

REPORT OF THE COMMITTEE ON GOVERNMENT RELATIONS

Chair: Don Hoenig, Belfast, ME
Vice Chair: Richard Breitmeyer, Sacramento, CA

Bruce L. Akey, NY; J Lee Alley, AL; Tony G. Frazier, AL; Steven L. Halstead, MI; William L. Hartmann, MN; James W. Leafstedt, SD; Bret D. Marsh, IN; Dr. Lee M. Myers, GA; Ms. Nancy J. Robinson, MO; Dr. Keith Roehr, CO;

Members Present: Bruce L. Akey, NY; J Lee Alley, AL; Steven L. Halstead, MI; William L. Hartmann, MN; James W. Leafstedt, SD; Bret D. Marsh, IN; Dr. Lee M. Myers, GA; Ms. Nancy J. Robinson, MO; Dr. Keith Roehr, CO;

Committee Chair Participants: Amelita Facchiano, TX; Robert Tully, KS; Daniel Lafontaine, SC; Scott Wells, MN; James Watson, MS

AAVLD Participants: Barbara Powers, CO; Donal O'Toole, WY; Alex Ardans, CA; Bruce Akey, NY

The Committee met February 26-27 in Washington, D.C., jointly with the American Association of Veterinary Laboratory Diagnosticians (AAVLD). A total of 17 members and guests attended, though some were unable to attend due to weather and travel problems. On February 26, the meeting convened at the American Veterinary Medical Association offices.

Dr. Steven Sundlof, Center for Veterinary Medicine (CVM), Food and Drug Administration (FDA), addressed the group on a number of topics. First was bovine spongiform encephalopathy (BSE). The CVM is committed to publishing a final rule on BSE but is still wading through some 850 comments received on the rule. Many comments accused FDA of underestimating the economic and environmental impacts of the rule, including the major issue of carcass disposal and disposal of additional banned materials. There is concern especially if rendering disappears as an option for disposal and other disposal options have not been identified. The final rule will include provision for time to come into compliance prior to the implementation of the rule and for the development of alternative disposal methods.

Second was the National Antimicrobial Resistance Monitoring System (NARMS). The NARMS is part of the national public health surveillance system focused on the development of antimicrobial resistance in enteric bacteria of human and animal health significance. It is a collaboration at the federal level between the FDA, the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA). Data collected describe the extent and temporal distribution of resistance, is used as a platform for research and helps inform FDA's decisions on approval of veterinary and human antimicrobial drugs. One particular focus of NARMS is tracking changes in resistance for pathogens such as *Salmonella* in cattle, chickens, turkeys and swine to drugs such as Ceftiofur which are the last, best treatment of choice for some human infections. Ceftiofur resistance rose markedly in cattle and chicken *Salmonella* isolates from 1997-2005. The National Antimicrobial Resistance Monitoring Service (NARMS) data also reveal shifts in the most prevalent species of *Salmonella* over time. The NARMS annual report is available on the CVM website, www.fda.gov/cvm.

Third was the Minor Use/Minor Species (MUMS) Act. Like the Orphan Drug Act for human drugs, the MUMS provides a pathway to bring drugs for minor species or uncommon diseases to market. It includes a provision for Conditional Approval of a drug so that it can be brought to market based on safety data alone so that effectiveness data can be gathered from the marketplace. Not all aspects of the MUMS are in effect yet, the final rule on Conditional Approval for example is due in February of 2008. Guidance documents for industry are in preparation, there will be a grants program developed and the MUMS Office will be conducting stakeholder outreach and minor use determinations.

The fourth topic was Integrated Consortium of Laboratory Networks (ICLN). The ICLN is comprised of laboratories from multiple federal agencies including the Food Emergency Response Network (FERN, some 134 labs) of the FDA. A counterterrorism exercise is being planned in conjunction with the USDA labs in the ICLN. The goals of the ICLN are to heighten food defense awareness and identify gaps in testing capabilities.

Finally, Dr. Sundlof addressed the Cloning Risk Assessment. The CVM is also tasked with evaluating the safety of meat and milk from cloned animals and their offspring for use as food. In general cloning is being viewed like other assisted reproductive technologies but a moratorium remains in effect until the risk assessment is concluded. No timeline was given for this effort.

