug will have sales of $100 million, which is $1/10^{th}$ the sales of a blockbuster in human medicine, and the vast majority of animal health products have a market size of around $1 million. There is no Medicare or Medicaid and, except in rare cases, no employer supported health insurance -- the cost of animal drugs is borne in full by the animal owner.

ADUFA Performance History

Congress created the ADUFA program to provide supplemental funding for "… expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug applications …." This charge recognized that

innovation and an adequately funded regulator go hand in hand. An efficient approval process – one that uses funds effectively to produce safe and effective products– is vital.

As we prepared to begin negotiations with FDA over the agreement before you, we carefully examined the public data available on the performance of the program over its nearly 20-year life. While there were some early improvements and successes, those benefits have diminished over time. The data shows that fees over the life of the program have increased 600 percent while the sentinel workload has declined 12 percent and the number of product approvals has been flat. We observed that a gap has developed between the capacity and the performance of the program, and so we began negotiation with three goals aimed at closing the gap:

1. Return our competitiveness to the US marketplace. Companies are finding it that products are being approved earlier in the EU, leading to a loss of competitiveness for the US Animal health industry and its customers.
2. Ensure the FDA review process is transparent, risk-appropriate, and efficient by implementing metrics that measure progress not activity. We need more transparency in data and information to ensure efficiency.
3. Optimize the robust capacity, both in terms of user fee funds and headcount at CVM to promote access to safe, effective, quality products.

ADUFA V Agreement

The agreement before you today implements some immediate steps toward closing the gap and proposes further discussion and data collection that will help lead to a successful ADUFA VI. Highlights of this agreement include:

- **Appropriate funding**: The agreement includes base funding of 33.5 million per year, as well as one-time allowances for IT enhancements and a third-party assessment. ADUFA

fees fund about 32percent of the new animal drug review budget, which we believe meets the Congressional intent of user fees being supplemental.

- **Program Enhancements**: A number of technical improvements include early feedback for presubmission conferences, updating policies and procedures for industry meetings with the agency, and, importantly, an annual, in-person educational conference for industry. We highly value face-to-face interaction and believe it is vital for the communication that must take place to reach mutually beneficial decisions.
- **A focus on metrics:** Some new metrics will be implemented immediately and there are commitments to explore new metrics in the future. We will begin working toward a key metric of measuring time in agency and time in industry. Under the current process of phased review, it is difficult to measure the total time it takes to get a product approved. But this is the key metric against which to measure the success of the program and finding a solution will be key to a successful ADUFA VI.
- **Financial Sustainability**: The agreement modernizes the workload adjuster, reduces and caps the carryover balance, requires annual publication of a 5-year financial plan, and, most importantly, calls for a third-party assessment. This is a tool that has been successfully used in other user fee programs to identify new efficiencies and develop new metrics.

As with any negotiation, we did not get all we had set out to achieve. We do believe, however, that on balance this agreement begins the process of closing the gap and providing needed data and information to inform the next round of ADUFA. Significant changes to this agreement would alter that calculation. We are aware that in the President's FY 2024 budget proposal CVM has asked for several new authorities to require label changes and additional studies without input from industry. These proposals would add significant burden and cost without benefit. FDA/CVM has post approval authority that protects human and animal health. Like in

other developed markets, CVM has inspectional authority, pharmacovigilance systems and tools for engaging sponsors when label changes are needed to better explain safety measures or provide educational materials. The track record is good. Adding additional burden without benefit will reduce rather than increase the number of therapies needed to meet unmet medical needs in animals.

The reauthorization of ADUFA will continue to provide the agency the resources necessary to maintain and improve the drug review process, provide new and innovative products to allow our pets to live longer and healthier lives, and contribute to food safety by keeping food animals healthy. I urge you to pass a clean ADUFA reauthorization.