



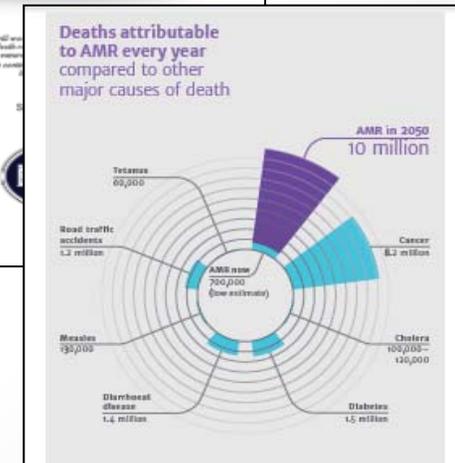
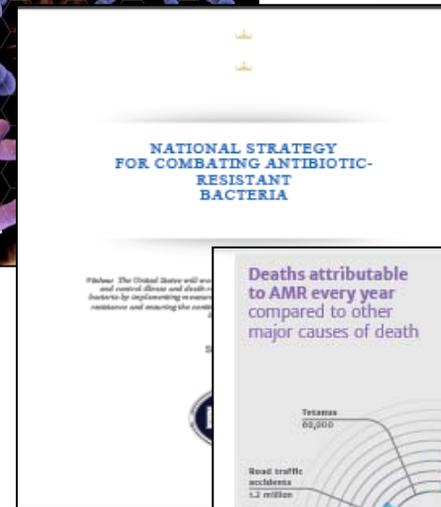
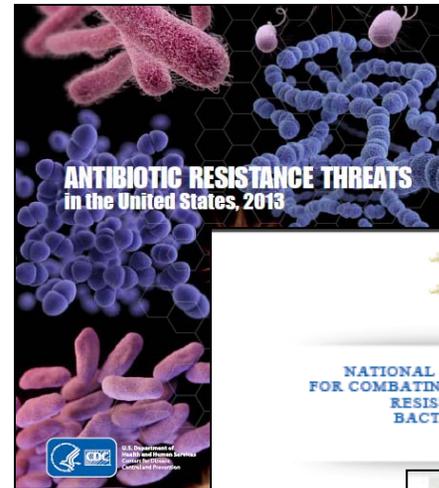
ANTIBACTERIAL PROGRAM

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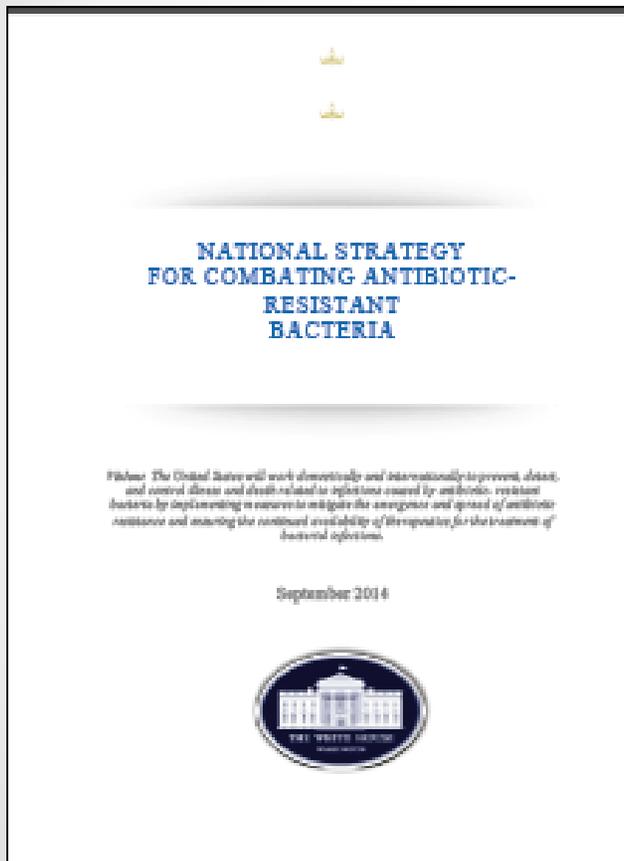
Resilient People. Healthy Communities. A Nation Prepared.

