

UNCLASSIFIED

Joint Program Executive Office for Chemical and Biological Defense Medical Virtual Industry Day

Joint Program Executive Office for Chemical and Biological Defense

Joint Vaccine Acquisition Program (JVAP) Overview

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Distribution Statement A: Approved for public release; distribution is unlimited.



Disclaimer



- **While we are presenting our currently planned Business Opportunities, we recognize that these may change given our changing fiscal environment and the strategic guidance of the Department of the Defense.**
- **New starts and increases to production levels in FY13 will be delayed until the Appropriations Bill is passed.**



JVAP Organizational Structure



MR DAVID HOUGH
TMT



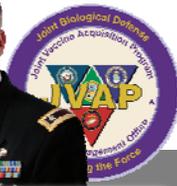
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LTC NANETTE PATTON
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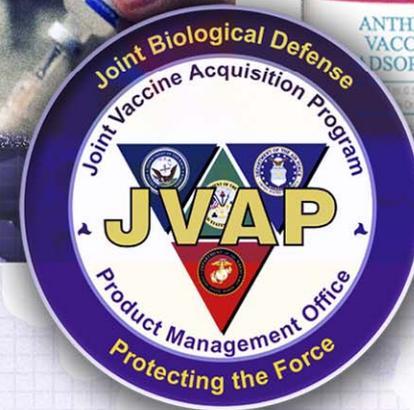


JVAP Mission/Vision



MISSION:

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



Biodefense Medical Countermeasures

Pre-Event

Post-Event



CURRENT

FUTURE



ANTHRAX VACCINE ADSORBED
AVA

VIG IV VACCINIA IMMUNE GLOBULIN



SPX SMALLPOX VACCINE



PLG PLAGUE VACCINE

BOT BOTULINUM VACCINE

FILO FILOVIRUS VACCINE

WEEVEE WESTERN EASTERN VENEZUELAN EQUINE ENCEPHALITIS VACCINE

RIC RICIN VACCINE





Biological Defense Medical Products

Vaccine Products-Fielded, Development, Planned



- **Fielded Vaccine Systems**
 - Anthrax Vaccine Adsorbed (AVA)
 - Smallpox Vaccine (SPX)
 - Vaccinia Immune Globulin (VIG IV)
- **Developmental Vaccines**
 - Recombinant Botulinum Vaccine (BOT) /FY2016
 - Recombinant Plague Vaccine (PLA) /FY2016
 - Trivalent Filovirus Vaccine (FILO) /FY2024
- **Funded New-Start Vaccines (FY13)**
 - Ricin Vaccine
 - Western/Eastern/Venezuelan Equine Encephalitis Vaccine (WEVEE)





Biological Defense Medical Products

Products in Advanced Development



- **Recombinant Botulinum Vaccine (rBV)**
 - Will protect the Warfighter against weaponized Botulinum toxin
 - BOT Program (serotypes A1 & B2)
 - Phase 2 clinical trial – complete
 - Phase 3 clinical trial to begin 3QFY13
 - Manufacturing process in final validation
- **Plague Vaccine (PLA)**
 - Will protect the Warfighter against weaponized pneumonic plague
 - Plague Vaccine Program
 - Phase 2a clinical trial - complete
 - Phase 2b clinical trial started in August 2010
 - International collaboration - US, UK, and Canada
 - New PA signed 1QFY10
 - MOA for information sharing with NIAID for product neutral animal model and assay development



International partnerships and intra-governmental MOAs contribute to program advances



Biological Defense Medical Products

Products in Advanced Development (cont.)



- **Filovirus Vaccine (FILO)**
 - Will protect the Warfighter against weaponized Ebola & Marburg Filoviruses
 - Pre-clinical competitive prototyping
- **Ricin Vaccine**
 - Will protect the Warfighter against weaponized ricin toxin
 - Recombinant vaccine candidates currently in Phase 1 clinical trials
- **Western/Eastern/Venezuelan Equine Encephalitis Vaccine (WEVEE)**
 - Will protect the Warfighter against weaponized Western/Eastern/Venezuelan Equine Encephalitis
 - Pre-clinical competitive prototyping
- **Requirements for vaccines in development expected to include parameters similar to other more mature developmental vaccines**
 - Efficacy
 - Onset and duration of protection
 - Shelf life





