



BARDA Development and Funding: Chemical, Radiological and Nuclear Portfolio

Biomedical Advanced Research Development Authority (BARDA)

**Chemical, Radiological and Nuclear Medical Countermeasures
HHS/ASPR/BARDA**



Outline of this Talk

- 1. Mission:** Administrative Structure & Coordination
- 2. Requirements:** Defining the Need, Mission Space
- 3. Events:** Characteristics, Operations (CONOPS), Modeling
- 4. Our Approach:** The Integrated Portfolio
- 5. Drug Development:** Creating a Pipeline – Timing and Cost
- 6. Accomplishments:** What we are doing now



Biomedical Advanced Research and Development Authority (BARDA)



**The Pandemic and All-Hazards Preparedness Act
(P.L. 109 – 417, December 2006)**

BARDA manages advanced development and procurement programs for vaccines, drugs, therapeutics and diagnostics for CBRN threats, pandemic influenza, and emerging infectious diseases.



Programs are supported by:

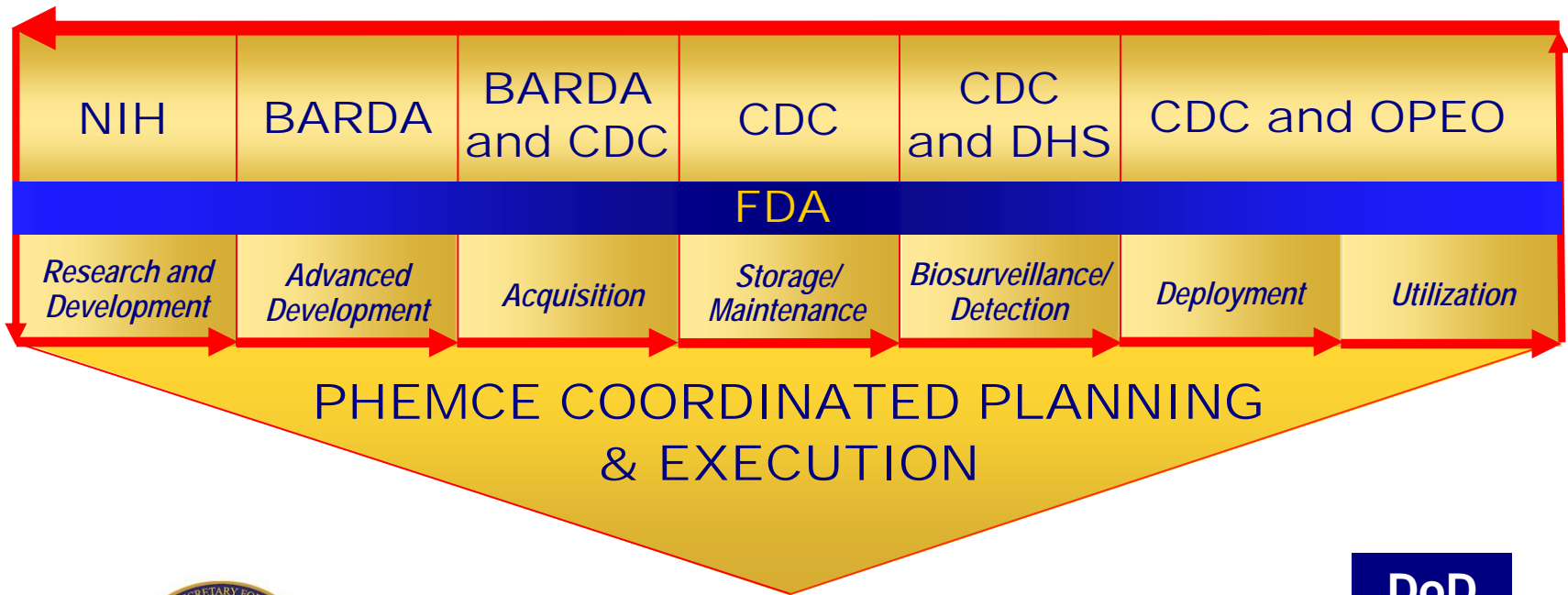
**Advanced Research and Development
Project BioShield Special Reserve Fund
Pandemic Influenza appropriations**



