REPORT OF THE USAHA COMMITTEE ON DIAGNOSTIC LABORATORY AND VETERINARY WORKFORCE DEVELOPMENT

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The Committee met on Monday, October 22, 2007, 7:00 pm to 9:30 pm at John Ascuaga's Nugget Hotel, Reno, Nevada. The meeting, Co-chaired by Bennie I. Osburn and Robert E. Frost, was attended by 15 Committee members and 66 observers.

Following a welcome and brief opening remarks by the Co-chairs, Neville Clark, National Center for Foreign Animal and Zoonotic Disease Defense, Texas A&M University gave a report on Leading Products for Reducing the Risk of Engineered and Exotic Animal Diseases which is printed in its entirety in these proceedings at the end of this Committee report.

Michael Chaddock reviewed the status of The Veterinary Public Health Workforce Expansion Act (VPHWEA) (HR 1232, S. 746), which previously came through the Committee to support obtaining resources to expand infrastructure at veterinary medical colleges to enable them to graduate more veterinarians. Senator Allard and Congresswoman Baldwin introduced a newer version of the bill in the 110th Congress expressing a need for more public practice/public health veterinarians. The committee unanimously passed a Resolution supporting HR 1232, and S. 746.

United States Animal Health Association (USAHA) and American Association of Veterinary Laboratory Diagnosticians (AAVLD) Executive Committees and Government Relations Committee members are urged to address the lack of capacity in the nation's veterinary medical colleges and the need to pass the VPHWEA as introduced with members of Congress during regular visits to Washington. Also USAHA and AAVLD members are urged to formally support VPHWEA and actively advocate its passage with their individual members of Congress.

Bennie Osburn reviewed the state of the National Veterinary Medical Service Act (NVMSA), PL 108-161, which became law during the 108th Congress. The Secretary of Agriculture may designate areas underserved by veterinarians in rural and urban areas as well as government agencies and veterinary disciplines. The United States Department of Agriculture (USDA) has not yet promulgated rules for the program and Congress has not funded the program to the needed level for implementation. The Committee unanimously passed a Resolution calling for USDA to promulgate rules within 270 days of this Resolution and also called upon Congress to provide $20 million in funding to the NVMSA for FY08 and FY 09.

The Committee Co-Chairs extended an invitation to USAHA members to attend an open Committee discussion about potential consequences to high containment bio-security laboratory facilities. The events leading up to the need for this discussion were:

1. The impact of a laboratory biosecurity breach resulting in a foot-and-mouth (FMD) outbreak in the United Kingdom,
2. A Government Accountability Office (GAO) report on high security laboratories, and
3. A hearing by the House Committee on Energy and Commerce – Subcommittee on Oversight and Investigations, into the growth of Biosecurity Level 3 and Level 4 laboratories in the United States.

Karen Conyngham provided a review of the hearing which is provided in its entirety at the and of this Committee Report.

Norman Willis began the high containment laboratory discussion citing this era as a critical time for preparation and laboratory capacity efforts that must be made to address the challenges, threats and changes that will come rapidly. He stated the process of building either an individual laboratory or a national laboratory network is not a one shot financial start up building program but rather a long term expensive maintenance funding effort emphasizing continued maintenance vigilance.

The United States Department of Agriculture (USDA), Animal and Plant Inspection Service (APHIS) Veterinary Services (VS) and Agriculture Research Service (ARS) personnel John Clifford, Beth Lautner and Steve Kappes gave testimony emphasizing why we have laboratory facilities in the first place and expressed concern that testimony on the hill had grave omissions as to the benefits of high containment laboratories. They expressed their facilities have state of the art training programs and operating procedures in place and are open to internal and external audits.

Committee member and guest conversations provided numerous concerns, talking points and next steps which are summarized below:

- Realization that the House Committee lacks appreciation of why we have so many laboratories
- Education of Congress and the public on the importance of high containment laboratories
- Education process – a combined resolution and white paper effort
- Work with Association of American Veterinary Medical Colleges (AAVMC) and others to forward education information to Congress
- Importance of high containment laboratories to our National Animal Health Laboratory Network (NAHLN)
- Need for animal health Breed-specific legislation (BSL)-4 capacity
- Impact a moratorium would have on laboratories below the BSL-3 level
- Need to collaborate with the Association of Public Health Laboratories
- White paper is needed on what regulation would look like
- Agreement that today's oversight is not perfect, and that oversight is needed
- USDA needs to be involved with inspections of animal health laboratories
- Work force development – needed increase in veterinary population

