



# The Domestic Biological Medical Countermeasure Program, A Coalition of the Willing

Michael S. Quinn  
Colonel, US Army  
US AWC-Fellow  
Michael.quinn@inta.gatech.edu

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# Background & Research Question



- Anthrax Letters
- The Department of Health and Human Services (HHS) receives an average of \$3.6 billion per year for civilian biodefense funding.
- The Project BioShield Act of 2004, authorized \$5.6 billion over a ten year period for advanced development and procurement of priority medical countermeasures for the Strategic National Stockpile.
- Question(s): 14 years after 9-11 and after such a large infusion of funds, how prepared is the United States at the federal level to respond to a domestic bio-terror attack? How has new legislation, policy, and appropriated dollars improved the MCM area?



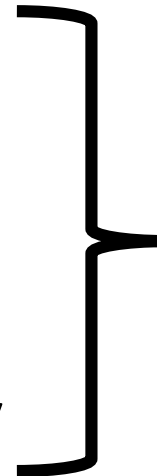
# Methodology



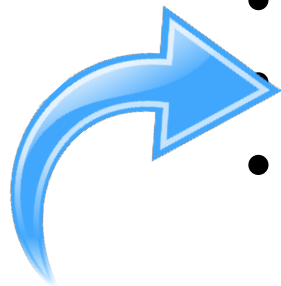
- Examine the HHS interdepartmental collaboration efforts with a focus on medical countermeasures.

- Framework-

- Policy and Authority
- Budgeting
- Acquisition Approach
- Strategic National Stockpile
- Inter-Governmental Synergy



DOD & Industry Comparisons  
Formal Reports (HHS & GAO)  
Interviews  
Congressional Testimony  
Historical Data

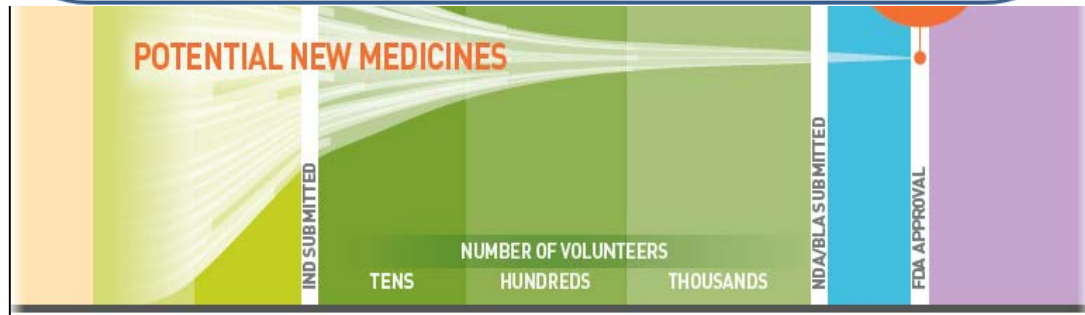
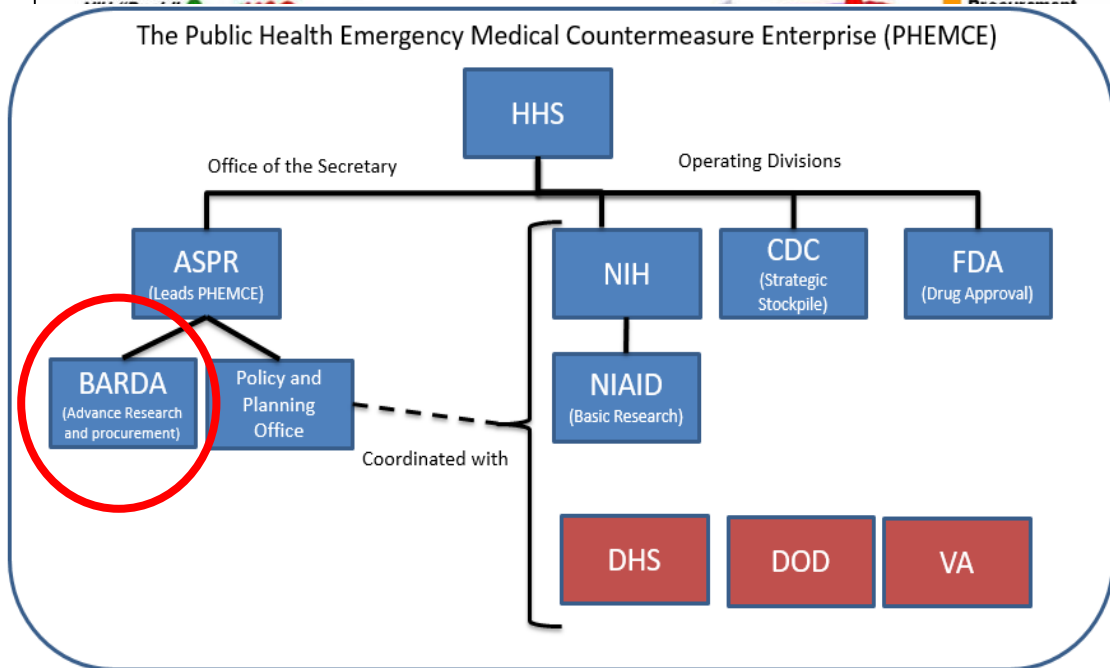
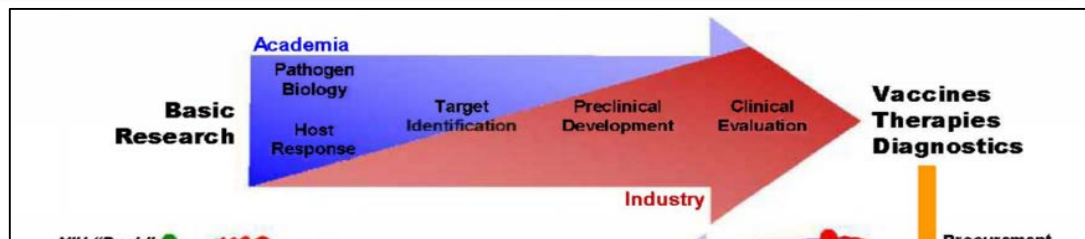




