BioDefense R&D

Priorities & Programs: NIH

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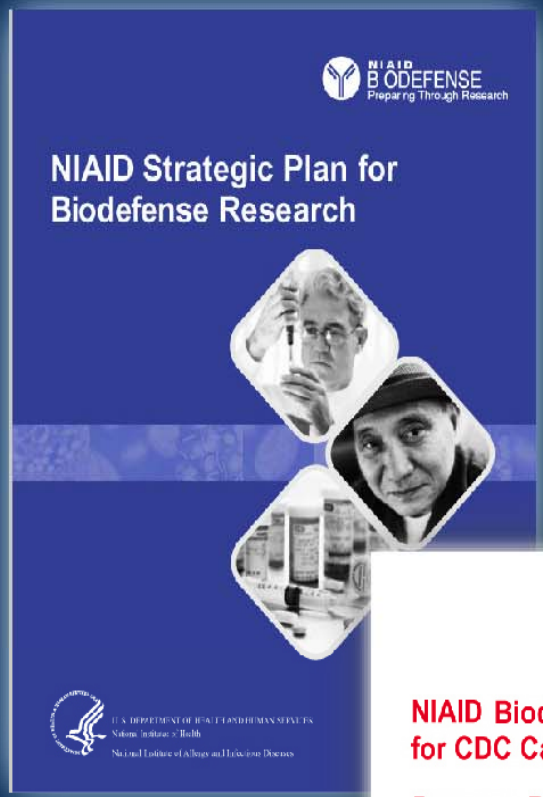
September 26, 2006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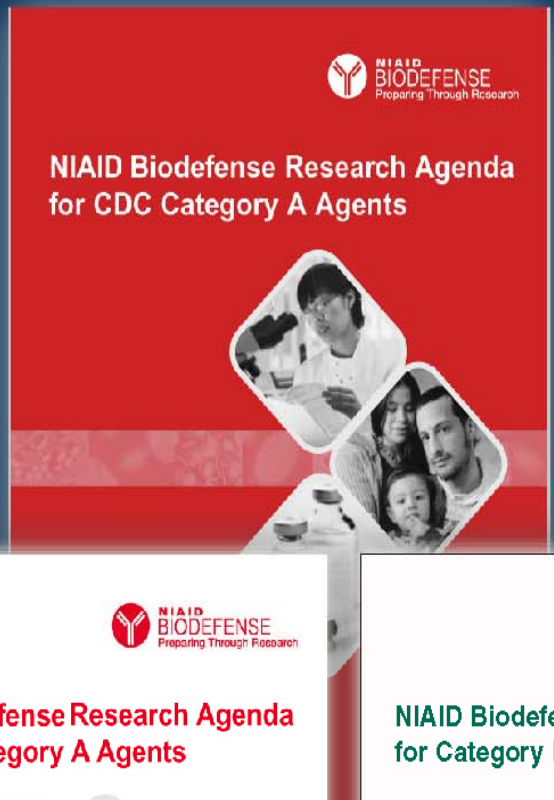
BIODEFENSE
Preparing Through Research
NIAID Strategic Plan for
Biodefense Research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NIAID Biodefense Research Agenda
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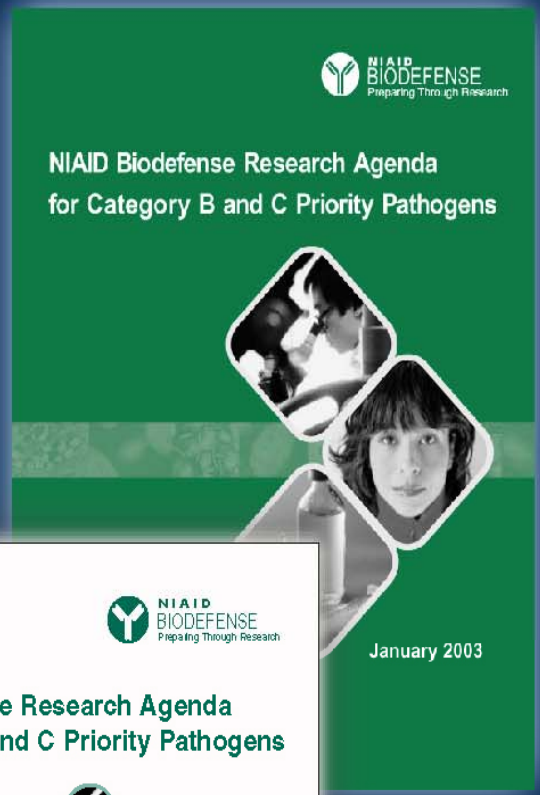
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January 2003


