# BARDA's Achievements Under the National Action Plan


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**COMMITTEE ON THE LONG-TERM MEDICAL AND ECONOMIC EFFECTS OF ANTIMICROBIAL RESISTANCE**

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# ASPR Mission

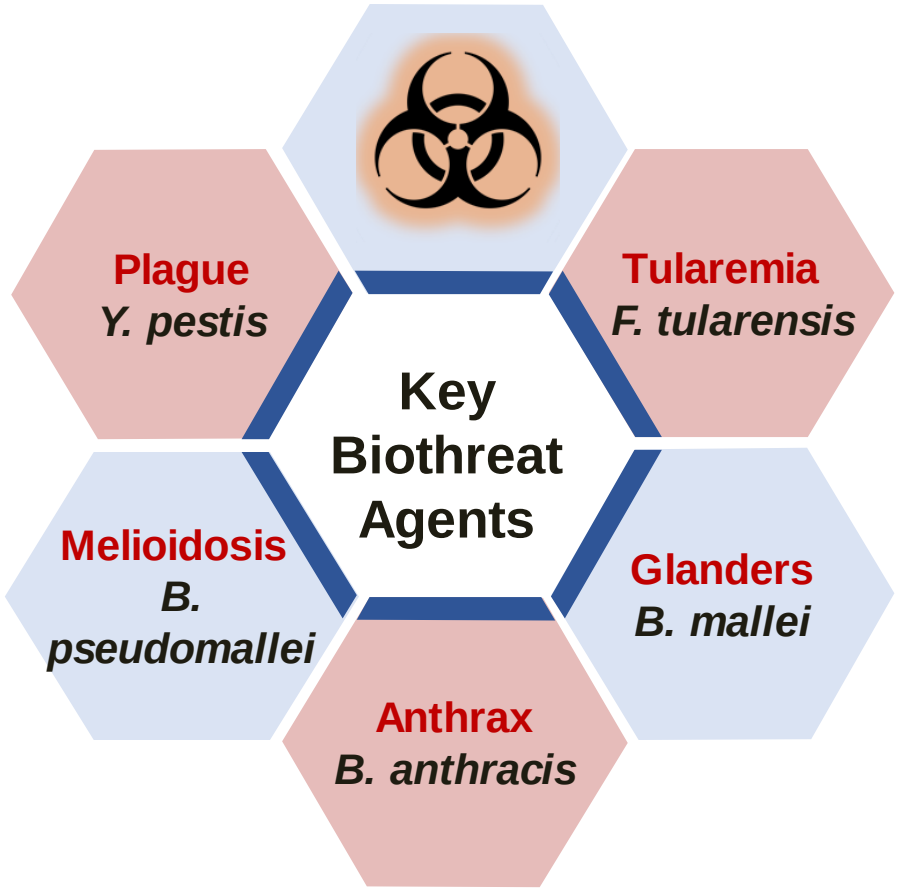
**Save Lives and Protect Americans from 21st Century Health Security Threats**


# The BARDA Model

BARDA develops and makes available medical countermeasures **(MCMs)** by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.

# Bacterial Threats in Multiple Dimensions

## Biothreat agents




## Opportunistic and Secondary infections

| | | | | |
|---|---|---|---|---|
| Chlorine | Dyspnea | Lung injury | Opportunistic infection | Persistent infection + sepsis |
| Sulfur Mustard | Blistering | Cellulitis | Opportunistic infection | Systemic infection + sepsis |
| Burns | Blistering | Skin sloughing | Opportunistic infection | Systemic infection + sepsis |
| Acute Radiation | Neutropenia | Immune ablation | Poor wound healing | Systemic infection + sepsis |
| Anthrax | Pneumonia | Disruption of gut flora | Opportunistic infection | Persistent infection + sepsis |
| Influenza | Fever | Congestion | Opportunistic infection | Systemic infection + sepsis |
| Ebola | Fever | Vomiting / diarrhea | Bleeding | Systemic infection + sepsis |
| Smallpox | Fever | Extensive rash / pustules | Opportunistic infection | Systemic infection + sepsis |

**The pace of drug development has not kept pace with the rate at which antimicrobial resistance is developing.**

**Antibiotic Resistance (AMR) causes**

# 700,000

**global deaths each year.**

**Common medical procedures are becoming too dangerous to undertake**

**May rise to**

# 10M

**deaths annually by 2050**

**costing**

# $100

**trillion**

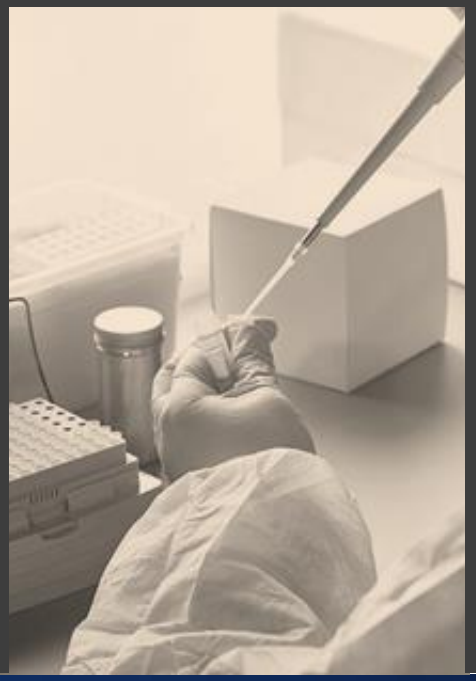
## THE LACK OF EFFECTIVE ANTIBACTERIALS CAN IMPEDE OUR ABILITY TO RESPOND TO ANY PUBLIC HEALTH EMERGENCY

