



United States Department of

**Health & Human Services**

Office of the Assistant Secretary for Preparedness and Response



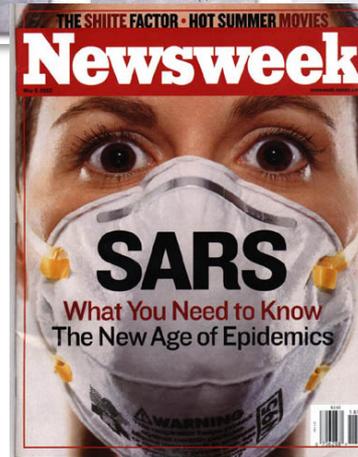
# **BARDA Transitions to Project BioShield II & Pandemic Influenza II**

*BARDA Industry Day*

**Dr. Robin Robinson, Director & Deputy Assistant Secretary  
Biomedical Advanced Research & Development Authority**

**November 12, 2013**

# Man-Made & Mother Nature's Threats Have Become Reality Since 9/11





# *BARDA's Commitment to Medical Countermeasures*



***Mission: Develop and provide countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases by product development, stockpile acquisition, building manufacturing infrastructure, & product innovation.***



**Tip O'Neil Building (FOB8)**



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



# *Book I: BARDA 2013 Summary*



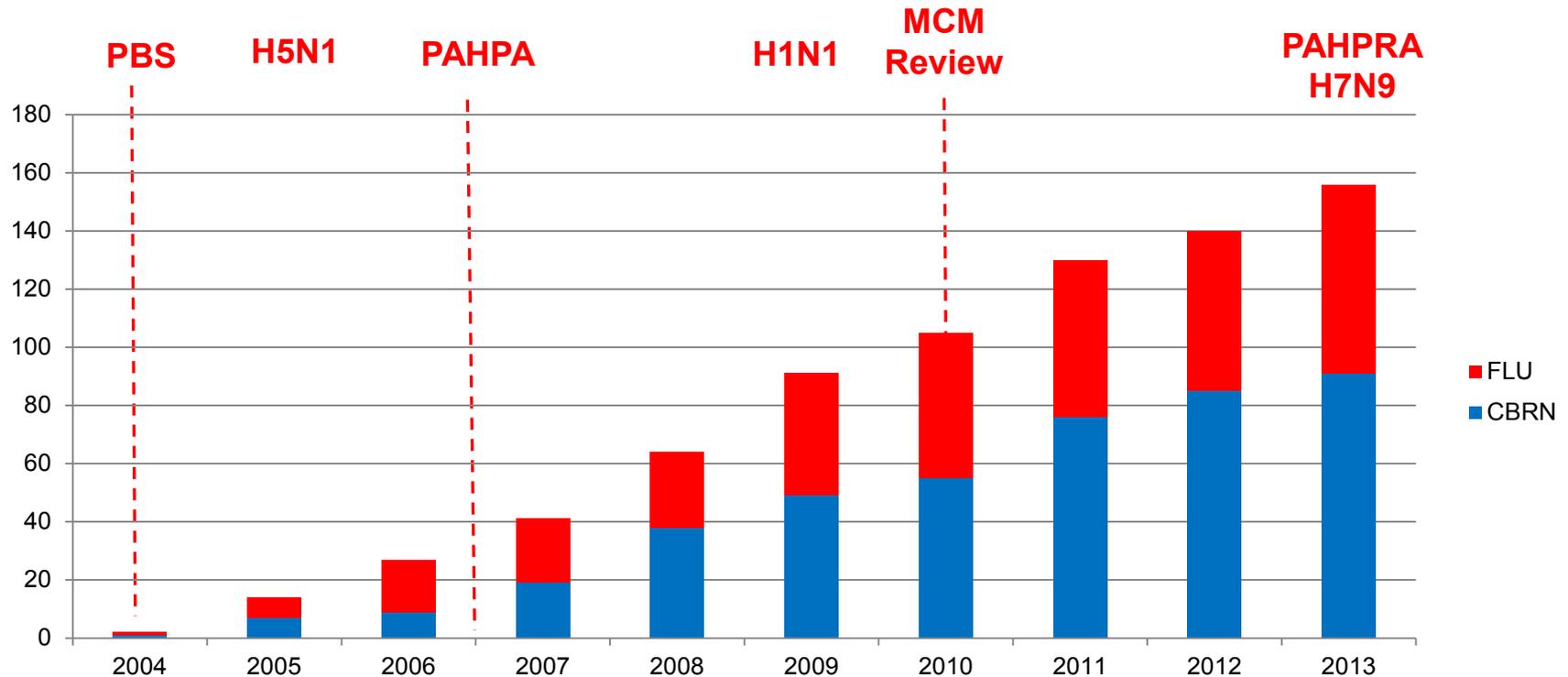
- **BARDA has built an unprecedented, robust MCM development pipeline for CBRN threats & pandemic influenza that delivers**
  - 150+ MCM candidates currently with better business practices (e.g. OTA, IPR) + 12 new CBRN MCM candidates and 5 new H7N9 vaccine candidates in FY2013
  - 12 MCMs in the SNS under PBS since 2004 with 12 more by 2019 and national stockpiles of H5N1 & H7N9 pre-pandemic vaccines & adjuvants
  - MCMs FDA-approved in 2012-13 with 3-5 more expected by the end of 2015
    - Simplexa influenza & RSV diagnostic POC device (Jun. 2012) – 3M/Focus [510K clearance]
    - Flucelvax cell-based influenza vaccine (Nov. 2012) – Novartis [licensure]
    - Raxibacumab anthrax antitoxin (Dec. 2012) – GlaxoSmithKline/Human Genome Sciences [approval]
    - Aura portable ventilator (Dec. 2012) –Covidien [510k cleared for adults]
    - FluBlok recombinant-based influenza vaccine (Jan. 2013) – Protein Sciences
    - HBAT botulinum antitoxin (Mar. 2013) – Cangene [licensure]
    - **COMING ATTRACTION:** Q-PAN H5N1 pandemic influenza vaccine (2012) – GlaxoSmithKline ( BLA submission)