Why is BARDA Funding Antibacterial Development?

- AMR is emerging faster than effective antibiotics are being developed
- AMR causes 700,000 global deaths each year and will rise to 10M deaths annually by 2050 with economic cost of \$100T
- Common medical procedures are becoming too dangerous to undertake
- To enhance biodefense and public health preparedness
- To meet the requirements in the National Strategy and Action Plan for CARB



National Strategy for CARB



- Goal 1: Slow the Development 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



National Action Plan for CARB

- **Objective 4.6** Enhance opportunities for public-private partnerships to accelerate research on new antibiotics and other tools to combat resistant bacteria through a “portfolio approach” in which companies investigate multiple drug candidates at the same time.
- **Objective 4.7** Create a biopharmaceutical incubator—a consortium of academic, biotechnology and pharmaceutical industry partners—to promote innovation and increase the number of antibiotics in the drug-development pipeline.
- **Objective 5.5** Establish and promote international collaboration and public-private partnerships to incentivize development of new therapeutics to counter antibiotic resistance.

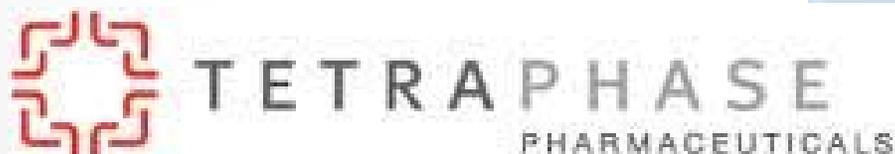


Antibacterials Program Objective

To help revitalize the antimicrobial pipeline by forming innovative public-private partnerships with companies engaged in antimicrobial therapy development



Partner Companies



BARDA's Antibacterial Pipeline

Sponsor	Compound	Development Stage			
		Preclinical	Phase I	Phase II	Phase III
Achaogen	Plazomicin	Next-Generation Aminoglycoside cUTI/AP, CRE, Plague, Tularemia			
Rempex	Carbavance	BL/BLI Combination CRE, cUTI			
Cempra	Solithromycin	Next-Generation Fluoroketolide CABP, GC, Anthrax, Tularemia			
CUBRC/Tetraphase	Eravacycline	Fully Synthetic Tetracycline cIAI, cUTI, MDR			
Basilea	Ceftobiprole	Cephalosporin ABSSSI, SAB, CABP, Plague, Tularemia			
Astra Zeneca	Aztreonam-Avibactam	BL/BLI Combination cIAI, HAP/VAP, cUTI, BSI, MDR gram-, Melioidosis, Glanders, Plague			
GlaxoSmithKline	Gepotidacin	Topo II Inhibitor CABP, GC, uUTI, Plague, Tularemia, Anthrax			
GlaxoSmithKline	GSK-830	Cephem BL cUTI, cIAI, HAP/VABP, MDR			
GlaxoSmithKline	GSK-680	Topo II Inhibitor TBD			
The Medicines Company	Carbavance	BL/BLI Combination HABP/VABP, MDR			
The Medicines Company	Mid/Early Stage Candidates	Multiple Compounds TBD			
Hoffman-La Roche	RG6080	Broad Spectrum BL cUTI, cIAI, HAP/VABP, MDR			
CRV Accelerator	-Clinic	Lead Optimization to IND			



Program Accomplishments

- Since 2010, initiated and built a portfolio of antibacterial therapeutics with a total value of ~\$1.36B (over \$2.93B including cost share) and provided ~\$548M in direct funding to nine companies
- Awarded four programs utilizing Other Transactional Authority focused on developing a portfolio of antibiotics
- Established international collaborations with companies and other funding agencies
- Six programs currently in Phase III development
- First FDA NDA approval expected 2016 (Second in 2017)
- Expanded portfolio to include non-traditional approaches
- Biopharmaceutical Accelerator launched in July 2016 to accelerate R&D of portfolio of preclinical assets



