



**United States Department of**

**Health & Human Services**

**Office of the Assistant Secretary for Preparedness and Response (ASPR)**

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# **Building a More Responsive Medical Countermeasure Capability through Technological Innovation**

**Biomedical Advanced Research and Development Authority (BARDA)**

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**HHS/ASPR/BARDA**

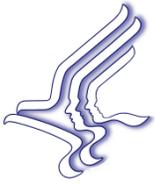


## BARDA's Mission

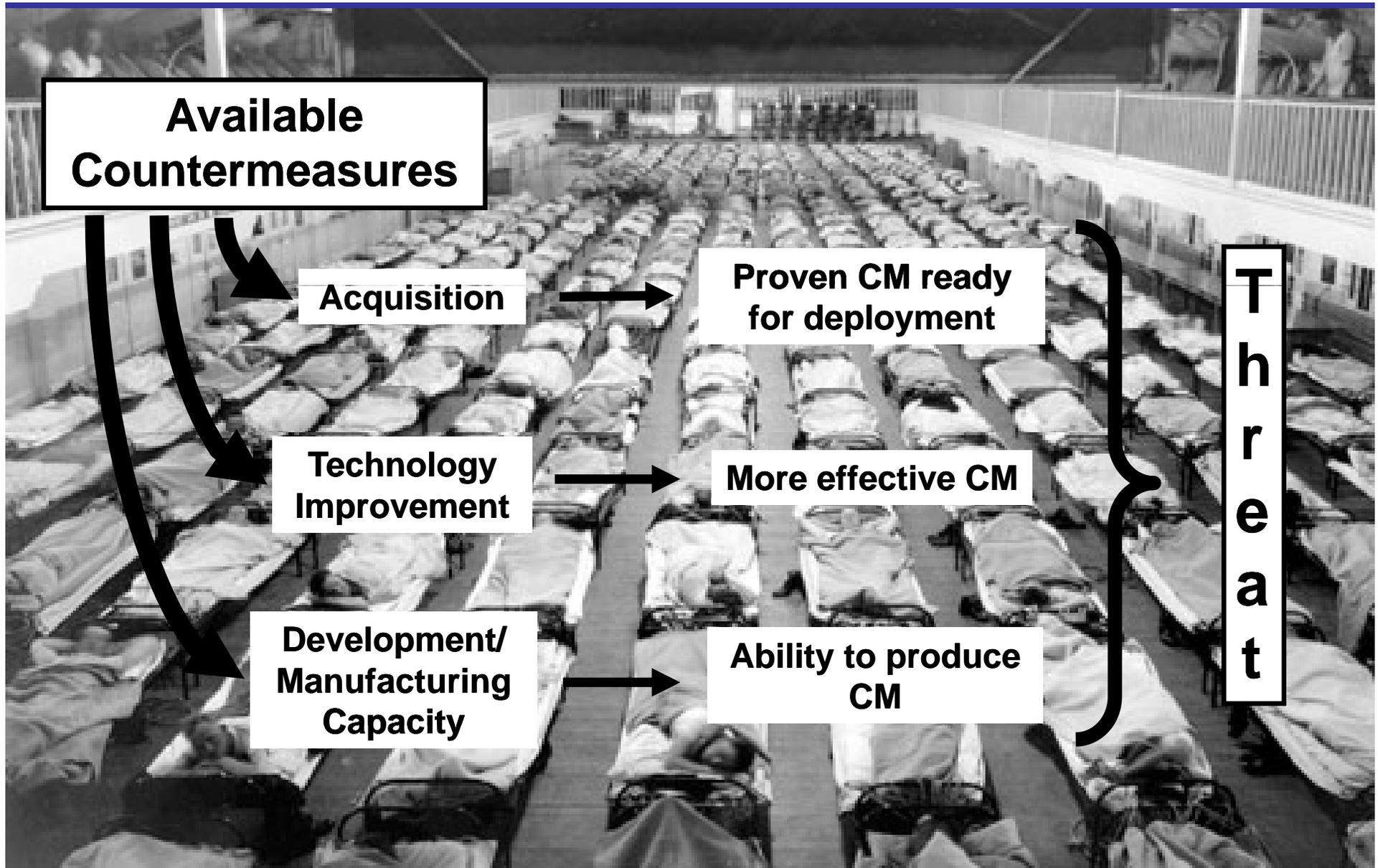
- To provide medical countermeasures that address public health and medical consequences of chemical, biological, radiological, and nuclear accidents and attacks, pandemic influenza, and emerging infectious diseases

