REPORT OF THE COMMITTEE ON PHARMACEUTICALS

Chair: Dr. Joe S. Gloyd, Wilmington, DE
Vice Chair: Dr. Thomas J. Burkgren, Perry, IA

Dr. Eric J. Bush, CO; Dr. William H. Fales, MO; Dr. Paula J. Fedorka-Cray, GA; Dr. Richard E. Hill, IA; Dr. John P. Honstead, CO; Dr. G. Dean Lindsey, IN; Dr. Patrick L. McDonough, NY; Dr. David J. S. Miller, England; Mr. Mark J. Owens, IA; Ms. Valerie H. Patten, NY; Ms. Tracy A. Raef, IA; Mr. Steven Roach, IA; Dr. Jane F. Robens, MD; Dr. A. David Scarfe, IL; Dr. Roy A. Schultz, IA; Dr. Paul L. Sundberg, IA; Dr. R. Flint Taylor, NM; Dr. Deepanker Tewari, PA; Dr. Jon C. Van Berkom, ND; Dr. Lyle P. Vogel, IL; Dr. Elizabeth K. Wagstrom, IA.

The Committee met on October 27, 2004 from 8:00 am–12:00 pm. Approximately 10 committee members and 5 visitors were recorded on the roll. The Chair welcomed the Committee members and gave all in attendance the opportunity to introduce themselves.

Dr. Paula Fedorka-Cray, United States Department of Agriculture (USDA), Research, Education and Economics (REE), Agriculture Research Service (ARS) Research Leader, gave an update on the National Antimicrobial Resistance Monitoring System (NARMS). Bacterial isolates come from veterinary diagnostic laboratories, sentinel farms and packinghouses. Resistance testing is done on *campylobacter, E. coli, enterococci, and salmonella*. The most common resistance among isolates is to tetracyclines but there is wide variation between species as well as serotypes. *Salmonella* serotypes vary over time and vary by species and source.

Dr. Lyle Vogel, American Veterinary Medical Association (AVMA), provided the AVMA perspective on several issues. The AVMA is moving forward with legislative efforts to secure adequate funding for the animal arm of NARMS. Vogel participated in an external review of the Centers for Disease Control and Prevention (CDC) activities within NARMS. This review concluded that this is valuable service to public health; however, the program needs improvement in *campylobacter* sampling. It also concluded that CDC was not timely in publishing its data. The review also recommended that an oversight committee be appointed for CDC NARMS. The AVMA judicious use guidelines are currently under review. The AVMA is also working to put together lists of antimicrobials important to veterinary medicine. Vogel reported that the Minor Use/Minor Species (MUMS) Act passed in 2004. He also reported that the AVMA is addressing the issue of compounding animal drugs through education of veterinarians.

Dr. Liz Wagstrom briefed the Committee on the development of the

National Pork Board's Responsible Use Program. This communication effort will target producers with information on appropriate use of antimicrobials. The goal is to raise awareness and educate on the issue. The program will debut in early 2005. At some point in the future there may be a transition to a certification program.

Dr. Dan McChesney presented information from the Food and Drug Administration (FDA)-Center for Veterinary Medicine (CVM) on several topics of interest to the Committee. He explained the issue of compounding of animal drugs. There is controversy over the legal requirements of compounding and the difference between compounding and manufacturing. The current Compliance Policy Guide on compounding is under revision. McChesney reported that the importation of U.S.-approved drugs from Canada is a non-issue. There is more concern over the sale of drugs over the Internet. FDA-CVM does approve the import of some companion animal drugs that are not available in the United States. McChesney reported that the FDA's Adverse Event Reporting System has improved over the last few years. Currently over 25,000 adverse drug events are reported per year.

Dr. Eric Dubbin, FDA-CVM Ruminant Drugs Team Leader, gave a presentation on a number of topics concerning the FDA-CVM. A number of new drugs have been recently approved: Excede, Navigator, Vetsuin, Surpass, and Optaflexx. The MUMS Act is being implemented within FDA-CVM to increase the number of drug approvals for these uses and species. So far, 22 requests for designation have been submitted but the law has only been in effect since August 2004. Dubbin also updated the Committee on the progress made under the Animal Drug User Fee Act (ADUFA). Under ADUFA sponsors pay fees. In return, FDA-CVM must improve their performance in approving new animal drugs. This should expedite and improve the FDA-CVM review of applications for new animal drugs. Lastly, he informed the Committee on the most recent meeting of the FDA-CVM Veterinary Medical Advisory Committee (VMAC). VMAC met in October 2004 to review a new approval for tulathromycin for use in swine and cattle.

The Committee discussed the need for a new Chair and Vice Chair. Drs. Liz Wagstrom and Larry Hawkins were recommended respectively, and this information will be forwarded to the USAHA President for consideration.

While the Committee did not approve a specific resolution, the Committee discussed their support for a resolution approved by the Committee on Food Safety concerning adequate funding for NARMS and the Food Animal Residue Avoidance Database.