Medical Chemical and Biological Defense Research

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Medical Chemical/Biological Defense
Rationale for Investment

- *...the threat or use of NBC weapons is "a likely condition of future warfare."* **Quadrennial Defense Review (May 1997)**
- **Direct payoff of chemical/biological defense R&D:** Reduction, even elimination, of casualties which would otherwise follow a CW/BW attack.
- **Indirect payoffs:** Effective products against CW/BW deter employment and proliferation of CW/BW capabilities.
- **Efforts address Joint Service/CINC requirements**

Medical Chemical and Biological Defense Research Program Mission

- **Provide medical solutions for military requirements to protect and sustain the force in a Chemical and/or Biological Warfare environment**

MCBDRP Vision

- **To Preserve Total Warfighter Effectiveness on a CW/BW Battlefield**
  - Prevent casualties
  - Provide effective treatment of casualties for rapid return to duty
  - Provide rapid, far-forward diagnosis of CW/BW disease

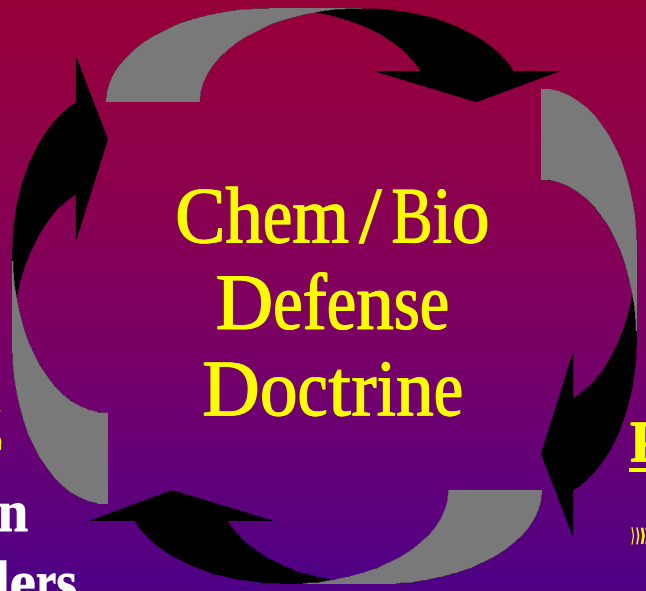
Protecting Warfighters Through Integration and Teamwork

Intelligence

- Agent
- Delivery System
- Organization
- Time

Education & Training

- Military and Civilian Health Care Providers
- Electronic Communication
- Distance Learning



Medical Countermeasures

- Vaccines & Prophylaxes
- Diagnostics
- Therapeutics

Physical Countermeasures

- Detection
- Physical Protection
- Decontamination

Product Development Overview

Acquisition of Products for
Future Warfighters
Soldier, Biological and Chemical Command
JPO-BD/JVAP
Other Commodity Area Managers

Medical Products for Chemical Agents

Medical Products for Biological Agents

USAMMDA

6.4 - 6.5 Advanced Development

JPO-JVAP

6.3 Concept Exploration

6.2 Applied Research

6.1 Basic Research

The "Tech Base" Products

- Basic Research Discoveries (Scientific Knowledge)
- Model Development for Agents of DoD Interest
- Vaccine/pretreatment Candidates
- Therapeutic Candidates
- Diagnostic Tests and Reagents
- Information
- Education
- Expertise & Consultation
- Technology Watch

Tech Base

Our Readiness Posture For Meeting Future Threats And Avoiding Technological Surprise

Medical Biological Defense

- **Technical Approach:**
  - **Identify mechanisms involved in disease process.**
  - **Develop and evaluate products (vaccines or drugs) to prevent or counter effects of biological toxins, bacteria, and viruses.**
  - **Develop methods to measure effectiveness of medical countermeasures in animal models which are predictive of human response.**
  - **Develop diagnostic systems and reagents.**