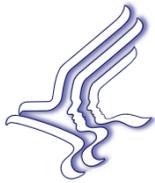


- Product licensure
- Countermeasure stockpiling
- Manufacturing capacity
- Effective delivery
- Development infrastructure
- Technical innovations



# BARDA 3-Front Battle Plan for Threat Preparedness





# The Preparedness Challenge



- Large number of threats, diverse types
  - Wide array of countermeasures needed
  - Possibility of new, unanticipated threats
  - Need for rapid response and delivery
- 
- Medical countermeasure enterprise well established for commercial products
  - Can the current enterprise be used or adapted to serve the purpose of public health threat preparedness and response?





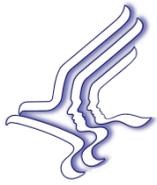
# The Medical Countermeasure Enterprise



- A collaborative effort of academic, medical, government, and commercial sectors
- Delivers safe, effective products for prevention and treatment of medical conditions that have transformed human health over the past century



- A sophisticated and successful development and manufacturing paradigm, along with compatible enabling technologies, has evolved to carry out this enterprise
- Has the capability to deliver medical countermeasures for public health threats



# Influenza Countermeasures for Pandemic Preparedness

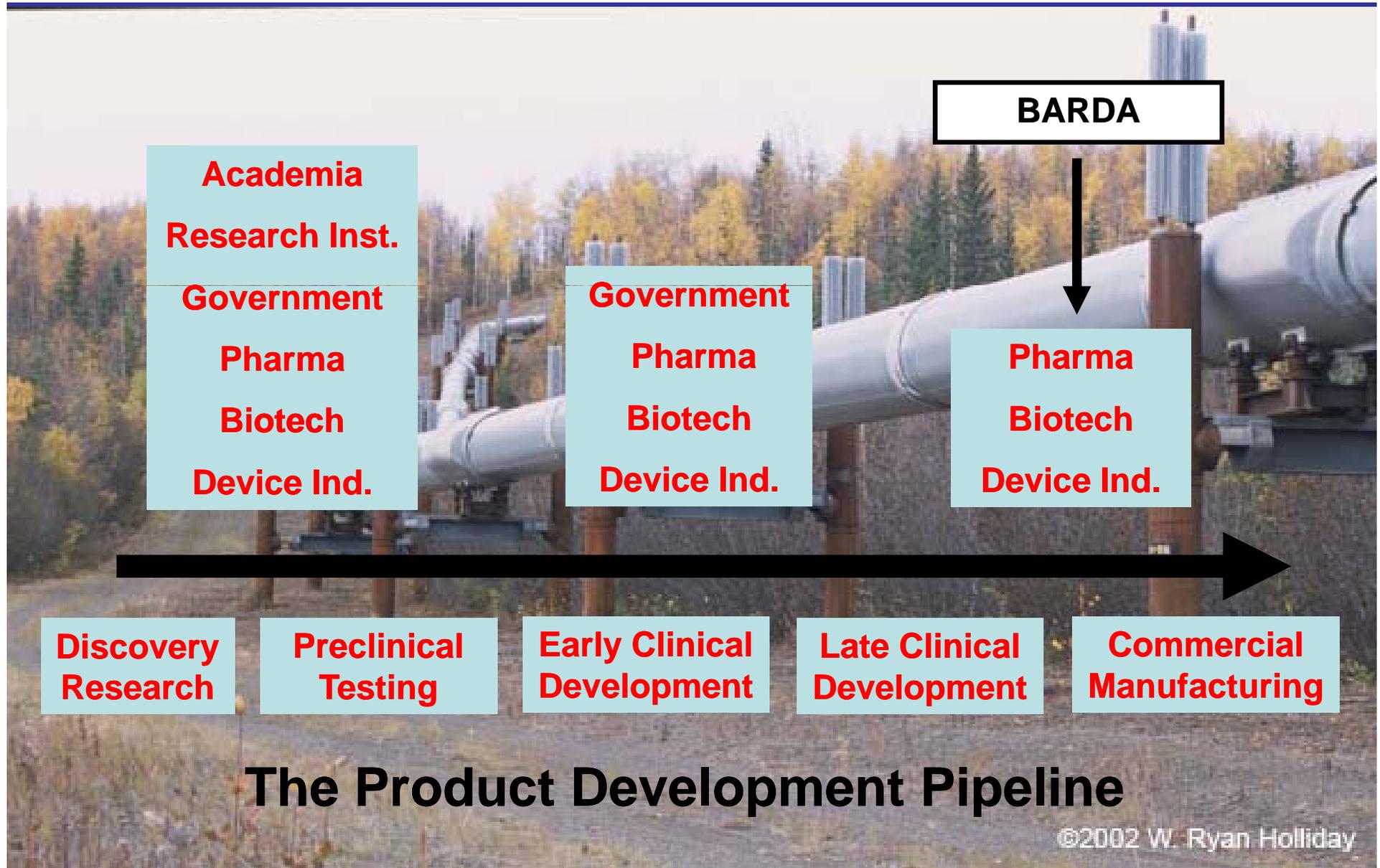


- **Vaccines**
  - Seasonal
  - Pandemic
- **Drugs**
- **Diagnostics**
- **Non-pharmaceuticals**
  - Respirators
  - Ventilators
  - Syringes

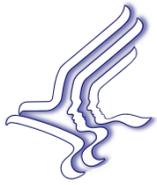




# Delivering Countermeasures Through the Commercial Enterprise



## The Product Development Pipeline



# Gaps in the Enterprise for Public Health Emergency Preparedness

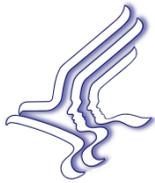


- The current enterprise did not evolve for the purpose of emergency preparedness and response