HHS Public Health Emergency Medical Countermeasures Enterprise



National Biodefense Science Board





Our Approach:

Integrated National Biodefense Medical Countermeasures Portfolio



- **HHS and DoD both develop and procure medical countermeasures for CBRN threats (civilian & military)**
- **An integrated, end-to-end national biodefense portfolio for medical countermeasure products is needed to leverage investments and achieve success**
- **Supports the MCM planning and alignment called for in Homeland Security Presidential Directive 18 (HSPD-18) and the vertical and horizontal coordination echoed in HSPD-21**



Integrated Portfolio: Accomplishments to Date



- **DoD and HHS have harmonized a common set of Technology Readiness Levels**
- **An improved understanding of the expected impact of animal rule on biodefense product development**
- **Pipelines for several biological threat MCMs have been mapped and are ready for top down / bottom up analysis**
- **MCM development “projects in common” have been identified and further coordinated between DoD and HHS and across HHS**
- **Communication network that results in:**
 - Cost-sharing
 - Knowledge sharing
 - Program sharing



Accomplishments:

Developing a Diverse, Balanced Portfolio of Medical Countermeasures



- **Calcium-DTPA and Zinc-DTPA:** Two forms of a decorporation agent that aids removal of transuranic radioactive particles from the body. Licensed in the U.S. and manufactured by Akorn, Inc. <http://www.akorn.com/>
- **Prussian blue (Radiogardase) :** A chelating agent that protects against the absorption of cesium-137. Licensed in the U.S. and manufactured by HEYL Chemisch-pharmazeutische Fabrik GmbH & Co. KG. of Berlin, Germany. <http://www.heyl.cti-nm.de/>
- **Potassium Iodide (KI) Tablets:** KI blocks the absorption of radioactive iodide by the thyroid gland. Licensed in the U.S. and manufactured by a number of companies. Currently forward deployed in states with population near nuclear power plants.
- **KI Liquid Formulation:** The liquid formulation can be taken more easily by children and adults who are unable to swallow tablets. Forward deployment pending. Licensed in the U.S. and manufactured by Fleming & Company, Pharmaceuticals. <http://flemingpharma.com/>
- **Growth Factors:** Could be used to treat the hematopoietic effects of Acute Radiation Syndrome. Not licensed in the U.S. for this indication but could be used under an Investigational New Drug protocol.



Radiation Countermeasure Mission Space



- **Acute Radiation Syndrome (ARS)**

- Hematopoietic ARS:

