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

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ICLAST
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• 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

BARDA - Biomedical Advanced Research Development Authority
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
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

<table>
<thead>
<tr>
<th>MCM Program</th>
<th>Initial 2004 Acquisition</th>
<th>2007 I-Plan Goals</th>
<th>Met near/mid-term delivery goal based on 2007 I-Plan</th>
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<tbody>
<tr>
<td>Ananthrax Antitoxin</td>
<td></td>
<td><strong>Mid-term</strong> - Phased acquisition of additional anthrax antitoxin</td>
<td>Yes</td>
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</table>
| Anthrax Vaccine              | 1a. 5M doses, 2006       | **Near-term** – 1. Acquire current vaccine 2. Acquire next generation vaccine     | 1. Yes [X]
|                              |                          |                                                                                 | 2. No [✓]                                          |
| Broad Spectrum Antibiotics    |                          | **Mid-term** - pursue potential acquisition of additional broad spectrum antimicrobials | 2010 contract awarded for AD                        |
| Broad Spectrum Antiviral(s)  |                          | **Long-term** - Due to its relative immaturity in the development pipeline, unlikely that it will be acquisition-ready |                                                     |
| Filovirus Medical Countermeasure(s) |                  | **Mid-term** - Continue to invest in research and development and will pursue an acquisition |                                                     |
| Smallpox Antiviral           |                          | **Mid-term** - 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. **Near-term** - pre-award stage of an MVA vaccine acquisition program. | 1a/1. 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
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 programing 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
Questions