

REPORT OF THE COMMITTEE ON GOVERNMENT RELATIONS

Chair: Dr. Bret D. Marsh, Indianapolis, IN
Vice Chair: Dr. Lee M. Myers, Atlanta, GA

Dr. J. Lee Alley, AL; Dr. Wilbur B. Amand, PA; Dr. Jones W. Bryan, SC; Mr. Bob Frost, CA; Dr. Donald E. Hoenig, ME; Mr. James W. Leafstedt, SD; Dr. Donald H. Lein, NY; Dr. R. Tracy Rhodes, WY; Dr. Richard D. Willer, AZ; Dr. Ronald B. Wilson, TN; Dr. Taylor Woods, MO; Mr. John F. Wortman, Jr., NM.

American Association of Veterinary Laboratory Diagnosticians (AAVLD) Members Present: President Willie Reed, MI; President-Elect Gary Osweiler, IA; Vice President Donal O'Toole, WY; Past President Terry McElwain, WA; Secretary/Treasurer Alex Ardans, CA; Chairman of AAVLD Government Relations Committee Bruce Akey, NY

The Committee met in Washington, DC, on February 8-11, 2004. The Committee met jointly with the Board of Directors of AAVLD. All United States Animal Health Association (USAHA) Committee Chairs were invited to the meeting. Eight Committee Chairs were present.

On February 8, 2004 an organizational meeting was held to prepare for the week's activities. The USAHA Executive Committee met that evening with Dr. Ron DeHaven, Deputy Administrator of the United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS), Veterinary Services (VS). The AAVLD Board of Directors also participated in this meeting. The discussion covered a variety of topics including the National Animal Health Laboratory Network (NAHLN), the completion of the National Centers for Animal Health (NCAH) in Ames, Iowa, the national animal identification plan, and the current status of disease control and eradication programs.

On February 9, 2004 the Committee traveled to the APHIS Riverdale facility. Drs. Larry Granger, Joe Anelli, Joe VanTiem gave the Committee a tour of the Emergency Operations Center (EOC). Each attendee received a CD presentation that describes the functions of the EOC. After the tour, the Committee received program reports from Dr. John Clifford with additional comments from members of the National Animal Health Programs staff.

Mr. Scott Charbo, Chief Information Officer for USDA reported on recent developments and efforts of USDA to immediately implement a verifiable system of national animal identification. Mr. Charbo has been charged by Secretary Veneman 'to expedite the development of the technology architecture to implement this system,' a system that is to facilitate traceback *within 48 hours* of any animal that enters intra- or

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interstate commerce, in case of disease emergency. Keith Collins, Chief Economist, and Nancy Bryson, General Counsel of USDA review economic and legal matters related to such a system. Fiscal year 2004 funding for design and developmental work comes from emergency appropriations, with \$33 Million proposed in the 2005 federal budget. Primary design goals are to have a system that:

1. Presents no extra burden on producers;
2. Leverages systems and developments that are already piloted or in place for several commodity groups; and
3. Be technology neutral.

The system should also be set up to be 'budget neutral.' Mr. Charbo envisions a system in which USDA proposes requirements and standards, and private industry is to develop the various technologies that are best adapted to needs and characteristics of different species or commodity groups.

The major challenge and potential roadblock to implementation of an efficient and transparent system is the concern of data confidentiality and related trade secrets. Data repositories need to be protected from improper access, including protection from requests for access under the Freedom of Information Act. Data items, such as, say, date of birth or age or others, to be associated with premise and individual animal or animal group ID, have to be carefully selected such as not to hamper the proper functioning and efficiency of the system.

The audience's main concern was the disruption of the normal flow of animal commerce due to implementation of various technologies, which could make it necessary for deploying several different readers at livestock assembly points (markets, slaughter houses, etc.). This could affect especially small producers and operators. Mr. Charbo however stated that it was not USDA's intent to impose a single technology platform, and that it would be left up to Industry to assure compatibility of various technologies.

Mr. Charbo concluded by reminding everyone that all stakeholders and the public needed to be educated as to not expect that implementation of a National Animal Identification System would 'cure disease problems.' The system will be an essential tool in controlling animal disease and addressing food safety concerns.

