

A whole of government approach to the ADMs



ADVANCED DEVELOPMENT AND MANUFACTURING TIGER TEAM FINDINGS



Michael Angelastro
Director (acting)
Pharmaceutical Countermeasures Infrastructure (PCI)
ASPR/BARDA
HHS

Timothy Belski
Director
Advanced Development & Manufacturing Capabilities (ADMc)
Medical Countermeasure Systems (MCS)
Joint Project Management Office
DoD

BUILDING AN ENDURING CAPABILITY

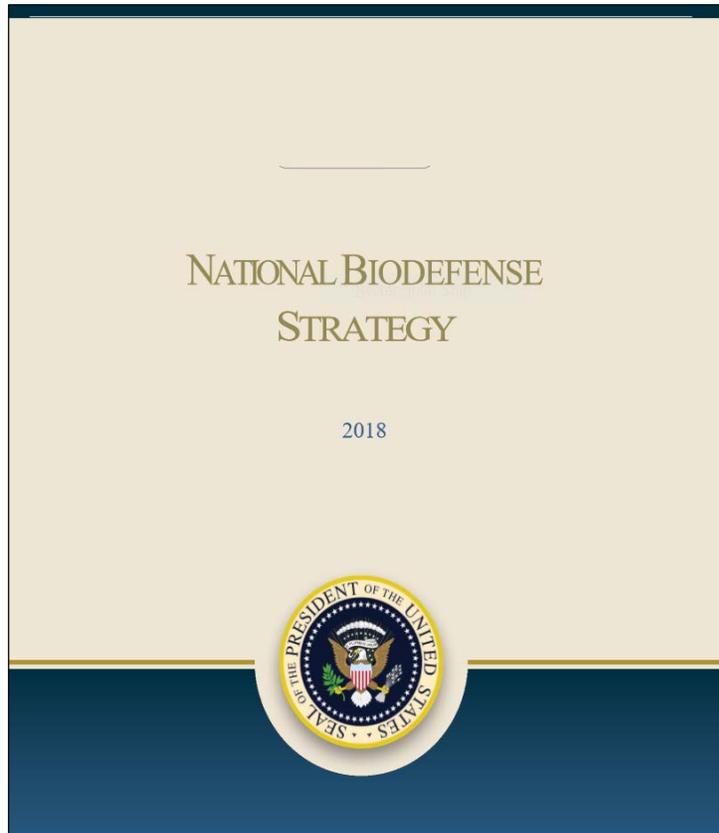
“Our Nation must have the **nimble, flexible capacity** to produce MCMs rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized, naturally occurring emerging infectious disease.”



*The Public Health Emergency Medical Countermeasures
Enterprise Review
August 2010*



BUILDING AN ENDURING CAPABILITY



“America’s biodefense enterprise needs to be nimble enough to address emerging infectious disease threats, the risks associated with the accelerating pace of biotechnology, and threats posed by terrorist groups or adversaries to use biological weapons.”

“The United States actively and effectively prevents, prepares for, responds to, recovers from and mitigates risk from natural, accidental, or deliberate biological threats.”

*National Biodefense Strategy
September 2018*

HHS CIADM REQUIREMENT

Centers for Innovation in Advanced Development and Manufacturing



Objectives

- Construct new or retrofitted facilities utilizing state-of-the-art flexible manufacturing approaches;
- Provide core services for the advanced development and manufacturing of CBRN biopharmaceutical countermeasures supported by the U.S. Government;
- Provide U.S.-based surge capacity to respond to an emerging infectious disease, pandemic influenza, and currently known or unknown threats; and
- Biopharmaceutical oriented workforce development through training programs aligned with current regulatory guidelines.

DOD ADMC REQUIREMENT

December 2010 White House Directive

1. Establish agile and flexible advanced development and manufacturing capabilities to support the development, licensure, and production of MCMs that address the needs of our military and the Nation.
2. Fund S&T efforts to develop the next generation of manufacturing systems and regulatory science technologies.
3. Establish a Medical Countermeasure Test and Evaluation (T&E) Facility to provide state-of-the-art capacity and services to address National demand for animal T&E studies and related requirements for product development.

“These efforts will build on existing MCM initiatives and programs in the Department of Health and Human Services and the Department of Defense, and the two Departments will work collaboratively and compliment each other’s efforts.



