

Development of a New Treatment for Anthrax in Partnership with DoD and HHS

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VP Corporate Development

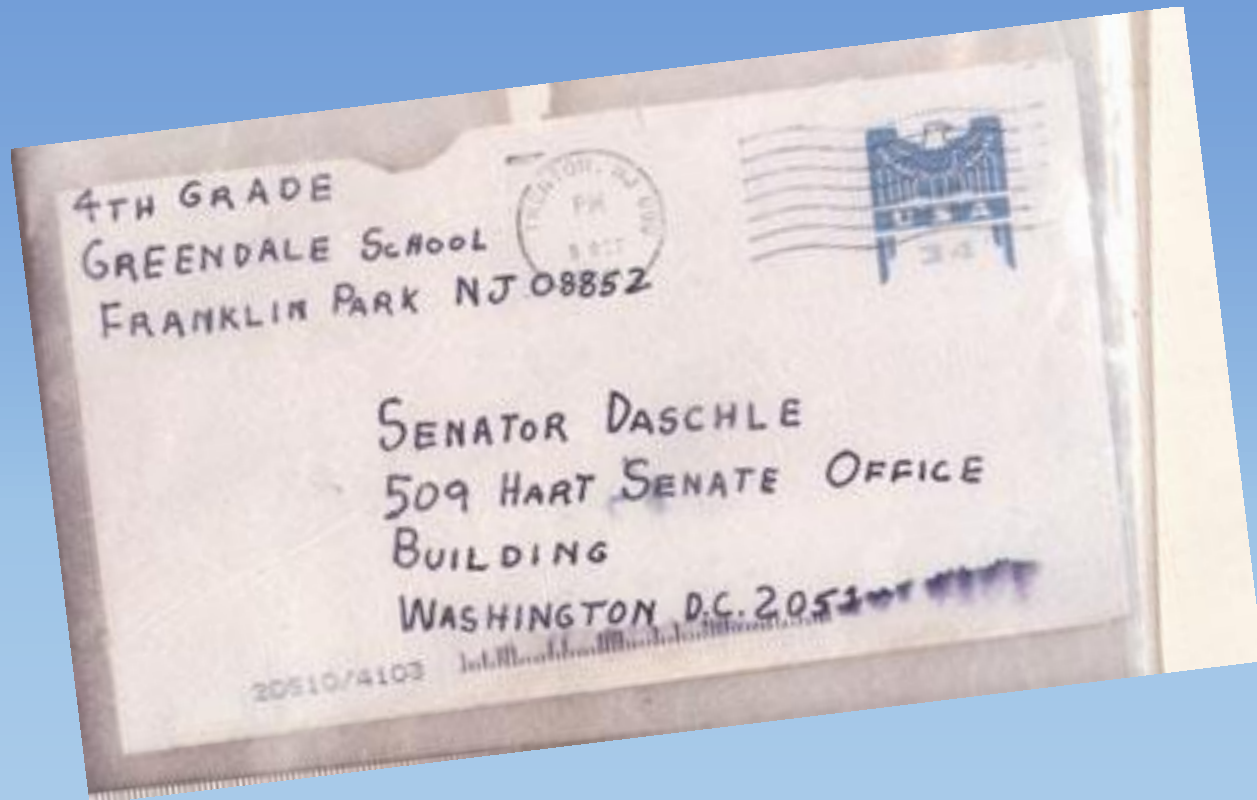




- STARTING IN 2002, Elusys developed Anthim[®] (obilttoxaximab), a monoclonal anthrax antibody antitoxin in partnership with the US government
- \$240M in funding from HHS, DoD and NIAID contracts to support Anthim development over 13 years
- \$45M procurement contract in November 2015 to manufacture Anthim for the US Strategic National Stockpile
- FDA licensure March 18, 2016



