Defense Health Board

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

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Background

- The Department of the Army Office of the Surgeon General requested the DHB 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 separately by the DSB
Background

- Memo dated 3 Oct 2008, asking for report by December 2008. Timeline requested was extremely short and not conducive to in-depth review and discussion

- DHB subcommittee 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

- **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)
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, Forest Glen, and the United States Army Medical Research Institute of Infectious Diseases

- November 20, 2008
  - Presentation and discussion – DHB virtual meeting

- December, 2008
  - Pentagon meeting to present to Service Secretaries
Need

• There is no dispute that the DoD biodefense research portfolio is unique or that the DoD needs a 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
Translation

- 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 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 with multiple and separate lines of authority
Major Change

• DoD directive to move from a goal of:
  – “Develop products to the IND stage”
  to
  – “Develop FDA licensed products”

• This occurred without concomitant changes in staffing, resources, facilities, organization, project management and processes.
While there are some objective markers of considerable ROI, more needs to be done:
- Define metrics
- Track results over time
- Report results
- Inability to “kill” 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
- Extent of external scientific review and input is unclear and inadequate
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 world-class program, with clear priorities, timelines and accountabilities, and an obvious and timely ROI to the warfighter and to the nation.
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
– Clear priorities
– Biosurety (recommend authorized red team to define and exploit vulnerabilities)
Summary

Recommendations

• DoD biodefense infrastructure needs to be retained, BUT:
  – Program planning needs to be centralized and joint
  – Priorities need to be explicit and transparent
  – TMTI may be a model

• Systematic progress and ROI metrics need to be established and used to evaluate programs
  – Early “kill” of some programs
  – Expand external scientific input and programmatic review
  – Consider industry best practices models and benchmarks
Summary
Recommendations

• Critical for credible, identifiable leaders with authority and accountability to be instilled in each unit
• Mechanisms to train future DoD biodefense scientific leadership must be established
• Realistic timelines and multi-year agreements need to be developed
• Collaborative (federal, industry, academia) efforts to optimize research productivity need to be initiated, incentivized, and accelerated
Summary

Recommendations

• Further attempts to create a national integrated biodefense campus are needed to insure accountability, enhance stronger leadership, and reduce costs and redundancies

• Authorize a red team to define, expose, and exploit biosurety vulnerabilities
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: *Prevent* M&M due to bioterrorism
  – DHHS: *Treat* a bio-event
DISCUSSION
Final Point

• Our observation is of highly dedicated, hard-working scientists and administrators determined to make a difference – but in the context of a major change of mission to developing FDA approved products - are now failed by a slow system that tolerates complexity, lack of clear priorities, inadequate accountability, redundancy, inadequate funding, and lack of experienced leadership.
Recommendation

• Add to Recommendation 2: In particular, collaborations involving federal agencies, academia, and industry should be further developed, incentivized and accelerated.

• Divide Recommendation 2: Make the red team a separate recommendation.
Finally, given the restricted time frame within which this Task Force developed these initial recommendations, we recommend that the DHB Task Force further engage in a more comprehensive overall evaluation of the DoD Biodefense Infrastructure and Research Portfolio.