Supporting Science & Technology Efforts



SCIENCE & TECHNOLOGY

ADVANCED DEVELOPMENT

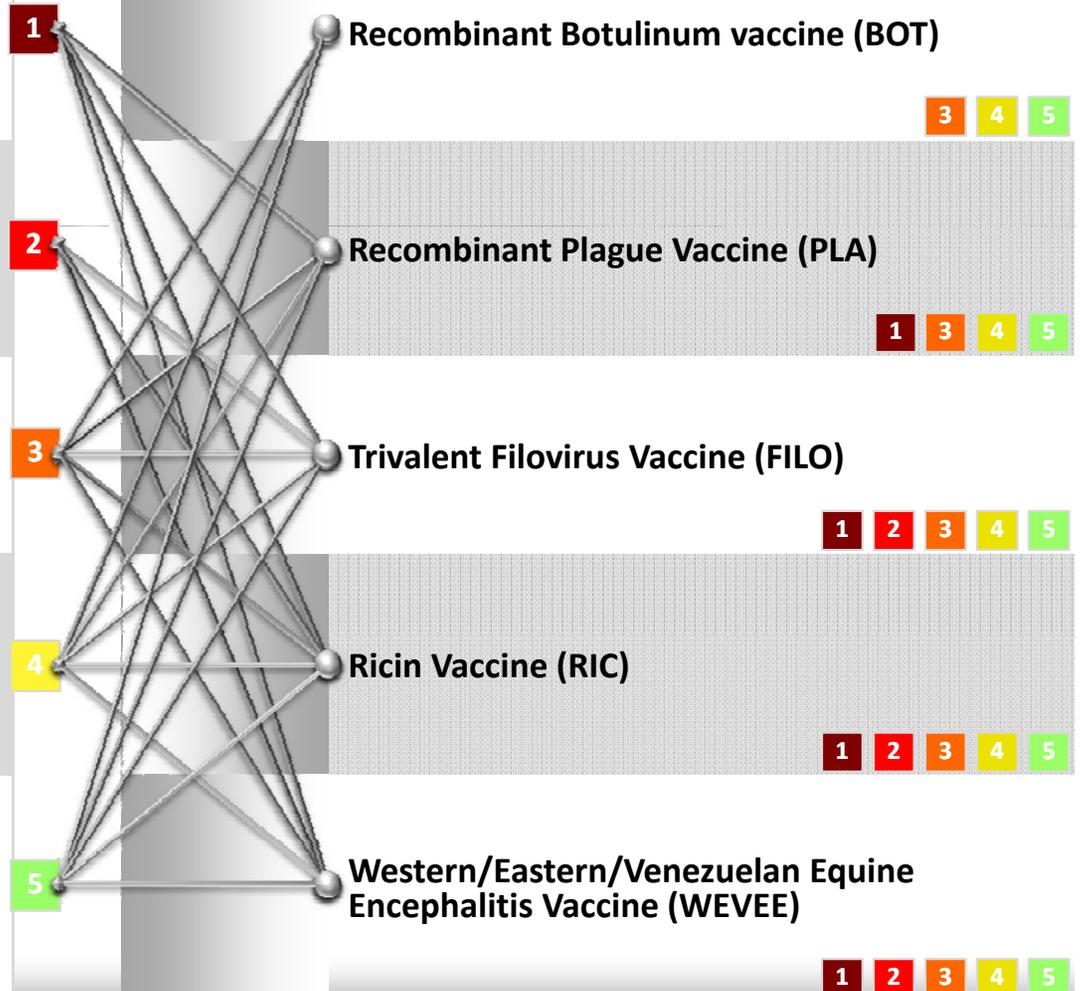
Initiate and develop assays to evaluate critical outcomes in animals and humans to establish a correlation of protection

Animal model development

Investigate other formulations to improve vaccine stability

Investigate other adjuvant formulations to elicit more rapid immune responses

Alternative routes of administration for vaccines





JVAP Partnerships



INDUSTRY

- Experienced Pharma Industry
- Dedicated Prime Contractors
- Small Biotechnology Companies
- Others

INTRA-AGENCY

- DTRA-JSTO
- U.S. AFHS
- USAMRMC
- Service Laboratories
- Service Hospitals
- ASD-Health Affairs
- DARPA
- Others

