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Committee on Health, Education, Labor and Pensions

February 27, 2013

Mr. Chairman and members of the Committee:

Thank you for holding this 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.

I am Dr. Richard Carnevale. I am a veterinarian by training with a degree from the University of Pennsylvania and I am here today on behalf of the Animal Health Institute (AHI), a trade association that represents companies that make medicines for animals. Our companies share a common mission: we contribute to public health by protecting animal health. With food animals in more demand from our growing global population, the importance of the nexus between animal health and human health has never been greater, and is one of the driving forces behind the Center for Disease Control's "One Health" initiative. As companion animals have become a more important part of our everyday lives they have moved from the backyard into our living rooms and bedrooms, increasing their importance to humans and requiring greater attention to their health needs. As medical breakthroughs from human medicine are adapted to animal medicine, our pets are living longer and healthier lives.

Animal health products also give veterinarians, and livestock and poultry producers, the necessary tools to protect the health and well-being of food producing animals. More and more evidence demonstrates that 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 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.

One significant challenge we face in animal health is the declining number of new animal drug approvals. The data we collected in preparation for ADUFA III clearly showed that while we significantly increased the amount of user fees going to the agency in ADUFA II, the workload has substantially declined. There are likely many reasons for this, but a big reason is the ever-increasing regulatory cost and burden. In a market as fractured as the animal health market, this increased regulatory burden results in fewer live-saving and extending drugs being brought to market. We hope Congress will consider ways to incentivize animal health research and provide for a regulatory environment that increases the availability of animal health products.

Animal health companies rely on a rigorous, efficient, predictable and science-based review process at the Food and Drug Administration's Center for Veterinary Medicine (CVM) to provide these products. That's why our companies supported the first authorization of the Animal Drug User Fee Act ten years ago. The Animal Drug User Fee Act of 2003 (ADUFA I) made it possible for our companies to bolster funding at CVM so that they could meet performance standards to improve the efficiency and predictability of the animal drug approval process and ADUFA II, passed in2008, continued that progress.

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.

AHI believes that the funding agreed to by the industry over the next five years is based on an objective assessment of agency resource needs and will allow the agency to maintain all current standards and also improve performance in key areas. The agreement calls for approximately $118 million in funding over the five years, depending on inflation. The funding agreement going forward differs from the funding provided over the last five years. AHI has agreed to an annual fee level adjusted by a variable

rather than the fixed annual inflation factor utilized in ADUFA II. The variable rate will be more closely aligned with actual cost increases that FDA might realize from year to year.

The financial agreement seeks to reduce the impact that fees may have on small businesses and smaller product markets by reducing the total percentage of fees coming from new animal drug applications and supplements from 25% to 20%. This should result in a substantial reduction in an individual application fee in FY 2014 and beyond. The 5% reduction is then distributed among the three remaining fee areas – sponsor, product and establishment. Since smaller companies have fewer products and facilities, they are hit hardest by the application fee. The agreement also includes a provision for FDA to make up potential fee shortfalls that may be experienced by allowing for adjustments to levied fees in the out years of the program.

FDA has consistently met timeframes for all sentinel submissions identified in the goals letter submitted to Congress and we are confident that the agency will continue to do so over the next five fiscal years. The new agreement continues all current submission review timeframes mandated in ADUFA II. However, the new agreement adds important enhancements to the review process.

The process for reviewing and approving animal drugs has evolved over the years and is somewhat different than that for human medicines. Animal drugs generally go through a phased review process whereby each specific area called technical sections of the new animal drug application is submitted and reviewed independently. Once the technical sections for safety, efficacy, manufacturing, and environmental impact are complete an administrative NADA is filed referencing those sections and approval of the product occurs within 60 days.

If technical sections can be completed more rapidly it will lead to earlier filing of the administrative NADA and, therefore, reduce overall time to market of safe and effective animal medicines. This will be accomplished under the new agreement by FDA agreeing to significantly shorten the review times of the second pass submissions that ordinarily are reviewed in the same time frame as the original or first pass submissions, when certain criteria in the goals letter are met. Depending on the type of submission this can result in up to a four month (120 day) decreased review time and could be critical in moving an important animal medicine to the market sooner.