- Limited or no commercial market for many threats
- Enterprise evolved for safety and efficacy, not speed and cost

- Preparing for and responding to the threats that fall under BARDA's mandate will strain its capabilities
  - Secretary's Countermeasure Review
  - PCAST report



Photo courtesy of CSIRO



# Adapting the Current Enterprise through Technological Innovation



- New technologies, tools, approaches, and capabilities will help adapt the current enterprise to operate according to a more “responsive” paradigm
- BARDA is actively working to advance elements that will make this shift possible

- BARDA’s Strategic Science and Technology Division is a focal point for ideas that will provide the solutions needed
  - Strategic vision
  - Scouting
  - BARDA’s Innovations program provides support for advancing and evaluating programs that offer new capabilities



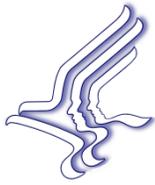


# Innovation is a Key Part of BARDA's Mandate<sup>1</sup>



- “shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for **innovation**, and the procurement of qualified countermeasures and qualified pandemic or epidemic products”
- “...shall guide...**innovation** in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products”
- “...shall coordinate the acceleration of countermeasure and product advanced research and development by...promoting **innovation** to reduce the time and cost of countermeasure and product advanced research and development”
- “**SUPPORTING INNOVATION**- ...may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote--
  - (i) **innovation** in technologies that may assist countermeasure and product advanced research and development;
  - (ii) research on and development of research tools and other devices and technologies; and
  - (iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.”

