

NIH Role in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

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NATIONAL INSTITUTES OF HEALTH



Public Health Emergency Medical Countermeasure Enterprise – PHEMCE

Interagency Enterprise Goals

- Define/prioritize requirements for public health medical emergency countermeasures
- Coordinate research and late-stage product development and procurement activities addressing the requirements
- Establish deployment and use strategies for medical countermeasures held in the Strategic National Stockpile



Coordination of Medical Countermeasures Activities

Federal Government

Homeland Security Council

National Security Council

Interagency Working Groups

DHS, DHHS, DoD, Other Agencies

DHHS

Office of Public Health
Emergency Preparedness

NIH, FDA, CDC

NIH

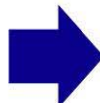
NIH BRCC

NIH ICs



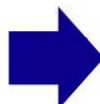
Biodefense: Complementary Roles within DHHS

CDC



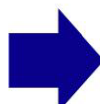
- Surveillance and Detection
- Train Local Response Teams
- Maintain Vaccine/Antimicrobial Stockpiles

NIH



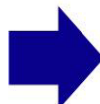
- Conduct Basic Research
- Develop Medical Interventions
- Develop Research Infrastructure

FDA



- Regulatory Approval
 - Vaccines
 - Therapeutics
 - Diagnostics

Office of Public Health Emergency Preparedness



- HHS-Wide Coordination



A Comprehensive Biodefense Research Agenda

NIH

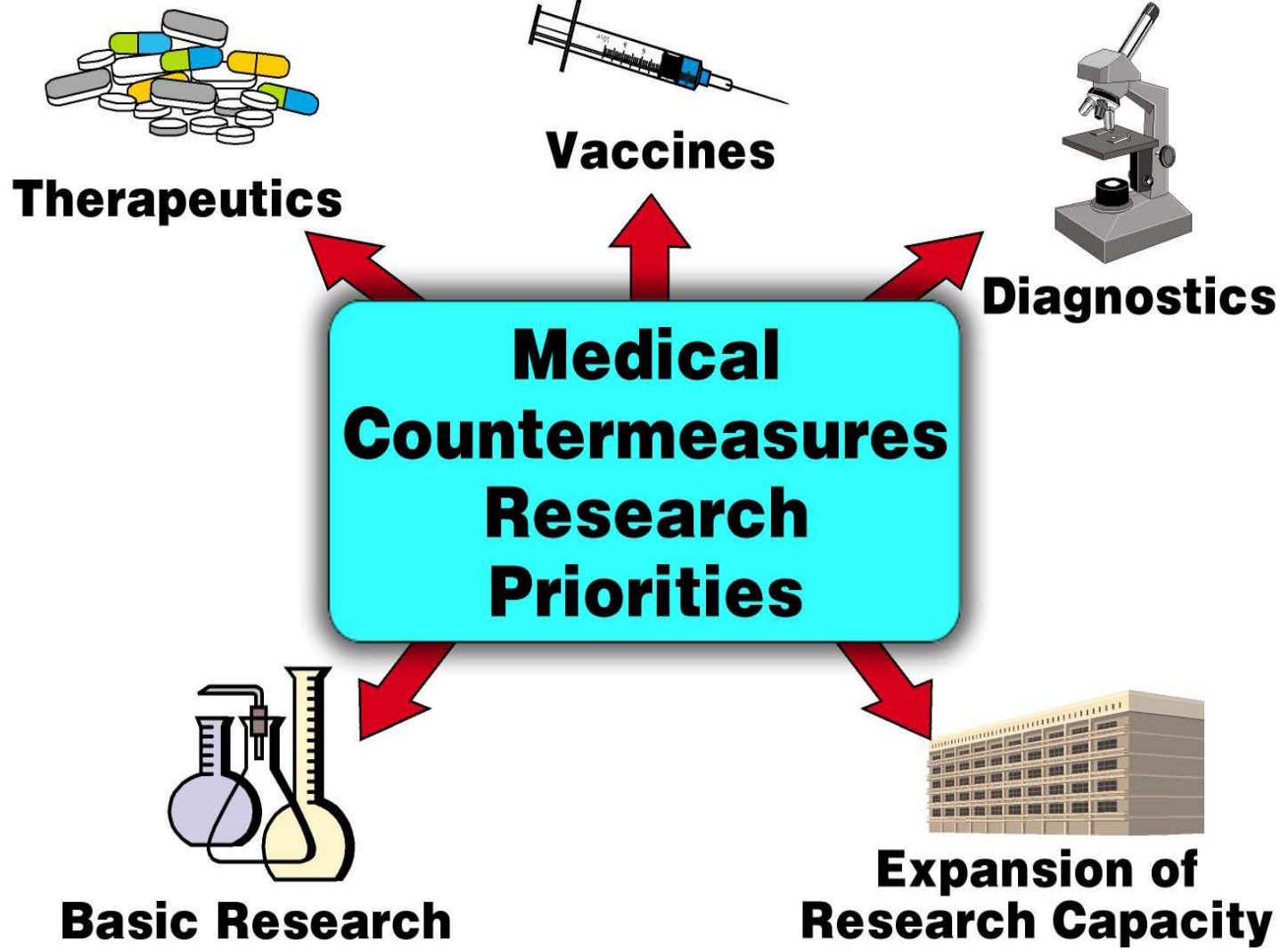
**Infectious
Diseases**

**DHS
EPA
DOE
DoD
FDA
USDA
etc.**

**Radiological
Threats**

**Chemical
Agents**





Biodefense Countermeasures: Key Achievements

Smallpox

- More than 300 million doses of smallpox vaccine now available
- "Next-generation" vaccine (MVA) in advanced testing
- Antiviral drug development, e.g. oral cidofovir

Anthrax

- New vaccine (rPA) tested and procured under Project Bioshield
- Development of novel antitoxins, e.g. monoclonal/polyclonal antibodies



Biodefense Countermeasures: Key Achievements (continued)

Ebola

- **Vaccine in human trials at NIAID Vaccine Research Center**

Botulinum Toxin

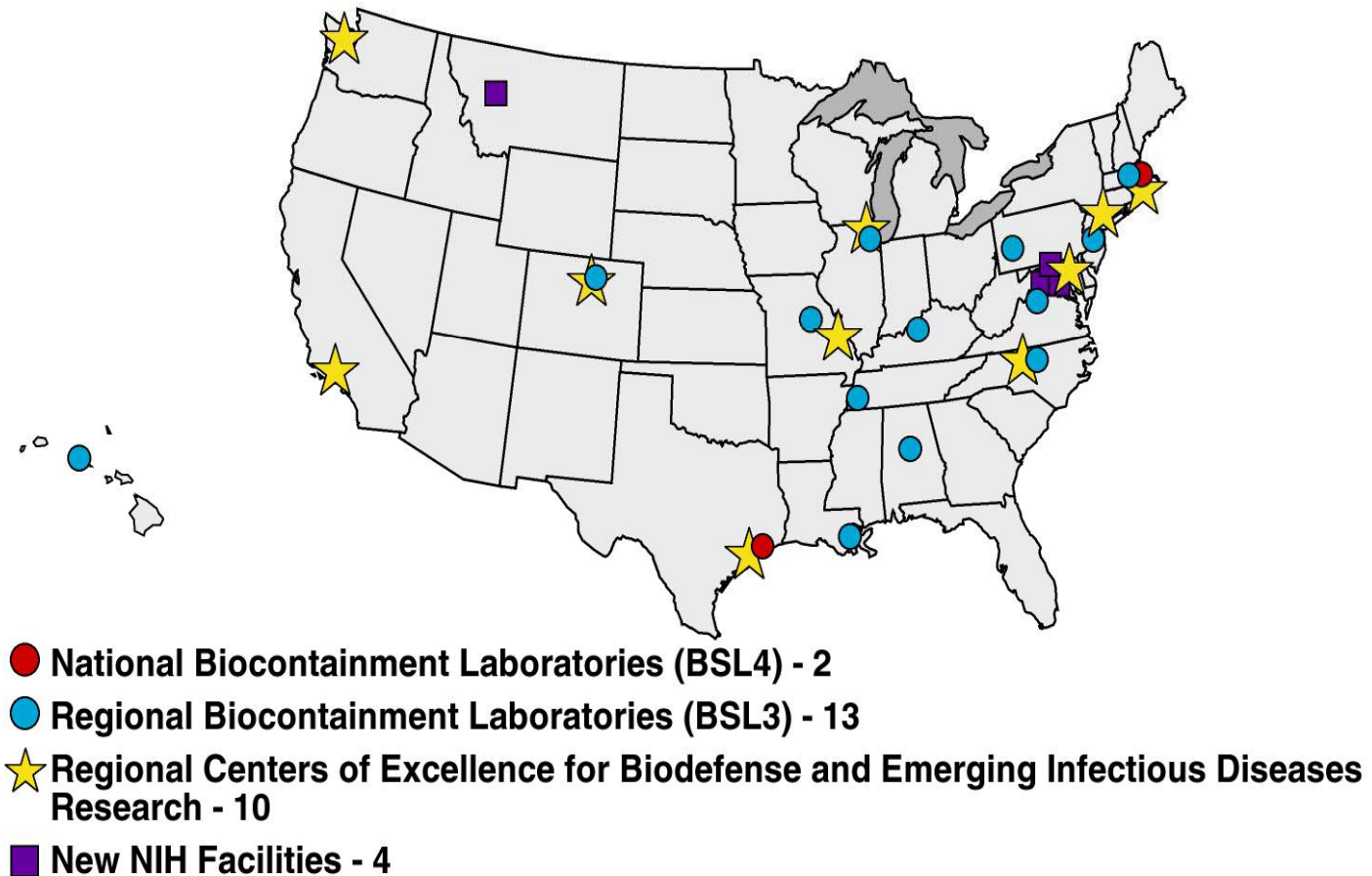
- **Development of vaccine and monoclonal/polyclonal antibodies**