How BARDA is Addressing Goals in the Action Plan

Milestone	
ASPR/BARDA will create at least one additional portfolio partnership (Objective 4.6, Year 1)	Complete
Two antibiotic drugs developed by portfolio partners will enter Phase III clinical investigation (Objective 4.6, Year 3)	On-Track
IND applications for two additional antibiotic drugs developed by portfolio partners will be submitted (Objective 4.6, Year 5)	On-Track
ASPR/BARDA and NIH will develop a strategy for establishing the Biopharmaceutical Accelerator (Objective 4.7, Year 1)	Complete
The Biopharmaceutical Accelerator will be operational (Objective 4.7, Year 3)	Complete
U.S. agencies will also explore collaborations with the New Drugs 4 Bad Bugs (ND4BB) programs of the Innovative Medicines Initiative (Objective 5.5, Year 1)	Complete



Looking Ahead

- Continue to support development of novel therapies to treat “Urgent” and “Serious” Gram-negative infections and drug-resistant biodefense pathogens
- Expand portfolio to include:
 - Treatment options for *C. difficile* infections
 - Approaches that can interdict/prevent infection upon entry into the health care setting
 - Non-traditional therapies (mAbs, probiotics, potentiators, host targets, etc)
- Continue utilizing innovative public-private partnering mechanisms to stimulate the therapeutic pipeline (where appropriate)
- Graduate projects from CARB-X Accelerator into Antibacterial Portfolio



Program Funding Priorities

Drug Class

- **Unprecedented**
 - Novel Target
 - Novel Chemistry
- **Precedented**
 - Reduced AR
- **Nontraditional Therapies**
 - mAbs, phage, host-based
- **Infection prevention/interdiction**
 - Vaccines
 - Microbiome

Antibiotic Resistance

- *C. difficile*
- CRE
- *N. gonorrhoea*
- MDR *Acinetobacter*
- ESBLs
- VRE
- MDR *P. aeruginosa*
- MRSA
- DR *S. pneumoniae*

Biothreat

- *B. pseudomallei*
- *B. mallei*
- *F. tularensis*
- *Y. pestis*
- *B. anthracis*



BARDA's CBRN Broad Agency Announcement

- BAA-16-100-SOL-00001, Area of Interest #3: Antimicrobial Therapeutics
- In accordance with the National Strategy for Combating Antibiotic-Resistant Bacteria and the Executive Order on Combating Antibiotic Resistant Bacteria, BARDA aims to form public-private partnerships to accelerate research and development of new antimicrobial therapeutics for the treatment or prevention of infections. Of particular interest to the Government are proposals which aim to:
 - Develop and test antibacterial products that are in advanced development for post-exposure prophylaxis (PEP) and treatment efficacy against one or more **biodefense threat** agents (Bacillus anthracis, Yersinia pestis, Francisella tularensis, Burkholderia mallei, and Burkholderia pseudomallei).
 - Develop **new small molecule drugs and nontraditional therapeutics** that treat or prevent resistant microbial infections either alone or in combination with another therapeutic
 - Products should possess activity against one or more of the pathogens categorized as **serious, urgent, or concerning threats** in the September 2013 CDC Report titled [Antibiotic Resistance Threats in the United States, 2013](#).



Additional Evaluation Factors

- Stage of development: IND, preferably Phase 1 data
- MDR Gram negative activity preferred
- Does product address an unmet medical need?
- Does the product fill a portfolio gap? (Drug class, pathogen spectrum, indication, etc.)
- Is the development approach sound?
- Has the sponsor met with, and obtained support from the FDA concerning the development plan for the drug?
- Does the product offer a substantial improvement and/or advantage over existing products?
- Does offeror have clear IP and FTO over the asset?

Cost sharing is preferred



Interfacing with BARDA

- www.phe.gov
 - Program descriptions, information, news, announcements
- www.medicalcountermeasures.gov
 - Portal to BARDA
 - Request a Tech Watch meeting
- www.fedbizopps.gov
 - Official announcements and detailed information about all government contract solicitations including the BARDA BAA (BAA-16-100-SOL-00001)
- Technical POC for Research Area #3: Antimicrobial Drugs: Christopher Houchens, christopher.houchens@hhs.gov 202-205-3633



Thank You!