# Rocky Start



- Initial acquisition strategy failed
  - \$'s ≠ Success
  - \$5 billion was budget dust
- Pharma 101
  - 10 year average from discovery to FDA approval
  - \$1 billion investment
  - Valley of Death
  - 5 or more candidates in Phase I ≈ FDA approval
- Homeland Security Presidential Directive -18
- Creation of PHEMCE and BARDA



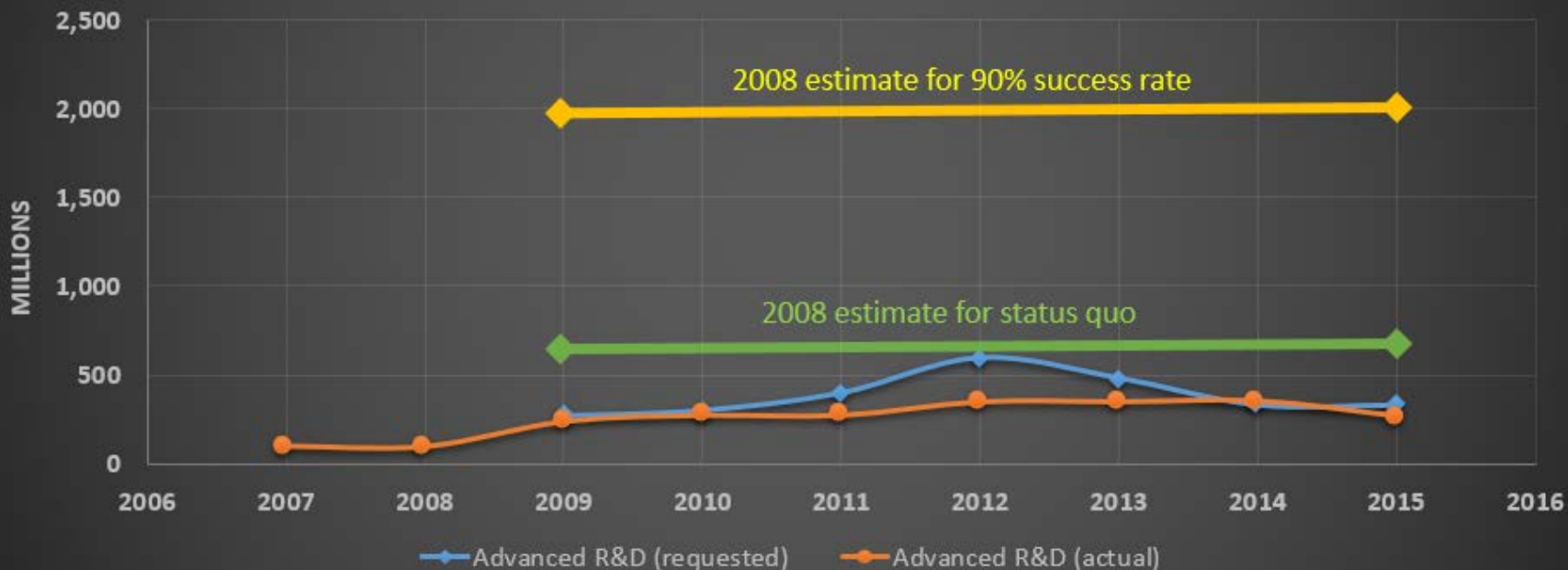


# Good Value or On Par



2008 Publication  
8 MCMs in the pipeline  
\$4.1 Billion over 7 yrs = 12%-85% FDA approval  
\$14 Billion over 7 yrs = 90% FDA approval

## Biomedical Advanced Research and Development Authority Budget





# Good Value or On Par



- Anthrax Vaccines
  - Est \$1.7 billion
  - BARDA spent \$369 million (2007-13)
- Anthrax Therapeutics
  - Est \$664 million
  - BARDA spent \$223 million (2007-13)
- Smallpox Antivirals
  - Est \$336 million
  - BARDA spent \$146 million (2007-13)

**\$14 Billion estimated.**

**BARDA Advanced  
Research budget 2007  
to 2015 = \$2.7 billion.**

*So what?*



# Delivery to the Strategic National Stockpile



MCM Program	Initial 2004 Acquisition	2007 I-Plan Goals Near-term (07-08) Mid-term (09-13)	Met near/mid-term delivery goal based on 2007 I-Plan
Anthrax Antitoxin		<b>Mid-term</b> - Phased acquisition of additional anthrax antitoxin	Yes
Anthrax Vaccine	1a. 5M doses, 2006	<b>Near-term</b> – 1. Acquire current vaccine 2. Acquire next generation vaccine	1. Yes 2. No
Broad Spectrum Antibiotics		<b>Mid-term</b> - pursue potential acquisition of additional broad spectrum antimicrobials	2010 contract awarded for AD
Broad Spectrum Antiviral(s)		<b>Long-term</b> - Due to its relative immaturity in the development pipeline, unlikely that it will be acquisition-ready	
Filovirus Medical Countermeasure(s)		<b>Mid-term</b> - Continue to invest in research and development and will pursue an acquisition	
Smallpox Antiviral		<b>Mid-term</b> - pursue acquisition	Yes