Dr. Barb Martin, USDA-APHIS-VS National Veterinary Services Laboratories (NVSL) provided an update on the validation of reverse transcriptase polymerase chain reaction (RT-PCR) tests. In February 2002, USDA-APHIS and USDA-Agriculture Research Service (ARS) signed an agreement in which APHIS took the responsibility to provide to ARS acceptable validation criteria for use in the process of diagnostic test development. A committee with inter-agency and international participation was formed in June 2002 to outline such criteria. The World Organisation for Animal Health (OIE), in its Manual of Stan-

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dards, has defined 'validation' as the 'process through which a test method is confirmed to be fit for the intended purpose,' and with which performance characteristics are defined. Validation is differentiated into 1. bench validation, allowing primer/probe development and optimization; determination of analytical sensitivity and specificity; preliminary estimation of accuracy and precision, and 2. field validation, providing estimates on diagnostic sensitivity and specificity, ruggedness, accuracy and precision, and allowing inter-laboratory comparisons (reproducibility).

APHIS and ARS have partnered in developing and validating several tests for foreign animal diseases in 2003, to be completed in 2004. Personnel has been hired for validation (1 fulltime, permanent; 3 fulltime, 2-yr terms) and subsequent proficiency testing (2 fulltime, permanent) of staff in laboratories in particular of the National Animal Health Laboratory Network (NAHLN). A validation template has been developed summarizing validation and acceptance criteria to provide guidance in the incremental validation process and promote quality of diagnostic assays.

Currently, tests for classical swine fever (CSF), foot and mouth disease (FMD), and vesicular stomatitis virus (VSV) infection, avian influenza (AI) and exotic Newcastle disease (END), African swine fever (ASF), rinderpest and lumpy skin disease are in various stages of the validation process. Completion of validation and deployment for tests for CSF and FMD are expected for May and June 2004, respectively. Specimens for field validation of the CSF test were assembled from the European Union reference laboratory, from the Dominican Republic, Columbia and Mexico. Samples for FMD test field validation currently are being assembled from Afghanistan, Argentina, Bolivia and Brazil, South Africa, Thailand and Kyrgyzstan. Although ARS has developed a FMD portable real-time RT-PCR that will be validated in the near future, Dr. Martin stated that these collected / stored samples and related data (results from virus isolation and serology) were available for field validation and comparison of an additional 3 diagnostic tests that were developed currently by other institutions and commercial entities.

Dr. Martin's unit is currently also evaluating Quality Control issues such as robustness of developed tests, providing appropriate protocols, monitoring of performance, and help with trouble-shooting. Equivalency testing of improved or scaled up tests needs to be evaluated and organized, and proficiency tests and internal controls need to be developed or improved. These processes are to ensure international acceptance of tests developed in the United States, and of results obtained from these tests.

Dr. Joseph T. Spence, Acting Associate Deputy Administrator, Animal Production, Product Value and Safety, USDA-ARS and Dr. Robert Heckert, National Animal Health Program Leader, USDA-ARS provided

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an update on organization and budgets of ARS, on ARS collaboration with APHIS and the Department of Homeland Security (DHS), especially as related the Plum Island Foreign Animal Disease and Diagnostic Laboratory (FADDL), on ARS activities related to bovine spongiform encephalopathy (BSE) and other food safety issues, and on ARS facilities.

Dr. Spence pointed out the good cooperation and interaction that ARS, which is the research arm of USDA, and APHIS enjoy. Both organizations work together and have shared goals with DHS. In particular, the DHS has taken control in June 2003 of the Plum Island FADDL, which has raised issues of program priorities and continuation. Indeed, presently DHS considers FMD its primary focus and threat to animal agriculture, which may lead to a reorientation of priorities at the laboratory. According to Dr. Heckert, DHS is to take the lead in development of diagnostics and in disease control activities, while ARS is to take the lead in fundamental pathogenesis research. He presented the progress made on several diagnostic tests, of which all phases including field testing had been completed for AI and END tests; tests for FMD, CSF, VSV were in the field testing process; tests for rinderpest, lumpy skin disease had been bench tested; no test was in development for contagious bovine pleuropneumonia. [Note: for non-foreign animal diseases, tests for bovine viral diarrhea (BVD), swine influenza virus (SIV), and porcine respiratory and reproductive syndrome (PRRS) were in the field testing process.]

