Project Bioshield 2006-2016

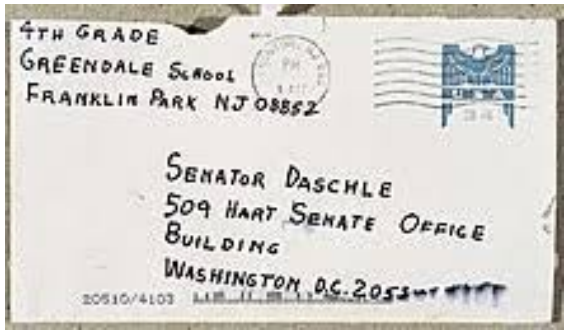
Joe Larsen, Ph.D.

Disclaimer

- The opinions expressed here are my own, and not of Venatorx Pharmaceuticals, BARDA, or the US government.

Historical Context

- Following the attacks of Sept 11th and the following Amerithrax attacks, there was keen interest in bolstering the supply of medical countermeasures (MCM) to protect the American public



Project Bioshield Act of 2004

- Signed into law by President George W. Bush on July 21st, 2004
- Created a $5.6B fund for the procurement of medical countermeasures
- Anthrax countermeasures were high priority

Push/Pull

To understand what made BARDA/PBS successful we need to discuss incentives:

Push incentives: subsidize development costs, de-risks programs for future development or procurement

Pull incentives: guaranteed ROI, awards successful research only

Early missteps: All pull, no push

WASHINGTON

The New York Times

Bid to Stockpile Bioterror Drugs Stymied by Setbacks

CIDRAP Center for Infectious Disease Research and Policy

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HHS cancels VaxGen anthrax vaccine contract

Filed Under: Anthrax; Public Health; Smallpox
By: Robert Roos | Dec 20, 2006

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Dec 20, 2006 (CIDRAP News) ☐ The US government yesterday canceled its $877.5 million contract with VaxGen Inc. for a new anthrax vaccine, after problems with the vaccine's stability caused the company to miss a deadline for starting a clinical trial.

The contract was the first and largest award under Project BioShield, designed to stimulate the production of medical countermeasures for biological weapons and related threats. The cancellation came the same day President Bush signed new legislation designed to revive the faltering $5.6 billion program.

Later missteps: All push, no pull

Antibiotics maker Melinta declares bankruptcy

Melinta is the latest victim in a troubling trend of unprofitability for antibiotics

by ***Ryan Cross***

January 2, 2020 | A version of this story appeared in **Volume 98, Issue 1**

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Antibiotics Developers Seek a Cure for Industry Ills

Recent bankruptcy of drug developer Achaogen reflects industry struggling to meet challenge of drug-resistant bacteria

Pandemic All Hazards Preparedness Act

Signed into law in December 2006, lowered PBS funding to $2.8B and switched to annual appropriation

Created the Biomedical Advanced Research Development Authority

Created the Office of the Assistant Secretary of Preparedness and Response

Authorized the use of funding to support the advanced research and development of medical countermeasures.

Re-authorized in June of 2019

Products Procured by PBS: Anthrax

- Biothrax Anthrax Vaccine Adsorbed (FDA Approved), Emergent Biosolutions
- Nuthrax, AVA+CPG 7909 (Stockpiled under EUA), Emergent Biosolutions
- Raxibacumab (FDA Approved), Emergent Biosolutions
- Anthrasil (FDA Approved), Emergent Biosolutions
- ANTHIM, obiltoxaximab (FDA approved), Elusys Therapeutics
- Nuzyra, Omadacycline (stockpiled under EUA), Paratek Pharmaceuticals