Smallpox Vaccine(s)	1a. 20M MVA doses	1. Pre-existing vaccine in SNS, potentially unsafe for persons with impaired immune systems. 2. <b>Near-term</b> - pre-award stage of an MVA vaccine acquisition program.	1a/1. Yes 2. Yes
Botulism Antitoxin (HBAT)	1a. 200K doses	<b>Near-term</b> -Contract awarded in 2006, (2007 target delivery - dependent on horse herd, 2007 BioShield report)	Yes

*The Challenge.....No More Low Hanging Fruit*



# Outside the Box Thinking



- Venture Capital Initiative or Strategic Investor
  - Leverages private funding and shares risk
  - Big Pharma uses
- Success stories
  - In-Q-Tel (CIA)
    - 200+ start-ups
    - Four government agencies as customers
    - 11:1 company to In-Q-Tel funding ratio
  - OnPoint Technologies (DOD - Army)
    - Army invested \$62 million
    - Saved Army/DOD \$375 million
    - 22:1 company to OnPoint funding ratio

April 2015, Secretary of Defense announced a one year program with In-Q-Tel in order to leverage Silicon Valley Technology

Congress disapproved BARDA's request for VCI funding 3 times






# Conclusions & Recommendations



*Is legislation, policy & funding working? Yes, but it's been a slow, rough and rocky start.*

- HHS is meeting delivery goals to Strategic National Stockpile.... but HHS could,
  - Appoint single office with appropriate budget and programming authorities
  - Request multi-year funding in support of R&D
  - Assume some risk with venture capital initiatives for R&D
- ...however, continue to
  - Sustain inter-agency collaboration (basic & advance development and production...the PHEMCE works!)
  - Refine program budget (5-year plan)
  - Develop MCM cost model

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- Framework-
    - Policy and Authority
    - Budgeting
    - Acquisition Approach
    - Strategic National Stockpile
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# Questions