\*Pandemic and All-Hazards Preparedness Act, Title IV, Sec. 319L



# Call for Innovation to Meet the Challenge of Public Health Emergency Preparedness and Response



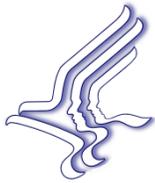
- **The call for innovation is a recognition that current thinking, approaches, and technologies do not provide adequate solutions to the problem posed**

## **Innovation:**

- **new idea or method:** a new invention or way of doing something
- **origination:** the act or process of inventing or introducing something new



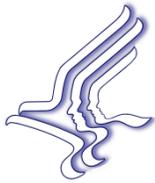
- **What does innovation mean in the context of developing and manufacturing medical countermeasures for public health threats?**



# Innovations Themes in BARDA Programs



- **New ways to make better countermeasures**
  - Safer
  - More effective
  - More stable
  - More easily manufactured
  - More cost-effective
- **Better ways to make new countermeasures**
  - Faster
  - More reliable and predictable
  - More flexible
  - More expandable (surge capacity)
  - More readily approvable
  - Less costly (capital investment and cost of manufacturing)



# Achieving a More Responsive Capability



## Current Enterprise

## “Responsive” Capability

### Product Development Paradigm

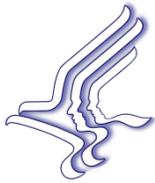
Driven by commercial markets  
Long time-to-market (10-20 yrs)  
Expensive development (~\$1B)  
Favors established techniques  
Conducted by large, integrated companies  
One cm/one indication/one approval/one plant regulatory calculus

Driven by public health  
Able to move quickly from need to solution  
Expedited, affordable  
Receptive to new technologies and organizations  
Versatile, flexible  
Able to prepare for potential threats or emerging threats in advance

### Enabling Technologies

Technology and process developed individually with each cm  
Fixed manufacturing infrastructure  
Expensive technology and facilities  
Deliberate manufacturing and release technology  
Safety-conscious, individualized regulatory approach

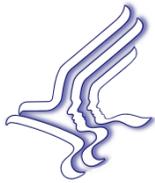
Broad-spectrum/multi-use products  
Platform technologies for development and manufacturing  
Template product designs  
Expedited product safety and efficacy testing  
Multi-use facilities  
Low-tech/low-cost manufacturing  
Rapid manufacturing and release  
Regulatory-friendly approaches



# BARDA Programs to Foster Innovation



- **Development programs targeting new technologies**
  - Request for Proposals
  - Focus on advancement of specific technology identified as key (e.g. cell-based and recombinant flu vaccines; flu vaccine adjuvants)
- **Call for new technologies in countermeasure development**
  - Broad Agency Announcements
  - Open to ideas in general Areas of Interest (e.g. CBRN countermeasures; Development/Manufacturing platforms)
- **Centers of Innovation for Advanced Development and Manufacturing (ADM)**
  - Public-private partnerships
  - Core development/manufacturing services; production surge capacity)
- **Strategic Investor**



# Innovative Solutions to Preparedness Challenges



- **Influenza Vaccine Capacity**
  - Cell-based and recombinant influenza vaccine
  - Adjuvanted pandemic influenza vaccine
- **Pandemic Influenza Vaccine Response**
  - Synthetic vaccine seed development
  - Accelerated sterility release testing
- ***In vitro* human immune system mimetic**
- **Optimized, high-yield recombinant protein production platform**
- **Formulation chemistries to increase vaccine stability**
- **Novel vaccine adjuvant formulations**
- **Rapid, high-throughput surveillance and diagnostic platforms**



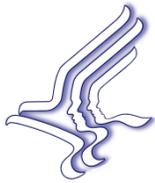
# Implementation of BARDA's Innovation Mandate



- **Look to the biopharm/biotetch community to provide fresh ideas for safeguarding public health**
- **Seek the technological tools to enable a rapidly responsive medical countermeasure capability**
  - More effective countermeasures
  - Multi-use products
  - Platform technologies
  - Improved manufacturing infrastructure



- **Will provide the flexibility to deal with diverse threats**
  - Bioterror
  - Pandemic Influenza
  - Emerging Infectious Diseases

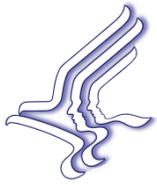


# Interfacing with BARDA



- [www.phe.gov](http://www.phe.gov)
  - Program description, information, news, announcements
- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
- [www.fedbizopps.gov](http://www.fedbizopps.gov)
  - Official announcements and detailed information about all government contract solicitations





# BARDA: Not Bigger. Smarter!