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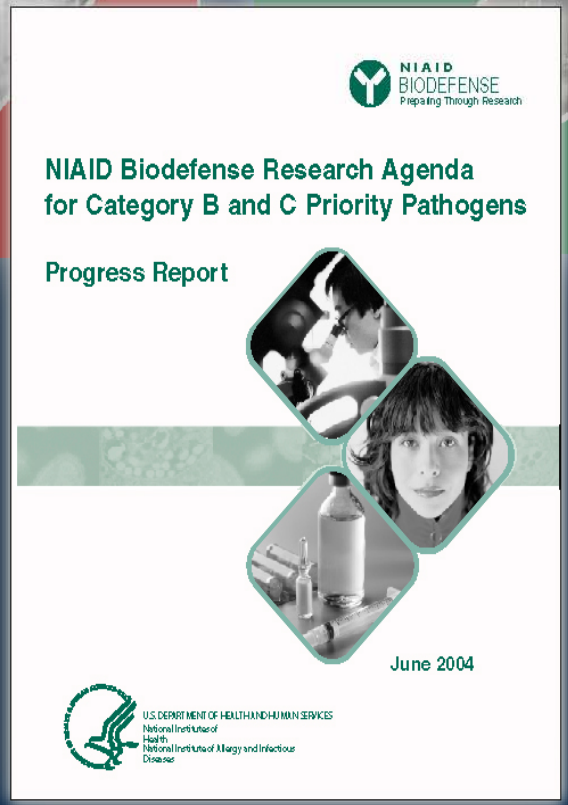
Progress Report
August 2003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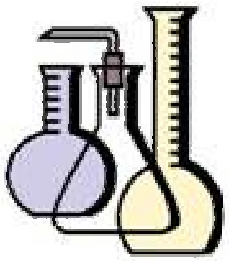
Progress Report
June 2004
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of
Health
National Institute of Allergy and Infectious
Diseases

Therapeutics

Vaccines

Diagnostics

Biodefense Research Priorities



Basic Research (including Genomics)

