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*
• 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
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
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
• 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.
Needed Capabilities (JRO)

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DTRA (up to milestone A)

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S & T Labs

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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