

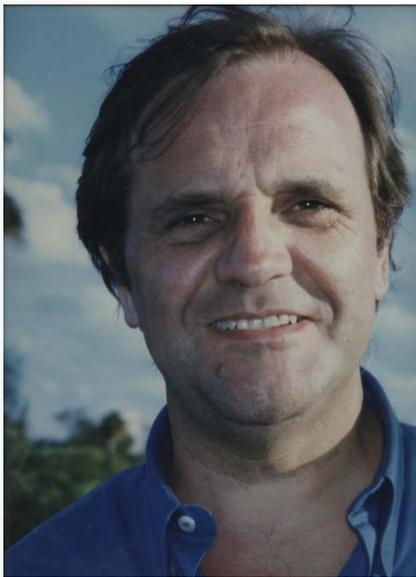


# WELCOME & STATE OF BARDA

**Richard J. Hatchett, MD**  
**Director (acting), HHS/ASPR/BARDA**  
**October 18, 2016**

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

# On the shoulders of giants



Roger Breeze  
10/19/46 – 6/14/16



D.A. Henderson  
9/7/28 – 8/19/16



Ellis McKenzie  
8/31/52 – 10/1/16



# Special Guests



RADM Nicole Lurie  
US Public Health Service  
DHHS/ASPR



Janet Woodcock  
Director, CDER  
U.S. FDA



George Korch  
Executive Director  
PHEMCE



Frederik Kristensen  
Senior Medical Officer  
CEPI

Breakout sessions will be held in Meridian D following  
Dr. Woodcock's and Dr. Kristensen's presentations  
(no registration required)



# Breakout Sessions

Session	Time
<i>Overview of PHEMCE and Requirements Process</i>	12:05 – 1:00
<i>Transitions in the PHEMCE – BARDA's Role</i>	1:00 – 2:00
<i>FDA / Regulatory Considerations</i>	2:00 – 3:00
<i>CARB-X Accelerator – How It Will Work</i>	3:15 – 4:15
<i>How BARDA Utilizes its Other Transaction Authority</i>	4:15 – 5:00
<i>How to Access BARDA's Core Services Pt. 1</i>	12:05 – 1:00
<i>How to Access BARDA's Core Services Pt. 2</i>	1:00 – 2:00
<i>CDC / Stockpile Considerations</i>	2:00 – 3:00
<i>Broad Agency Announcements: Tailoring White Papers and Proposals for Success</i>	3:15 – 4:15
<i>Economic Incentives for Emerging Infectious Diseases</i>	4:15 – 5:00

All pre-registered breakout sessions are in Oceanic



# Growth of Interest in BARDA

- Our mission is expanding
  - Combatting antibiotic resistant bacteria
  - Emerging infectious diseases: Ebola, MERS, Zika
  - New initiatives in traditional domains: Blood products, influenza therapeutics and vaccines, chemical threats, diagnostics
- Our track record speaks for itself
  - 24 products cleared, approved or licensed since 2007
  - 14 products procured for the SNS
- We are increasingly flexible in how we partner
  - Traditional contracts, grants, and cooperative agreements
  - Portfolio partnerships
  - Partnerships centered on BARDA's core services
  - CARB-X



# Goals for BARDA Industry Day

- Convey information you can use
- Provide opportunities for formal and informal interaction with BARDA and AMCG staff
- Entertain dialogue about BARDA's direction, priorities, and investments
- Gather feedback from our most important constituents and stakeholders



# BARDA's Present

- BARDA is at a strategic inflection point
  - New leadership will be installed
  - New administration coming in 2017
  - Unprecedented global focus on infectious disease threats
  - *BARDA Strategic Plan 2011-2016* will soon be obsolete
- We would like to share our vision of BARDA's future
  - We welcome your thoughts and input
- We are working within BARDA to foster a culture of
  - Innovation
  - Empowerment
  - Transparency
  - Inclusion



# Four Strategic Priorities

- Sustainable preparedness for established threats
- Unparalleled capacity to respond to emergent threats
- Programs that drive innovation in products, platforms, and enabling technology
- Partnerships of global reach and unprecedented efficiency



