



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 be briefed to the Service Secretaries on December 3, 2008**



DISCUSSION