# SECTION 809 PANEL MEETINGS "GETTING ACCESS TO COMMERCIAL R&D"

# A PROGRAM PROSPECTIVE

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*Resilient People. Healthy Communities. A Nation Prepared.*

# Introduction

## Background

- **Tyler Merkeley MS, MBA, PMP,** is the co-founder of CARB-X and serves as the BARDA's CARB-X Program Manager. He joined BARDA in 2009 as a Health Scientist to accelerate the advanced research and development, procurement, stockpile and sustainment of medical countermeasures (MCM) against biological, chemical, radiological, and nuclear (CBRN) agents under Project BioShield.
- During his tenure at BARDA he has led the **smallpox antiviral procurement**, BARDA's Total Life Cycle **Costs containment initiative**, designed and launched HHS's Combating Antibiotic Resistant Bacteria (CARB) Accelerator **[CARB-X],** managed BARDA's 1st agreement using **Other Transaction Authority (OTA)** and served as the Acting Chief of Staff for BARDA

## Disclaimer

- My focus is on building novel public private R&D Partnerships
- I represent the program side of the house, not contracting
- The opinions expressed herein are my own and do not reflect the view of the Biomedical Advanced Research and Development Authority (BARDA), the Department of Health and Human Services, or the United States Government

# Objective

- Guidance from Section 809 panel was to:
  - Highlight BARDA's public private partnership business model to promote product innovation and enhance our nations public health preparedness and response capability
  - Highlight challenges we face when implementing innovative R&D efforts based on acquisition policy, practices and procedures

# BARDA's Mission

***Support advanced development of and make available medical countermeasures (MCM) for CBRN threats, pandemic influenza, and merging infectious diseases by transitioning MCM candidates from early development across the "Valley of Death" into advanced development to regulatory approval***

Medical Devices

Antimicrobials

Diagnostics

Vaccines

Therapeutics

# Business Model

- **What We Do:** Advanced development, evaluation, production, procurement, storage and testing of MCMs and reagents/standards
- **How We Do It:** Forming novel public private partnerships to promote R&D with Biotech and Pharma companies
- **Vehicles We Leverage:** The best vehicle [Grant/Acquisition/Agreement] to fit our tailored business needs to accomplish the mission

# The Model has supported the following FDA Approvals

## Cell-based Influenza Vaccine

FLUCELVAX Influenza Virus Vaccine

*Novartis*

## Influenza IV Antiviral Drug


BioCryst Pharmaceuticals, Inc.

## H1N1 & H5N1 Vaccines w/ Adjuvant


*GlaxoSmithKline*

## Next-Generation Portable Ventilators

*Covidian*

## Flu/RSV POC Diagnostic


## Recombinant-based Influenza Vaccine


*Protein Sciences Corp.*

## Botulinum Antitoxin

*Cangene*

## Anthrax Antitoxins


*HGS/GSK*


*Emergent*


*Amgen*



ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

# Finding the appropriate Vehicle to support the right partnership

BARDA leverages the following Vehicles to support R&D

- Broad Agency Announcement
- Request for Proposal
- Request for Task Order Response
- Purchase Order
- Interagency Agreement
- Grant and Cooperative Agreement
- Other Transaction Authority

# BAA Lessons Learned

Broad Agency Announcements (BAA) are a great vehicle for supporting advanced research and development (ARD) efforts

- Area of interests provide enough flexibility for industry partners to propose novel solutions with enough structure to ensure government can identify and support products to address our needs
- BAA require significant pre-award efforts by the Government/Industry
  - In a high attrition R&D environment (widgets, MCM) some program fail or are down selected rather quickly, resulting in excessive pre-award efforts
- BAA can be a platform to support rapid R&D response efforts, when the vehicle is available in advance

# OTA Lessons Learned

- OTA are great vehicles for R&D Portfolio Partnerships
  - OTA are not the solution for all our problems
    - They are not a “flexible” solution for forgoing pre-award acquisition planning
    - We should acknowledge OTA creates new risk for programs.
    - Must game plan out risk exposure prior to award
  - Internal policy for approval of OTA can be challenging
    - Delegation of authority via statue to lower level could remove layers of approval
  - Acquiring commercial partners with a 30-50% cost share to be compliant with Cost Accounting Standards (CAS) and implement EVM leads to questionable ROI
    - Could programs with cost share over XX% with less than XX% associated with labor, be given an exemption if their doing commercial R&D?
    - Could EVM be right sized to increase ROI to USG and Industry?
  - With each OTA award the “OTA Agency Handbook” gets more complex. With each award we creep back to the FAR based structure (e.g. Justification to utilize OTA, internal approval process, Notice of Intent process)
    - Is a culture change needed?

# General Thoughts

- Agencies ability to leverage various Vehicles and Financial products [Loans, etc.] is dependent on each agencies authorities
- A program team may not be able to select the best vehicle, not by choice, but due to their Agencies limited authority
  - Using RFP/BAA to stimulate industry commercial R&D capability is often the right tool, but is some cases a repayable/forgivable loan might be a better vehicle to ensure dual utility products with a government need is sustained by industry over the long term
  - Do we have the right combination of authorities for both Push and Pull incentives
  - Do agencies need more financial vehicles to solve their R&D innovation challenges
- Flow down clauses are needed but may scare away non-traditional partners and impact our ability to form novel international co-funding partnerships. Challenges include:
  - Balancing equity across partnerships
  - Agreement compliance when there are multiple legal authorities
  - Challenges implementing cost share policy and compliance/liabilities
  - Should international programs funded jointly be provided some relief from flow down clauses, in recognition for shared financial contributions?