Influenza

- **Development of vaccines against potential pandemic strains**



Expansion of Research Capacity for Emerging Infectious Diseases





U.S. Department of Health and Human Services

NIH News

National Institutes of Health

National Institute of Allergy and Infectious
Diseases (NIAID)

<http://www.niaid.nih.gov/>

FOR IMMEDIATE RELEASE
Wednesday, May 3, 2006

NIH Dedicates the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases



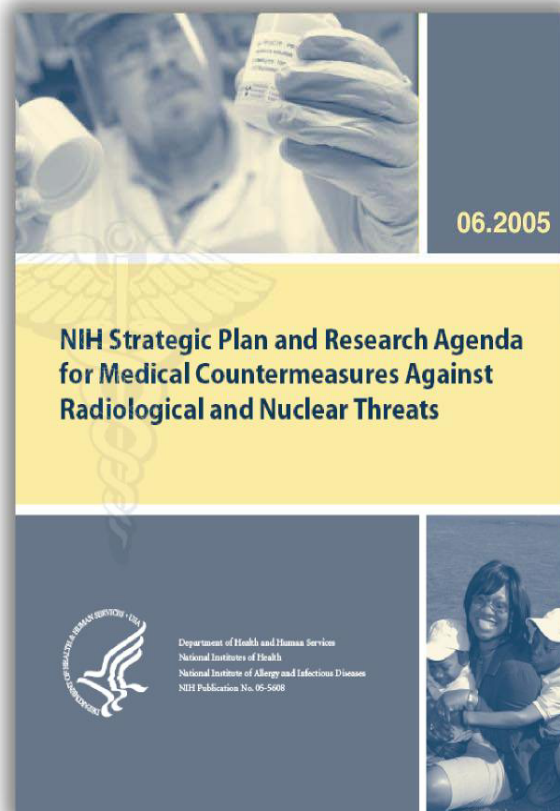
A new building focused on research on infectious diseases of global importance — those that occur naturally or that may be caused by agents intentionally released through an act of bioterrorism — was dedicated yesterday on the Bethesda, Maryland campus of the National Institutes of Health (NIH).