Medical Biological Defense Organizational Taxonomy

MEDICAL BIOLOGICAL DEFENSE

Medical Countermeasures (MC) against BW Agents

DTO Efforts

- CB.24 MC for Encephalitis Viruses
- CB.25 Multiagent Vaccines for Biological Threat Agents
- CB.26 Common Diagnostic Systems
- CB.31 MC for Brucellae
- CB.32 Needleless Delivery Methods for Recombinant Protein Vaccines
- CB.33 Recombinant Protective Antigen (rPA) Vaccine Candidate
- CB.34 Recombinant Plague Vaccine Candidate

TASK AREAS

- **Vaccines**
- **Therapeutics**
- **Diagnostics**

Medical Biological Defense Transitions

- **FY99/00**
  - Multivalent (A,B,C,E,F) Recombinant Botulinum Vaccine - MS I
  - Plague (F1-V) Antigen Vaccine - MS 0
  - Recombinant VEE Vaccine - MS 0

- **FY01**
  - Next Generation Anthrax Vaccine - MS I
  - Plague (F1-V) Antigen Vaccine - MS I
  - Common Diagnostics - MS 0
  - Multiagent Vaccine - MS 0
  - Brucella Vaccine - MS 0
  - Marburg (Filovirus) Vaccine - MS 0

Medical Biological Defense Products in Development (Projected Fielding)

- Q-Fever Vaccine – 2004 ?
- Smallpox Vaccine (Cell Culture Derived) - 2005
- Recombinant Plague Vaccine - 2006
- Venezuelan Equine Encephalitis Vaccine - 2008
- Tularemia Vaccine - 2008
- Recombinant Botulinum Vaccine - 2009
- Brucella Vaccine - 2010

Emerging Medical BD Products

- VEE/EEE/WEE Combined Vaccine
- Staphylococcal Enterotoxins Vaccine
- Ricin Vaccine
- Common Diagnostic System for BD Threats and ID Diseases
- Next Generation Anthrax Vaccine

Medical Biological Defense Investment in the Future

- **Countermeasures for Genetically Engineered Microbes**
  - Genomic sequencing of BW threat agents to identify and understand virulence factors, toxins and drug resistance genes
- **Immunomodulators and Therapies**
  - Alternatives to agent-specific vaccines or therapies
- **Multiagent Vaccines**
  - Alternative to one vaccine for one BW threat agent