Expansion of Research Capacity

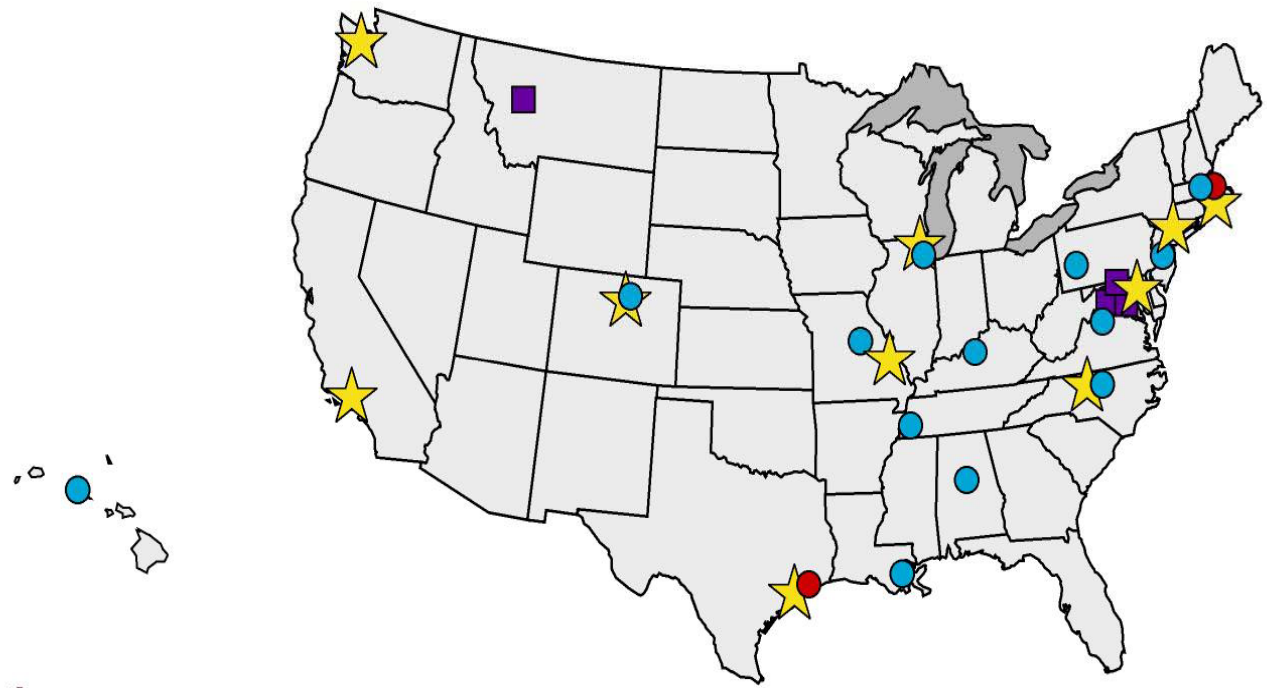
Developing Capacity

- **Intellectual**
- **Facilities**
- **Reagents / Services**
- **Clinical Testing**

Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCEs)

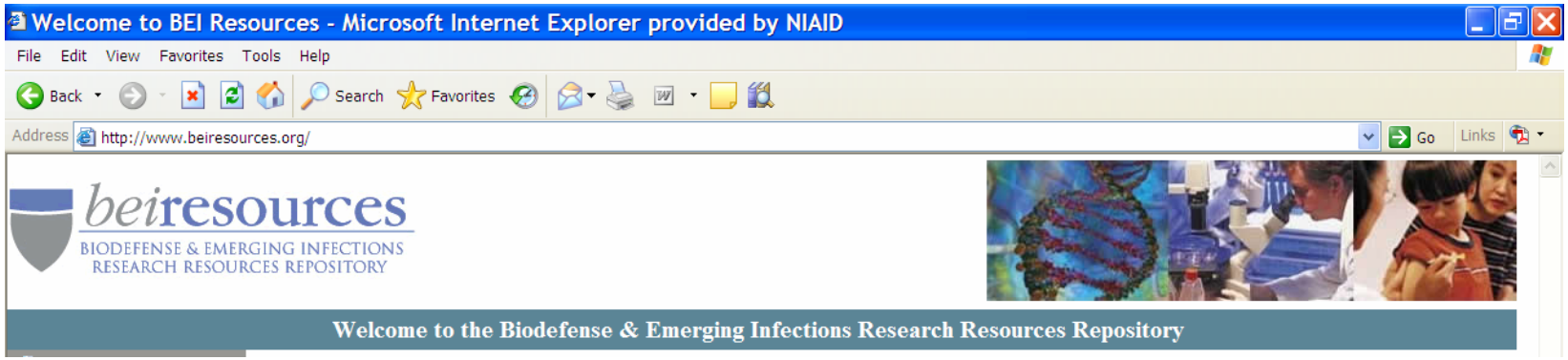
- RCE Network established in 2003
- 10 centers (8 funded in 2003, 2 in 2005)
- >150 research projects; ~100 pilot projects; >60 career development projects
- $350M total funding over 5 years
- >170 publications on Category A, B and C pathogens, host immunity, countermeasure development