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Insert date

Medical Countermeasures Against Radiological and Nuclear Threats



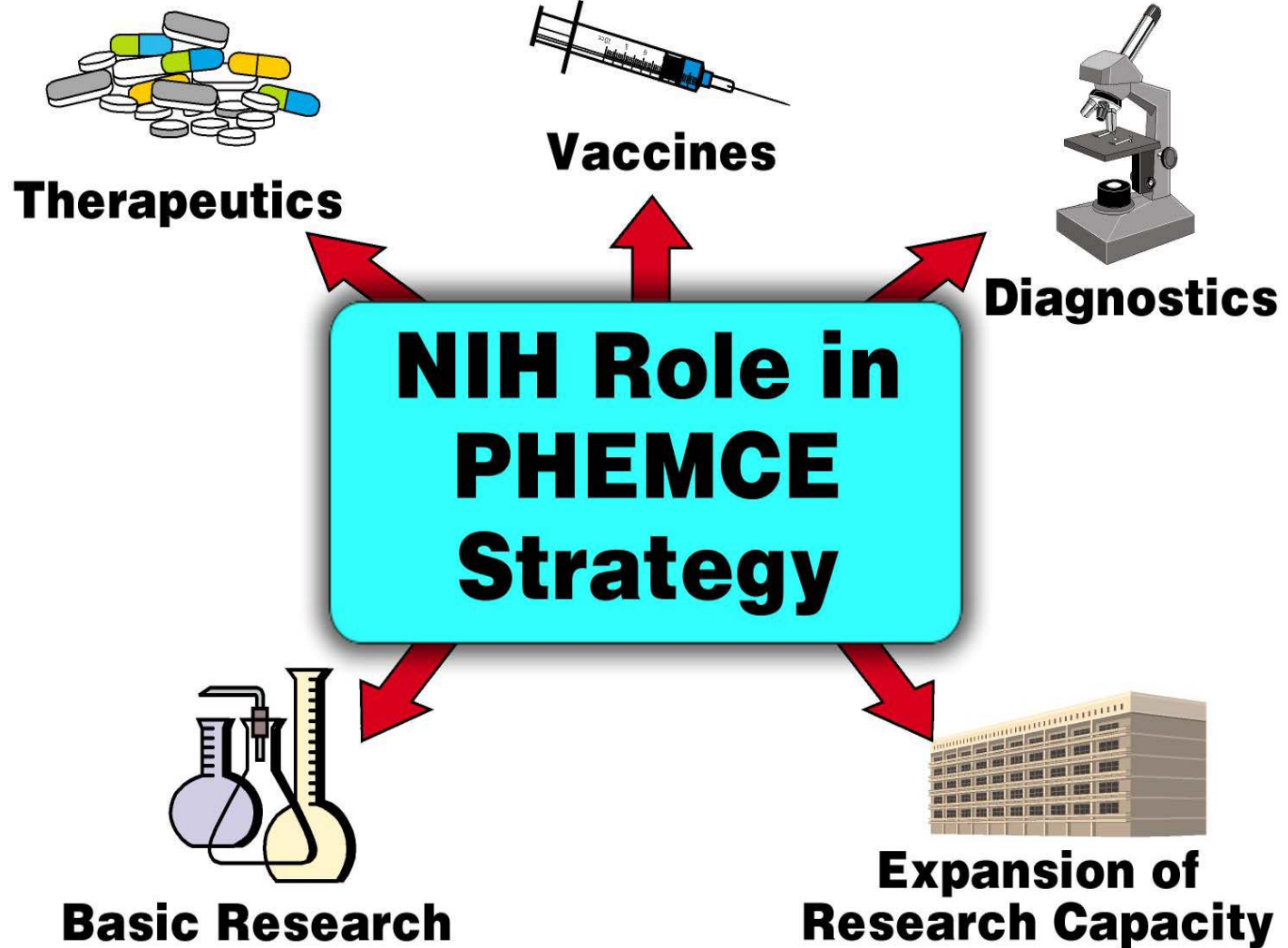
Research Priorities:

- Basic and translational research
- Methods to measure radiation doses
- Focused product development
- Infrastructure for research and product development



NIH Strategic Plan and Research Agenda for Medical Countermeasures Against Chemical Threats





Published in the
Federal Register
September, 2006



Draft

Public Health Emergency
Medical Countermeasures
Enterprise Strategy for
Chemical, Biological,
Radiological and Nuclear
Threats

“...HHS will continue to support a robust basic research program that will aim to develop broad-spectrum solutions using flexible technologies that enable more flexible next generation interventional concepts...”



BioShield Stakeholders Workshop



Bioshield Stakeholders:

- Pharmaceutical and biotechnology industries
- Professional societies
- State and local public health organizations and emergency response planners
- Academic research and development community
- Public interest groups
- Other stakeholder federal agencies (such as the Department of Homeland Security and Department of Defense) and Congress

