



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



BARDA CBRN Program Accomplishments, Goals, and New Threat Initiatives

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Countermeasures**

BARDA Industry Day
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Overview



- BARDA CBRN Division
- Project BioShield
- Advanced Research and Development



Commitment



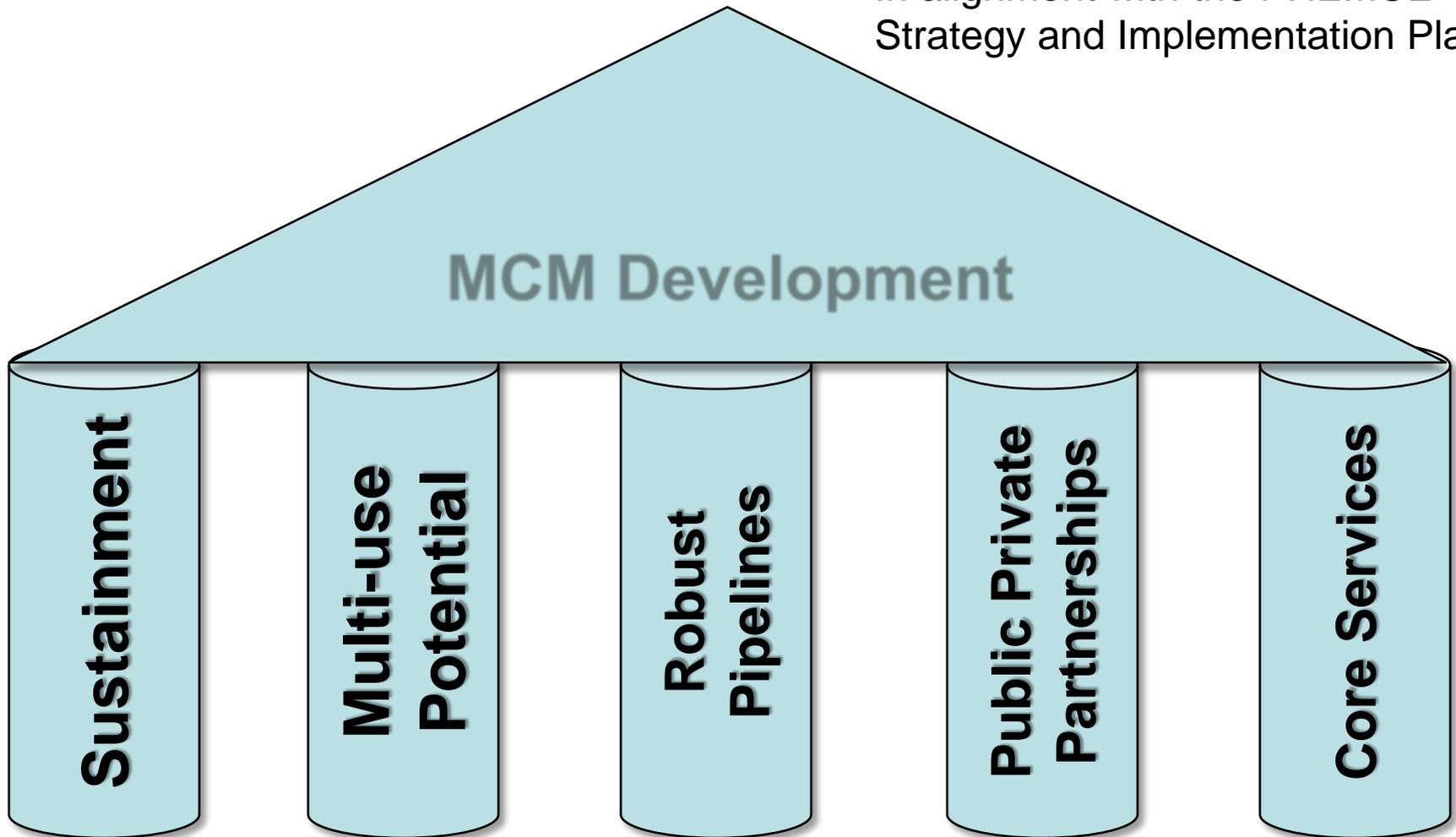
BARDA Mission

Develop and procure medical countermeasures that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases