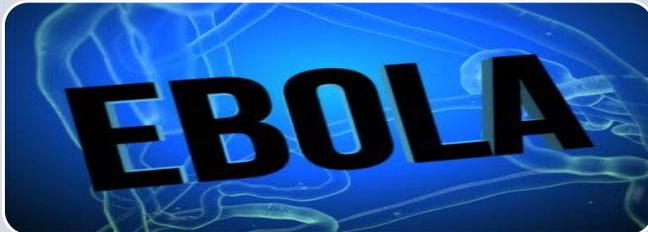
# Six Operating Principles

- Public-private partnerships
- Platform and enabling technologies
- Multipurpose products
- Control of total lifecycle costs
- Rigorous portfolio and project management
- Coordinated effort



# BARDA in Response

- Close to \$750M committed for response in FY2014-7
- 21 MCMs supported so far for Ebola and Zika
- Still no appropriation to support our EID program



Supported development of

- 4 vaccine candidates
- 1 supported diagnostic with EUA for oral, fluid and blood
- 3 therapeutics

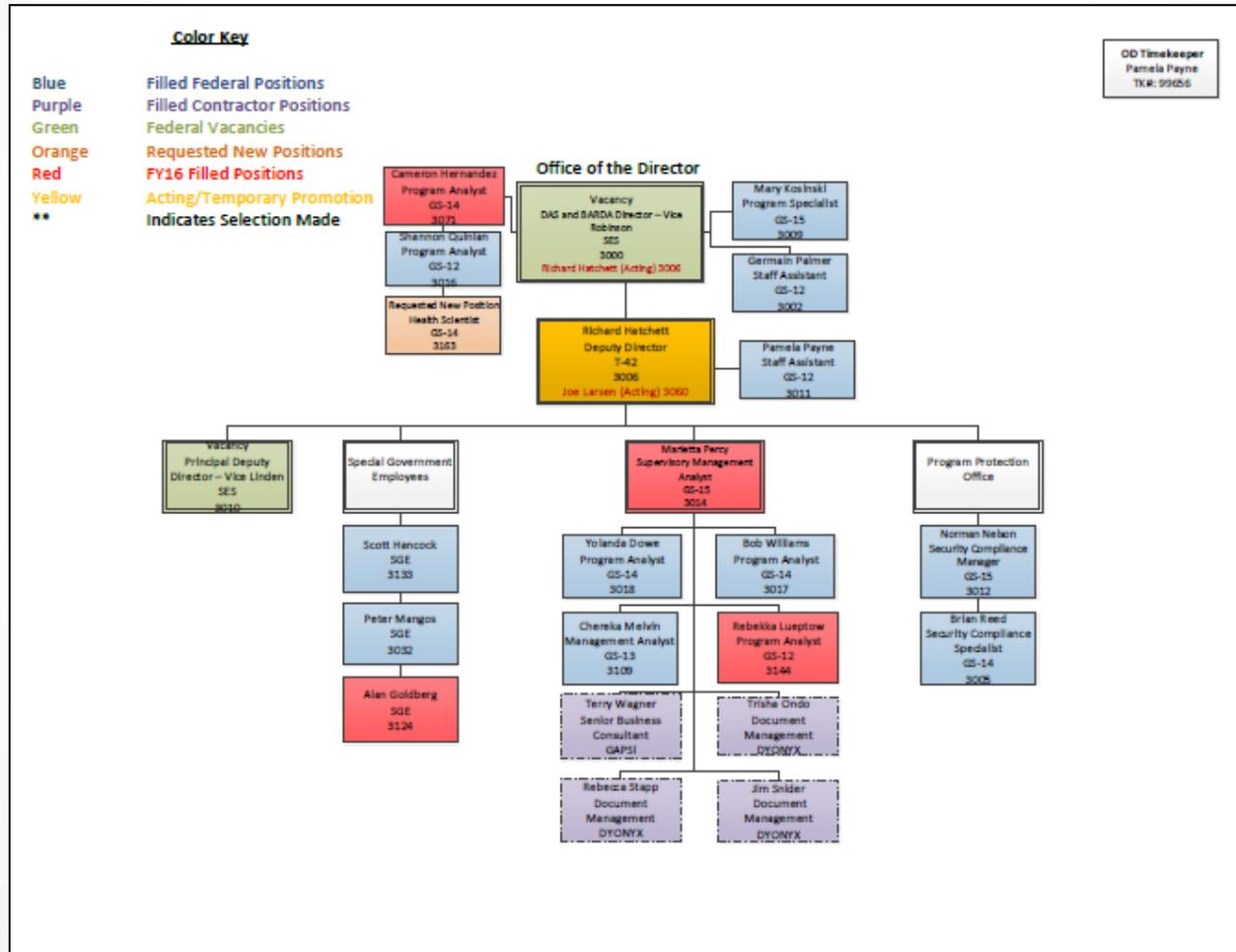


Supporting development of:

