

**UNCLASSIFIED**



# Joint Program Executive Office for Chemical and Biological Defense

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## Chemical Biological Medical Systems BARDA Industry Day

**DR. ANTHONY MACALUSO**  
CBMS/JPEO-CBD

**December 10, 2012**

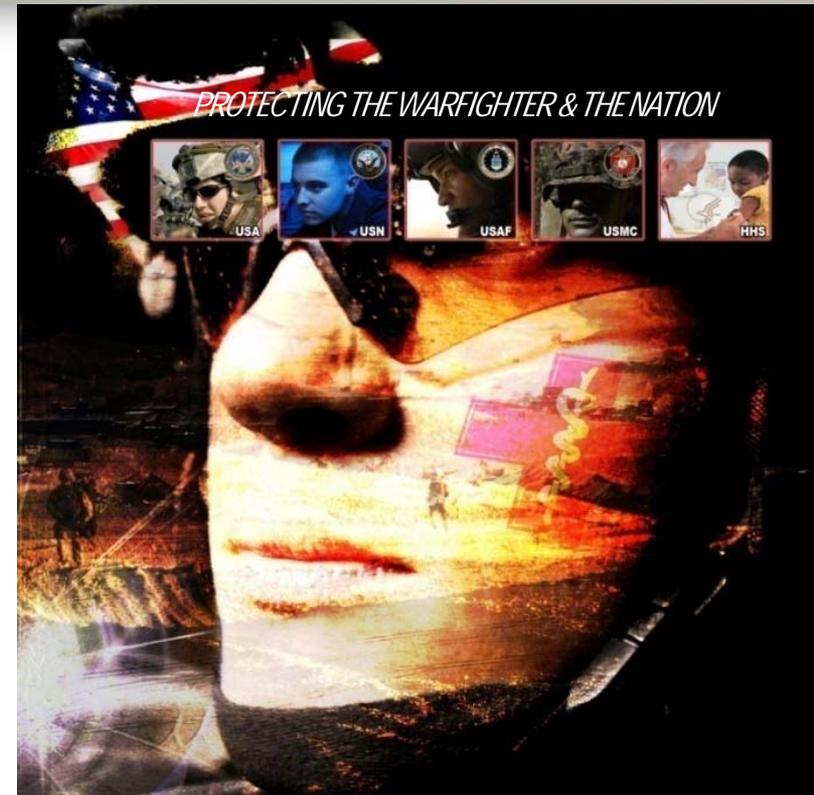


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# Agenda

- Overview
- S&T and Warfighter Needs
- Technical Challenges
- Acquisition Strategy / Funding / Schedule
- Upcoming Business Opportunities
- Contacts





# Warfighter Needs

- **Medical Priorities from the Chemical Biological Defense Program 2012 Joint Priority List (JPL)**
  - **FDA Approved**
    - **Prophylaxis**
      - Biological Prophylaxis
      - Chemical Prophylaxis
      - Radiological Prophylaxis
    - **Medical Diagnosis**
    - **Therapeutics**
      - Biological Therapeutics
      - Chemical Therapeutics
      - Radiological Therapeutics





# U.S. Military Needs

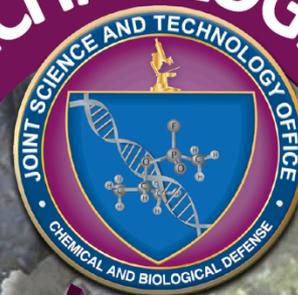
## REQUIREMENTS



### Capability Documents

- ✓ Initial Capabilities Document (ICD)
- ✓ Capability Development Document (CDD)
- ✓ Capability Production Document (CPD)
- ✓ Key Performance Parameter = FDA Licensure

## TECHNOLOGIES



### Technology Agreements

- ✓ Capability Technology Agreement (CTA)
- ✓ Technology Transition Agreement (TTA)



**SAFE & EFFECTIVE FDA APPROVED PRODUCTS**



# CBMS Past Successes



- 2002** Anthrax Vaccine Adsorbed
- 2003** Soman Nerve Agent Pretreatment Pyridostigmine
- 2003** Reactive Skin Decontamination Lotion
- 2005** Vaccinia Immune Globulin - Intravenous
- 2005** JBAIDS Anthrax Diagnostic Assay
- 2007** JBAIDS Tularemia Diagnostic Assay
- 2007** JBAIDS Plague Diagnostic Assay
- 2010** JBAIDS H5N1 Influenza Diagnostic Assay
- 2011** JBAIDS Q-Fever Diagnostic Assay
- 2011** JBAIDS A/B Influenza Typing Kit
- 2011** JBAIDS A Influenza Sub-Typing Kit



*FDA Licensed, Approved, or Cleared Products*





# Chemical Biological Medical Systems

## *Vision & Mission*

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



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.