Diana Whipple, USDA-ARS, National Animal Disease Center, Ames, Iowa, gave a start-up review for the new 155,000 square foot, 21 animal room BSL-3 laboratory which is a part of the $466 million Ames federal reference laboratory modernization project. A deliberate process is being implemented for this high containment large animal facility by coordinating safety protocols, animal care, life safety, emergency response, facilities engineering and what if? scenarios. Prior to going on line they will start with clean animals, conduct beta testing, move to BSL-2 procedures, and then go hot. This one-of-a-kind world class BSL-3 Ag facility is designed to contain domestic livestock and wildlife such as bison, deer and elk. Both ARS and VS will be able to utilize separate portions of this facility simultaneously. Dr. Whipple expressed USDA's appreciation for all the support USAHA and AAVLD put forth to make the new facilities a reality.

The Committee unanimously passed six Resolutions and were forwarded to the Committee on Nominations and Resolutions for consideration by the general membership.

Leading Products for Reducing the Risk of Engineered and Exotic Animal Diseases

Neville P. Clarke
National Center for Foreign Animal and Zoonotic Disease Defense

In an era of terrorism, the United States requires products that defend the nation from the intentional use of animal borne diseases (such as Rift Valley Fever, Avian Influenza, and Foot and Mouth Disease) to cause catastrophic harm, as well as from the accidental or natural introduction of exotic animal disease. Recognizing this need, the Department of Homeland Security established in 2004 the National Center for Foreign Animal and Zoonotic Disease Defense. The National Center for Foreign Animal and Zoonotic Disease Defense (FAZD) is an integrated, full-spectrum center charged with generating a stream of products to protect America from the exotic and engineered animal diseases that threaten public health and economic stability. These products offer the dual benefit of protecting against natural or accidental outbreaks. Organized by the diseases they address, here are examples of leading, cutting-edge FAZD Center products that will help members of the United States Animal Health Association (USAHA) reduce the risks posed by exotic animal disease.

Rift Valley Fever (RVF)

• **Vaccines** – In responding to RVF as an important emerging disease, the FAZD Center is developing candidate vaccines based on the human MP-12 vaccine that is being modified to provide the "DIVA" capacity – distinguish vaccinated from infected animals. Another modified live vaccine candidate uses a vaccinia platform with similar goals. These vaccines have performed well in laboratory challenges with small animals and large animal trials are anticipated in early 2008.

• **Diagnostics** – Companion diagnostic tests that detect the DIVA vaccinates from infected animals are also performing well in the laboratory and are ready for field testing. Important relationships with the private sector are being developed to take the products into production.

• **Models** – Quantitative epidemiologic and economic models based on experience with RFV in the Horn of Africa and on the opinions of subject matter experts have been developed and applied to an early assessment of the national economic impact of RVF as part of the Biothreat Risk Assessment being done by the Department of Homeland Security for the White House.

Foot and Mouth Disease

• **Vaccines and Antivirals** – The FAZD Center is collaborating with the Plum Island Animal Disease Center in the development of a next generation vaccine for FMD. A candidate component of the vaccine is a new antiviral from the FAZD Center that promotes "natural killer cells" that attack the FMD virus, providing protection within three days. The antiviral narrows the onset of immunity by three to seven days, thus severely reducing the time that animals are vulnerable to FMD infection.

• **Diagnostics** – The Center is also developing new inexpensive field (chute side) Enzyme Linked Immunosorbent Assay (ELISA) based antigen detection diagnostic tests that will support emergency responders in the event of an outbreak by providing immediate results to determine the presence of infection, thereby reducing unnecessary slaughter of healthy animals. This will also be a DIVA product to distinguish FMD vaccinates from infected animals. These tests will be complimentary to those being employed in the National Animal Health Laboratory Network (NAHLN) laboratories. Tests are ready for evaluation at the Plum Island Animal Disease Center.

• **Models** – National epidemiologic and economic models of FMD are being employed in early evaluation of options and alternatives for prevention of and intervention following outbreaks of FMD. Specific scenarios include modeling the intensive dairy industry in California and feedlots in Texas. The FAZD Center cooperates with the Department of Energy (DOE) national laboratories and USDA model developments in this area. A major new effort is underway to develop a national interstate transportation component model as a means of estimating rapid dissemination of FMD. Models will be used both for strategic planning and for informing decisions during emergency response during an outbreak. The FAZD Center is now involved in tracking and assessing the lessons learned relative to the U.S. from the FMD outbreak in the United Kingdom.

