



*United States Department of*  
**Health & Human Services**  
Office of the Assistant Secretary for Preparedness and Response



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# ***BARDA's Broad Spectrum Antimicrobial (BSA) Program***

**Joe Larsen, Ph.D.**  
**Acting Deputy Director**  
**BARDA Division of CBRN Medical Countermeasures**

**PCAST Briefing**  
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*ASPR: Resilient People. Healthy Communities. A Nation Prepared.*



# BARDA Principles at Work



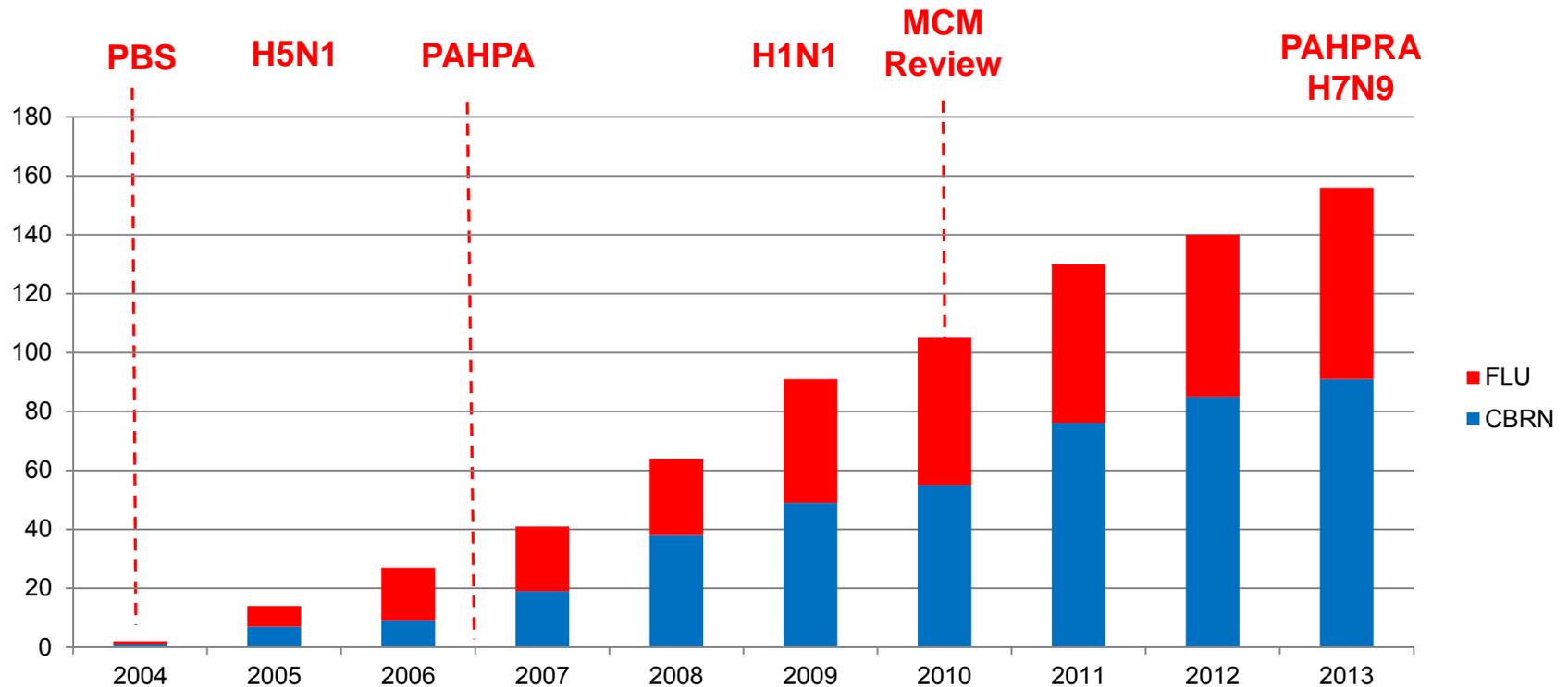
- **Exists to address the medical consequences of biotreats, pandemic influenza and emerging infectious diseases, including antimicrobial resistance.**
- **Works with our federal partners to transition medical countermeasures from early development into advanced development towards ultimate FDA approval.**
- **Has established public-private partnerships with industry; sharing in development costs.**
- **Established a network of core services to assist developers in non-clinical, clinical, manufacturing, and fill/finish activities.**
- **Provides subject matter expertise in all aspects of product development.**
- **Make sure that safe and effective products are available if needed during an incident or public health emergency.**