2001 Anthrax Attacks

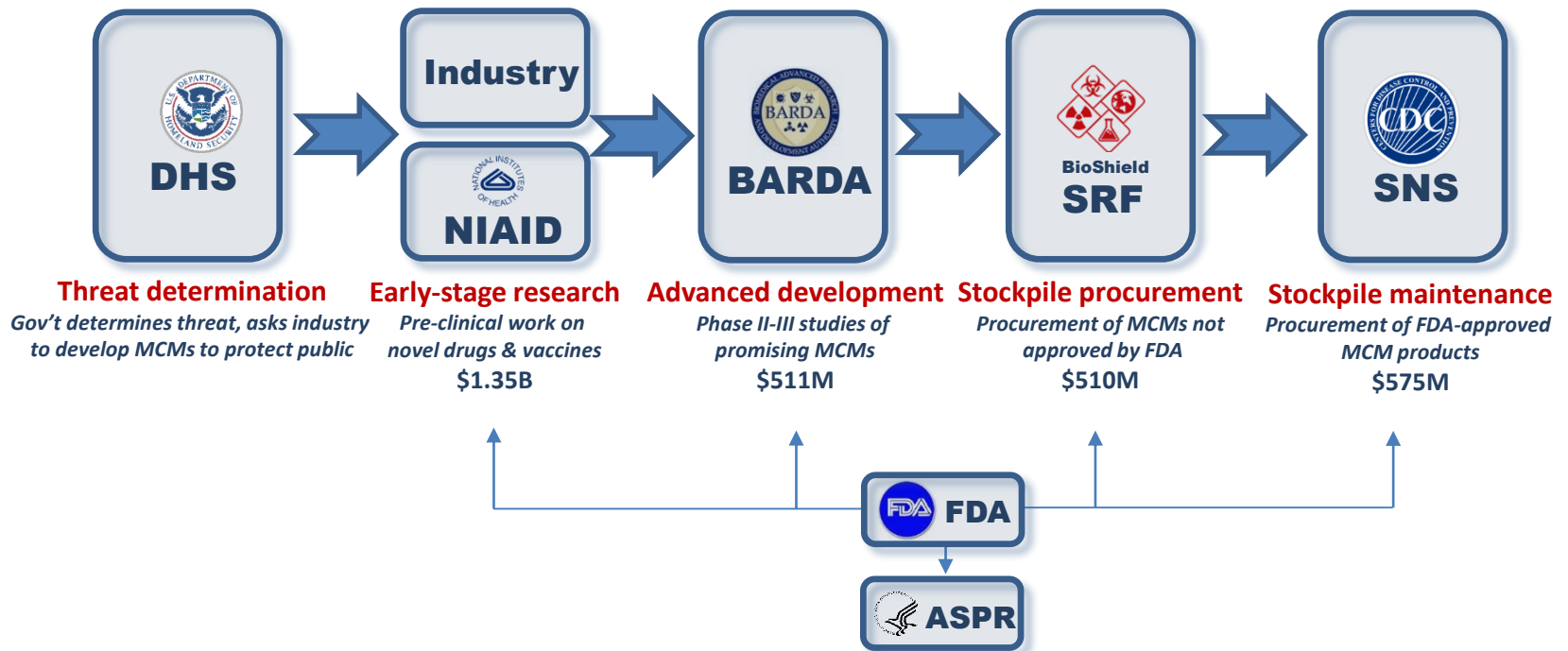




Category A Priority Pathogens:

- Bacillus anthracis (anthrax)
- Clostridium botulinum toxin (botulism)
- Yersinia pestis (plague)
- Variola major (smallpox) and other related pox viruses
- Francisella tularensis (tularemia)
- Viral hemorrhagic fevers
 - Arenaviruses
 - Junin, Machupo, Guanarito, Chapare, Lassa, Lujo
 - Bunyaviruses
 - Hantaviruses causing Hanta Pulmonary syndrome, Rift Valley Fever, Crimean Congo Hemorrhagic Fever
 - Flaviviruses
 - Dengue
 - Filoviruses
 - Ebola
 - Marburg