If a product fails, it should only be the result of failure of the product to achieve the desired safety or efficacy thresholds, and not as a function of our inability to provide the proper support from a technical, business and regulatory perspective

CBRN Strategic Pillars

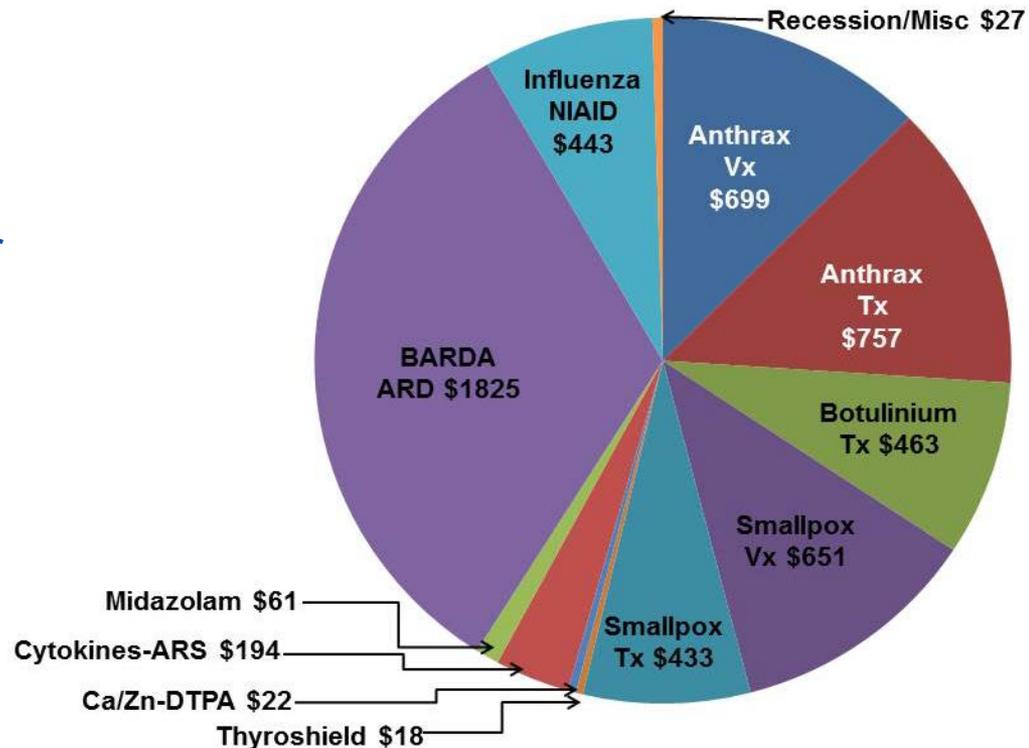
In alignment with the PHEMCE
Strategy and Implementation Plans





Project BioShield

- Had early difficulties – has transformed into a successful program
- Meeting the stated goal(s) of the program
 - Acting as a market guarantee for developers of products for which there is no commercial market
- Success of PBS led to the reauthorization of PAHPA in March 2013
- BARDA has a stated goal to deliver 8 – 12 new products to the SNS between FY 2014 – 2018