# BARDA Created a Robust & Productive MCM Development Pipeline



- More than 150 MCM product candidates in development since 2004





# *BARDA Has Established Robust CBRN MCM Development Pipeline*



- **BARDA CBRN MCM development pipeline has supported 85+ candidates since 2004 (\$2.2 B)**

- **Biothreats**

- Anthrax vaccines (7) and antitoxins (7)
- Smallpox vaccine (3) and antiviral drugs (2)
- Botulinum antitoxin (1)
- Other biothreat antimicrobial drugs (7)



- **Rad/Nuc threats**

- Acute Radiation Syndrome drugs (36)
- Decorporation agents (6)
- Thermal burn therapies (9)
- Biodosimetry devices (11)

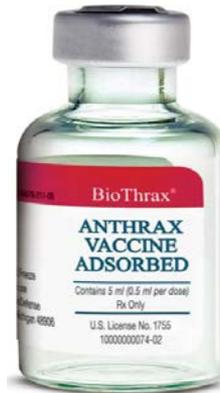


- **Chem threats — antidotes & decon (4)**

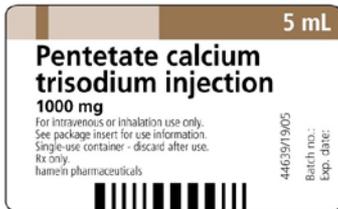
# BARDA MCMs under Project BioShield



**Smallpox**



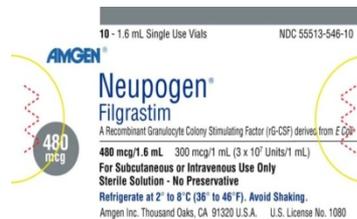
**Anthrax**



**Radiation**



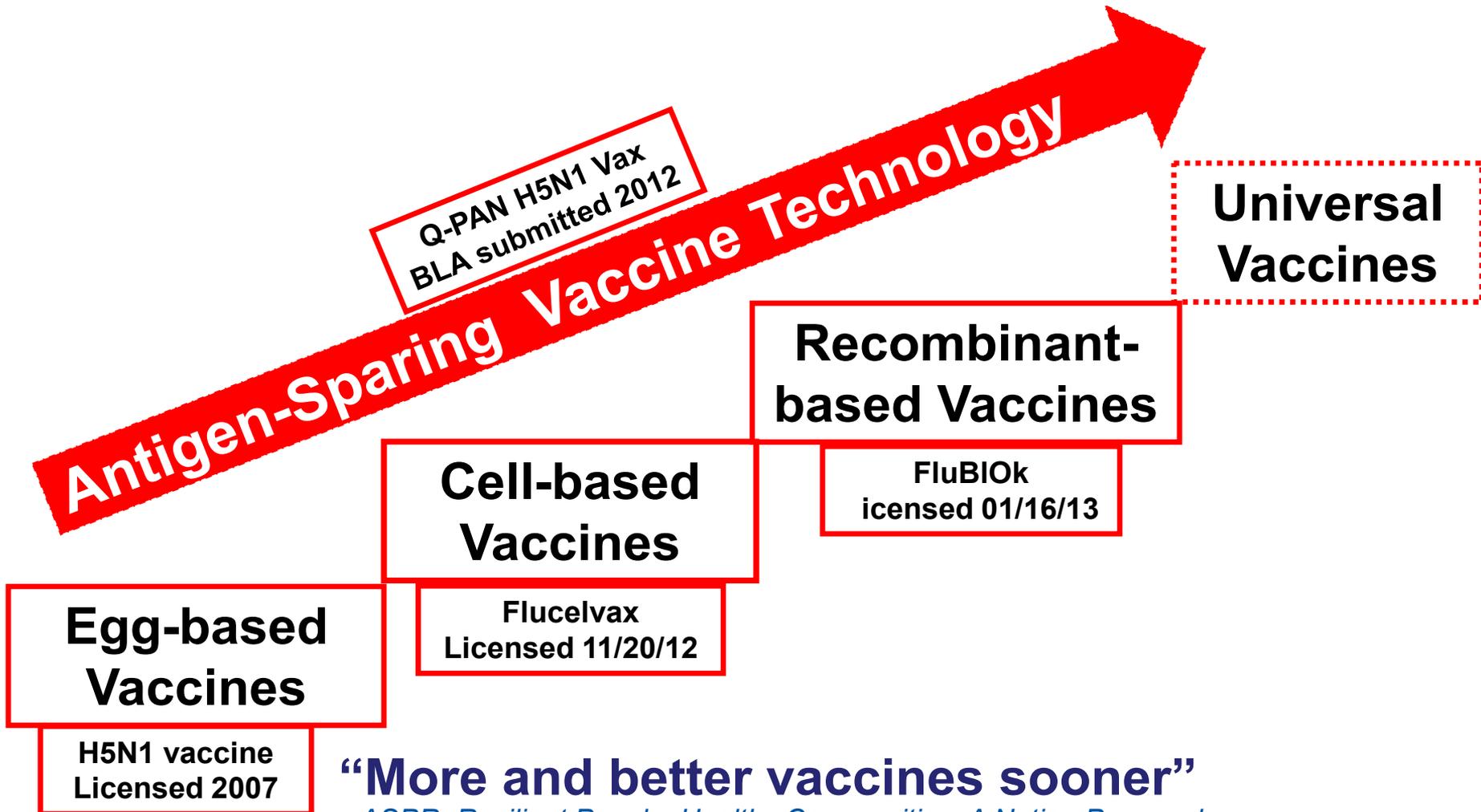
**Botulism**



**Chemical**



# BARDA Nurtured Influenza Vaccine Development to Achieve National Pan Flu Vaccine Goals



**“More and better vaccines sooner”**

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

## Q-PAN H5N1 Vaccine



GlaxoSmithKline

## Cell-based Influenza Vaccine



Novartis

## Next-Gen Portable Ventilators



Covidien

## Recombinant-based Influenza Vaccine



Protein Sciences

## Flu/RSV POC Diagnostic



3M/Focus



# *Book I: BARDA 2013 Summary*



- **BARDA has established solid public-private partnerships with industry/academia providing critical core service assistance & expanding response capabilities**
  - S Public-Private Partnerships
    - sanofi pasteur & MedImmune – retrofitting manufacturing facilities (2007)
    - Novartis – new manufacturing facility (2009)
    - CIADMs – TAMUS, Novartis, Emergent (2012)
    - BSA – GSK (2013)
  - Core Service Assistance Programs
    - Animal Studies Network (17 CRO labs) - 2010
    - Centers for Innovation in Advanced Development & Manufacturing (3 consortia) - 2012
    - Fill Finish Manufacturing Network (4 CMOs) – 2013
    - **Coming Attraction:** Clinical Studies Network - 2014



