



BARDA INDUSTRY DAY

BARDA's Division of CBRN Medical Countermeasures

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October 29, 2018

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



21st Century: An Increasingly Complex & Dangerous World



CBRN Priority Investment Areas

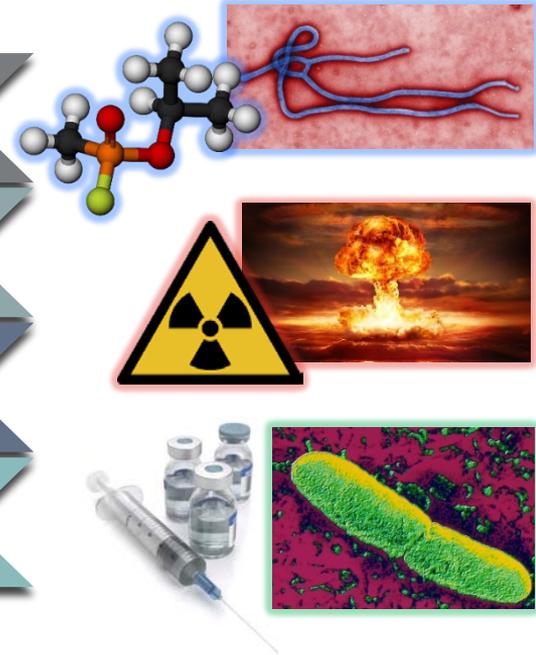
Stockpile at least one countermeasure for all threats that have a material threat determination

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



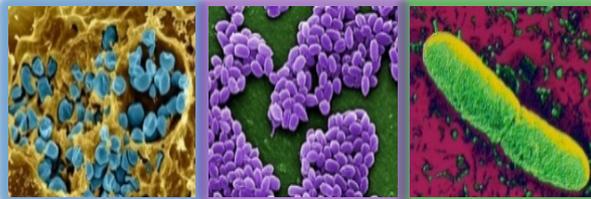
Antibacterials Program

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

ACHAOPEN

 **Melinta**
THERAPEUTICS

 **REMPEX**
Pharmaceuticals

 **cempra**
PHARMACEUTICALS

 **basilea**
PHARMACEUTICA

 **TETRAPHASE**
PHARMACEUTICALS

 **CUBRC**
Advantage through technology

AtoxBio

 **summit**

 **SPERO**
THERAPEUTICS

Combatting Antimicrobial Resistant Bacteria Accelerator (CARB-X)

CARB-X

Combating Antibiotic Resistant Bacteria

Global nonprofit partnership and accelerator consortium provides science and business services

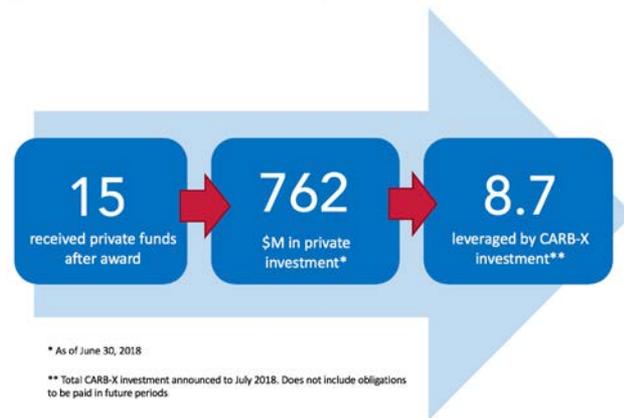
FUNDERS



ALLIANCE PARTNER

BILL & MELINDA GATES foundation

ACCELERATORS



Every \$1 that CARB-X invested in *Powered by CARB-X* projects was followed by \$8.7 in private funding



Saving Lives. Protecting Americans.

CARB-X Supports Programs in Early Development

Therapeutics & Preventatives



Diagnostics & Devices



- 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



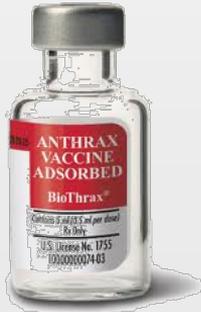
STRATEGY

- **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



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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** (Anthraxil) – 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

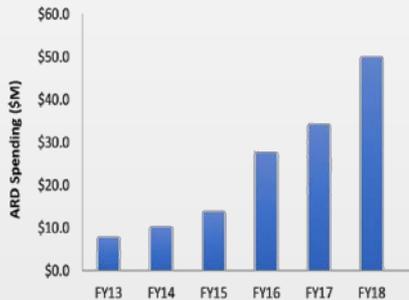
STRATEGY

- 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

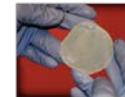
Non-surgical
debridement



Autograft
sparing



Skin
substitutes



Thermal Burn Program Partners

Transforming Burn Care and Building Preparedness

Government Partners



U.S. Food and Drug Administration
Protecting and Promoting Your Health

Non-Profits/Societies



American Association of Tissue Banks



AMERICAN COLLEGE OF SURGEONS
Inspiring Quality.
Highest Standards, Better Outcomes

100+years



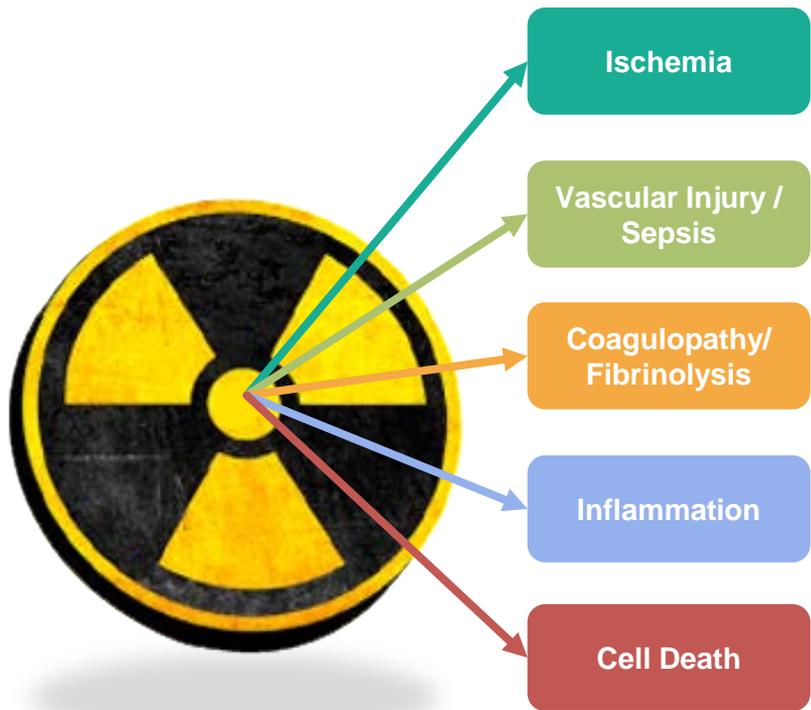
Industry Partners

Advanced R&D; Project BioShield



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Radiological and Nuclear Program



National Institute of
Allergy and
Infectious Diseases



National Heart, Lung,
and Blood Institute



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Radiological and Nuclear Program Accomplishments

**FIRST CBRN-
WIDE OTA**



**EUA PACKAGE
COMPLETED**

**ARS
Therapeutic**

**FDA APPROVAL
MARCH 2018**

PTx PARTNER
THERAPEUTICS



**FIRST IN CLASS
BLOOD
PRODUCT
APPROVED TO
MOVE INTO
PHASE II**

Cellphire



ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE



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CBRN Accomplishments in FY2018



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
Project Officer