Dr. Spence also presented ARS support of APHIS animal health programs, notably for bovine tuberculosis, brucellosis, Johne's disease, scrapie and screwworm control and/or eradication. He especially pointed to the use of ARS resources in support of APHIS for detection and characterization of the first US BSE case: ARS performed the confirmatory testing at the National Animal Disease Center (NADC) in Ames, IA with western blots and genotyping of the prion gene, and confirmed the origin of the BSE index case, at the Meat Animal Research Center (MARC) in Clay Center, Nebraska, using microsatellite and SNP (single nucleotide polymorphism) genotyping within 48 hours of first detection.

With the change-over of control of Plum Island to DHS, budgets for ARS were adjusted. Resources for maintenance are now included in the DHS budget, representing a loss to ARS; however, research funding for various activities of ARS on Plum Island will stay with ARS. Staff resources will be shared by both agencies. Dr. Heckert presented an organizational chart for FADDL: A Board of Directors (administrators of APHIS, ARS and a DHS representative), and a Scientific Advisory Board will provide direction to and oversee activities of the Center Director (Dr. Beth Lautner). Three branches, representing each of the 3 participating agencies, are led by 1. the APHIS-FADDL Chief, maintaining

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the diagnostics and forensics capabilities; 2. the ARS Research Leader, overseeing CSF, FMD and emerging diseases research; and 3. the DHS Scientific Director, who oversees three sections, including targeted advanced development in high priority and security areas; pathology, microscopy and sequencing services, including use of animal models; and disease assessment and epidemiology, and a strain repository. Dr. Heckert pointed out that implementation of this organizational plan should accelerate given the recent appointment of Dr. Beth Lautner, former Vice-President for Science and Technology of the National Pork Board, as the new director. Given Dr. Lautner's credentials as, Dr. Heckert was confident that interests of various stakeholders in animal agriculture and animal health would be defended.

Dr. Spence further presented other areas of collaboration between ARS-APHIS and the Food Safety Inspection Service (FSIS), specifically the Collaboration on Animal Health, Food Safety and Epidemiology (CAHFSE), in which an animal production surveillance system focused on animal health and food safety is designed and implemented. With periodic sampling from production through slaughter (starting with swine), the goal is to detect disease threats and trends early and to benefit both animal and human health. In these collaborative programs, APHIS leads the on-farm efforts and animal health component, having currently enrolled farms in four states (Iowa, Minnesota, North Carolina, Texas); FSIS does the in-plant sampling of sentinel farm animals; and ARS leads the laboratory efforts for food safety, including antibiotic resistance testing.

Finally Dr. Heckert reported on progress and maintenance of different ARS laboratories, in particular the Southeast Poultry Research Laboratory (SEPRL) in Athens. This laboratory founded in 1962-63 is in need of new or renovated / expanded facilities. The Biosafety Level-3 (BSL-3) section was built in 1972, following an outbreak of Newcastle Disease. Fourteen investigators and 32 support staff conduct research on END and AI, and on Salmonella, poult enteritis mortality syndrome (PEMS) in turkeys and on avian pneumovirus. The Arthropod-borne Animal Diseases Research Laboratory (ABADRL) in Laramie, Wyoming, is also in need of improvements, but Dr. Heckert pointed out the satisfaction of the agency with the final installment of funds proposed for the FY05 budget to complete facilities in Ames, Iowa by 2007.

Dr. Heckert concluded by stating the absolute need of the United States for a BSL-4 facility on United States soil to meet the growing research and developmental needs for maintaining and protecting the nation's animal agriculture and health, and human health.

The day concluded with a meal at Sir Walter Raleigh's restaurant. Guests included the USAHA Committee on Government Relations and Committee Chairs, AAVLD Board of Directors, USDA, APHIS and ARS, and the American Veterinary Medical Association (AVMA) including

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President Jack Walther.