# *BARDA Uses Public-Private Partnerships to Build Domestic MCM Manufacturing Capacity*



- **Expanding Existing Capacity by Retrofitting Vaccine Manufacturing Infrastructure**



**sanofi pasteur – Swiftwater, PA**

- **Changing Flu Vaccine Industry**

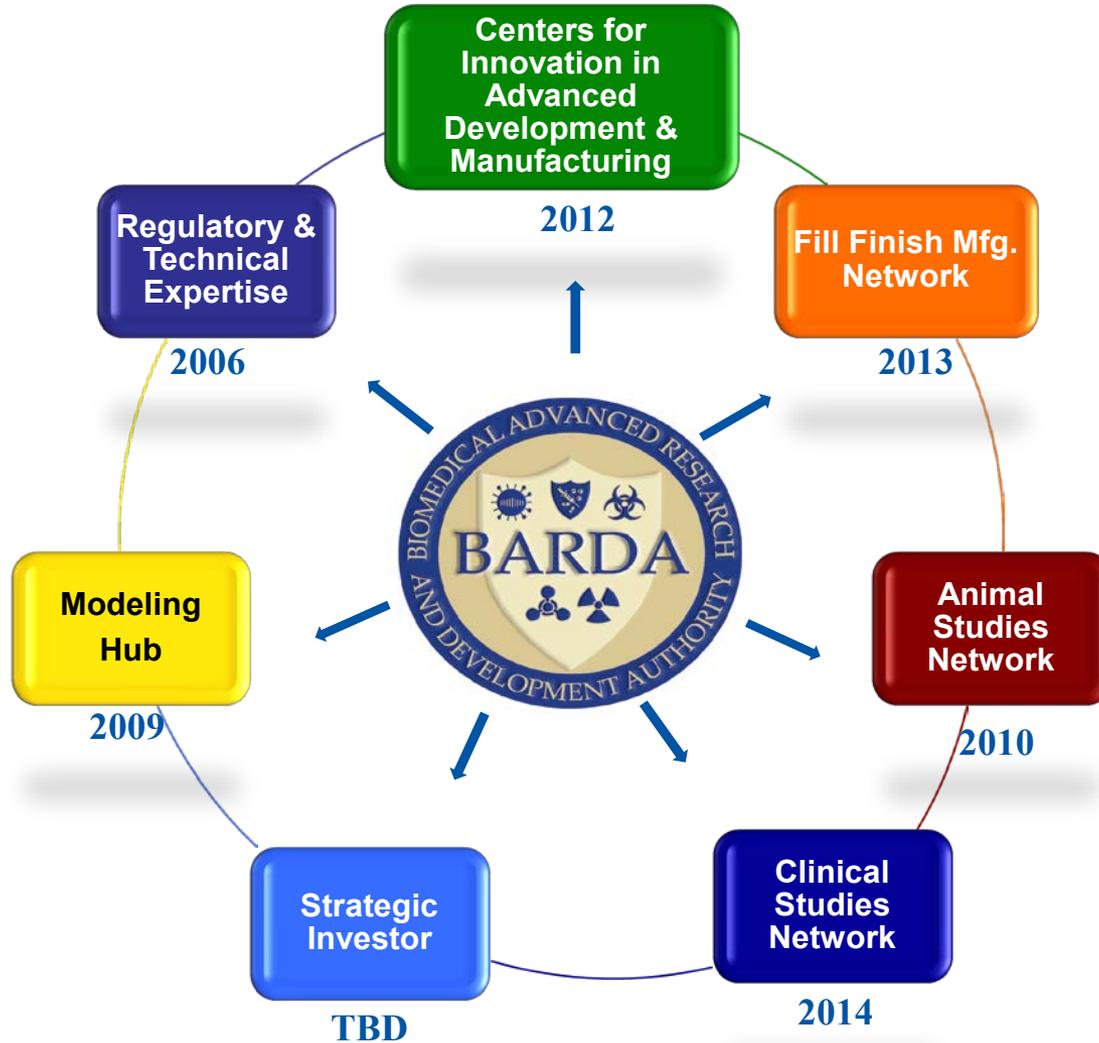


**2013 ISPE Facility of the Year**

**Novartis – Holly Springs, NC**



# BARDA Provides Critical Core