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

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.

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.