CBRN Products Procured for SNS Under PBS/SRF FY 2004 – 2013



At-Risk Pop

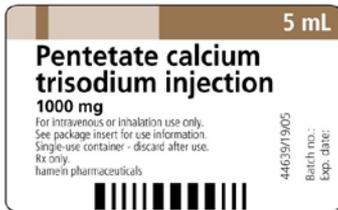
Smallpox



Anthrax



BLA submitted



Radiation



Pediatric

Chemical



Botulism



Sustainment

- Maintaining capabilities and capacities previously established
- Antitoxins
 - Raxibacumab anthrax monoclonal
 - Anthrax immunoglobulin
 - Heptavalent botulism antitoxin
- Antivirals
 - ST-246
- Vaccines - enhancements
 - Anthrax vaccine
 - Modified vaccinia Ankara





Multi-Use Potential



- Continued focus on products for which there is a commercial market
 - Decrease the necessity to stockpile products
 - Substantial savings for the USG
 - Acute radiation syndromes
 - Focus on advanced research and development candidates
 - Defining/characterizing endpoints for animal models of GI or pulmonary injury
 - Burn products
 - Blood products
 - Broad-spectrum antimicrobials
 - Address emergency preparedness with public health needs



Project BioShield – Future Funding



- The impact of a continuing resolution will mean that we receive the same level of funding provided in FY 2014
 - Received \$255M in FY 2014
 - Could have a negative impact on our ability to transition programs to late stage development and procurement
- New Acquisitions planned for 2014 – 2018
 - Biodosimetry devices
 - Thermal burn treatments
 - ARD drugs and therapies
 - Broad Spectrum Antimicrobials
 - Next generation vaccines
 - Chemical antidotes
 - Others, as available