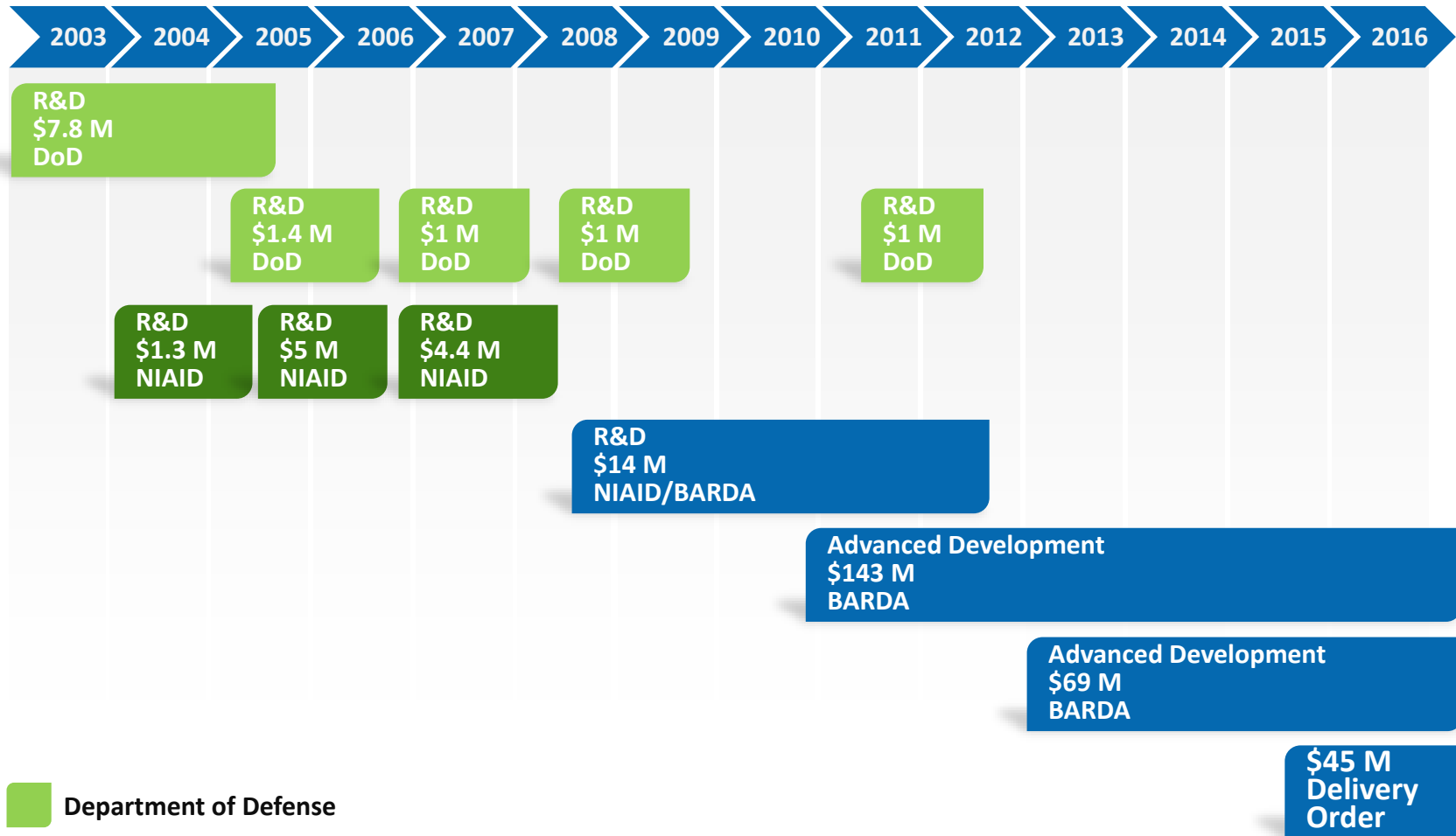
HHS Medical Countermeasure Development Pathway



DOD also works with industry to develop MCMs for some of these same threats, with a focus on the needs of the warfighter