• **Public Policy** – The FAZD Center has organized stakeholder workshops on mass animal mortality that address the existing gaps, bottlenecks and roadblocks in existing public policy that would hamper the safe and timely disposal of animal carcasses in the aftermath of pandemic (such as the 2001 FMD outbreak in the United Kingdom) or other catastrophe. These workshops

brought together major stakeholders from the livestock industry: industry representatives, policymakers, scientists and regulators. Stakeholders examined current policy and suggested changes to improve response and recovery. Perhaps more importantly, they established working relationships that will prove invaluable during a crisis. Sessions have been held in Texas and California. A white paper resulting from the Texas workshop was presented to the Extension Disaster Education Network, and a state has inquired about holding a workshop of its own.

Avian Influenza

• **Training** – The FAZD Center is using products developed under its Avian Influenza School to provide hands-on training for extension agents, veterinarians, researchers and farmers that prepares them for potential outbreaks of Avian Influenza, thus improving response and recovery rates. The training modules are being employed both in the U.S. and internationally to meet the urgent need to train early responders in industry and government to be prepared to expediently deal with outbreaks of avian influenza. The school trains the trainers and provides training modules for use by extension agents, veterinarians, researchers and farmers – for prevention, intervention and recovery from outbreaks. Sessions have been conducted in multiple states. The training modules are also being used in a program aimed at small minority poultry operators in collaboration with multiple 1890 and 1994 minority serving institutions.

Report on the Hearing by the House Committee on Energy and Commerce – Subcommittee on Oversight and Investigations, into the Growth of Biosecurity Level 3 and Level 4 Laboratories in the United States

Karen Conyngham
International Llama Registry

Committee member Karen Conyngham gave a brief report on the hearing held October 4, 2007 by the House Committee on Energy and Commerce – Subcommittee on Oversight and Investigations, into the growth of Biosecurity Level 3 and Level 4 laboratories in the United States. The webcast of this hearing along with the prepared statements of the panel witnesses has been archived on the Committee's web site:
http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.100407.BSL.shtml

The Subcommittee hearing was chaired by Rep. Bart Stupak (D-MI). They took testimony from four panels of witnesses including the Government Accountability Office (GAO), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Dr. Ed Davis, Interim President of Texas A and M Univ., two biosecurity experts and one representative from the Sunshine Project, a non-governmental watchdog group that focuses on biodefense safety.

This hearing was the first in a series to investigate the proliferation of federal, state, academic and private BSL-3 and BSL-4 labs. Future hearings not scheduled as of the date of this Committee meeting will look into foreign laboratory safety including Pirbright in the United Kingdom (UK), and one hearing will be devoted to the future of the Plum Island Animal Disease Center and the proposed National Bio and Agro-Defense Facility, currently undergoing final site selection. In his opening statement, Rep. Stupak said, "We must ask if all these labs are necessary. No one is in charge here".

The Subcommittee received the results of a just-released Government Accountability Office (GAO) preliminary report (GAO-08-108T; available at www.gao.gov) entitled High-Containment Biosafety Laboratories. This initial report found that the number of BSL-3 and BSL-4 labs have increased rapidly in the aftermath of the 2001 anthrax attacks and passage of the 2002 Bioterrorism Act, but exact numbers of labs are unknown and most importantly, there is no one U.S. agency that has oversight for all laboratories, particularly those that operate without government funding. The GAO investigator was of the opinion that only one federal agency should oversee all labs, however that agency will then become a coordinating agency as well.

The GAO investigator cited several lab security breaches including the August 2007 FMD outbreak in the UK which has been attributed to the leak of contaminated wastewater from the Institute for Animal Health (IAH) facility at Pirbright.

The CDC/NIH panel testified that a needs assessment should be conducted before more labs are built and stressed the importance of a high level of biosafety training for all lab personnel. Human error is the cause of the majority of lab accidents. Risk-benefit analyses should be considered before new experiments are approved for funding. They recommended a "no-fault" accident reporting system be considered for all labs, to encourage transparency and allow labs to learn from each others experience.

Dr. Davis testified about the incident where a Texas A and M lab worker was infected with *brucella*; she has made a full recovery. This accident caught the attention of the Sunshine Project and prompted that organization to delve further into conditions in labs around the country. Dr. Davis stated that institutions with BSL-3 and BSL-4 labs need to practice good science, coordinate with other labs and provide absolute compliance with reporting and regulatory oversight.

Mr. Edward Hammond, Sunshine Project, a public advocacy group, testified that the US needs a transparent and accountable biodefense system. He felt that the recent publicity surrounding the Texas A and M incident had prompted more disclosure by other labs. Hammond stated that the United States does not need 400 labs and 15,000 lab workers. He recommended that Congress impose a moratorium on new labs and outright kill plans for National Bio- and Agro- Defense Facility (NBAF).