HHS AND DOD ADM INVESTMENTS



Total Base Period Capital Investment: \$602 M

ADM INFRASTRUCTURE

State-of-the-art Capacities

Seqirus Facility



*First “Cell-Based”
US Flu Vaccine Manufacturing Facility*



Base Period Improvements

- New clinical filling suite
- New Tech Services Bldg.
- Warehouse retrofit
- Process Improvements

ADM INFRASTRUCTURE

State-of-the-art Capacities

Texas A&M Facilities



- Pandemic Influenza
- Live Virus Vaccine
- NCTM Retrofit



**Workforce
Development**
*(established and
in progress)*



ADM INFRASTRUCTURE

State-of-the-art Capacities

Emergent Facility



Bayview Manufacturing Facility
56,000 SF | 3 9,000 SF GMP Suites



Ribbon Cutting May 2017



Flexible Single-Use Platform

Multi-product Manufacturing

- Live viral vaccines
- Cell culture
- Microbial
- Pilot scale facility

ADM INFRASTRUCTURE

State-of-the-art Capacities

Ology Facility



180,000 SF Manufacturing Facility

- Four processing rooms
- Single Use Technologies
- Modular Clean Room Design



Pilot Plant



Vector Development



BSL-3 Lab

ADM PROGRAM CHALLENGES

- **OPERATIONAL CAPABILITY** has not been adequately developed and must be prioritized going forward with a goal of ever increasing competency to meet biodefense MCM mission requirements.
- **CONTRACTUAL ARCHITECTURE** is completely inadequate under the existing prime/subcontractor structure and FAR-based contracting model.
- **SUSTAINMENT** of this infrastructure, using a mix of traditional core service activity from commercial clients and PHEMCE programs, has not been successful under the current architecture.



ADM TIGER TEAM

Charge

Propose recommendations and develop an interagency action plan to guide the future direction of the ADM programs

Goals

- Develop a 'whole of government' approach that exploits interdependencies among existing HHS & DoD capacity investments to respond to known, unknown and emerging threats for warfighter and civilian populations
- Leverage established technologies with reputable industry partners establishing capabilities that are positioned to accelerate MCM development and manufacturing
- Identify partnerships and contracting mechanisms that will most effectively support program sustainment



ADM TIGER TEAM

ACTIVITIES OVERVIEW

ADM Tiger Team Established

Michael Angelastro, BARDA Co-Lead
Timothy Belski, DoD Co-Lead

Keith Wells, Ph.D., BARDA SME
Mark Michalik, BARDA SME
Jean Hu-Primmer, FDA

Chris Southworth, DoD ADMC Support
Patricia Haigwood, BARDA CIADM Support
Barry Sayer, DoD ADMC Support

ADM Assessment Activities

Data Gathering

Discussions and Site Visits

- Emergent
- Ology
- Texas A&M
- Seqirus

Stakeholder Input / Landscape Analysis

- JVAP, JSTO
- PRISM
- DARPA
- SIP
- Biodefense Blue Ribbon Panel
- National Academies
- ASPR
- ASH
- WRAIR

