BARDA’s Division of CBRN Medical Countermeasures

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21st Century: An Increasingly Complex & Dangerous World

CBRN Priority Investment Areas

- Develop innovative rapid response capabilities to address unknown threats
- Repurpose products to treat injuries from radiological, nuclear and chemical threats
- Invest in new antibacterial agents, vaccines and rapid point of care diagnostics
- Deliver countermeasures against chemical and viral hemorrhagic fever threats

Stockpile at least one countermeasure for all threats that have a material threat determination
Antibacterials Program

**GOAL**
Revitalize the antibacterial pipeline through innovative public-private partnerships

**FOCUS**
- Rapid diagnosis
- Biothreat agents
- Secondary and Opportunistic infections

**STRATEGY**
- Incentivize industry
- Accelerate development
- Reduce risk w/ expertise
- Facilitate interactions w/ interagency partners

Antibacterials Program Highlights

3 FDA Approvals

- VABOMERE™ meropenem and vaborbactam for injection (4 g)
- ZEMDRI™ (plazomicin) Injection
- XERAVA™ (eravacycline) for injection

4 OTA Partnerships

- Roche
- gsk GlaxoSmithKline
- Pfizer
- The Medicines Company

Diverse R&D Portfolio

- Achaogen
- Melinta Therapeutics
- Rempex Pharmaceuticals
- Cempra Pharmaceuticals
- Tetraphase Pharmaceuticals
- Cubrc
- Ato*Bio
- Summit
- Spero Therapeutics
Combatting Antimicrobial Resistant Bacteria Accelerator (CARB-X)

Global nonprofit partnership and accelerator consortium provides science and business services

Every $1 that CARB-X invested in Powered by CARB-X projects was followed by $8.7 in private funding
CARB-X Supports Programs in Early Development

- 33 projects from 7 countries
- 27 therapeutics
- 10 new antibiotic classes
- 11 new molecular targets
- 11 non-traditional candidates
- 3 microbiome-based approaches
- 5 diagnostics
- 1 vaccine
- 5 candidates advanced into clinic
Vaccines Program

**GOAL**
Enhance sustainability, protect special populations, and establish new portfolios

**FOCUS**
- Maintain/enhance preparedness and pursue licensure for Smallpox, Anthrax, Ebola
- Advance early stage efforts for Sudan ebolavirus, Marburg virus, and bacterial threats

**STRATEGY**
- Develop rapid response capabilities against unknown threats
- Expand existing capabilities
- Improve operational logistics
- Reduce life cycle costs
- Focus on studies to support licensure

Vaccines Program Highlights

Successful transition of R&D Programs to Late-Stage

Emergent Biosolutions

Janssen

Bavarian Nordic

IDT

NewLink Genetics

Antitoxin and Antiviral Program

GOAL
Develop safe and effective anthrax and botulism antitoxins and antiviral to treat smallpox and viral hemorrhagic fever

FDA Approved Products

• **Raxibacumab** – November 2012
• **AIG IV** (Anthrasil) – March 2015
• **Obiltoxaximab** (Anthim®) – March 2016
• **hBAT** – March 2013
• **ST-246/TPOXX** – July 2018

All these products are in the Strategic National Stockpile and are available for deployment
Antitoxin and Antiviral Program Strategy

- Coordinate with industry and ASPR SNS to ensure medical countermeasure preparedness
- Address the current gaps in our requirements, i.e. Filovirus therapeutics
- Invest in next generation products with transformational potential
- Support response to recurring Filovirus outbreaks
Chemical Medical Countermeasures Program

GOAL
To improve health outcomes for all victims of chemical exposure

FOCUS AREAS
- Traditional chemical weapon agents
- Chemical agents of opportunity
- Next generation opioids

STRATEGY
- Community preparedness
- Improved decontamination
- Dual-use medicines
- Treat the Injury, Not the Agent
Chemical MCM Program Highlights

Growing Program

Diverse Partners

Fielded Solutions

Thermal Burn Program

GOAL

Mitigate treatment bottlenecks and transform current standard of burn care with adoptable MCMs

FOCUS AREAS:
• Provide initial burn care
• Prevent burn conversion
• Reduce the need for surgery

STRATEGY:
• Comprehensive – From initial care to definitive care
• Adoptable – Partner with American Burn Association
• Sustainable – Embed in routine care

Non-surgical debridement
Autograft sparing
Skin substitutes
Thermal Burn Program Partners
Transforming Burn Care and Building Preparedness

Government Partners
- ASPR
- C6C
- CDC
- FD3

Non-Profits/Societies
- American Association of Tissue Banks
- American College of Emergency Physicians

Industry Partners
- Advanced R&D; Project BioShield

Radiological and Nuclear Program

- Ischemia
- Vascular Injury / Sepsis
- Coagulopathy / Fibrinolysis
- Inflammation
- Cell Death
Radiological and Nuclear Program Accomplishments

- **FIRST CBRN- WIDE OTA**
- **EUA PACKAGE COMPLETED**
- **FDA APPROVAL MARCH 2018**
- **FIRST IN CLASS BLOOD PRODUCT APPROVED TO MOVE INTO PHASE II**

ARS Therapeutic

Janssen

PTx

Cellphire

CBRN Accomplishments in FY2018

$1.12 BILLION
Awarded

17
New Contracts
Awarded

81
Contract
Options
Awarded

9
Interagency
Agreements
Executed

6
New Product
Approvals

28
Publications

7
Animal Model
Contracts
Awarded
Summary

BARDA has successfully developed and stockpiled MCMs against multiple threats.

Significant threats remain unaddressed.

Developing countermeasures against unknown threats is a challenge but highest priority.

BARDA seeks to partner with industry to address the remaining gaps with flexible, nimble public private partnerships.
CBRN Program Talks and Speakers

**BURN**

**JULIO BARRERA-ORO**  
*Project Officer*

**ANTIVIRAL AND ANTITOXINS**

**DAVID BOUCHER**  
*Project Officer*

**ANTIBACTERIALS**

**MARK ALBRECHT**  
*Acting Chief*

**CHEMICAL**

**EFRAIN GARCIA**  
*Project Officer*

**RADIOLOGICAL AND NUCLEAR**

**ERIKA DAVIES**  
*Project Officer*

**VACCINES**

**DANIEL WOLFE**  
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