# CBMS Current Advanced Development Efforts

- **CBMS products are integrated into the DoD “System of Systems” approach by providing the medical materiel solutions required to protect, diagnose and treat Service Members exposed to the effects of CBRN agents**
  - **Joint Vaccine Acquisition Program (CBMS-JVAP)**
    - **Develop, produce, and stockpile FDA-licensed vaccine systems to protect the Warfighter from biological agents**
  - **Medical Identification & Treatment Systems (CBMS-MITS)**
    - **Rapidly provide the Warfighter and the Nation robust & affordable FDA-approved lifesaving medical countermeasure drug capabilities against chemical, biological, radiological and nuclear threats**
  - **Biosurveillance (CBMS-BSV)**
    - **Develop and integrate chemical, biological, radiological, and nuclear (CBRN) technologies to enable early warning, identification, and continued situational awareness of potential global health threats**



# CBMS Current Advanced Development Efforts (cont.)

- **Biological Prophylaxis**
  - **CBMS-JVAP partners with DynPort Vaccine Company (DVC) using the prime systems contractor approach to**
    - **Obtains and maintains FDA licenses**
    - **Recombinant Botulinum Toxin A/B Vaccine Program (rBV A/B)**
    - **Recombinant Plague Vaccine**
  - **CBMS-JVAP serves as the integrator role for the following vaccines**
    - **Filovirus Vaccine**
    - **Ricin Vaccine**
    - **Western Eastern Venezuelan Equine Encephalitis (WEVEE) Vaccine**
- **Chemical Prophylaxis**
  - **Bioscavenger is a broad spectrum prophylactic that protects against toxic nerve agent induced incapacitation and death**



# CBMS Current Advanced Development Efforts (cont.)

- **Medical Diagnostics**
  - **Joint Biological Agent Identification and Diagnostic System (JBAIDS)** provides portable diagnostic capability to warfighter
    - System capable of identifying 10 Biological Warfare Agents (BWAs)
    - Ongoing effort to optimize food and water pathogen assays
  - **Next Generation Diagnostic System** is an evolutionary acquisition program that will provide increments of capability across the Combat Health Support, environmental surveillance and the CBRN community
    - Platform components; FDA clearance for diagnostic components
    - Low complexity, low-resource components
    - Enabling components (screening, collection and preservation tools)
    - Range of threats include endemic, emerging and re-emerging Infectious Diseases (ID) of military importance and traditional and bio-engineered BWAs
  - **Critical Reagents Program (CRP)** provides biological threat agent and genomic reference material as well as assays for fielded systems
    - Over 200 strains in inventory



# CBMS Current Advanced Development Efforts (cont.)

- **Radiological Therapeutics**
  - **Medical Radiation Countermeasure (MRADC)**
    - Several countermeasures will be required to treat the spectrum of acute radiation syndrome (ARS) injuries
    - With HHS as the US Government lead in developing MRADC, the DoD will leverage HHS efforts on both gastrointestinal and hematopoietic sub-syndromes of ARS to fully meet broad spectrum protection
      - DoD is currently investigating a GI-ARS capability
      - DoD will also investigate prophylactic prototypes as HHS does not have a prophylaxis requirement
- **Chemical Therapeutics**
  - **Advanced Anticonvulsant System (AAS) will replace Convulsant Antidote Nerve Agent (CANA) system**
  - **Improved Nerve Agent Treatment System (INATS) active ingredient will replace and provide better protection than the fielded oxime, 2-PAM**



# CBMS Technical Challenges

- **Leverage emerging technology to accelerate development**
- **Adapt to evolving FDA Guidance**
  - Animal Rule
  - Large scale manufacturing process validation
  - Leverage FDA Action Teams to facilitate mutual understanding of product concepts of employment
- **Sustain industrial base/infrastructure**
- **Comply with biosurety requirements for BSL 3/4 commercial facilities**
- **Ensure product specifications are fully compatible with medical logistics/sustainment needs of diverse military operations**
- **Enhance product thermostability/increased drug formulation stability**
- **Develop alternate delivery platforms to reduce number of injections**
- **Leverage interagency involvement to assist with diagnostic clinical trials**



# Advanced Development Product Portfolio

MDD MSA MSB MSC (LRIP)

JPM	CAPABILITY	PRODUCT	IND	PHASE 1	PHASE 2	PHASE 3	BLA	NEXT MS	FDA LICENSURE
	Prophylaxis Vaccines	Recombinant Botulinum A/B Vaccine						MSC 2013	2016
		Plague Vaccine						MSC 2013	2016
		Filovirus Vaccine						MS B 2015	2025
		Ricin Vaccine						MS A 2013	2024
		WEVEE Vaccine						MS A 2013	2024

MDD MSA MSB MSC (LRIP)

