Our Vision is a U.S. military force that is fully sustained to fight and win in any CBRN battlespace worldwide.

Chemical Biological Medical Systems Overview

May 18, 2011

Presented to:
CBRN Survivability for Weapon Systems Conference
National Defense Industrial Association (NDIA)

LTC Philip L. Smith
Joint Product Manager
Joint Vaccine Acquisition Program (JVAP)
Chemical Biological Medical Systems (CBMS)
philip.l.smith@us.army.mil
Agenda
CBMS Overview

• Mission/Organization
• Core Competencies
• Warfighter Needs
• Integrated DoD Acquisition & FDA Regulatory Processes
• Product Development
• CBMS Products
• Medical Capabilities
• Take Aways
Meeting the Warfighter needs through the development of FDA-approved products

Chemical Biological Medical Systems (CBMS) Organization

Deliver safe, effective and robust medical products that protect U.S. forces against validated CBRN threats. We apply government and industry best practices to develop or acquire FDA-approved products within rigorously managed cost, schedule and performance constraints.

Develop, produce & stockpile FDA-Licensed vaccine systems to protect the Warfighter from biological agents.

Develop and integrate chemical, biological, radiological, and nuclear (CBRN) technologies to enable early warning, identification, and continued situational awareness of potential global health threats.

Rapidly provide the Warfighter and the Nation robust & affordable FDA-approved lifesaving medical countermeasure drug capabilities against chemical, biological, radiological & nuclear threats.
1355 Person Years of Advanced Drug Development Experience
All functional units are co-located!

- Pharmaceutical Development
- Assay Development
- Manufacturing

- Science
  - 324 Years
  - Pharmacological Development
  - Assay Development
  - Manufacturing

- Acquisition/Program Management
  - 316 Years
  - DoD 5000.02
  - Risk Management
  - Life Cycle Management

- Life Cycle Logistics
  - 110 Years
  - FDA
  - Biosurety
  - PESHE

- Operations
  - 224 Years
  - Regulatory
  - Contracts/Legal
  - Finance
  - DoD 5000.02
  - Risk Management
  - Life Cycle Management

- Finance
  - 92 Years
  - PPBES
  - EVMS
  - Cost Analysis

- Contracts/Legal
  - 162 Years
  - Intellectual Property
  - Industrial Base
  - International/Interagency
Acquisition Documents
- Initial Capabilities Document (ICD)
- Capability Development Document (CDD)
- Capability Production Document (CPD)
- Key Performance Parameter = FDA Licensure
Animal Rule vaccine development requires integrated clinical and non-clinical programs.

- Allows for approval of products in which efficacy testing in humans is unethical
- Extensive Animal Model Development
  - Efficacy is demonstrated in more than one, well defined animal model
  - Well controlled animal studies provide data that are likely to predict a benefit in humans
### Integration of DoD Acquisition Model & FDA Regulatory Process

<table>
<thead>
<tr>
<th>MRL 1 - 4</th>
<th>MRL 5 - 6</th>
<th>MRL 7 - 8</th>
<th>MRL 9</th>
<th>MRL 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRL 1 - 4</td>
<td>TRL 5 - 6</td>
<td>TRL 7</td>
<td>TRL 8</td>
<td>TRL 9</td>
</tr>
</tbody>
</table>

#### DoD
- Materiel Solution Analysis
- Technology Development
- Engineering & Manufacturing Development
- Production & Deployment
- Operations & Support

#### FDA
- Research/Discovery
- Pre-Clinical/Clinical Development
- Clinical Development
- Regulatory Submission
- Post Licensure

### Milestone A
- IND Submission - Product Commitment
  - **DoD 5000.02 Documentation**
    - ICD
    - TDS
    - AoA
  - Process Development & Pilot Lot Production
  - Manufacturing Scale Up
  - Clinical Assay Development
  - Phase 1 Human Trials (safety)
  - Animal Efficacy Trials
  - Animal Efficacy Trials

### Milestone B
- DoD 5000.02 Documentation
  - Validation & Demo Lots
  - Consistency Lots
  - Phase 2 Human Trials (safety/dose/schedule)
  - Phase 3 Human Trials (expanded safety)
  - Pivotal Animal Efficacy Studies

