



Defense Health Board

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

Gregory A. Poland, MD
Vice-President, Defense Health Board
Chair, Infectious Diseases Control Subcommittee



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

- **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)



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.



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 “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



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.



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.