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