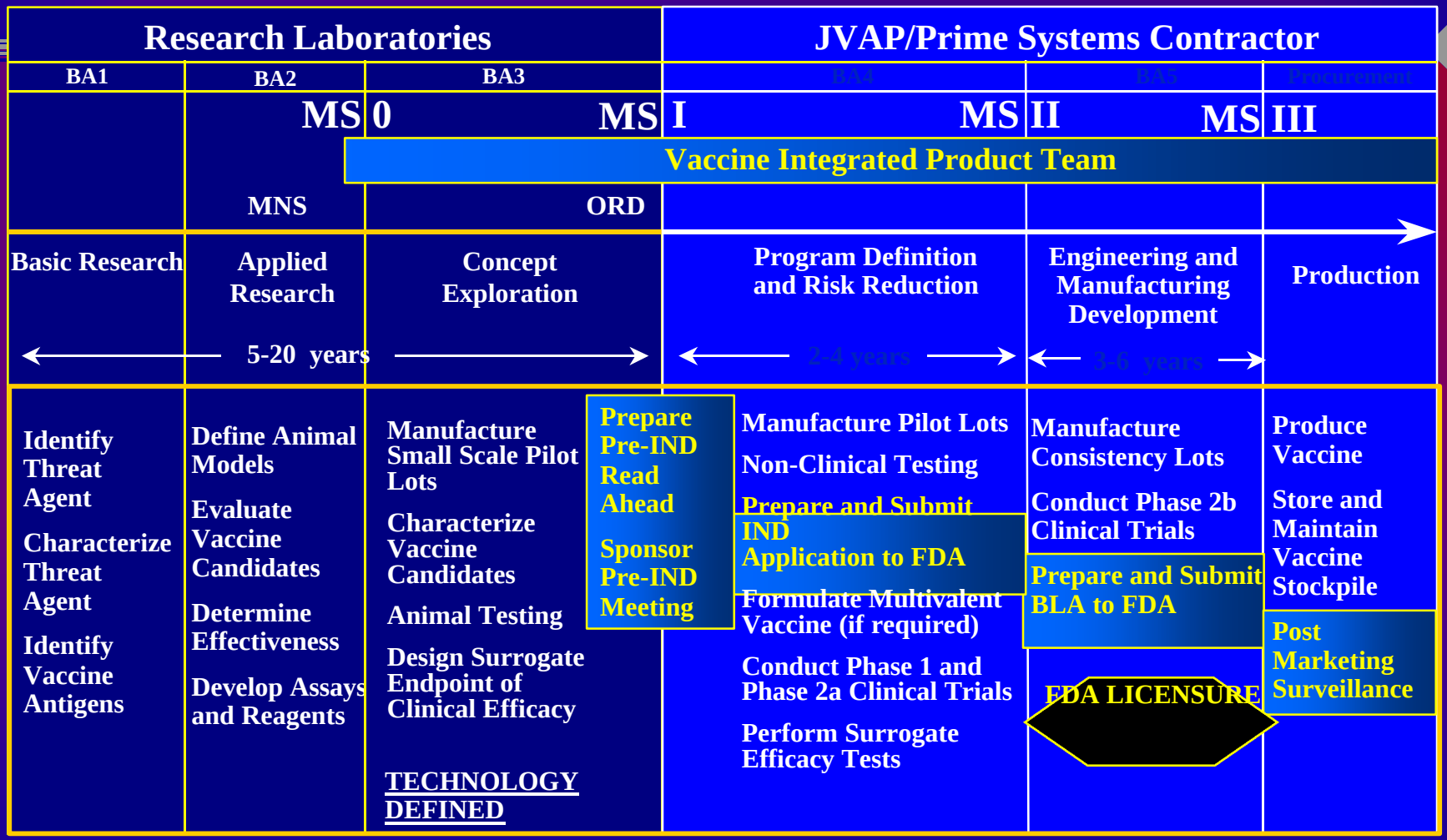
Strategic Challenges
Medical Chemical and Biological Defense RDT&E