The Department of Homeland Security (DHS) presented a number of speakers and topics to the Committee, highlighting the current structure and initiatives of DHS.

Tam Garland, Science and Technology (S&T) presented the S&T Mission, which is to protect the homeland by providing Federal and local officials with state-of-the-art technology and other resources. This includes development of systems, equipment, protocols, training procedures, assessment methods, technical standards to prevent, detect and mitigate attacks. In the Agriculture Security arena, the goal is to determine diseases of high risk, and develop diagnostic assays, vaccine and other countermeasures to overcome these risks. These diseases are identified as foot and mouth disease (FMD), classical swine fever (CSF), avian influenza (AI) and Rift-valley fever (RVF). Assays and training for high throughput testing for FMD through the National Animal Health Laboratory Network (NAHLN) has been done in two laboratories. FMD vaccines are being investigated and production planned for 2007-8. On-going FAD work at Plum Island on Agriculture Security; New Director interviews in progress; working with USDA and Lawrence Livermore National Laboratory on research of new assays and vaccines. DMS working with the National Center for Foreign Animal and Zoonotic Disease Defense centered at Texas A and M and Food Protection and Defense Center of Excellence at the University of Minnesota. On-going development of the Plan for the National Bio- and Agro- Defense Facility (NBAF) is underway.

Willie Johnson and David Ostlund, discussed DHS' Grants and Training (G&T). The G&T training program identifies gaps in training, fills those gaps, builds 'train the trainer' programs, measures competence and builds partnerships. To-date, 1,377,713 responders trained and another 5,700,000 need training. With training partners, courses and modules have been developed. Some courses approved by USDA prior to release, others in progress of development. Training Toolkit developed at website FirstResponderTraining.gov. This has course templates and guides, and "lessons learned" after action reports. The G&T also incorporates the National Preparedness Goal to achieve and sustain risk-based target levels of capability to prevent, protect against, respond to and recover from major events. Within the Target Capabilities list is Food and Agriculture Safety and Defense. G&T directs Homeland Security grants and has provided billions to state and national programs. Equipment grants related to agriculture available. There is also a Homeland Security Exercise and Evaluation Program that coordinates, plans, delivers and evaluates exercises. Another program is the Homeland Security Preparedness Technical Assistance Program.

Jeff Grode, provided an overview on Customs Border and Patrol (CBP). CBP does Agriculture Inspections, transferred from USDA to DHS in 2002. Agriculture Specialists develop and implement programs and policies to prevent pests and diseases from being introduced. It is estimated that 1,872 inspectors are needed at ports of entry and DHS has 400 vacancies short of this goal. The Agriculture Specialists inspect, seize and issue violations, as well as conduct special operations to uncover smuggling operations. They work with USDA, Fish and Wildlife Services (FWS), FDA and CDC to develop rules and share data. Compared to 2004, the number of interceptions has increased by 16 percent, averaging 4,500 intercepts a day.

The Committee met in the afternoon with the Animal Ag Coalition (AAC). John Adams presented a new title for the Farm Bill on Emergency Management. AAC intends to propose authorization of following items (below). Comments from USAHA/AAVLD Chairs should be as

soon as possible to provide feedback to John Adams. The following items are included in the new subtitle for the bill.

- Food sector continuity of business all hazard national demonstration project to DHS, to be coordinated by USDA-APHIS.
- Coordinated livestock mortality and specified risk material (SRM) disposal plan, with Secretary of Ag's authority.
- USDA to provide funding for demonstration projects to provide disposal options from livestock mortality.
- Adequate funding to modernize labs under National Animal Health Lab Network (NAHLN). Suggest funding come through APHIS not the Cooperative State Research, Education and Extension Service (CSREES).
- Enhance National Veterinary Stockpile to inventory and deliver vet supplies within 24 hours emergency in case of foreign animal disease agents
- Research initiative on development and commercialization of vaccines and antivirals against foreign animal diseases, including APHIS, ARS, and DHS resources at Plum Island.
- Ensure that current research and development activities conducted at Plum Island be continued in future laboratory facility
- New Current Research Information System (CRIS) project for ARS to perform research related to contamination of food and dairy products.
- Permanently fund Food Animal Residue Avoidance Database (FARAD) by CSREES.
- National Animal Health Emergency Management Center in APHIS.
- Direct CSREES to implement the National Veterinary Medical Service Act to attract young veterinarians in food animal veterinary practice in shortage areas.
- National indemnification and insurance program to insure producers can sustain operations in case of foreign animal disease outbreak.
- Increased operational support for the National Veterinary Services Laboratory (NVSL) to support animal health.