On February 10, 2004 the Government Relations Committee gathered at the office of the AVMA Governmental Relations Division to meet with their staff, AVMA President Jack Walther and with American Association of Veterinary Medical Colleges (AAVMC) and their director, Dr. Larry Heider.

Dr. Heider explained his organization that is made up of the 28 veterinary colleges in the United States, plus 6 schools from Canada and Europe, as well as some colleges with departments of veterinary science. They lease offices in the AVMA floor space in DC and strive to help AVMA in legislative endeavors that will benefit all veterinarians. He stressed that AAVMC cannot legally act as a lobbyist. One of their biggest goals is to get some extended federal funding to help states upgrade the infrastructure of their veterinary schools.

Dr. Mike Chaddock director of the AVMA-Government Relations Division (GRD) introduced his staff of 8, gave an outstanding description of the work and role the GRD plays to benefit veterinary and agricultural interests on the legislative front. He also offered the USAHA to use AVMA office space and personnel when they come to DC, and to see if the USAHA resolutions could be worked on in a joint manner with the AVMA-GRD.

Dr. Jack Walther, President of the AVMA, discussed some of the items that AVMA is dealing with, and expressed his view that to succeed politically, we need to develop and maintain coalitions with other groups, such as American Medical Association (AMA), American Kennel Club, USAHA, etc., that can offer benefits to all. He also described the new legislative task force that will be available to aid states with their own legislative issues. Dr. Walther also expressed his hope that the AVMA and the USAHA can continue their mutual co-operation in advancing the issues involved with animal health.

The Committee then met at USDA's Jamie L. Whitten Building with Mr. John Baughman and Mr. Gary Taylor of the International Association of Fish and Wildlife Agencies (IAFWA). The Committee had a good discussion on issues of mutual interest.

The Committee also met with members of the Animal Agriculture Coalition (AAC) to discuss issues of interest.

On February 11, 2004 the Committee met with Agriculture Secretary Ann Veneman. Since Secretary Veneman was appointed to her position three years ago, many of the major issues she has dealt with have been animal health related. The Washington state BSE case was difficult due to timing, but the USDA still got information out quickly, honestly, and in a way that maintained consumer confidence. Veneman stated the U.S. needs to increase its BSE testing. The current testing capacity of NVSL is 61,000 samples per year. She said that it is important to get rapid screening tests for BSE approved and to expand test-

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ing to veterinary diagnostic laboratories. Her staff is currently working on opening trade with other counties, implementing the national animal identification system, and BSE surveillance issues. In regards to animal identification, Secretary Veneman said the USDA will need to include season of birth, premise, and animal identification numbers. She acknowledged that a number of states already have identification systems in place. A national identification system will eventually evolve into a mandatory program. The Secretary indicated that the USAHA and AAVLD could assist USDA with ideas on how to continue surveillance for BSE following the changed requirements for non-ambulatory cattle. It will be important to discuss rendering and disposal alternatives in the future. The Secretary concluded by saying avian diseases, like AI, pose a threat because of the impact on people, backyard birds, and agriculture.

The Committee met with Jeff Green, Acting Associate Deputy Administrator, USDA, Wildlife Services (WS). The mission of the WS is to provide federal leadership and expertise to resolve human/wildlife conflicts allowing for people and wildlife to coexist peacefully. Nationally, wildlife damage to agriculture is estimated at \$600 million to \$1.6 billion annually. More than half of all farmers and ranchers experience some kind of wildlife damage every year. Current areas of interest for WS are airport safety, rabies, and wildlife diseases. A goal for the future is to develop and implement a national wildlife disease surveillance and emergency response program. This program would assist with investigations involving Tuberculosis (TB), CWD, BSE, AI, Pseudorabies, Swine Brucellosis, and Salmonella/E. Coli around the country.

