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)

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

Radiation

Anthrax

Chemical

Botulism

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

Egg-based Vaccines
- H5N1 vaccine Licensed 2007

Cell-based Vaccines
- Flucelvax Licensed 11/20/12

Recombinant-based Vaccines
- FluBioK licensed 01/16/13

Universal Vaccines
- Q-PAN H5N1 Vax BLA submitted 2012

Antigen-Sparing Vaccine Technology

“More and better vaccines sooner”
BARDA Influenza MCMs

Q-PAN H5N1 Vaccine
GlaxoSmithKline

Cell-based Influenza Vaccine
Novartis

Next-Gen Portable Influenza Vaccine
Recombinant-based Influenza Vaccine
Protein Sciences
Covidien

Flu/RSV POC Diagnostic
3M/Focus

BARDA has established solid public-private partnerships with industry/academia providing critical core service assistance & expanding response capabilities

- **Public-Private Partnerships**
  - 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
- Changing Flu Vaccine Industry

2013 ISPE Facility of the Year

sanofi pasteur – Swiftwater, PA

Novartis – Holly Springs, NC
BARDA Provides Critical Core Service Assistance to MCM Developers

Centers for Innovation in Advanced Development & Manufacturing

Regulatory & Technical Expertise

Fill Finish Mfg. Network

Modeling Hub

Animal Studies Network

Strategic Investor

Clinical Studies Network

TBD

2012

BARDA Assists MCM Developers thru our Animal Models Network

Battelle Pacific Northwest Division
SRI International
Lovelace Respiratory Research Institute
MRIGlobal
IIT Research Institute
University of Illinois, Chicago
Battelle Memorial Institute
BioQUAL, Inc.
Southern Research
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)

Contract Awardees:

Emergent Manufacturing Operations Baltimore LLC
Novartis Vaccines & Diagnostics, Inc.
The Texas A&M University System (TAMUS)

BARDA Assists MCM Developers thru our New Fill Finish Manufacturing Network

Cook Pharmica

JHP Pharmaceuticals

DSM Pharmaceuticals

Nanotherapeutics/Baxter
• 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
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

BUDGET$ SUSTAINMENT
BARDA:
URL: http://www.phe.gov
BARDA e-mail: BARDA@hhs.gov
- Upcoming Events
- PHEMCE Strategy and Implementation Plan
- CBRN and Pan Flu Programs
- Business Toolkit
   - www.phe.gov/amcg

MedicalCountermeasure.gov
- Tech Watch program
- Federally-sponsored conferences
- Funding opportunities
- Resources 7 core service programs
- Regulatory guidance
- Federal strategies and reports