Expansion of Biodefense Research Capacity



- National Biocontainment Laboratories (BSL4) - 2
- Regional Biocontainment Laboratories (BSL3) - 13
- Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research - 10
- New NIH Facilities - 4

Reagents / Services



- In vitro screens
- Small animal models
- Toxicology & immunogenicity for vaccines
- Clinical isolate panels
- Non-human primate models
- Toxicology & pharmacology for Therapeutics

Clinical Testing

NIAID's Network of Vaccine and Treatment Evaluation Units (VTEUs)

- Established in 1962
- >110 Phase I, 2, 3 Clinical Trials since 1995
- Highlights
  - childhood vaccines
  - adult immunization
  - combination vaccines
  - novel delivery system
  - vaccine safety
  - challenge studies
  - biodefense

Product Development Activities

Basic **Applied** **Advanced** | **Acquisition**

Scientific Activities at NIH

Basic
- ❑Microbiology
- ❑Immunology
- ❑Pathogenesis

Advanced
- ❑Product formulation
- ❑Pilot lot production
- ❑Animal rule correlates
- ❑IND enabling studies
- ❑Phase I/II clinical trials
- ❑Animal efficacy models

Applied
- ❑Target ID/validation
- ❑Assay development
- ❑In vitro screening
- ❑Medicinal chemistry for SAR
- ❑Animal model development
- ❑In vivo infectious models

Commercial Product Demonstration Activities defined by Procurement Requirements

- ❑Commercial scale process development
- ❑Commercial scale manufacturing
- ❑Facility construction
- ❑Large scale safety trials
- ❑Animal rule efficacy studies
- ❑Other BLA/NDA enabling activities

NIH Mechanisms for Supporting Research

- Research Grants
- Small Business Grants (SBIR/STTR)
- Cooperative Agreements
- Contracts
- CRADAs

Current Programs

- Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine
- Production and Testing of a Modified Vaccinia Ankara Vaccine
- Development, Testing and Evaluation of Candidate Vaccines Against Plague
- Neutralizing Monoclonal Antibodies for Type A Botulinum Toxins

Recent Initiatives

- **RFP – Services for Pre-Clinical Development of Therapeutic Agents**
- **BAA for selected Viral Diseases**
- **RFP - Development of 3rd Generation Anthrax Vaccine**
- **BAA for selected Bacterial Diseases**

Radiological / Nuclear Countermeasures: Mission

- **Expand the physical and human infrastructure devoted to radiation countermeasures research**
- **Promote focused research and product development**
- **Transition promising countermeasures to advanced product development**

Programmatic Goals

- **Centers for Medical Countermeasures against Radiation**
  - Biodosimetry tools/techniques for accurate & rapid dose assessment
  - Prophylactic agents to protect against radiation injury
  - Agents to mitigate & treat radiation injury
- **Product Development Support Services**
  - GLP capability
  - Rodent and NHP Screening and Efficacy Evaluation of Candidate Drugs

NIAID BioShield Initiatives

- Therapeutics for CDC Category A Agents (DMID)
- Protecting the Immune System Against Radiation (DAIT)
- Production of Botulinum Toxin Monoclonal Antibodies (serotype A) for Clinical Evaluation (DMID)
- Production of a Recombinant Botulinum Toxin Vaccine (serotype E) for Clinical Evaluation (DMID)
- Medical Countermeasures against Radiological Threats (DAIT)

NIH Medical Chemical Countermeasures Program

- **Multiple NIH ICs** (initiated in FY06)
  - NIAID, NINDS, NIEHS, NIAMS, NIGMS, NEI
- **Close collaboration with DOD (USAMRICD)**
- **Advance candidate products towards licensure**
  - Pre-clinical GLP testing facility
  - Clinical trials
- **Develop next generation products**
  - Infrastructure for product development
- **Centers for Medical Countermeasures Against Chemical Threats (CounterACT)**
  - Basic research focused on civilian applications

NIAID Biodefense Research

http://biodefense.niaid.nih.gov