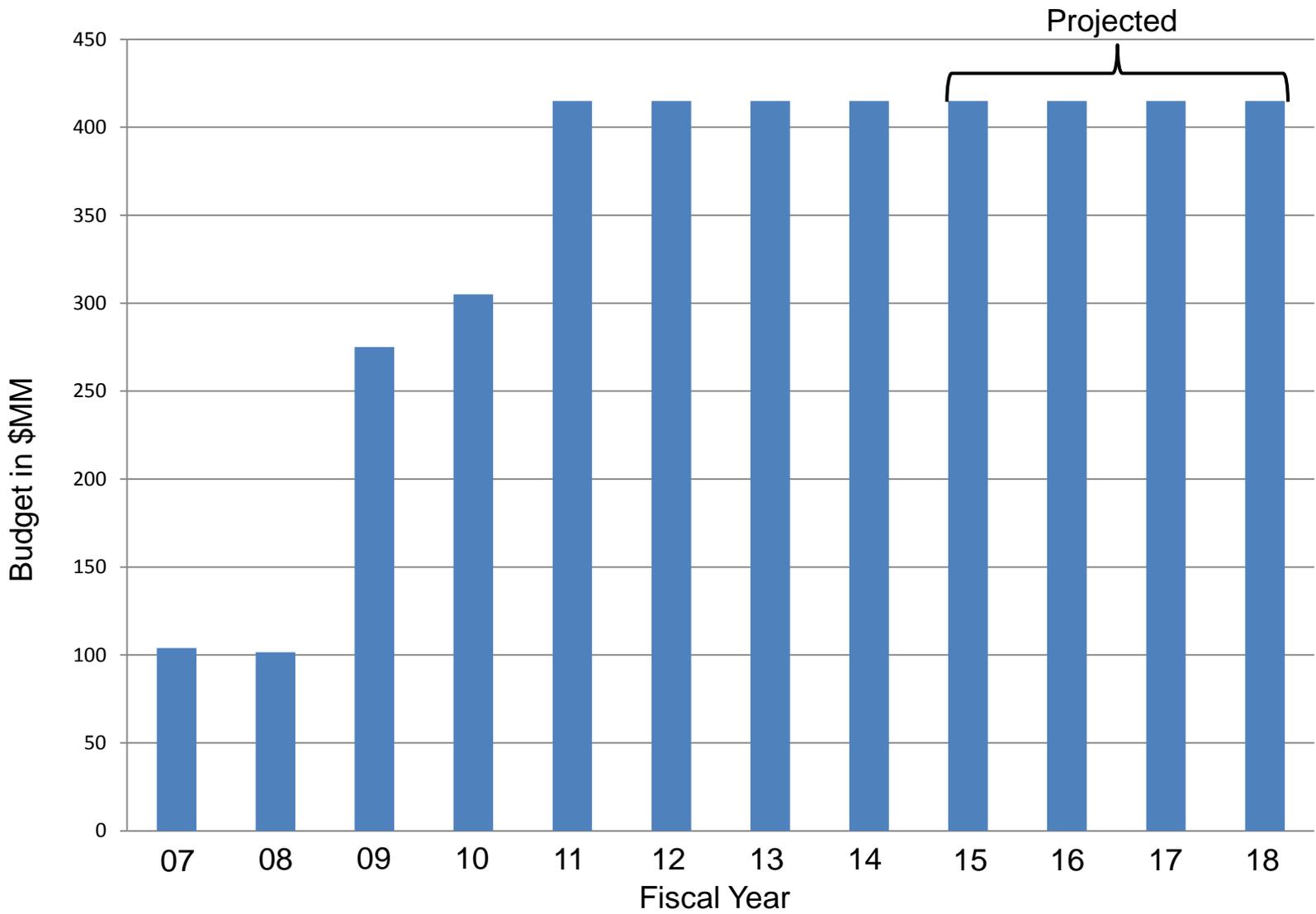
ARD Accomplishments



- Pipeline
 - Developed a robust pipeline of over 85, aggregate, candidate products
 - Currently 4 candidate products in Phase III clinical development
 - Initiated advanced research and development programs to address all threat agents
 - Addressing the needs of special populations
- Utilized novel partnering mechanisms, like other transactional authority, to effectively partner with industry
- Leveraged our Nonclinical Development Network
 - Develop
 - Animal models
 - Key reagents
 - Evaluate
 - Licensed/approved products (repurposing)
 - Candidate products to inform concepts of operations



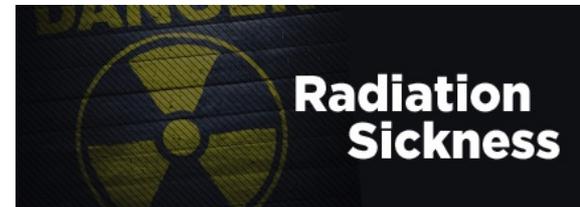
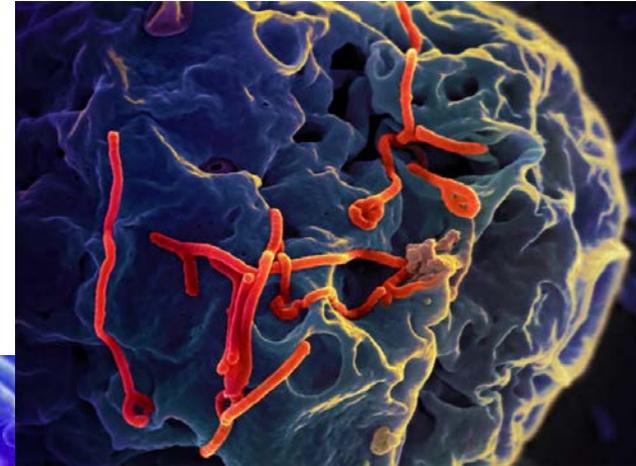
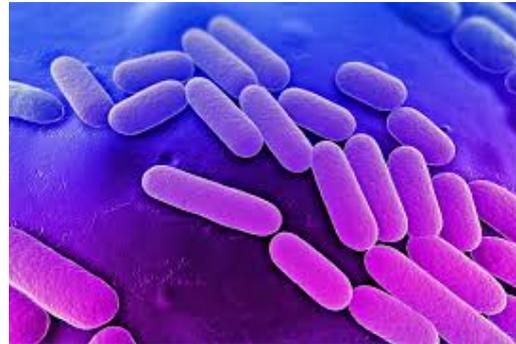
Advanced Research and Development Budget



