



Defense Health Board

Defense Health Board (DHB) Task Force Review
of the Department of Defense (DoD)
Biodefense Infrastructure and Research Portfolio:
An Update

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Background

- The Department of the Army Office of the Surgeon General requested the DHB Task Force address the following three questions:
 - **NEED**: 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?
 - **TRANSLATION**: Are the current processes effective in transferring the results of basic biological research to advanced product development and licensure?
 - **ROI**: Does the current infrastructure provide scientific or strategic return on investment for previous and current Research, Development, Training and Education (RDT&E) efforts?
 - *The Surety question(s) will be reviewed and answered by the DSB*



Background

- **Timeline requested is extremely short and not conducive to in-depth review and discussion**
- **DHB decision:**
 - **High level review with interim findings and recommendations**
 - **Focus initial review/findings on DoD biologic BD products (i.e. not PPE, drugs, etc.)**
 - **Focus on unclassified programs initially**
 - **Later meetings will be concerned with additional issues**



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, certified UN WMD inspector)**
- **Dr. Ennis (Director, Center for Infectious Disease and Vaccine Research, University of Massachusetts Medical School)**
- **Dr. Silva (Infectious Diseases and Dean's Office, School of Medicine, University of California, Davis)**
- **Dr. Lane (Deputy Director for Clinical Research and Special Projects, National Institute of Allergy and Infectious Diseases)**



Background

- **Meetings:**
 - **October 24, 2008**
 - Telecon to review charge, plan of work, etc.
 - **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, Walter Reed Army Institute of Research, and the United States Army Medical Research Institute of Infectious Diseases
 - **November 20, 2008**
 - Presentation and discussion – DHB virtual meeting



Preliminary Insights - Need

- **There is no dispute that the DoD biodefense research portfolio is unique or that the DoD needs BD infrastructure**
 - **Deterrent capabilities**
 - **Responsiveness and turn-around of military labs to threats is quick (anthrax letter example)**
 - **Provides nation with a surge capacity**
 - **Labs in academia and industry are unwilling to engage in research with high level of risk, and no profit motive for “orphan” vaccines**
 - **“Buy” vs. “make” concept**
 - **High demand for BSL4 containment laboratories – especially for animal efficacy studies**
 - **FDA “2 animal” rule**
 - **Unique aerosol and aeromedical isolation capabilities**
 - **Unique critical agent and culture archive assets**
 - **Unknown pathogen identification capability**



Preliminary Insights - Translation

- **Basic science research is sound, but barriers towards advanced product development and licensure include:**
 - **Complex and unwieldy table of organization with multiple and separate lines of authority**
 - **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**



Preliminary Insights - ROI

- **While there are some objective markers of considerable ROI, more needs to be done**
 - Define metrics
 - Track results over time
 - Report results
 - Inability to “eliminate” non-productive programs
 - No systematic evaluation metrics, processes, or procedures are evident to evaluate programs
 - With the move from a goal of “develop products to the IND state” to “develop FDA-licensed products”, people, processes, expectations, and progress is unclear



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**
- **Inadequate external scientific review and input**



Bottom Line

- **The DoD enterprise involves thousands of people and hundreds of millions of dollars per year. The clear expectation should be of a tightly focused, highly productive state-of-the-art program, with clear priorities, timelines and accountabilities, and an obvious and timely ROI to the warfighter and to the nation**



Future

- **The board heard about the recent initiative to integrate the BD portfolio with DHHS (Integrated National Portfolio)**
 - Joint Portfolio Governance
 - Portfolio Advisory Committee
- **While a clear step forward, more thought needs to be given to being explicit about what this can and cannot do**
 - DoD: Prevention of M&M due to bioterrorism
 - DHHS: Treat a bio-event



Final Point

- **Our observation is of highly dedicated, hard-working scientists and administrators determined to make a difference – who are failed by a system that is slow and tolerates complexity, lack of clear priorities, inadequate accountability, redundancy, and lack of experienced leadership.**



Following the Line of Authority

Needed Capabilities (JRO)



DTRA (up to milestone A)



S & T Labs



JPEO



Draft Summary of Recommendations for Productive Biodefense Research

- **Biodefense research infrastructure be retained**
- **Centralization and Joint programmatic planning**
- **Development of evaluation metrics**
- **Sustained and identifiable leader accountability**
- **Mechanism to provide education and training for future leaders**
- **Time lines and multi-year funding**
- **Collaboration**
- **Clear priorities**
- **Biosurety (recommend authorized red team to define and exploit vulnerabilities)**



DISCUSSION