Assessment of Key Inputs and Actions

Synthesis of Barriers and Potential Solutions

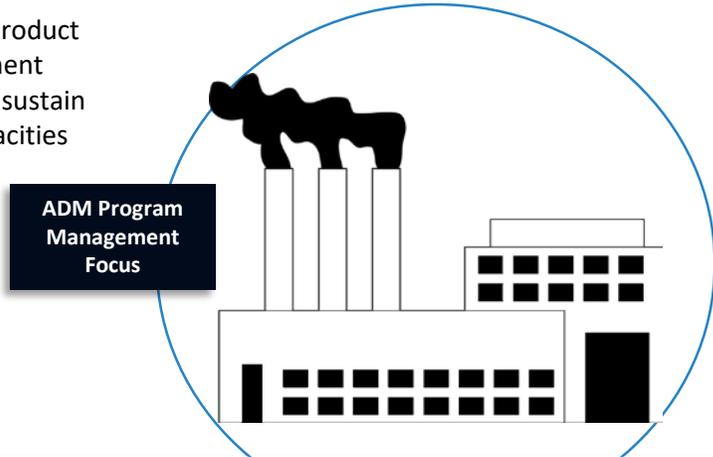
Lists are not all inclusive



CHANGING THE ADM PARADIGM

Current Approach: Forced Occupancy Focus

Funding product development efforts to sustain ADM capacities



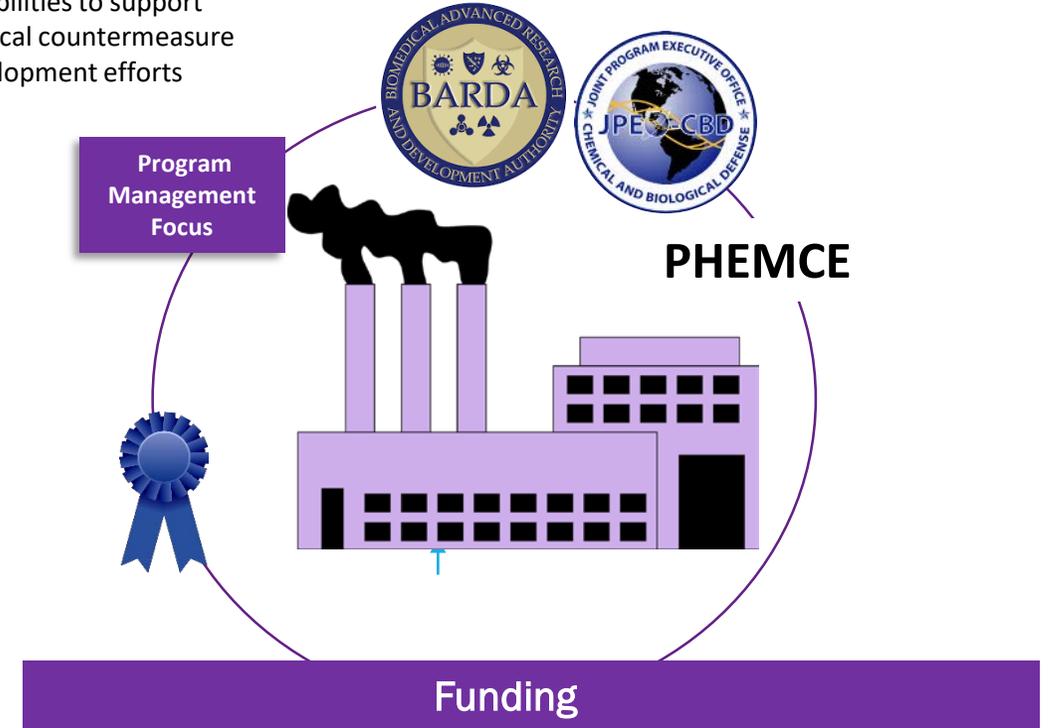
R&D Program Sustainment

Risk: Shifting priorities in capability building only go as far as the specific products that are planned.