The Administrator of USDA, FSIS, Dr. Garry L. McKee, met with the Committee. Currently, the FSIS is the largest employer of veterinarians. FSIS will increase the training for its Veterinary Medical Officers in the future. FSIS has the leading role in the Food Emergency Response Network (FERN) which will integrate the nation's laboratory infrastructure in order to detect agents in food at the local, state, and federal levels. The Electronic Laboratory Exchange Network (eLEXNET) will be used by all laboratories in the FERN system to report results from bioterrorism and chemical terrorism related analyses. FSIS has been part of the PulseNet system which uses DNA "fingerprinting" to identify strains of bacteria and rapidly detect and control outbreaks of foodborn illness. Last September, FSIS held a symposium to discuss ways to reduce the levels of *E. coli* 0157:H7 in live animals before slaughter. A pre-harvest best management practices Guide is being developed that will be distributed to producers. FSIS veterinarians enforced the December 30, 2003, ban that Secretary Veneman made on all non-ambulatory cattle entering the food supply. FSIS issued four other regulations to further enhance safeguards to prevent BSE from

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entering the food supply. A notice was sent to all inspectors to no longer mark cattle as "inspected and passed" until confirmation is received that cattle have tested negative for BSE. The skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle 30 months and older and small intestines from all cattle are considered specified risk material. FSIS expanded its regulation on advanced meat recovery to include the dorsal root ganglia and spinal cord tissue. The practice of using air-injection stunning was banned to insure portions of the brain were not dislocated into the carcass. FSIS will be holding teaching workshops until March 2004 to ensure all processors understand the new regulations

Dr. Curt Mann, Homeland Security Council (HSC), White House, spoke to the Committee. After September 11, 2001, the federal government underwent reorganization due to the new threats in the United States. The DHS was established and includes the following divisions: Science and Technology; Information Analysis and Infrastructure Protection; Emergency Preparedness and Response; and Borders and Transportation Security Management. The HSC was also established and has a staff of 60 people. The council acts as an advisor to the President. The mission of the HSC is to develop and coordinate the implementation of a comprehensive national strategy. To coordinate the executive branch's efforts to detect, prepare for, prevent, protect against, respond to, and recover from terrorist attacks within the United States. Homeland Security Presidential Directive 9 is the nation's policy to defend agriculture and food systems against terrorist attacks, major disasters, and other emergencies. President Bush's FY 05 budget would allocate \$568 million for agricultural emergencies and \$239 million for food emergencies.

During the afternoon of February 11, 2004, the Committee heard reports from several key leaders. Dr. Robert Smith, National Program Leader, Agriculture Homeland Security, CSREES and Dr. Peter Johnson, National Program Leader, Animal Health, CSREES reported on the NAHLN. There are twelve participants in the NAHLN, and the current budget of \$3.7 million is not enough to expand the network. The President's budget requests \$30 million, and all Committee members were encouraged to engage in the budget process. Dr. Smith reminded the Committee that the requested funds are for a plant and an animal laboratory network, so the entire amount in the budget would be shared with the plant network.

Dr. Stephen Sundlof, Director, Center for Veterinary Medicine, Food and Drug Administration (FDA) discussed issues regarding BSE. He referred to the Harvard Risk Assessment as a significant source of information for developing policy for the agency. Currently, the FDA is considering several additional restrictions on the use of meat and bone meal to further mitigate the risks associated with BSE. Inspection teams

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for the FDA have conducted extensive checks of feed mills nationwide, and these inspection reports indicate a greater than 99% compliance rate. If enforcement actions are necessary, warning letters, recalls and injunctions could be used to gain compliance. Further, Dr. Sundlof discussed user fees for the approval of drugs, streamlining the drug approval process, and continuing activities in policy development regarding compounding of drugs

The Administrator of APHIS, Bobby Acord, met with Committee members. He was joined by Drs. Rick Hill and Andrea Morgan. Mr. Acord discussed the extensive APHIS activity regarding AI, END and BSE. He appreciated the support of states to accomplish these eradication programs. He encouraged states to be judicious in the use of interstate restrictions because of the impact of these actions on international trade opportunities. He also discussed the national animal identification system, and he encouraged everyone to stay engaged in the process of implementing the program nationwide.

Acting Administrator of USDA-ARS Dr. Edward Knipling, and Acting Associate Administrator Dr. Caird Rexroad met with the Committee. They discussed the goals of the ARS to utilize research to support the goals of USDA. There was a discussion about Plum Island and the new relationship with the DHS in managing the facilities and research initiatives.