For 2007 Budgets, Adams shared that Continuing Resolution was passed, with \$12 million for John's Disease to APHIS. The group discussed veterinary workforce expansion. Brian Smith indicated that the bill is to be presented in Congress this week titled the Veterinary Public Health Workforce Expansion Act, a new name with \$150 million per year for 10 years. The goal is to train more veterinarians in veterinary schools to increase capacity. As a point of interest, the AAVMC Symposium has been scheduled at CDC in April 2007. Details to follow.

Regarding AAC 2007 Budget priorities, because the continuing resolution just passed, and agencies have not yet made decisions regarding funds decisions. AAC will be evaluating this.

On the President's 2008 Budget proposals, Congress plans to ignore and add earmarks which leaves too many questions to provide further discussion.

Drs. Caird Rexroad and Steve Kappes addressed the GRC this year on behalf of the Agriculture Research Service (ARS). Dr. Cyril Gay was on the road and not available. Dr. Rexroad reported that the FY07 budget for ARS is flat. There will be no new construction during this period. The National Centers for Animal Health's BSL-3Ag building for large animal containment is coming on line. There is concern in ARS that so much of its budget consists of earmarks (~\$200M added since 2001 as 'earmarks') - this part of its budget is vulnerable as the president wants to redirect earmarks. A handout was passed out that contained ARS's budget for FY2008. Its request was for a budget of \$1.128B. The Office of Management and Budget (OMB) suggests this be cut by \$212M. The emphasis of ARS will be on functional genomics, HPAI, FMD and the TSEs on animal side.

Dr. Kappes reported that Dr. Rob Heckert has left to work with a private company. The position has been advertised and should be filled by Oct 2007. ARS reduced the number of focused diseases from 56 to 49. Current focus areas are immune modulators and innate immunity; host and pathogen genomes; neonatal immunity and colostral interference; virulence

factors esp. in diseases such as CSF; validation of an FMD vectored vaccine; improvement of diagnostic assays for Asia strains of H5N1; pre- and post-harvest food safety.

The attendees asked several questions of Drs. Rexroad and Kappes:

Q: Can ARS scientific personnel write competitive grants?

A: Yes, they can now. This used to be discouraged as double dipping for federal support, but is not currently. It is considered a good learning experience.

Q: How does ARS see the current push in congress to have a single food safety agency?

A: This was not answered directly - ARS sees animals as multipliers of organisms, and maintains an interest in both plants and animals in food safety. No statement was made about the desirability of a single food safety agency, but it might be difficult to deliver due to the number of agencies involved and differences in culture.

Q: How much BSL-3Ag space does ARS need? Can ARS partner with states in developing BSL-3 space?

A: Legally, ARS can't mix federal funds with state funds to create BSL-3 space. It can however lease state BSL-3 space and can also build adjacent to state facilities. ARS has not quantified the amount of BSL-3Ag space it needs. It now has space in the new National Centers for Animal Health (NCAH). The next set of BSL-3Ag space will be in whatever replaces the Foreign Animal Disease Diagnostic Laboratory (FADDL) (i.e., NBAF), and in the southeast poultry research center.

Q: ARS was asked to clarify the difference between a project and a program review.

A: A project review is comparable to a grant proposal. ARS project reviews are done for the most part by academics and are generally prospective and follow the National Institutes of Health (NIH) model. Animal health program reviews are retrospective assessments of past accomplishments. This is done by a 50/50 split of stakeholders and scientists.

Q: What is holding up the development of the perfect FMD vaccine?

A: Several answers were given: absence of facilities in which to do the animal work (NBAF is '10 years away'); there is a delay in getting the product to market since there must be a pass on to a private company of ARS test vaccine; there are substantial scientific challenges including the number of FMD strains; need to use immunomodulators; species differences; carrier state of vaccinated animals.

On Tuesday, February 27 convened at the U.S. Department of Agriculture's Whitten Building.