- Neutropenia
- Thrombocytopenia
- Anemia
- Lymphopenia

- GI ARS

- CNS Injury

- Lung Injury

- Kidney Injury

- **Cutaneous Injury**

- **Combined injury**

- **Radionuclide Threats**

- Co-60

- Cs-137

- Sr-90

- I-131

- Ir-192

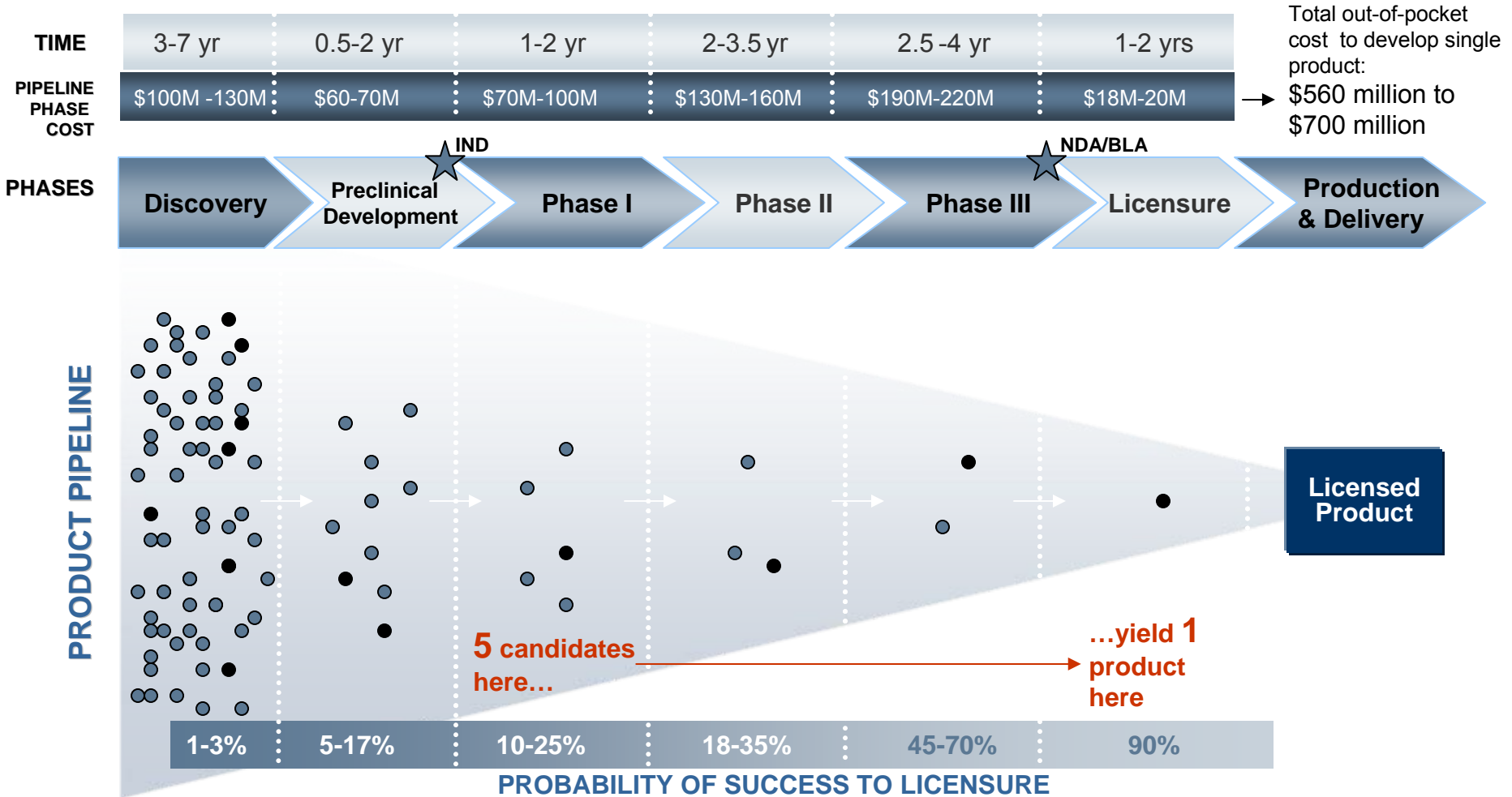
- Po-210

- Ur-235

Improved MCM's for treatment of radioisotope ingestion, inhalation, and wound contamination are needed.



Drug Development: Lengthy, Risky and Costly



Risk mitigation strategies are required to manage the inherently risky drug development process

* Source: PRTM & Industry Data



Technology Readiness Levels



- 1. Review of Scientific Knowledge Base**
- 2. Development of Hypotheses and Experimental Designs**
- 3. Target/Candidate Identification and Characterization of Preliminary Candidate(s)**
- 4. Candidate Optimization and Non-GLP In Vivo Demonstration of Activity and Efficacy**
- 5. Advanced Characterization of Candidate and Initiation of GMP Process Development**
- 6. GMP Pilot Lot Production, IND Submission, and Phase I Clinical Trial(s)**
- 7. Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)**
- 8. Completion of GMP Validation and Consistency Lot Manufacturing, Pivotal Animal Efficacy Studies or Clinical Trials, and FDA Approval or Licensure**
- 9. Post-Licensure and Post-Approval Activities**



2009-2010 BARDA Offerings



- **BAA-BARDA-09-34: Pre-solicitation Notice issued on February 17 targets several areas including:**
 - Radiological and Nuclear Threat Countermeasure
 - Clinical Diagnostic Tools
- **BARDA foresees additional solicitations (RFPs or BAAs) to address other systems and organs affected in ARS.**



Contact BARDA

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- Upcoming Events – **PHEMCE Stakeholders Workshop and BARDA Industry Day, December 2-4, 2009**
- Acquisitions
- BioShield
- Influenza Programs



MedicalCountermeasures.gov

- Federally-sponsored conferences
- Funding opportunities
- Resource programs
- Regulatory guidance
- Federal strategies and reports