The new agreement also commits the agency to work with industry to examine longer term goals:

AHI and FDA will enter into discussions on how to more broadly extend the conditional approval process currently available only to minor species to major species applications. The Minor Use/ Minor Species Act of 2004 provided a new mechanism for the approval of animal drugs. For minor species or minor uses, a sponsor can submit an application to FDA allowing the firm to market the product while continuing to collect effectiveness data to satisfy the “substantial evidence” requirement under the FD&C Act, as long as enough data has been submitted to allow the agency to determine there is a “reasonable expectation” of efficacy before it goes on the market. Of course, the application must still meet all requirements for animal, human, and environmental safety, manufacturing quality, and be properly labeled prior to marketing. The conditional approval lasts for five years after which time the

product is fully approved or withdrawn from the market if the sponsor fails to demonstrate substantial evidence.

AHI believes that a strong case can be made to extend this provision to certain drugs proposed for major species other than those specifically for minor use. This allows earlier marketing of important products that can be studied and thoroughly tested for effectiveness because the sponsor is adding revenue to fund such studies. The data gathered under a conditional approval will be much more robust and allow the agency to have better confidence in the safety and effectiveness of the product before it issues final approval. The advantage to FDA is that it can easily terminate the marketing of a product if the sponsor fails to complete the data commitment. There is no increased risk to animal for public health since safety will be assured prior to marketing. Additionally, conditional approvals are currently in place at USDA, which regulates animal vaccines and at EPA, which regulates flea and tick products for animals. Conditional approvals could be one mechanism to address the current decline in animal drug submissions and bring much needed new product development to the market for major species.

The other policy issue that will be discussed under the new agreement will be the issue of combination medicated feed new animal drug approvals. It is common practice in the field to combine two or more drugs in a medicated feed being given to cattle, pigs, or poultry. For the past 40 plus years FDA has required that two or more approved drugs added to an animal feed must first also be approved by the agency before they can be mixed concurrently. There is a long history of FDA requiring this and dates back to a policy first established in the 1960's that considered animal feeds containing an animal drug to be a finished drug formulation. A producer or feed manufacturer can only combine approved animal drugs in feed if an application for that combination has been approved by FDA. Therefore, an animal drug sponsor obtaining an approval for a drug to be added to animal feed is responsible for filing additional new animal drug applications providing for the concurrent mixing in the feed of the newly approved drug with other approved drugs. These are essentially administrative NADA's that simply reference the approvals of the other products but still require submission of some limited data and new labeling.

This has been an onerous requirement since it can significantly delay the ability of a sponsor to market a new product because the sponsor may not submit these other application for review and approval by FDA until the new drug is first approved. Some relief was realized in 1996 at the passage of the Animal Drug Availability Act, which lessened the requirements for the approval of these combination applications, but did not eliminate the need to submit an NADA for these combinations. Experience has shown since the ADAA that few problems can be identified by the mixing of two or more approved drugs concurrently in the feed in the way of interference with the active ingredients or with changes to animal safety or human food residues.

FDA has agreed to enter into discussion with the animal drug and animal feed industry and state regulatory authorities overseeing animal feed manufacturers over the next 3 years to determine how these requirements might be modified. This could have significant future importance with the advent of the FDA proposal to move more antimicrobials used in feed to a Veterinary Feed Directive program by allowing for veterinarians to more efficiently write VFD orders for antibiotics to be mixed into feed with

other non-VFD drugs. Eliminating the requirement for combination feed approvals could pave the way for a smoother implementation of the VFD program and ensure that antimicrobials added to feed are being use for therapeutic purposes only under the order of a veterinarian.

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 move a clean ADUFA bill in a timely manner so this program can continue without interruption.

Again, thank you for holding this hearing and I would be happy to answer any questions.