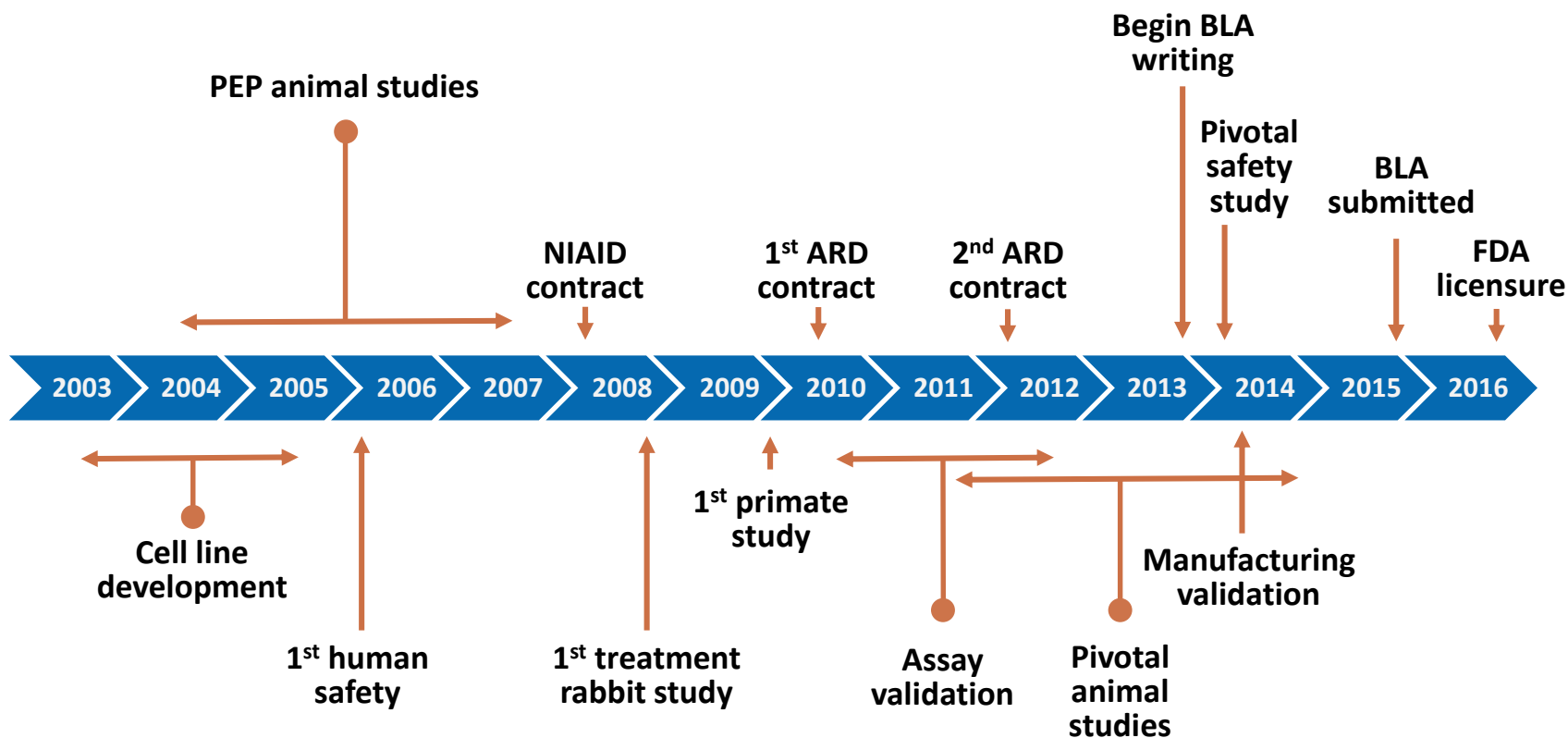
**Funding figures reflect FY16 Omnibus level*