- Acquisition Model
- FDA Regulations
- Multiplicity of Threats

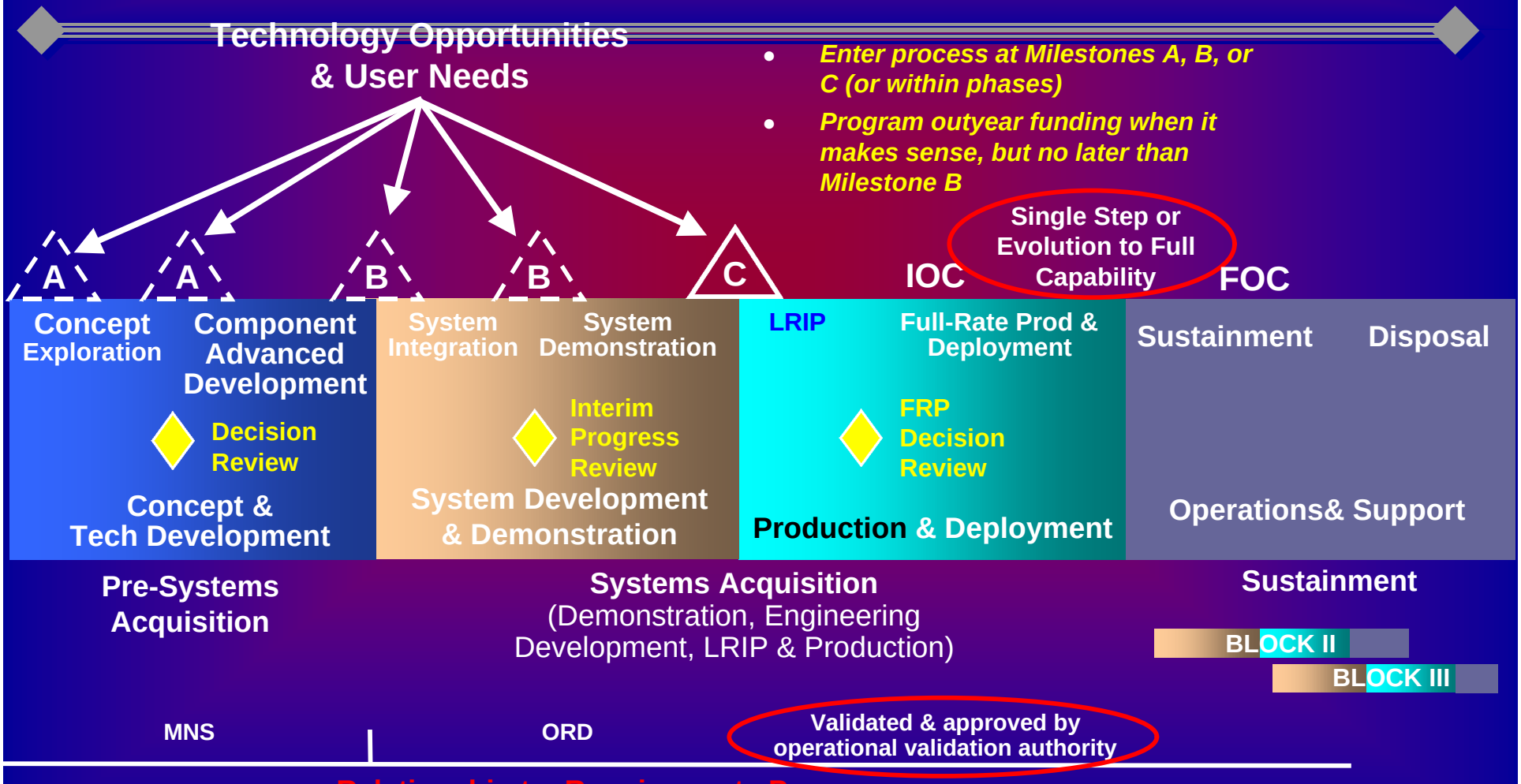
Strategic Challenges

- **Acquisition Model - Linear**
  - Old DoD 5000
  - New DoD 5000
  - Technology Readiness Levels
  - Risk Reduction
- **Biologicals/Pharmaceuticals – Recursive**
  - Iterative testing of numerous candidates
  - Kill products early
  - Finite lifetime

Integration of DoD Milestones and FDA Licensure Process



Defense Acquisition Management Framework



Strategic Challenges

- **FDA Regulatory Requirements**
  - Products must be safe
    - Demonstrate in animals
    - Demonstrate in humans
  - Products must be effective
    - Demonstrate in animals
    - Demonstrate in human clinical studies and field trials
- **Medical Chem/Bio Products – we can:**
  - Demonstrate safety in animals and humans
  - Demonstrate efficacy in animals
  - Estimate efficacy in humans

Strategic Challenges

- **Proposed new FDA Rule**
  - Allows consideration of animal efficacy studies in support of licensure request
  - Additional requirements
    - Understand mechanisms of action of the disease-causing agent
    - Understand basis of action of the vaccine or drug
    - Demonstrate efficacy in two relevant animal models
    - Identify surrogate markers of efficacy

Strategic Challenges

- **Multiplicity of Threats**
  - Chemical Warfare Agents
    - Nerve agents
    - Mustards
    - Blood/Choking agents
  - Biological Warfare Agents
    - Viruses
    - Bacteria
    - Toxins
  - Emerging Threats

Summary

- Medical chemical and biological defense research presents unique challenges
  - Chemical threat agents
  - Biological threat agents
  - Medical regulatory compliance and DoD acquisition
- We need cutting edge technologies to develop medical countermeasures for the warfighter
  - Biotechnology
  - Informatics
  - Genomics and Proteomics
- Partnerships with the science community & industry are essential
  - CRADAs
  - Contracts