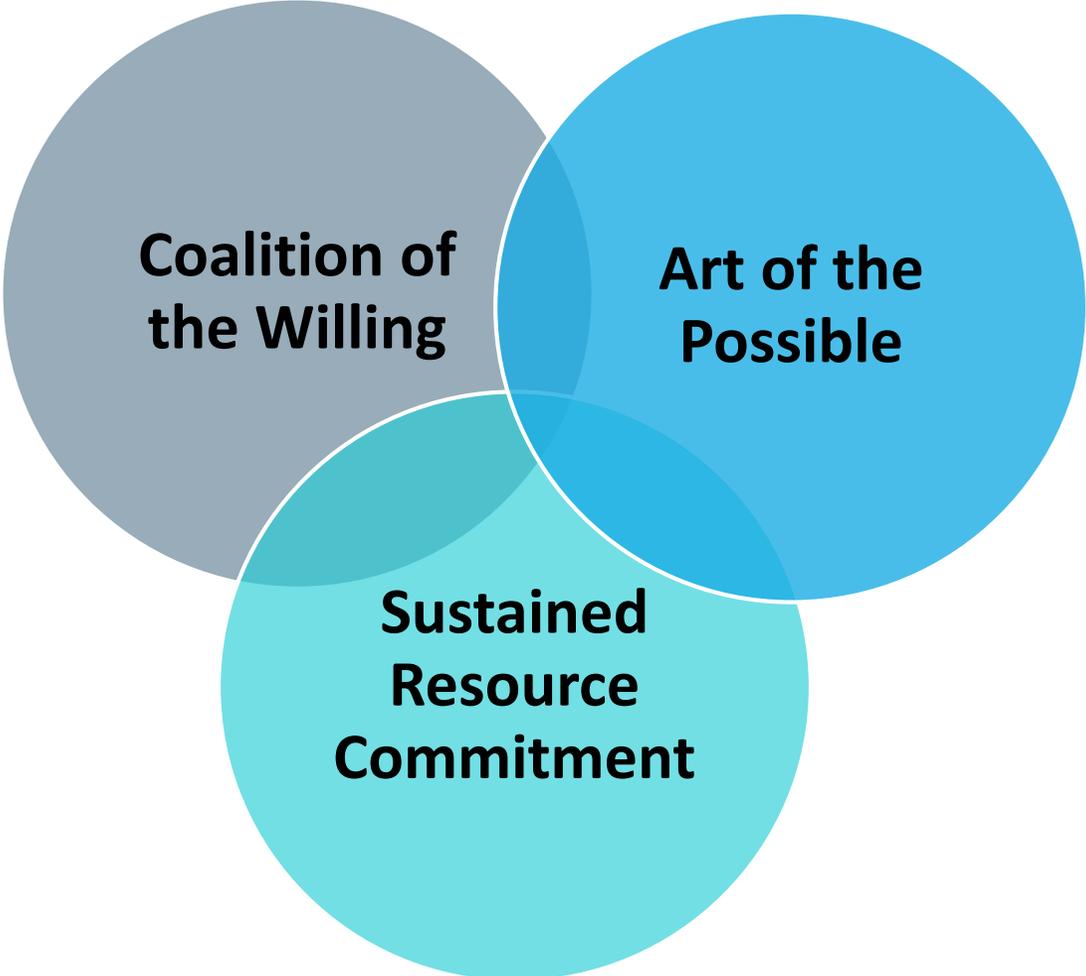
Risk: Limits the number of capabilities being added and create funding uncertainty.

Shift: Partnership Approach

Directly Funding ADM capabilities to support medical countermeasure development efforts