Elusys Contract Awards

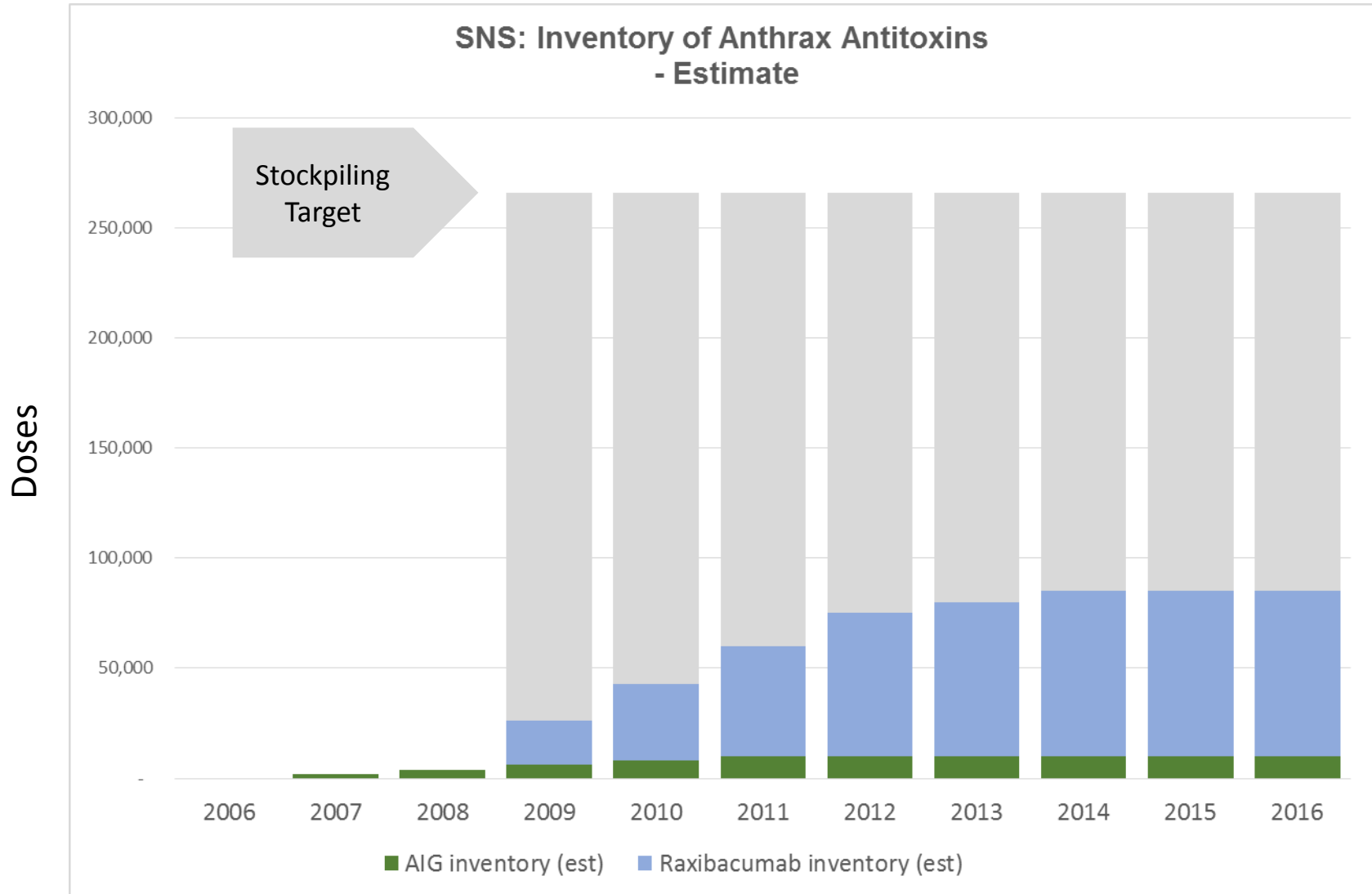


- Department of Defense
- NIAID
- BARDA

Anthim Development Timeline



SNS Inventory Shortfall

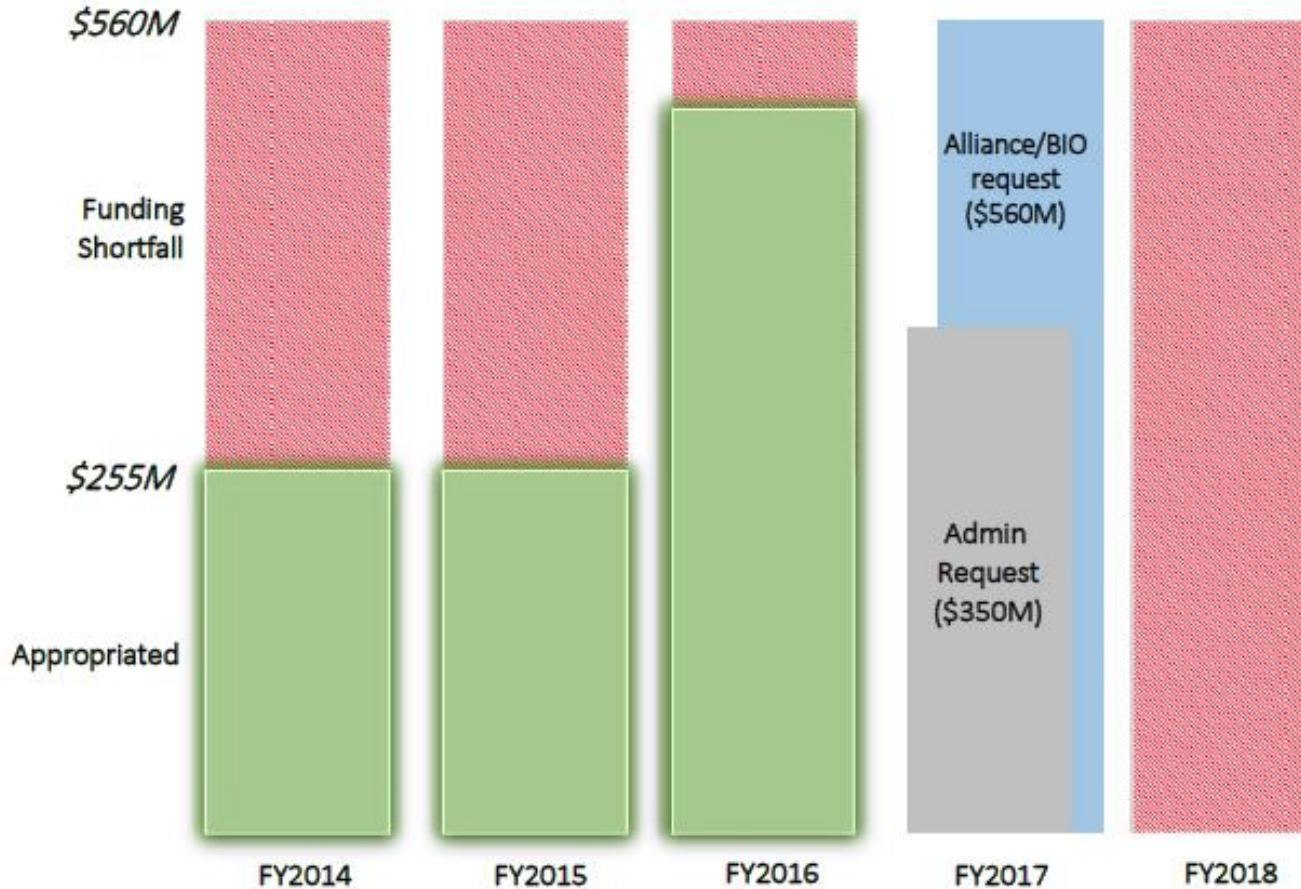


BioShield SRF Funding Shortfall

\$2.8B Authorized by Congress over FY14-FY18



Only \$1.02B (36%) appropriated





Targeted – “One Drug – One Bug”

e.g.

- Vaccines
- Monoclonal Antibodies



- *Incremental R&D*
- *Predictable Development Path*
- *Lower Risk*
- *Dependent on Single Purchaser (usually US Government)*

Broad Spectrum – “One Drug – Many Bugs”

e.g.

- Antibiotics
- Antivirals



- *Radical R&D*
- *Unpredictable Development Path*
- *Higher Risk*
- *Commercial Potential (beyond USG)*

