

#### Defense Health Board

Defense Health Board (DHB) Task Force on the Department of Defense (DoD) Biological Surety Review Program and Biodefense Research Portfolio Panel: An Update

**Gregory A. Poland, MD**President, Defense Health Board



## Background

The Department of the Army Office of the Surgeon General requested the DHB Task Force address the following three questions:

- Is there a national and/or strategic need for the Military Service Departments (MSD) to own and operate an infrastructure in support of mission requirements for defense capabilities (abroad and homeland) for biodefense?
- Are the current processes effective in transferring the results of basic biological research to advanced product development and licensure?
- Does the current infrastructure provide scientific or strategic return on investment for previous and current Research, Development, Training and Education (RDT&E) efforts?



## Background

#### Workgroup Members

- Dr.Poland (Director, Mayo Vaccine Research Group, Translational Immunovirology and Biodefense)
- Dr.Lednar (Global Chief Medical Officer and Director, Integrated Health Services, DuPont Human Resources)
- Dr.Breidenbach (Assistant Clinical Professor of Plastic and Reconstructive Surgery, University of Louisville)
- Dr.Herbold (Director, Center for Biosecurity and Public Health Preparedness, University of Texas School of Public Health)
- Dr.Clements (Chairman, Department of Microbiology and Immunology, Tulane University School of Medicine)
- Dr.Ennis (Director, Center for Infectious Disease and Vaccine Research, University of Massachusetts Medical School)
- Dr.Silva (Dean's Office, School of Medicine, University of California, Davis)



## Background

- Meetings:
  - November 7, 2008: Briefings from:
    - Defense Threat Reduction Agency (DTRA)
    - Joint Program Executive Office (JPEO)
    - Army
    - Air Force
    - Navy
    - Office of the Special Assistant for Chemical & Biological Defense and Chemical Demilitarization
  - November 19, 2008
    - Site visits to Edgewood Chemical and Biological Center, Forest Glen, and the United States Army Medical Research Institute of Infectious Diseases



## **Preliminary Insights**

- There is no dispute that the DoD biodefense research portfolio is unique or that the DoD needs infrastructure
  - Deterrent capabilities
  - Responsiveness and turn-around of military labs to threats is quick
  - Labs in academia and industry are unwilling to engage in research with high level of risk or no profit motive for "orphan" vaccines
  - High demand for BSL4 containment laboratories especially for animal efficacy studies



## **Preliminary Insights**

- Basic science research is sound, but barriers towards advanced product development and licensure include:
  - Fragmented organizational structure that strays from the industry best-practices model
  - Lack of one person accountability and senior leadership with vaccine development expertise and experience
  - Complex management/oversight issues by DTRA
  - Loss of intellectual capital due to difficulties inherent in transitioning junior level military personnel to higher level leadership positions and retaining qualified scientists
  - Separate lines of funding from different entities are not amenable to project sustainability
  - Processes more concerned with inputs rather than outputs
  - Complex and unwieldy table of organization



#### Other Issues

- Lack of communication between responsible entities – this should be a "joint" program (Integrated national Portfolio) is a good start
- TMTI is a novel experiment and results should be evaluated and if successful, generalized
- No systematic evaluation metrics are evident to evaluate programs
- Ability to "kill" projects not evident



#### Potential Recommendations

# Productive Biodefense Research requires:

- Centralization and Joint programmatic planning
- Development of evaluation metrics
- Sustained and identifiable leader accountability
- Time lines and multi-year funding
- Collaboration



#### Interim Report

 Answers to the three questions in the memorandum will briefed to the Service Secretaries on December 3, 2008



#### **DISCUSSION**