

**Testimony of Dr. Richard Carnevale
Animal Health Institute**

Subcommittee on Health, Energy and Commerce Committee

March 14, 2018

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. Richard Carnevale 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. Fueled by \$9.9 billion in sales of medicines, the U.S. animal health industry employs 21,257 workers, accounts for more than \$1.2 billion in wages and \$1.2 billion in taxes and maintains a positive balance in trade.

Furthermore, animal health products directly contribute to the economic activity of other industries including veterinary services, animal production, meat and dairy production, and pet services.

Combined, these four industries generated \$548 billion in output, created almost 1.4 million jobs, and paid over \$52 billion in wages in 2016. These contributions extend to every state, and every Congressional district, where people own pets and where people rely on food to be safe.

But the contribution of animal health goes far beyond dollars and cents. Over 67% of U.S. households own pets, with nearly half owning a dog and over one-third owning a cat. In total, American households

own approximately 393 million pets. These households rely on routine veterinary care and animal health products to keep pets healthy. Animal owners can enjoy their companions without the fear of exposure to diseases like rabies or pests like fleas and ticks. As pet owners look for solutions to increase the length and quality of life for their pets, cutting edge treatments for pet health problems, such as arthritis and cancer, are becoming more common. These are the statistics behind what we call the human-animal bond, and this bond is strengthened by medicines to both treat and prevent diseases in pets and keep families safe by preventing the transfer of disease from pets to humans.

Animal health products also give veterinarians, and livestock and poultry producers, the necessary tools 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.

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. 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, 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.

Animal health companies rely on a rigorous, efficient, predictable and science-based review process at the FDA's Center for Veterinary Medicine (CVM) to provide these products that are not only safe and effective, but also affordable. The Animal Drug User Fee Act, first enacted in 2003, made it possible for our companies to bolster funding at CVM so that the agency can meet performance standards to improve the efficiency and predictability of the animal drug approval process.

This new ADUFA agreement builds on the success of this program. Funding will increase from a total of \$118 million in ADUFA III to a total of \$150 million over the five years, including a one-time influx of funds that will be devoted to information technology so that CVM can transition to electronic filing of new animal drug submissions and eliminate all paper submissions. Current inflation and workload adjustment factors remain as is while AHI has agreed to allow FDA to use over collection of funds from one year for program needs in subsequent years. Existing sentinel timeframes will remain the same or be slightly reduced, and all current review process changes from the previous ADUFA agreement will remain in place.

In addition to reducing the time for combination clearances, FDA agreed to work on three important efforts.

1. CVM agreed to work towards implementing the US/EU agreement on mutual recognition of Good Manufacturing Practices inspections, which were negotiated during the last months of the previous Administration.
2. FDA will implement a new performance metric of 120 days for FDA validation of tissue residue methods with additional dedicated funds to accomplish this metric. This process has taken considerable time in the past and delayed approval of new drugs.

3. CVM will institute an expedited meeting schedule for critical pre-NADA submission conferences.

The agreement contains some technical corrections in the Act to permit user fees to apply to Minor Use/Minor Species Drug Application reviews, as well as a change in a label requirement on indexed minor species products. It also provides an amendment to legally require the NADA number be placed on the labels of all approved products. While identification of the NADA on labels has been voluntarily adopted by most AHJ member for many years this requirement for all sponsors of approved products will differentiate - for the producer and veterinarian - legally approved versus unapproved or illegally manufactured products.

There are also a number of minor changes made to the performance standards in an effort to create new efficiencies.

Passage of this important legislation will have several benefits:

1. FDA/CVM benefits by having additional resources to meet its mission of protecting public health.
2. Animal health sponsors benefit from a stable and predictable review process, allowing them to make informed decisions about the investment risks of research and development dollars.
3. Veterinarians benefit from having new and innovative medical advances available to treat, control and prevent diseases in their patients.
4. Livestock and poultry producers, and the veterinarians on whose advice they rely, also have the tools needed to keep food animals healthy.

5. Pet owners benefit by having their animals live longer and healthier lives, increasing their enjoyment of these companions.
6. Consumers reap the food safety benefits that come as a result of the availability of additional tools to keep food animals healthy.

There is one important piece of unfinished business from ADUFA III which we are asking Congress to help complete. ADUFA III contained a provision that FDA and AHI would enter into discussions on how to more broadly extend the conditional approval process currently available only to minor use/minor species products to major species applications. Those discussions took place and were productive, bringing each side to near agreement on an approach. However, when negotiations began for ADUFA IV, FDA/CVM was precluded from considering this issue as part of the agreement.

More than a year ago, this committee commendably came together and approved the 21st Century Cures Act to spur innovation in human therapies. By all indications, it is working, and now we ask you to include in this legislation a measure to similarly spur innovation in animal health.

This is a tool that exists in other areas of animal health. Conditional approval exists at the Environmental Protection Agency which reviews flea and tick products. It exists at the U.S. Department of Agriculture that reviews veterinary vaccines. It even exists at FDA, where Congress in 2004 authorized conditional approval for minor uses and minor species. Expanding this current authority to major species would drive innovation and approval of new products for serious diseases for which there are no available therapies and for which it is difficult to establish clinical effectiveness via controlled studies. This is often the case where a long term progressive condition takes time to manifest, or where there is a lack of effective disease models for use in controlled studies. Conditional approval could also aid in the research and discovery in pursuit of alternative therapies to antibiotics.

Authorizing conditional approval in no way reduces safety. Conditional approval requires sponsors to provide safety and meet all technical packages but changes the efficacy standard from “substantial evidence” to “reasonable expectation” of efficacy. Sponsors can then market the product while continuing to collect effectiveness data to satisfy the “substantial evidence” requirement and gain full approval. A case can be made that conditional approval authority could improve animal safety. Providing a veterinarian with a product that has been proven to be safe and has a reasonable expectation of efficacy would provide that veterinarian with a better-defined expectation for the product than the unapproved drug and off-label human drug now currently used to address unmet medical needs.

Mr. Chairman, CVM has a rigorous, science-based approval process that provides to the American public the products necessary to protect public health by protecting animal health. Every year scientists uncover new diseases in animals, some of which potentially pose a threat to human health. As more animals are raised to feed the planet and as animals are reared closer to people, we will continue to need new medicines to protect animal and human health.

The reauthorization of ADUFA will continue to provide the agency the resources necessary to maintain and improve this approval 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 an enhanced ADUFA that improves upon the agreement by authorizing the Agency to extend the conditional approval pathway to spur innovation in animal health.