REPORT OF THE COMMITTEE ON PHARMACEUTICALS

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The Committee met on October 28, 2008 at the Sheraton Greensboro Hotel, Greensboro, North Carolina, from 8:00 a.m. to 12:00 p.m. There were 13 members and 12 guests present. Three presentations were given.

Steve Vaughn, Office of New Animal Drug Evaluation (ONADE), Center for Veterinary Medicine (CVM), Food and Drug Administration (FDA) presented on several key issues regarding animal drug availability. He reported that Animal Drug User Fee Act (ADUFA) II was passed and signed into law resulting in user fees from the research pharmaceutical manufacturers amounting to $98 million over the five year term. The fees are directed at keeping the review times to 180 days. There were several other enhancements that should allow for a more efficient work process. Under ADUFA II, annual reports shift to a calendar year basis rather than anniversary date status. This includes volume sold reporting by molecule unless there is only a single company producing a specific drug in which case volumes are reported by class. Secondly he reported that AGDUFA, user fees from generic manufacturers, passed and has targeted a reduction in review times for Abbreviated New Animal Drug Applications (ANADAs) from 700 days to 270 days. Both should result in speedier approval processes for animal drugs to producers and veterinarians.

He next reported on Minor Use/Minor Species (MUMS), the method used to make approved drugs available to minor species or production classes that result in minor use. This is designed to make these opportunities more attractive to industry. The process does not preclude safety (human or animal) filings. The specifics are available on the CVM website http://www.fda.gov/cvm/minortoc.htm. More than 50 drugs have been designated for this process and there has been one approval. In the realm of global harmonization, FDA continues to work with the appropriate non-government organizations (NGOs) and expert committees to assure rigorous scientific review. Both scientific and political progress is being made, but progress is slow and maximum residue levels are weapons used in global trade.

Lastly, Vaughn discussed the Proposed Final Order to ban the extra-label use of cephalosporin antibiotics in animals destined for food. The agency issued the order to combat a potential risk to human health. The agency is receiving comments to the docket until November 1. The order is to take effect November 30, unless rescinded or modified. This was a key point of discussion in the roundtable discussion with members and guests expressing concerns about losing valuable tools in the treatment, control and prevention of animal disease. Vaughn encouraged comments to the docket.

Drs. Lisa Tell, University of California-Davis, and Ron Baynes, North Carolina State University presented a review of the history of the Food Animal Residue Avoidance Databank (FARAD). This organization, a collaboration of three universities: University of Florida, North Carolina State University, University of California-Davis, has been in existence since 1982, helping veterinarians and producers determine the necessary withhold or withdrawal period when dugs have been used in an extra-label manner. Historically, the funding was through the United States Department of Agriculture (USDA). Several times in the recent past, funding has been delayed such that the organization has been forced to close. They are currently beginning layoffs and will close their doors permanently on July 1, 2009, leaving veterinarians with no centralized independent source of information on the pharmacology and pharmacokinetics of drugs used in an extra-label manner. FARAD has averaged approximately 1300 cases per year with a targeted turnaround time of 24 hours. Dr. Tell explained that each case is handled as a new case with a complete literature search being conducted and the information entered into a patented algorithm used to estimate time to return to tolerance level (U.S.) or minimum residue level (MRL) if there is no U.S. established tolerance. While the incidence of residues creating a risk for human health is relatively

low, the potential for a residue to trigger a trade action is high. With the US livestock and poultry industry heavily dependent on the global marketplace and drug residues one of the weapons in technical barriers to trade, it is important that there be a source of information when extra-label use has accidentally or intentionally occurred. Funding has been authorized in the 2008 Farm Bill, but the money has not been appropriated.

Dr. Christine Huoang, American Veterinary Medical Association (AVMA), presented the AVMA's concerns about the proposed final order to ban the extra-label use of cephalosporins in food animals and provide an update on pending/proposed legislation that might impact the availability of drugs to veterinarians and producers. Strategies to Address Antimicrobial Resistance (STAAR) Act runs contrary to FDA's science based approval process, but is supportive of enhancing research and surveillance through the public health action plan. The proposed Preservation of Antibiotics for Medical Treatment Act (PAMTA) is also pending in Congress and would restrict the availability of drugs used for nontherapeutic purposes in particular. She pointed out that both acts use the term nontherapeutic which is undefined. This language is also prevalent in the report of the PEW Commission Report on Industrial Farm Animal Production and again is poorly defined. There will be a proposal in the AVMA House of Delegates to ban antimicrobial use in feed, for growth promotion and to make all veterinary products delivered by any route prescription only. The AVMA opposes this proposal because there are too few veterinarians to have valid veterinary-client-patient relationships to care for the nations animals. She discussed the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) which codified the right of veterinarians to use approved animal and human drugs in an extra-label manner as long as human health was not compromised. The AVMA disputes the legal authority of FDA-CVM to prohibit the extra-label use of cephalosporins in food animals and identifies several areas of policy contradiction and potential lack of sound science in their implementation of the proposed final order. The AVMA response to the docket will be posted by the deadline and available for public review.

A discussion followed that focused on the proposed ban and its unintended consequences including reduced animal welfare and potentially unsafe food. Concerns were expressed about the lack of transparency in the decision process and the use of the precautionary principle instead of a sound risk analysis. Dr. Vaughn implored the audience to respond to the docket with information that shows what the industry is doing to preserve the long-term effectiveness of the cephalosporin class of drugs. A second concern expressed by the committee members was the lack of harmonization of MRLs and the risk to the U.S. products traded globally.

Committee Business:

Three Resolutions were passed and submitted to the Committee on Nominations and Resolutions.