- 2 pathogen reduction technologies
- 2 blood screening technologies
- 4 serologic diagnostic assays; 1<sup>st</sup> commercial assay under EUA
- 5 vaccine candidates



# Office of the Director Reorganization



# Project BioShield Acquisitions

Threat	Product	Award Date
Anthrax	AVA vaccine	2007
	Nuthrax Vaccine	2016
	Anthrax Immune Globulin	2005
	Raxibacumab	2005
	Obiltoxaximab	2016
Botulinum Toxins	Heptavalent BAT	2006
Smallpox	MVA vaccine	2008
	Tecovirimat	2011
Radiological/Nuclear	Potassium iodide	2005
	Calcium/Zinc DTPA	2005
	Neupogen	2013
	Neulasta	2016
	Leukine	2013
	DxTerity Biodosimetry	2016
	MRIGlobal Biodosimetry	2016
Thermal Burns	Silverlon Dressings	2015
	NexoBrid Topical Gel	2015
	StratGraft Skin Substitute	2015
	ReCell	2015
Volatile nerve agents	Midazolam	2013

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	Leukine	2013
	<b>DxTerity Biodosimetry</b>	<b>2016</b>
	<b>MRI Global Biodosimetry</b>	<b>2016</b>
Thermal Burns	<b>SilverIon Dressings</b>	<b>2015</b>
	<b>NexoBrid Topical Gel</b>	<b>2015</b>
	<b>StratGraft Skin Substitute</b>	<b>2015</b>
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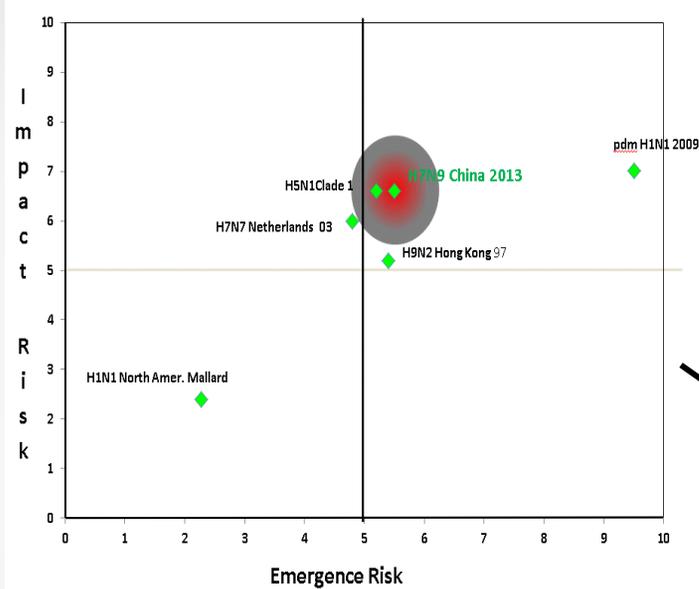
# FDA Approvals in FY2016

- **Nov. 2015** Neulasta (Amgen) pegfilgrastim, h-ARS following radiation exposure [approval]
- **Nov. 2015** AVA (Emergent) anthrax vaccine, for post-exposure prophylaxis [licensure]
- **Mar. 2016** Anthim (Elusys) anthrax monoclonal antibody antitoxin treatment [approval]
- **Aug. 2016** Building 55 sBLA approved (Emergent) [licensure]
- **Sept. 2016** Q-Pan H5N1 vaccine (GSK) pandemic egg-based inactivated, subunit monovalent influenza vaccine with AS03 adjuvant, pediatric indication [licensure]



# Expanding Use of Core Services

## Influenza Risk Assessment Tool



## BARDA Readiness in Times of Emergency Clinical Trial



**Bulk Pre-pandemic Influenza Vaccine Stockpiles (H5N1, H7N9)**

# New Global Partnerships

- Establish new global partnerships to address the problem of antimicrobial resistance and counter the threat of emerging infectious diseases by
  - Participating in the implementation of the World Health Organization's R&D Blueprint for EIDs
  - Participating in efforts such as GloPID-R to coordinate global funding of research on EID threats
  - Increasing direct collaboration with NGOs that fund R&D of medical products or play a role in the response



**CARB-X**  
*Xccelerating global antibacterial innovation*



innovative  
medicines  
initiative



Coalition for Epidemic Preparedness Innovations