Drs. Mark Robinson and Gary Sherman presented information on the Cooperative State Research, Education and Extension Service (CSREES). Also attending was Ralph Ott, Assoc. Administrator, CSREES. Sherman reported on the FY 2007 budget, saying there will be no earmarks in this budget. This will "zero out" the minor use animal drug program as well as FARAD. There will be a one year bump up in the Hatch line item of \$180 million and how this is handled will be at the direction of the Experiment Station directors. Regarding the National Veterinary Medical Services Act (NVMSA): there is \$495,000 appropriated for FY '07 while the NAHLN has \$9.9 million to be divided between plants and animals. Sherman detailed how a working group was assembled and has been discussing some innovative ideas to distribute this funding as soon as possible. Phase 1 will be temporary until Phase 2 rules can be written. Phase 1 is under legal review and, if approved, there may be some recipients within the year but he was not at liberty to allow us to make these plans public yet.

Dr. Curt Mann, Deputy Undersecretary, Office of Food Safety, USDA, addressed the group next. He spoke of his recent experience as chair of the Government Coordinating Council (GCC). Former Secretary of Homeland Security Tom Ridge often stated that "you can't do homeland security from DC" and Curt has used this as his philosophy also. After September 11, agriculture wasn't even on the table but currently agriculture has been recognized as part of the national security apparatus of the country and this is a huge change. Unfortunately, for food and agriculture, 100% of the infrastructure is privately owned which makes protecting it very difficult. The Sector Coordinating Council was therefore formed to delve into these issues.

As chair of the GCC, Curt made some changes to the charter and set some strategic goals which allowed some short term gains so people could feel good about progress. The 2006

goals set for the SCC were to improve 2-way communication to industry and state, clarify what are agriculture and food systems and discuss continuity of business operations. He mentioned CARVER shock assessments.

Lee Myers asked that now that the chair has changed to FDA, who do we turn to for assistance? David Acheson is the point of contact. It might be helpful to have a meeting with him and Jeremy Stumpf in the Secretary's office. Rich Breitmeyer noted that the model of CDC and state health agencies should be adopted by DHS for state agriculture agencies and Curt responded that the funding for now will continue to flow through DHS. Curt also stated that the contact for us should be the infrastructure protection section of DHS noting that Sebastian Heath has been detailed there as a USDA liaison to staff up the food and agriculture desk. Somehow, states need to be more involved and Gary Christie from Florida has been detailed up to DC to work at DHS. We may want to meet with him at some point also. USAHA and AAVLD should actively support the continuation of this position.

Dr. Beth Lautner, NVSL, presented an update on NVSL. She reported that the Deputy Director position for NVSL is about to be announced. Also, they will be hiring an LPA person on March 19.

At Plum Island Animal Disease Center (PIADC), Tom McKenna is FADL leaving to take a position in Wisconsin and they are advertising for a new director. In the interim, they will be rotating heads filled by the current staff. The partnership with DHS is moving forward on selecting a new head of the PIADC.

On the National Bio and Agro Defense Facility (NBAF) site selection, the list has been narrowed down to 18 sites and they will all be visited in May. These will be further narrowed down to 2-3 sites by July after which environmental impact statements will need to be done and the current timetable is to announce a final selection by October 2008 with construction to begin in 2010, becoming operational in 2013.

Beth provided a handout provided on NCAH

VS Memo 580.4 will be updated to allow NAHLN labs to conduct screening tests with final testing to still be done at Ames. ISO 1725 certification was recently achieved by NVSL.

The NAHLN review is underway and the plans are for this to be completed by the annual meeting in Reno. The goal continues to be a NAHLN lab with BSL 3 Ag space in all 50 states.

Dr. Heidi Schleicher, NAHLN, provided more information regarding the NAHLN, and some of its initiatives with improving its information technology resources. Schleicher also provided an update on surveillance activities, such as with BSE

Dr. David Goldman, Acting Administrator, Food Safety Inspection Service (FSIS), USDA addressed the Committee. FSIS is developing methodology to begin risk-based inspections of meat and poultry processing plants. All plants would continue to be visited daily, however, the inspection time and intensity at each plant would be based on plant regulatory compliance and the type products produced. The concept will be evaluated at 250 plants beginning in April 2007. This new concept is not applicable to slaughter plants.