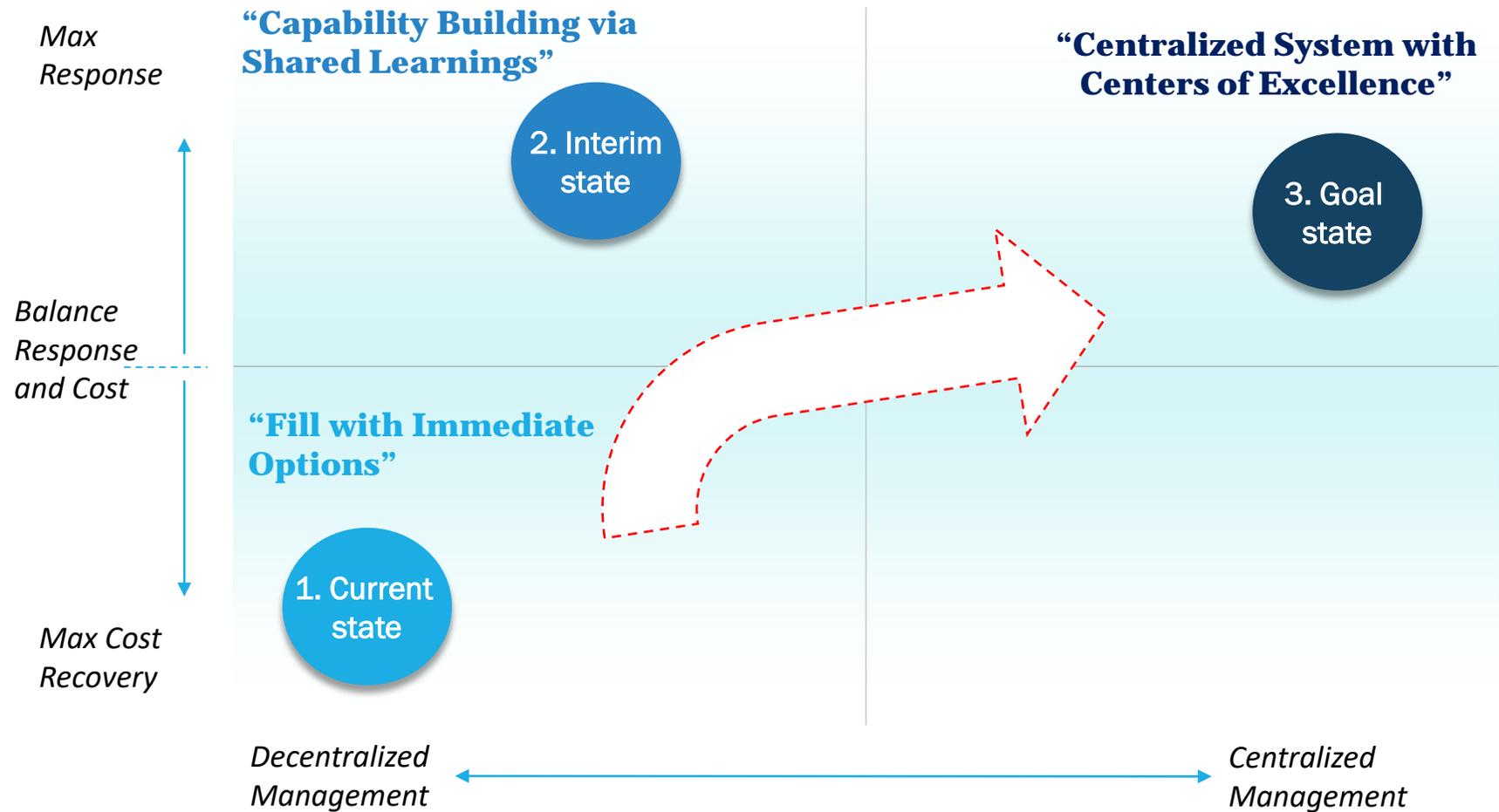


ADM PARTNERSHIP PRINCIPLES



TRANSFORMING CAPABILITIES

Balancing Response & Cost Coverage



ADVANCED DEVELOPMENT AND MANUFACTURING PARTNERSHIP

VISION: A Whole-of-Government *Innovation-Driven* Approach to Accelerating Development and Rapid Delivery of MCMs



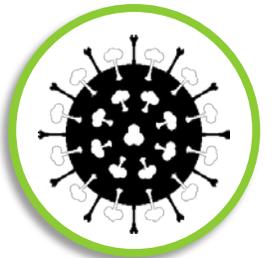
Building Momentum for MCM Innovation

Scout, recruit, evaluate, and transfer existing and future bioprocess technologies into a network of partners



Strengthening Partnerships

Innovative regulatory approaches to guide our partner organizations toward novel technologies



Leveraging Legacy Investments

Leverage infrastructure investments and proven expression systems complemented with the latest innovations in bioprocess science, engineering, and technology



Flexible Contracting

Speed-promoting contracting mechanisms to engage with all companies at the forefront of discovery.

PARTNERSHIP GOALS

ADM MODEL	PARTNERSHIP APPROACH
<ul style="list-style-type: none"> • ADM facilities worked independently 	<ul style="list-style-type: none"> • HHS and DOD will collaborate, create a 'whole of government approach'
<ul style="list-style-type: none"> • Funded industry partners were required to use ADM facilities for certain efforts 	<ul style="list-style-type: none"> • HHS and DOD will work with industry to provide incentives to use ADM facilities
<ul style="list-style-type: none"> • Any IP and legal challenges were left to the ADM facilities and industry partners to work out 	<ul style="list-style-type: none"> • All challenges (IP, legal issues, etc) will be worked on as a team with support from USG
<ul style="list-style-type: none"> • Product-focused 	<ul style="list-style-type: none"> • The ADM facilities will have the capability to handle a broad array of threats with proven technologies such as cell lines, adjuvants, and monoclonal antibody technologies
<ul style="list-style-type: none"> • Specific, often rigid, funding vehicle 	<ul style="list-style-type: none"> • Exploring alternate funding vehicles for ease of contracting for industry
<ul style="list-style-type: none"> • Challenges due to ADM facilities being constructed, staffed, standing up 	<ul style="list-style-type: none"> • Construction of all ADM facilities are complete and staffed with experienced manufacturing personal