Service Assistance to MCM Developers





# BARDA Assists MCM Developers thru our Animal Models Network



**Battelle Pacific Northwest Division**

**IIT Research Institute**

**University of Illinois, Chicago**

**Battelle Memorial Institute**

**SRI International**

**BioQUAL, Inc.**

**Southern Research**

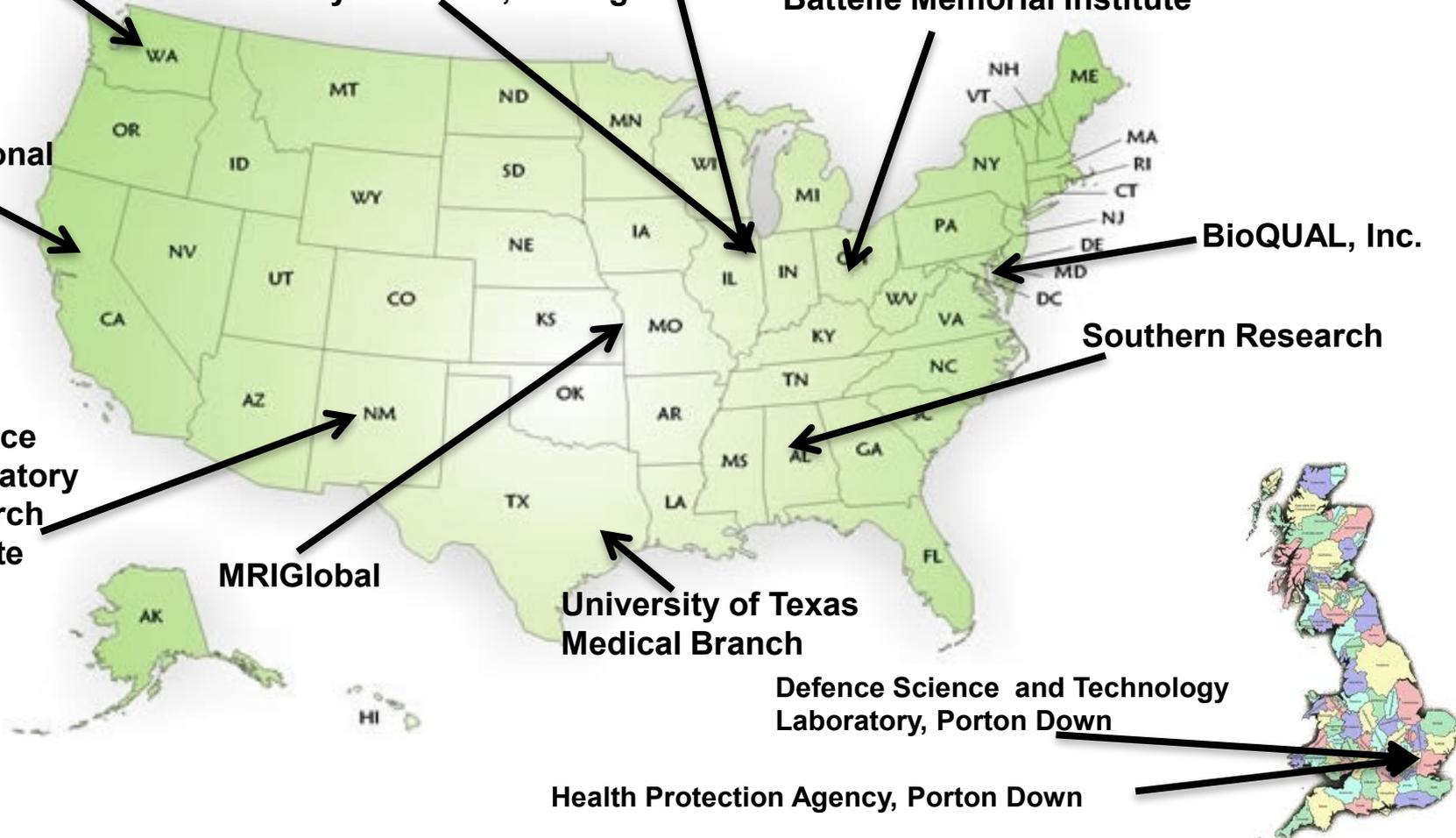
**Lovelace Respiratory Research Institute**