A baseline study for the presence of *E. coli* 0157:H7 in raw ground beef components (i.e. beef trim) has been completed. A baseline study is starting for qualitative and quantitative presence of *Salmonella* and *Campylobacter* on chicken broiler carcasses.

A public health data system is being developed which will dedicate resources to analyze existing data (e.g. PulseNet, FoodNet, etc.) to create a "dashboard" of pertinent information for management personnel.

State meat and poultry inspection programs are considered important partners to FSIS. It is anticipated there will be an increase in FY 2007 funding for state programs.

The need for lifting the prohibition against state inspected meat and poultry products shipped interstate was discussed extensively. Committee members explained this statutory prohibition needs to be removed based on a very comprehensive review of all state programs during the last three years and an USDA report to the U.S. Congress that state programs are considered "at least equal to" the federal program.

Dr. Jose Diez, Associate Deputy Administrator, USDA-APHIS-VS, along with his associate Dr. John Slack, next met with the Committee.

Diez addressed 2006 USAHA Resolution 6: Continuity of Business Plan. Jose indicated that he met with John Adams of the AAC and that he is on board with the concept of COBP that will be put forth by the AAC.

Regarding the ESF 11 rewrite, all hazards approach, VS will be involved in pet rescue but are they going to be involved in all animals, all hazards? Who does it, who pays? It seems from Jose's comments that these important issues have yet to be sorted out. Resolution #7 was discussed and the issue of how much DHS will be involved and who will be in charge. VS Animal Care will take leadership on the pet rescue.

Diez discussed the coordination of test exercises: He related that this was one of his major initiatives, to attempt to put some coordination and sense into the test exercise process. He told us that CAN was due to conduct 60 AI exercises around the country but when they modeled the "game" they had proposed to use, the participants were not impressed so they're going back to the drawing board. It's the role of the AEC's to make the AVIC's and the state vets aware of exercises and training so we can tap into these opportunities. Yet the frustration at the state level is that there is a need for people to do the work! Many of us need bodies. There will be three more AEC's per region next year. Keith reported that the performance measures for the AEC's are great but that the NAHEMS guidelines are not being followed.

Secretary of Agriculture Mike Johanns took a moment to hear key concerns from USAHA and AAVLD. The group limited our discussion to the funding stream for the NAHLN which currently goes through CSREES. Secretary Johanns asked Dr. DeHaven to convene a working group with the CSREES folks to discuss the issue and report back to him.

Drs. John Clifford and Ron DeHaven reviewed budget expectations for FY 2007, based upon the passage of Continuing Resolution, and the removal of all earmarked items. They shared that the APHIS budget is estimated at \$842 million, including money designated for avian influenza. The loss of earmarked funding results in \$16 million in cuts for Veterinary Services (VS). Clifford shared a list of programs that are impacted by this loss, and their funding amounts. They would be submitting the spending plan within 30 days. The funding process with the Office of Management and Budget was also explained, citing programs such as John's as an example.

The National Centers for Animal Health, Ames, Iowa, operation funding was discussed. Clifford indicated that the operating budget is included in the 2008-2009 requests, and shared among participating agencies.

The process of Cooperative Agreements with USDA was brought up, noting some of the challenges in the application process. Members asked for more support in simplifying the process, and also indicated that the training and templates provided by USDA are useful. Also, opportunities for cross-collaboration on projects needs to be assessed from a big-picture perspective.

The NBAF was further discussed, following up on Dr. Lautner's information. Clifford and DeHaven indicated that any strategic input on the facility can be sent to their attention. The budget proposal is \$450 million, which includes all aspects of the facility. DHS is expected to have a growing role in the center, including research. The concern about FMD testing in the new facility was discussed, and a change in laws regarding its presence on the mainland.

Members inquired about the national plan for the generic database and its evolution. Clifford indicated he would set up a conference call with the National Assembly, USAHA and AAVLD to share their status and goals. The need for federal information technology support was stressed. VS has a strategic plan forthcoming, to address areas of surveillance, rapid detection and rapid response. Data portability is a key concern for the laboratories, referencing the database process used in the exotic Newcastle disease outbreak in California. A need for a federal champion of this project was identified.

DeHaven and Clifford noted that animal ID is still a priority for the Secretary, and the administration is committed to the program.