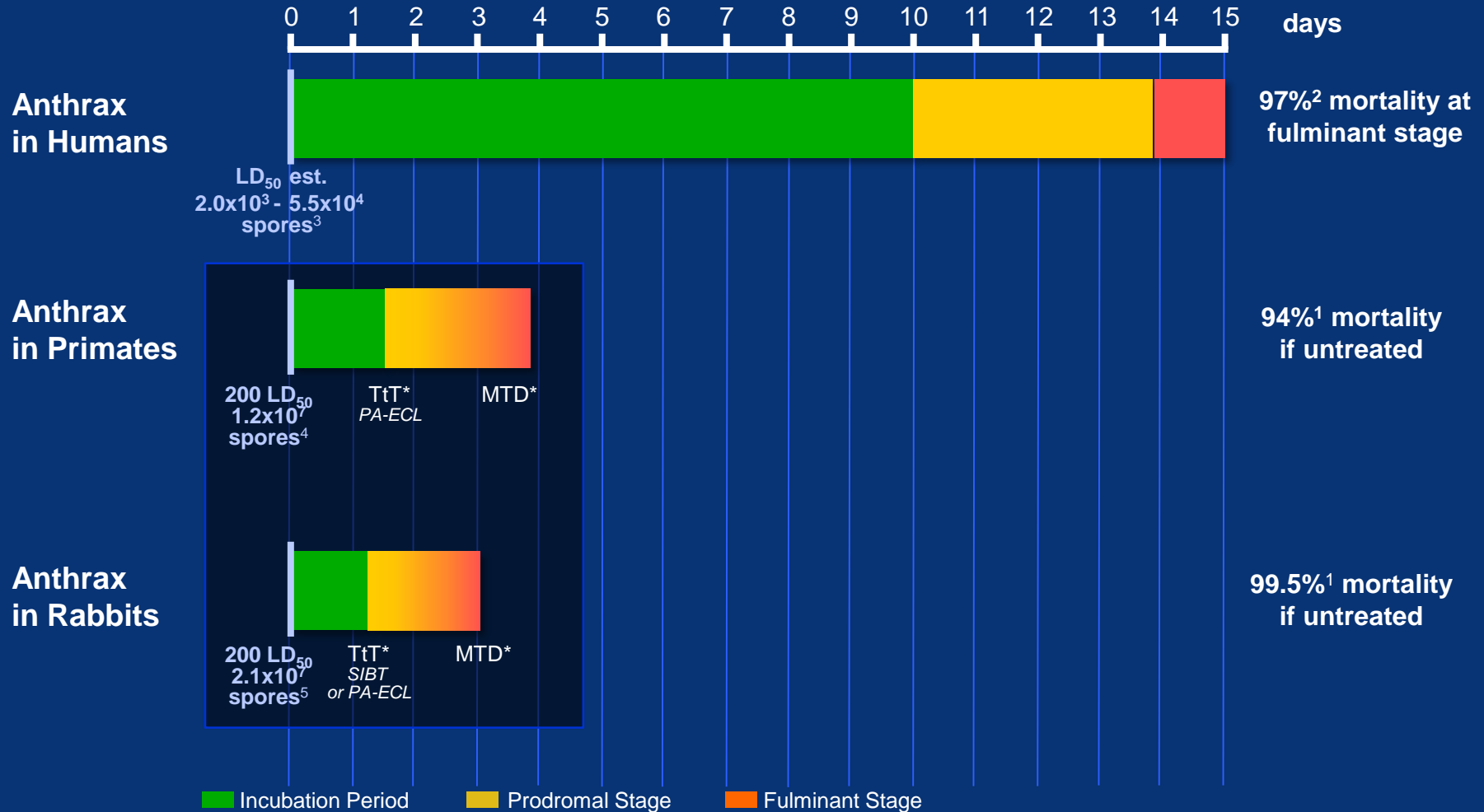


- Understanding disease pathophysiology
- Demonstrating efficacy in well-characterized animal models
 - FDA requires randomized double blind placebo controlled studies
- Pharmacokinetics and pharmacodynamics of the countermeasure
 - Measuring drug and target antigen in:
 - Infected animals
 - Uninfected animals
 - Uninfected humans



Predictive dose in infected humans

Interspecies Comparison on Inhalational Anthrax Disease Progression



TtT: Trigger to Treat; MTD: Median Time to Death

¹Based on BARDA sponsored Updated Statistical Meta-Analysis of Anthrax Therapeutic Studies dated February 22, 2013 (SN0120, April 10, 2013).

²Based on Holty et al. *Ann Intern Med.* 2006;144:270; ³Based on Inglesby et al. *JAMA.* 2002; 287: 2236; ⁴Based on Vasconcelos et al. *Lab Invest.* 2003; 83:1201;

⁵Based on Zaucha et al. *Arch Pathol Lab Med.* 1998; 122



- Anthim licensure demonstrates value & success of industry and the USG working together to develop needed MCMs
 - NIAID, DOD and BARDA Advanced Research and Development (ARD) awards have sustained the development of several important MCMs
- Procurement of Medical Countermeasures is not guaranteed!
- Development and FDA approval of Medical Countermeasures under the animal rule is complex time consuming but possible