**MRIGlobal**

**University of Texas Medical Branch**

**Defence Science and Technology Laboratory, Porton Down**

**Health Protection Agency, Porton Down**





# BARDA Assists MCM Developers Directly with Product Development & Manufacturing



## CENTERS FOR INNOVATION IN ADVANCED DEVELOPMENT AND MANUFACTURING (CIADM)

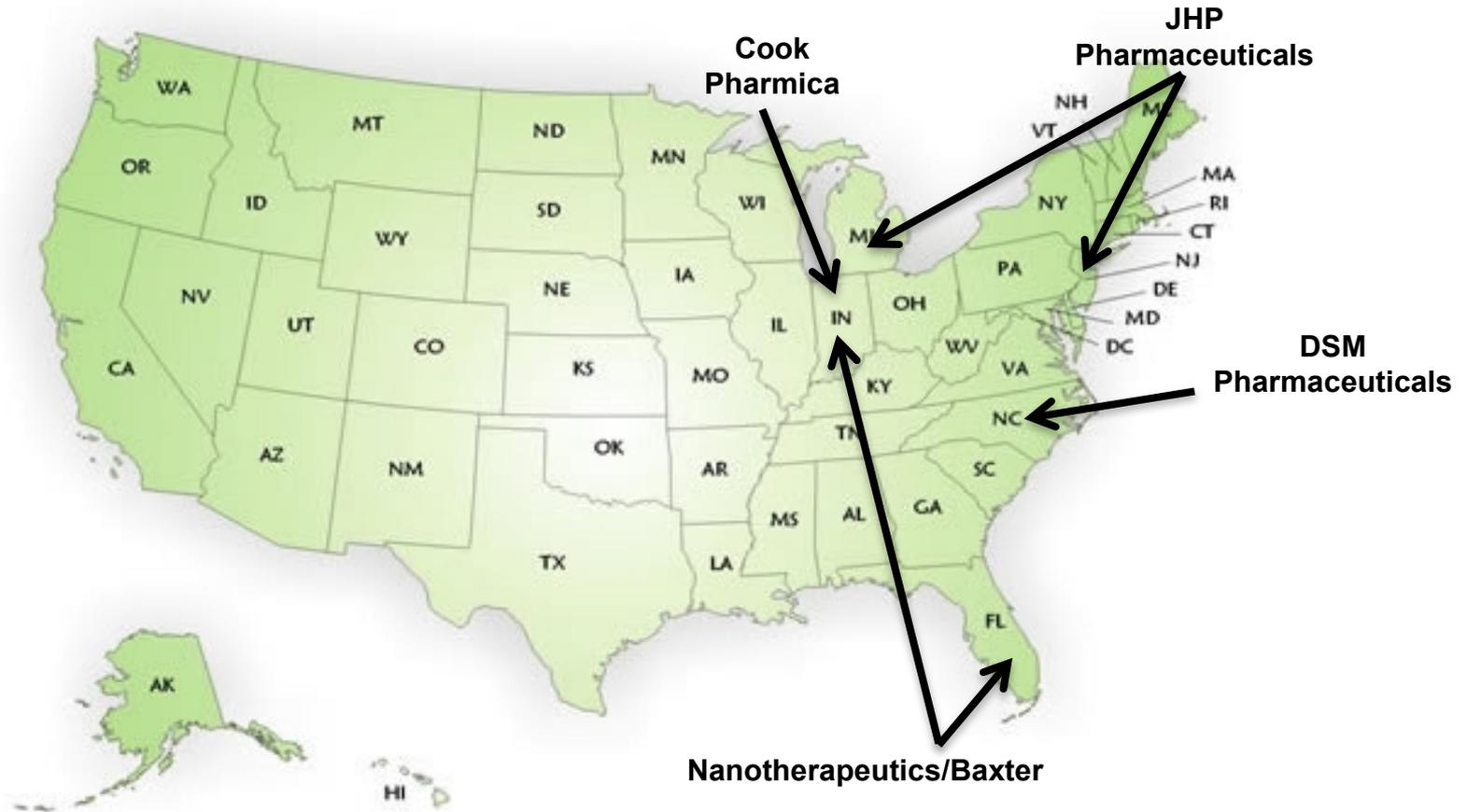


ASPR: Resilient People. Healthy Communities. A Nation Prepared.

Updated 1 August 2013



# *BARDA Assists MCM Developers thru our New Fill Finish Manufacturing Network*





## *BARDA 2013 Summary*



- **BARDA has prioritized development of repurposed and multipurpose MCMs to address life-cycle management and sustainability issues**
  - Antimicrobial drugs: new classes of broad spectrum antibiotics
  - Antiviral drugs: Nitazoxanide licensed for parasitic infections and under development for influenza and MERS-CoV
  - Acute Radiation Syndrome therapeutics: oncology cardiovascular drugs & therapies

# *BARDA Prioritizes Repurposed and Multipurpose MCM Candidates*

## REPURPOSED

**Romark: Nitazoxanide**

**FDA-Approved for parasitic infections**

**Under development for influenza,**

**& MERS-Cov**



## MULTIFUNCTIONAL

**Glaxo-Smith Kline:**

**Broad spectrum antibiotics**

**Using Other Transaction**

**Authority Agreement**



# *BARDA Responds to New Threats*



- H7N9 outbreaks in China
  - Brings biosynthetic technology with Novartis and JCVI forward to prepare H7N9 vaccine seed strains faster than before
  - Supports development, manufacturing, and clinical testing of H7N9 vaccines