# Co-/Secondary Bacterial Infections During Pandemics

A common complication of respiratory viral disease can be secondary bacterial infection

**11%-35%**

of laboratory confirmed cases of influenza exhibit bacterial co-/secondary infection (Klein 2016 Influenza Other Respir. Viruses 10, 394–403.)



Secondary bacterial pneumonia identified in

**29-55%**

cases of H1N1 in 2009 (CDC 2009)

**1/3 to 1/2**

of all deaths resulting from the 2009 H1N1 pandemic in the U.S. were caused by secondary bacterial pneumonia that was contracted by hospitalized patients

During the 1918-1919 Spanish Flu pandemic, bacterial pneumonia is estimated to have occurred in

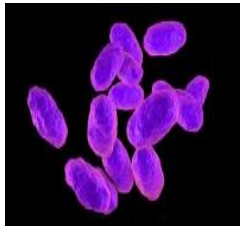
**95%**

of all fatal cases with many of these deaths directly attributable to a bacterial infection (Morens 2008 J. Infect. Dis. 198, 962–970)

The leading etiologic pathogens of bacterial pneumonia are:

*Streptococcus pneumoniae*

*Staphylococcus aureus* (including MRSA)



*Haemophilus influenzae*

# Bacterial MCM Program

## MISSION

Reduce the morbidity and mortality caused by a biothreat or antimicrobial resistant (AMR) infection following a mass casualty event or a disease outbreak

## STRATEGY

Revitalize and incentivize the antimicrobial pipeline through innovative public-private partnerships

## PRIORITIES

Invest in new types of antimicrobials and products that target both MDR pathogens and bioterrorism infections

# The National Action Plan: National Coordinated Response to AMR

- **Goal 1:** *Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections*
- ***Goal 2:*** *Strengthen National One Health Surveillance Efforts to Combat Resistance*
- **Goal 3:** *Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria*
- **Goal 4:** *Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines*
- **Goal 5:** *Improve International Collaboration and Capacities for Antibiotic-resistance Prevention, Surveillance, Control and Antibiotic Research and Development.*

# CARB-X

as of 8/3/2020

**67 Projects**

**50** drugs | **9** diagnostics | **4** microbiome | **4** vaccines

**7** graduates | **6** FIH studies | **1** ARD contract

New Classes ♦ New Targets ♦ New Mechanisms of Action ♦ Non-traditional Approaches

**$180M** (2016-2021)

**BARDA Investment**

**40%** of companies indicated not receiving prior USG funding

**$270M**

**Additional Donor Funding**

NIAID, Wellcome Trust, UK GAMRIF, Germany BMBF, Bill and Melinda Gates Foundation

Companies in **10** **Countries**

**$1.57B**

Follow-on private sector investment in product developers

# Antibacterials Advanced Research and Development (ARD) Program Partners











The Medicines Company SD LLC

# Project BioShield: A First for Antibacterials

PARATEK

NUZYRA®
(omadacycline)


Biothreat agents may be resistant to antibiotics already in Strategic National Stockpile (SNS)

Emerging antibiotic resistance may complicate a response to any public health emergency

Novel broad spectrum antibiotics that overcome resistance may enhance national security; stockpiling offers an additional market

# BARDA Antibacterials: A Decade of Investment

VABOMERE™
meropenem and vaborbactam
for injection (4 g)

ZEMDRI™
(plazomicin) Injection

XERAVA™
(eravacycline) for injection

- 10+ years of partnerships
- Over $1.5 billion invested
- 3 FDA Approvals so far
- Emphasis on bringing drugs to market based on established regulatory pathways
  - Complicated UTIs & Acute Pyelonephritis
  - Complicated Intra-abdominal Infections
- Operational goal:
  - Make antibiotics commercially available in pharmacies and hospital formularies
  - Generate biothreat data to support Emergency Use Authorization (EUA)

# Incentivizing and Catalyzing Antibiotic Development

**BARDA will continue to leverage its unique authorities to provide innovative business tools that support end-to-end product development, from the earliest stages under CARB-X to commercial procurement via PBS, while at the same time exploring technical solutions to the challenges facing the commercial market.**

# How to Contact BARDA

**medicalcountermeasures.gov**

*Portal to BARDA:* ***Register to request a TechWatch meeting!***

**beta.sam.gov/**

*Official announcements and info for all government contract solicitations*

**phe.gov/BARDA**

*Program description, information, news, announcements*

**drive.hhs.gov**

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