The Integrated National Biodefense Portfolio Initiative

“One-Portfolio”

Advance Planning Briefing for Industry

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COL Jonathan Newmark, MD, FAAN
Deputy for Medical Systems
Joint Program Executive Office for Chemical and Biological Defense
Jonathan.Newmark@jpeocbd.osd.mil
### The Integrated National Biodefense Portfolio Initiative

**Report Documentation Page**

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**Standard Form 298 (Rev. 8-98)**

Prepared by ANSI Std Z39-18
The Integrated National Biodefense Portfolio Initiative

“One-Portfolio”

• An effort to integrate Medical Countermeasures (MCM) efforts
• Primary partners are the Department of Defense (DoD) and Department of Health and Human Services (HHS) with participation by agencies who’s mission involves medical countermeasures
• The vision is government-wide coordination of research and development (R&D) of medical countermeasures for biological, chemical, radiation and nuclear threats.
• The working group formed A Portfolio Advisory Committee of government organizations that fund and manage MCM R&D
“One Portfolio” Objectives

• An integrated, end-to-end national Biodefense portfolio for medical countermeasure products is needed to leverage investments and maximize preparedness

• Major Objectives:
  – Describe state of the National Biodefense Portfolio
  – Evaluate risk and required investment
  – Identify portfolio gaps and overlaps
  – Develop recommendations for portfolio
  – Implement Joint Portfolio Oversight
  – Enhance intra-Departmental and inter-Departmental collaboration
  – Build portfolio plan into budget planning
Unified National Portfolio: Membership

- Department of Health and Human Services
  - Office of the Secretary
  - Biodefense Advanced Research and Development Agency
  - National Institutes of Health/National Institute of Allergy and Infectious Diseases
  - Food and Drug Administration
- Department of Defense
  - Chemical/Biological Defense Program, Office of the Secretary of Defense
  - Joint Program Executive Office for Chemical/Biological Defense
  - Joint Staff, Joint Requirements Office
  - Office of the Assistant Secretary of Defense for Health Affairs
  - Defense Threat Reduction Agency
- Other government agencies participating/attending
  - Executive Office of the President
    - Homeland Security Council
    - Office of Science and Technology Policy
  - Office of the Vice-President
  - Office of Management and Budget
  - Department of Homeland Security
  - Department of Veterans’ Affairs
No Single Agency has Visibility into the Entire Development Portfolio

Basic Research
- In Vitro & Animal Models
- Animal Testing
- Lab-Scale Production

Preclinical Development
- Human & Animal Efficacy, Dose, & Safety Testing
- Formulation
- Production of Clin. Supplies

Clinical/Non-clinical Development
- Regulatory Submission
- Manufacturing Scale-Up

Filing & Launch preparation
- Full-Scale Production
- Safety Follow-Up

Commercialization & Procurement
- Warm base production

Readiness & Stockpiling

Civilian Programs
- NIH
- BARDA
- OPEO
- CDC

Military Programs
- DARPA
- CBDP
- DTRA-JSTO
- Joint Program Executive Office - CBD
- TMTI
- Individual Services

UNCLASSIFIED
Progression and Scope of Portfolio Analysis

• Progression of analysis:
  – Biological threats
  – [Chemical, Radiological / Nuclear threats]
  – [Diagnostics]

• Scope Includes:
  – Medical Countermeasures (Vaccines, Therapeutics, & Diagnostics)
  – Technology Platforms
  – Infrastructure to support MCM development

• Currently Not Addressing:
  – Non-Medical Countermeasures
  – Pandemic Influenza and other naturally occurring Emerging Infectious Diseases
  – Environmental detection
Framework for Structured Portfolio Analysis

Validated Threats | Countermeasures Programs | Development Projects

For each threat or required capability...
... a set of programs is required, each comprised of...
... a set of development projects to yield the required MCM

Based upon analysis of type and severity of threat and likely consequences of attack

Threat Determinations (DHS, DoD) → Requirements Definition → Integrated Portfolio

HHS Programs
- MCM: vaccine
- MCM: therapeutic
- MCM: diagnostic

DoD Programs
- MCM: vaccine
- MCM: therapeutic
- MCM: diagnostic

Technology Platforms / Infrastructure

Based upon analysis of event scenarios, including medical, technical, and security implications, and considering availability of MCMs and enabling technologies
Integrated National Biodefense MCM Portfolio Requirements – Unique and Convergent

**DoD-Unique**
- Brucellosis Vx
- VEE/EEE/WEE Vx & Rx
- Plague Vx
- Botulism Vx
- SEB Vx & Rx
- Tularemia Vx
- Ricin Vx & Rx
- (other, unfunded)

**Common**
- Anthrax Vx & Rx
- Smallpox Vx & Rx
- Ebola / Marburg Vx & Rx
- Tularemia Rx
- Botulism Rx
- Radiation Rx
- Nerve agent Vx & Rx

**HHS-Unique**
- Smallpox Vx for special populations
- Burkholderia sp. Rx
- Junin Rx
- Plague Rx

**DoD focus is on protecting forces prior to exposure. HHS focus is on response to threats to general civilian population after exposure**

\[ V_x = \text{Prophylaxis} \quad R_x = \text{Therapeutic} \]
Integrated Portfolio
Accomplishments to Date

• DoD and HHS have harmonized a common set of Technology Readiness Levels
• An improved understanding of the expected impact of animal rule on biodefense product development
• Pipelines for several biological threat MCMs have been mapped and are ready for top down / bottom up analysis
• MCM development “projects in common” have been identified and further coordinated between DoD and HHS and across HHS
• Discuss approaches to portfolio integration
  – Cost-sharing
  – Knowledge sharing
  – Program sharing