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

Maintaining and Building Robust Pipelines

- Ebola and Marburg drugs/vaccines
- Broad spectrum antimicrobials
 - Novel drugs
- Improved anthrax vaccines
- Chemical MCMs
 - Volatile nerve agents
- Acute radiation MCMs
 - Skin, Lung, GI injury
- Burn products
- Blood products





FY 2014-18 ARD Investments Continued



Program	Investments	Comments/Gaps
Broad Spectral Antimicrobial	Slight increase	<ul style="list-style-type: none"> • Supporting WH initiative on antimicrobial resistance • Addressing public health threat
Ebola and Marburg	Increase	<ul style="list-style-type: none"> • Currently one program • Need funding to support additional programs • Cost/burden sharing with our PHEMCE partners
Anthrax Vx and Tx	Maintain	<ul style="list-style-type: none"> • Stockpile established • Looking for transformative improvements in anthrax vaccines
Smallpox Vx and Tx	Maintain	<ul style="list-style-type: none"> • Stockpile established • Supporting approval of products • Transitioning to a more cost effective vaccine
Chemical	Maintain	<ul style="list-style-type: none"> • Enhancing stockpile (CHEMPACKS) • Limited pipeline • Animal models lacking
Radiation and Nuclear	Refocus	<ul style="list-style-type: none"> • Stockpiling for H-ARS • Transitioning towards a pipeline of advanced stage candidates • Limited pipeline (Lung, GI, Skin) • Developing animal models for GI and Lung
Burn and Blood	Maintain	<ul style="list-style-type: none"> • Working with the ABA to develop products w/desired characteristics • Animal models are difficult • Approval pathways unclear

New Threat Focus: Ebola

- Immediate, near-term expansion to ramp up production of candidate product(s)
 - ZMapp
- Expansion of portfolio is needed, but is dependent on securing additional funding
- Working in close collaboration with PHEMCE partners
 - DoD, NIH
- Goal is to develop promising vaccines and therapeutic candidates in support of licensure/approval

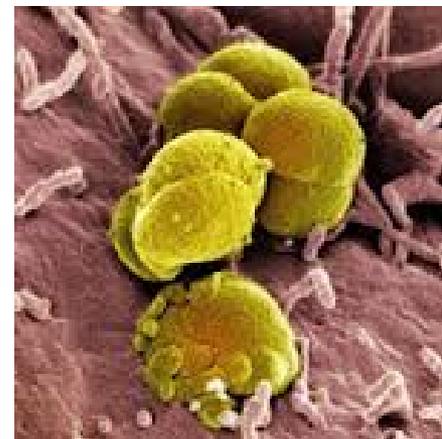




New Threat Focus: Antimicrobial Resistance



- White House Initiative on Combatting Antimicrobial Resistant Bacteria (CARB) driving continued emphasis
- Near term-modestly increase portfolio to address areas of greatest unmet medical need
- If additional funding is received will look to more aggressively expand portfolio of public:private partnerships in this area.





- The impact of a continuing resolution will mean that we will receive the same level of funding provided in FY 2014
 - BARDA anticipates the ARD budget to remain constant from 2015 – 2018
- However, funding will become “tighter” as programs progress and become more expensive
 - Changes have been made to the CBRN BAA reflecting our inability to continue transitioning programs at lower technology readiness levels
- Potential increases to support CARB or Ebola epidemic
 - Without additional funding – there will limited increase in number of programs



Summary

- Overall the level of CBRN program expansion is low
- No anticipated expansion
 - Anthrax antitoxins and vaccines
 - Smallpox vaccines and antivirals
 - Botulism
- Modest expansion
 - Broad spectrum antimicrobials
- Broader expansion
 - Ebola
- Core services will continue to support our industry partners



CBRN New Threat Initiatives



Questions?

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