Innovation in products and partnerships for flexible, dynamic response capabilities

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09-11-01

You can not stop us. We have this anthrax. You die now. Are you afraid? Death to America. Death to Israel. Allah is great.

09-11-01
This is next
Take penicillin now
Death to America
Death to Israel
Allah is great

SPECIAL REWARD
Up to $2.5 million

For information leading to the arrest and conviction of the individual(s) responsible for the mailing of letters containing anthrax to the New York Post, Tom Brokaw at NBC, Senator Tom Daschle and Senator Patrick Leahy:

AS A RESULT OF EXPOSURE TO ANTHRAX, FIVE (5) PEOPLE HAVE DIED.

The person responsible for these deaths...
• Likely has a scientific background/work history which may include a specific familiarity with anthrax
• Has a level of comfort in and around the Trenton, NJ area due to present or prior association

Anyone having information, contact America's Most Wanted at 1-800-CRIME TV or the FBI via e-mail at amerithrax@fbi.gov

All information will be held in strict confidence. Reward payment will be made in accordance with the conditions of Postal Service Reward Poster 296, dated February 2000. Source of reward funds: U.S. Postal Service and FBI $2,000,000; ADVO, Inc. $500,000.
The Threats are Real

CBRN

Pandemic Influenza

Emerging Infectious Diseases
Establishment of BARDA

- $5.6B advanced appropriation to develop MCMs against CBRN threats
- Established the ASPR and BARDA
- BARDA – CBRN, PI, and EID threats
- Authority to invest in ARD
- EUAs

PBS – 2004

PAHMA – 2006

PAHPRA – 2013

- New, yearly funds for ARD: $415M
- Reauthorization of PBS: $2.8B

- Restore BARDA Contracting
- MCIP Program

21st Century Cures Act – 2016
BARDA’s Mission: Saving Lives, Protecting America
The BARDA Model

MCM Development

MCM Stockpiling

Core Services

Infrastructure

FDA Approvals

Partnerships

Dedicated & Talented Team
BARDA’s Core Services: Our Response Infrastructure

- CIADMs: Centers for Innovation in Advanced Development & Manufacturing
- Fill-Finish Manufacturing Network
- Nonclinical Development Network
- Clinical Studies Network
- Quantitative Analytical Modeling Hub
- Regulatory & Quality Affairs

Timeline:
- 2006: Regulatory & Quality Affairs
- 2009: Quantitative Analytical Modeling Hub
- 2011: Nonclinical Development Network
- 2012: CIADMs
- 2013: Fill-Finish Manufacturing Network, Clinical Studies Network
Over $1.5 Billion Invested in FY17

Total: $1,556,906,321

- Project BioShield: $531.1 M
- Pandemic Influenza: $268.1 M
- Zika: $262.9 M
- Advanced Research & Development: $452.0 M
- Ebola: $42.8 M
Growing Investments

FY15
$1,013,570,435

FY16
$1,192,451,778

FY17
$1,556,906,321

- Ebola
- PanFlu
- Zika

AR&D
PBS
PanFlu
Zika
Our Industry Partners
Our Federal Partners

Office of Infectious Diseases
Office of Public Health Preparedness and Response
National Center for Immunization and Respiratory Diseases (NCIRD)
CDC Immunization Safety Office
National Center for Emerging and Zoonotic Infectious Diseases
HHS.gov
National Vaccine Program Office
Office of the Assistant Secretary for Health

NIH National Institutes of Health
National Institute of Allergy and Infectious Diseases
National Heart Lung and Blood Institute
National Institute of Neurological Disorders and Stroke
Division of Veterinary Resources
OLAW

CBER
Center for Biologics Evaluation and Research
FDA

BAAEDA
BAAEDA

NIH
National Institutes of Health
FDA Approvals, Licensures, and Clearances
Project BioShield

Our **pledge** to you...

- **27** products supported
- **14** products added to the Strategic National Stockpile
- **6** products taken to FDA approval/licensure/clearance
Looking to the Future
2018 Priorities

Sustain
- Industry Partnerships
- Capabilities
- Capacity

Streamline
- Single BARDA BAA
- BARDA Contracting
- Communications

Foster Consortia & Partnerships
- Other Transaction Agreements
- Strengthen alignment with DoD

Promote Innovation
- End-to-End Focus
- Last Mile
CBRN Preparedness

Preparedness Gaps

VESICANTS
CYANIDE
CHLORINE
PHARMACEUTICAL-BASED AGENT
SUDAN
MARBURG
EBOLA
GLANDERS
MELIIOIDOSIS
NERVE AGENTS
NUCLEAR
RADIOLOGICAL
BOTULISM
TULAREMIA
PLAGUE
SMALLPOX
ANTHRAX
Rapid Response Capability

MCM Development Stage

- Preclinical
- Phase I
- Phase II
- Phase III
- Licensure

MCM candidate based on Platform Technology

Outbreak!

New Threat Data

CIADMs

New MCM candidate

For any outbreak:
- Rapid development
- Rapid manufacturing
- Rapid response

Large Scale Production
Innovation in Diagnostics

For any outbreak:
- Faster identification
- Faster response
- Real-time epi-data

Wearable diagnostic for faster identification, faster response, and real-time epi-data.
Respiratory Protection: Innovation in Design and Materials

Example: Reusable respirators

Develop respirators that are:
- Safe
- Effective
- Comfortable
- Reusable
- Simple
- Minimally interfering

N95 requirement for single-use respirators
N95 requirement for reusable respirators
CARB-X: A Model for Early-Stage Development Partnerships

A private sector approach to funding and portfolio management

Portfolio currently contains 23 candidates
Other Transaction Agreements: Model for Late-stage Development

A more flexible, portfolio-based approach to partnerships
Committing to a More Effective BARDA

• **Improved Communication**

• **Improved Responsiveness**
Streamlining our Engagement of Industry

- Single, secure web-based system
- Integrate market research, outreach, application reviews, and project management
- Real-time tracking of portfolio/product landscapes, with data analytics and visualization tools

Faster, integrated engagement, reviews, and partnering
BARDA TechWatch: Accelerating Success

TechWatch

Strategy - Exchange

Expertise - Planning

Next Steps

BARDA Knowledgebase

BARDA Portfolio

Continue Developing in Private Sector

Connect to Other Agencies

Medical Countermeasures.gov
Our Greatest Resource

We Look Forward to Partnering With You!

ASPR: Saving Lives...Protecting America
https://www.medicalcountermeasures.gov/home.aspx
• Portal to BARDA: **Register to request a TechWatch meeting!**

https://www.fbo.gov/ (“FedBizOpps”)
• Official announcements and info for all government contract solicitations

https://www.usajobs.gov/
• Join the team!

https://www.phe.gov/about/BARDA/Pages/default.aspx
• Program description, information, news, announcements

Medical Countermeasures.gov

ASPR: Saving Lives…Protecting America