### Milestone C
- FRP (Drugs) - Full Rate Production
- LRIP (Vaccines) - Low Rate Initial Production
- Biologic License Agreement
- BLA - FDA Review
- Licensure

### DoD 5000.02 Documentation
- • CDD
- • LCMP
- • APB
- • etc.

### FDA
- Development timelines are in line with industry standard
- The product sponsor is the only direct interface with the FDA
- DoD has no special relationship with the FDA
- TRLs agreed to by DoD and HHS

---

**LEGEND:**
- **DoD** = Manufacturing Readiness Levels
- **FDA** = Technology Readiness Levels

---

20110518 CBMS Overview Briefing to NDIA
CBMS Products

- **Joint Vaccine Acquisition Program (JVAP)**
  - Anthrax Vaccine Adsorbed
  - Filovirus Vaccine
  - Plague Vaccine
  - Recombinant Botulinum A/B Vaccine
  - Smallpox Vaccine
  - Vaccinia Immune Globulin

- **Biosurveillance**
  - Critical Reagents Program (CRP)
  - Joint Biological Agent Identification & Diagnostic (JBAIDS)
  - Next Generation Diagnostic System (NGDS)

- **Medical Identification & Treatment Systems (MITS)**
  - Advanced Anticonvulsant System (AAS)
  - Bioscavenger
  - Centrally Acting Nerve Agent Treatment System (CANATS)
  - Improved Nerve Agent Treatment System (INATS)
  - Inhalation Atropine (IA)
  - Medical Radiation Countermeasures (MRADC)
## Medical Capabilities Delivered to the Warfighter

### Partner Inputs:
- 8 – Capability Transition Agreements (CTAs)
- 8 – Technology Transition Agreements (TTAs)
- 73 – Assays for Pre-Emergency Use Authorization (EUAs)
- 8 – Relevant Congressional Special Interest Projects (CSIs)

### CBMS Expertise:
- 14 – Investigational New Drugs (INDs)
- 13 – Phase 1 Clinical Trials
- 8 – Phase 2 Clinical Trials
- 1 – Phase 3 Clinical Trials
- 3 – Phase 4 Clinical Trials
- 8 – Food & Drug Administration (FDA) Approvals
  - 1 – New Drug Application (NDA)
  - 1 – Biological License Application (BLA)
  - 6 – 510(k)s

### Results in Fielded Products:
- **CANA 4.4M**: Convulsant Antidote for Nerve Agents
- **ATNAA 6.4M**: Antidote Treatment Nerve Agent Autoinjector
- **SNAPP 421.6K**: Soman Nerve Agent Pretreatment Pyridostigmine
- **CRP Assay Kits: ECL 2.7K**: Critical Reagents Program Assay Kits: Electrochemiluminescence
- **JBAIDS Platforms 316**: Joint Biological Agent Identification Diagnostic System
- **JBAIDS Assay Kits 316**: Critical Reagents Program (CRP) Assay Kits: Lateral Flow Immunoassays (LFI)
- **AV A Doses 11.3M**: Anthrax Vaccine Adsorbed
- **VIG Doses 48**: Vaccinia Immune Globulin
- **SPX Doses 3.7M**: Smallpox Vaccine
- **CRP Assay Kits: PCR 29.1K**: Critical Reagents Program (CRP) Assay Kits: Polymerase Chain Reaction (PCR)
Take Aways

• CBMS protects the Warfighter by developing and delivering FDA licensed CBRN medical countermeasures

• Focus on shortening the requirement to fielding timeline
  – Partnering with international and other government agencies
  – Using DoD and industry best practices
    • Seamless transition from Science & Technology to Advanced Development
  – Total Life Cycle management

• Successes from FY2002 to date
  – 8 Food & Drug Administration (FDA) Approvals
  – 14 Investigational New Drugs (INDs)
  – 1 Emergency Use Authorization (EUA)
  – 73 Pre-Positioned EUAs

• 12 FDA Approvals in the next 5 Years
COL Charles B. Millard
Joint Project Manager, CBMS
301-619-7400
charles.b.millard@us.army.mil

Dr. Edward T. Clayson
Deputy, Joint Project Manager, CBMS
301-619-7400
edward.clayson@us.army.mil