# BARDA Created a Robust & Productive MCM Development Pipeline



- More than 150 MCM product candidates in development since 2004 (aggregate)





# BARDA's MCMs Have Been Approved by the FDA



## Cell-based Influenza Vaccine



## Influenza IV Antiviral Drug



## Recombinant-based Influenza Vaccine



Protein Sciences Corp.

## H1N1 & H5N1 Vaccine w/ Adjuvant



GlaxoSmithKline

## Botulinum Antitoxin



Cangene

## Anthrax Antitoxin



HGS/GSK



## Next-Gen Portable Ventilators

Covidien

## Flu/RSV POC Diagnostic

3M/Focus



# The BARDA Model



- The BARDA model works to address market failures
  - Products FDA approved/cleared for biotreats and pandemic influenza
  - Products stockpiled for emergency use
- This model is being successfully applied to antimicrobial resistance
  - Utilization of novel public:private partnerships to incentivize antibiotic research and development
  - 4 products in Phase III clinical development
  - 2 products have hit endpoints in Phase III trials



# Current BARDA Program Investments



## BARDA's BSA Supported Product Pipeline

	Sponsor	Compound	Development			
			Preclinical	Phase I	Phase II	Phase III
Antibiotics	Achaogen	Plazomicin (ACHN-490)	Next-generation aminoglycoside: Broad Spectrum plague, tularemia and carbapenem resistant Enterobacteriaceae (CRE)			
	CUBRC/ Tetrphase	Eravacycline (TP-434)	A novel fully synthetic tetracycline: Broad Spectrum plague, tularemia, complicated intra-abdominal and urinary tract infections (cIAI, cUTI)			
	Cempra	Solithromycin (CEM-101)	Next-generation fluoroketolide: Broad Spectrum anthrax, tularemia, gonorrhoea and community-acquired bacterial pneumonia (CABP)			
	Basilea	BAL30072	A novel surfactam: Broad Spectrum MDR Gram negative infections, melioidosis, glanders			
	Rempex	Carbavance™ (meropenem/RPX7009)	Carbapenem/β-lactamase inhibitor: Broad Spectrum CRE, cUTI, hospital-acquired pneumonia/ventilator-associated pneumonia (HAP)/(VAP), melioidosis, glanders			
	GSK	A portfolio approach	Broad Spectrum Antibiotic Portfolio A partnership to fund multiple compounds to combat antibiotic resistance at various stages of development			

Disclaimer: The above projects are supported by BARDA's BSA Program utilizing non-dilutive funding via a contract and/or agreement. The stage of development is approximate as of July 2014 (please refer to the sponsors site for updated information). The table represents the compounds most advanced commercial indication being pursued by the developer.



## BARDA's Portfolio Partnership for Antibacterial Drug Development



- Established 5 year \$200M public:private partnership in May 2013
- Utilizes HHS's first use of Other Transactional Authority
- Supports the development of multiple antibiotic candidates
- Allows for activities and resources to be adjusted fluidly to adapt to technical risk and programmatic priorities
- Governance is through a BARDA:GSK Joint Oversight Committee
- Partnership model we want to replicate going forward



# BARDA BSA Program Budget Projections

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- Current Funding for FY15: \$79M
- Requested Funding in FY16 budget: \$192M
- Additional Funding would support:
  - 2-3 Diagnostics Programs
  - 2-3 Additional Partnerships to support development of novel antimicrobial therapies
  - Emphasis on utilizing Other Transactional Authority as a means to form innovative partnerships with industry



# BARDA's Broad Spectrum Antimicrobial Program

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- Summary:
  - BARDA's antimicrobial program will continue to support the development of novel antimicrobials and diagnostics to address the growing public health threat of antimicrobial resistance and biothreat pathogens
  - Limited expansion of current program projected at current funding levels