  - Prepares vaccine stockpiles
  - Tests antiviral drug candidates to H7N9 viruses
- MERS-CoV outbreaks in Middle East
  - Tests host-targeted antiviral drug candidates to MERS-CoV



## *Book II: BARDA Next Steps*



### **NEW DEVELOPMENT**

- Antimicrobial Drug Resistance  
→ Continue BSA Program
- Viral Hemorrhagic Fever MCM  
Gap → Accept New Candidates
- Influenza Vaccine  
Effectiveness → Universal  
Influenza Vaccines
- Flu Antiviral Drug Resistance  
→ Influenza Antiviral Drugs for  
Critically Ill
- Drug & vaccine delivery  
systems
- EID Response Capability →  
Utilize Core Service Resources  
(e.g., MERS-CoV)

### **NEW ACQUISITION**

- Project BioShield (New MCMs  
from BARDA ARD)
  - Biodosimetry devices
  - Thermal burn therapies
  - ARS drugs & therapies
  - Broad spectrum antimicrobials
  - Next generation anthrax  
vaccines
  - Chemical agent antidotes
  - Others as available
- Pre-pandemic Influenza  
Vaccine Stockpiles (e.g.,  
H7N9)



## *Key BARDA MCM Challenges*



# BUDGETS

# SUSTAINMENT



# Contact Us



## BARDA:

URL: <http://www.phe.gov>

BARDA e-mail: [BARDA@hhs.gov](mailto:BARDA@hhs.gov)

- Upcoming Events
  - PHEMCE Strategy and Implementation Plan
  - CBRN and Pan Flu Programs
  - Business Toolkit
- [www.phe.gov/amcg](http://www.phe.gov/amcg)



## MedicalCountermeasure.gov

- Tech Watch program
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- Funding opportunities
- Resources 7 core service programs
- Regulatory guidance
- Federal strategies and reports