- Congressional Special Interests
- University Affiliated Research Centers

CONGRESSIONAL

- Health and Human Services
- Department of Homeland Security
- Others

INTERAGENCY

- Medical Countermeasures Working Group
- US/UK/CAN/AUS
- Many Others

INTERNATIONAL



Business Opportunities



- **CBMS Tech Watch Seminar Program**
- **CBMS Broad Agency Announcement (BAA)**
- **Unfunded Requirements (UFRs)**
- **Small Business Innovation Research (SBIR)**



JPM-JVAP Funding Profile FY14-18

Based on POM14 President's Budget



Adv Dev \$K	FY14	FY15	FY16	FY17	FY18	TOTAL
TOTAL	\$211,622	\$185,115	\$156,633	\$142,006	\$168,893	\$864,269



JVAP Points of Contact



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Acronym Glossary



ADM: Acquisition Decision Memorandum or Advanced Development & Manufacturing

AoA: Analysis of Alternatives

APUC: Acquisition Procurement Unit Cost

AS: Acquisition Strategy

BARDA: Biomedical Advanced Research and Development Authority

BBP: Better Buying Power

BLA: Biologics License Application

BSV: Biosurveillance

CBMS: Chemical Biological Medical Systems

CDD: Capability Development Document

CPD: Capability Production Document

cGMP: Current Good Manufacturing Practice

CONOPS: Concept of Operations

CPIF: Cost Plus Incentive Fee

DARPA: Defense Advanced Research Projects Agency

DHS: Department of Homeland Security

DoD: Department of Defense

DSTL: Defense Science Technology Laboratory

DTRA/JSTO: Defense Threat Reduction Agency/Joint Science and Technology Office

EMD: Engineering Manufacturing and Development

EPA: Environmental Protection Agency

FDA: US Food & Drug Administration

FFP: Fixed Firm Price

FOC: Full Operational Capability

FRP: Full Rate Production

FY: Fiscal Year

HHS: Health and Human Services

IBR: Integrated Baseline Review

ICD: Initial Capabilities Document

IND: Investigational New Drug

IOC: Initial Operational Capability

JILA: Joint Integrated Logistics Assessment

JPEO: Joint Program Executive Office(r)

JPM: Joint Project/Product Manager

JPM-ADM: Joint Project Manager- Advanced Development & Manufacturing

JPMO: Joint Project/Product Management Office

JRO-CBRND: Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense

JVAP: Joint Vaccine Acquisition Program

KPP: Key Performance Parameter

KSA: Key System Attribute

LCCE: Life Cycle Cost Estimate

LCMP: Life Cycle Management Plan

LCSP: Life Cycle Sustainment Plan

LRIP: Low Rate Initial Production

MDA: Milestone Decision Authority

MIT: Medical Identification and Treatment Systems

MS: Milestone

MSR: Manufacturing Sustainment Rate

NDA: New Drug Application

NGDS: Next Generation Diagnostic System

NIH: National Institutes of Health

NTA: Non-Traditional Agent

O&M: Operation and Maintenance

OASD (HA): Office of the Assistant Secretary of Defense (Health Affairs)

OGA: Other Government Agency

OSD (NCB/CB): Office of the Secretary of Defense (Nuclear/Chemical Biological)

OSTP: Office of Science and Technology Policy

OUSD(C): Office of the Under Secretary of Defense (Comptroller)

PAIO: Joint CBRN Defense Program Analysis Integration Office

RDT&E: Research, Development, Test and Evaluation

RFP: Request For Proposal

SEP: Systems Engineering Plan

SNS: Strategic National Stockpile

SPA: Special Protocol Assessment

TD: Technology Development

TDP: Technical Data Package

TED: Troop Equivalent Dose

THP: Trained Health Care Provider

TMT: Transformational Medical Technologies

TOA: Total Obligation Authority

TRA: Technology Readiness Assessment

TRL: Technology Readiness Level

USAMMDA: US Army Medical Materiel Development Activity

USAMRIID: US Army Medical Research Institute of Infectious Disease

USAMRICD: US Army Medical Research Institute of Chemical Defense

USAMRMC: US Army Medical Research and Materiel Command