Products Procured by PBS: Smallpox

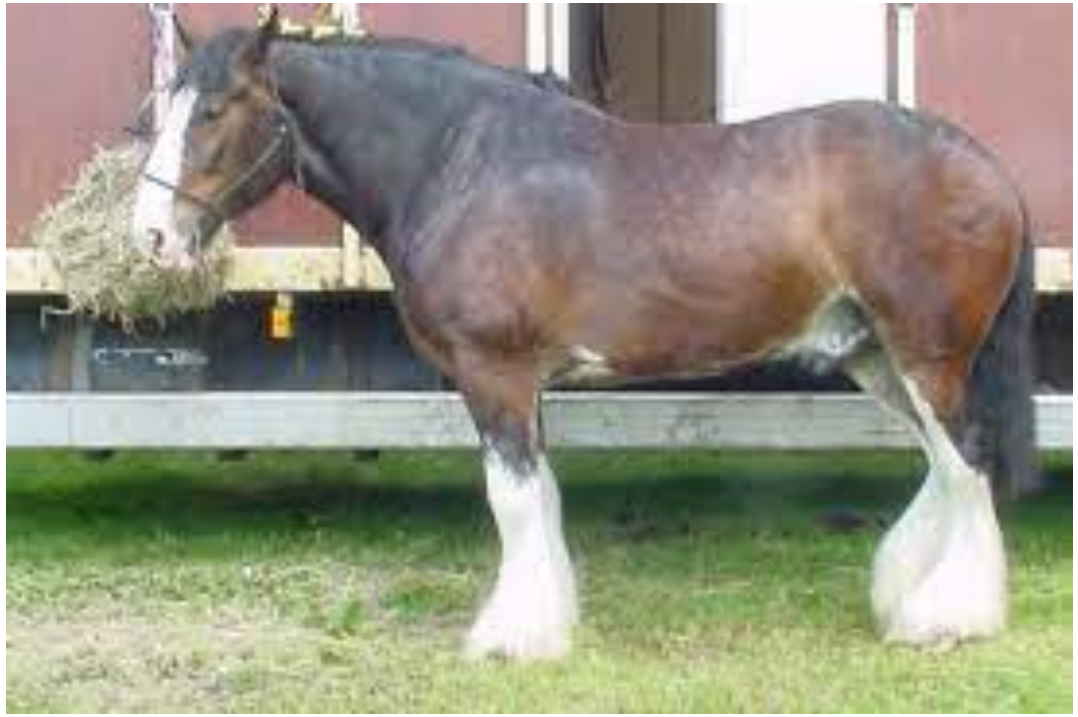
IMVAMUNE, modified vaccine Ankara (FDA approved), Bavarian Nordic

TYPOXX, tecovirimat (FDA approved), SIGA Technologies

TEMBEXA, brincidofovir (FDA approved), Chimerix

Products Procured by PBS: Botulism

- Heptavalent botulism antitoxin HBAT (FDA approved), Emergent Biosolutions



Products Procured by PBS: Ebola

- Ervebo, VSV-vectored vaccine (FDA approved), Merck
- Zabdeno/Mvabea Ad prime, MVA boost vaccine (EMA approved, EUA in US), Janssen
- Inmazeb REGN-EB3, (FDA approved). Regeneron Pharmaceuticals

Other products developed but not procured by PBS:

- Ebanga (Ansuvimab/mAb114) treatment for Ebola virus disease (EVD), (FDA Approved) Ridgeback Biotherapeutics
- OraQuick Ebola Rapid Antigen (diagnostic) Test by OraSure Technologies was cleared by FDA in 2019.

Products Procured by PBS: Rad/Nuc

- Neulasta, pegfilgrastim (FDA approved), Amgen
- Neupogen, filgrastim (FDA approved), Amgen
- Leukine, sargramostim (FDA approved), Partner Therapeutics
- Biodosimetry Devices
- Chelating Agents

Products Procured by PBS: Thermal Burn

- Silverlon silver impregnated bandage (FDA approved) Argentum
- Nexobrid, enzymatic debridment, (stockpiled under EUA) Mediwound
- Recell, autograft sparing tech, (FDA approved) Avita Medical
- Stratagraph, skin substitute, (FDA approved), Stratatech

Conclusion

BARDA and Project Bioshield have successfully generated a medical countermeasure portfolio to address CBRN threats of concern

Both push and pull incentives are required to effectively manage risk and reward successful product developers

Sustainability and broadening the scope of the program to other threats (e.g., AMR pathogens, Emerging Infectious Diseases) remain key challenges.