JPM	CAPABILITY	PRODUCT	DEVELOPMENT	PRE-CLINICAL	ANALYTICAL	CLINICAL	510K	NEXT MS	FDA CLEARED
	Diagnostics Devices	Next Generation Diagnostic System – Increment 1						MSC 2015	2014
		Next Generation Diagnostic System – Increment 2						MS A 2013	TBD
		Joint Biological Agent Identification & Diagnostic System						★	★
		JBAIDS Pre-EUA Diagnostic Kit: Typhus						Pre-EUA	2013
		JBAIDS Pre-EUA Diagnostic Kit: Burkholderia/Melioidosis						Pre-EUA	2013
	Environmental Detection	Food & Water Pathogens						FRP	N/A

MDD MSA MSB MSC (FRP)

JPM	CAPABILITY	PRODUCT	IND	PHASE 1	PHASE 2	PHASE 3	NDA	NEXT MS	FDA APPROVAL
	Prophylaxis/Pretreatment/Treatment Drugs	Advanced Anticonvulsant System						MSC 2013	2014
		Bioscavenger						MSC 2017	2019
		Medical Radiation Countermeasures						MS B 2018	TBD
		Improvement Nerve Agent Treatment System						MS B 2014	2018
		Centrally Acting Nerve Agent Treatment System						MS A 2015	TBD

As of Date: 09/26/12

LEGEND: JVAP BSV MITS DoD FDA ★ = FDA Cleared



# CBMS FY13-17 Funding\*

\$K	FY13	FY14	FY15	FY16	FY17	TOTAL
<b>CBMS</b>						
<b>BA4/5/7</b>	\$ 192,477	\$ 361,576	\$ 293,520	\$ 276,215	\$ 264,385	\$ 1,388,173
<b>PROC</b>	\$ 32,597	\$ 28,598	\$ 20,960	\$ 22,519	\$ 36,669	\$ 141,343
<b>Total</b>	\$ 225,074	\$ 390,174	\$ 314,480	\$ 298,734	\$ 301,054	\$ 1,529,516

BA4 = Pre-Milestone B  
 BA5 = Post-Milestone B

FY13 include RECLAMA CUTS (Aug 18, 2012)

\*Data derived from FY13 BES (Presidents Budget) scenario.



# CBMS Program Upcoming Business Opportunities

Program	Description	Year
<b><i>CBMS - Broad Agency Announcement</i></b>		
<b>Broad Agency Announcement: Chemical Biological Medical Radiological and Nuclear Countermeasure Research &amp; Development (CBMS BAA)</b>	<a href="http://www.smdc.army.mil/2008/CAMO-BAA.asp">http://www.smdc.army.mil/2008/CAMO-BAA.asp</a>	<b>Ongoing</b>
<b><i>Request For Proposal</i></b>		
<b>Filovirus Vaccine Program</b>	Process development, manufacturing, and Phase 1 clinical testing for filovirus vaccine (multiple RFPs anticipated) <a href="http://www.fbo.gov">http://www.fbo.gov</a>	<b>FY13-15</b>
<b>Ricin Vaccine Program</b>	Process development, manufacturing, and Phase 1 clinical testing for filovirus vaccine (multiple RFPs anticipated) <a href="http://www.fbo.gov">http://www.fbo.gov</a>	<b>FY13-16</b>
<b>WEVEE Vaccine Program</b>	Process development, manufacturing, and Phase 1 clinical testing for filovirus vaccine (multiple RFPs anticipated) <a href="http://www.fbo.gov">http://www.fbo.gov</a>	<b>FY13-16</b>
<b>Centrally Acting Nerve Agent Treatment System (CANATS)</b>	CANATS encompasses the addition of centrally-acting therapeutics to the current or future nerve agent antidote treatment regimens to improve the efficacy against traditional nerve agents and NTAs. RFI release 2QFY14 and RFP anticipated 1QFY15 for candidate development through Food and Drug Administration approval. <a href="http://www.fbo.gov">http://www.fbo.gov</a>	<b>FY14-15</b>
<b>Improved Nerve Agent Treatment Systems (INATS)</b>	Advanced development of an improved oxime and additional indications for pyridostigmine bromide to support use against traditional nerve agents and NTAs. Anticipated RFI release date 2QFY13; RFP release late FY13. <a href="http://www.fbo.gov">www.fbo.gov</a>	<b>FY14-FY19</b>



# JPEO – CBD Virtual Industry Day



- **Thursday, November 15, 2012**
- **JPEO-CBD participants:**
  - Chemical Biological Medical Systems
  - Transformational Medical Technologies
- **[www3.natick.army.mil/JPEO-CBD/](http://www3.natick.army.mil/JPEO-CBD/)**
- **RSVP by: Friday, November 9, 2012**
- **POC: LTC Nanette Patton**
  - **[Nanette.s.patton.mil@mail.mil](mailto:Nanette.s.patton.mil@mail.mil)**



# CBMS Points of Contact

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**CBMS Medical CBRN Broad Agency Announcement: <http://www.smdc.army.mil/2008/CAMO-BAA.asp>**