Facing Biological Threats: the Role of Biomedical Research

Anthony S. Fauci, M.D.

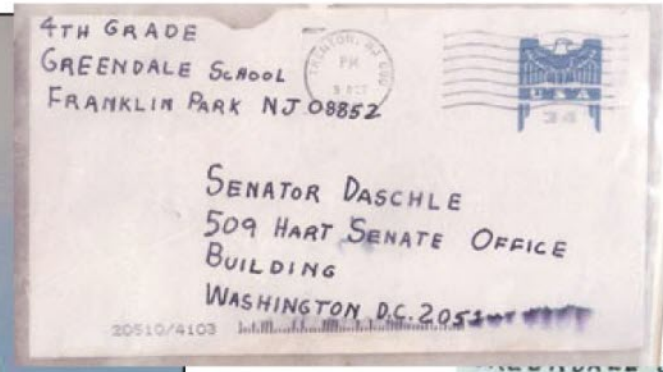
Director

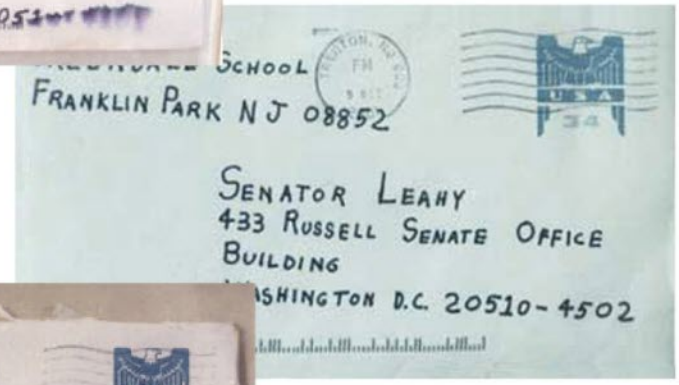
National Institute of Allergy and Infectious Diseases

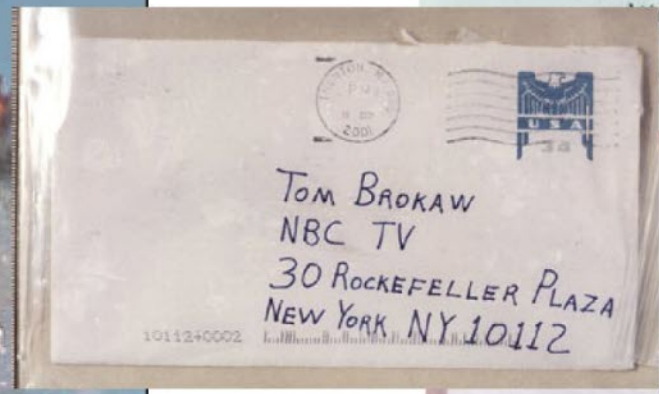
National Institutes of Health

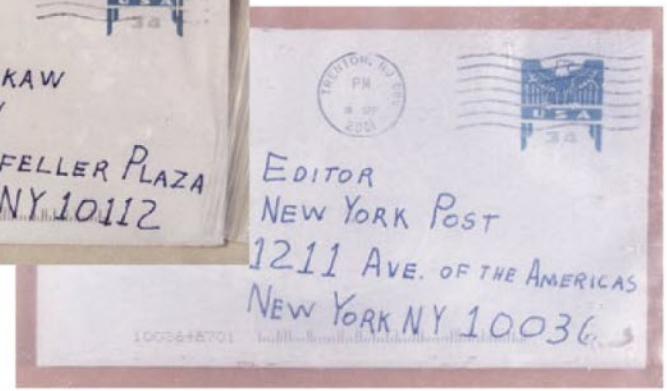
October 25, 2017

Juxtaposition of Events of September 11, 2001 and the Deliberate Release of Anthrax









THE FIGHT AHEAD

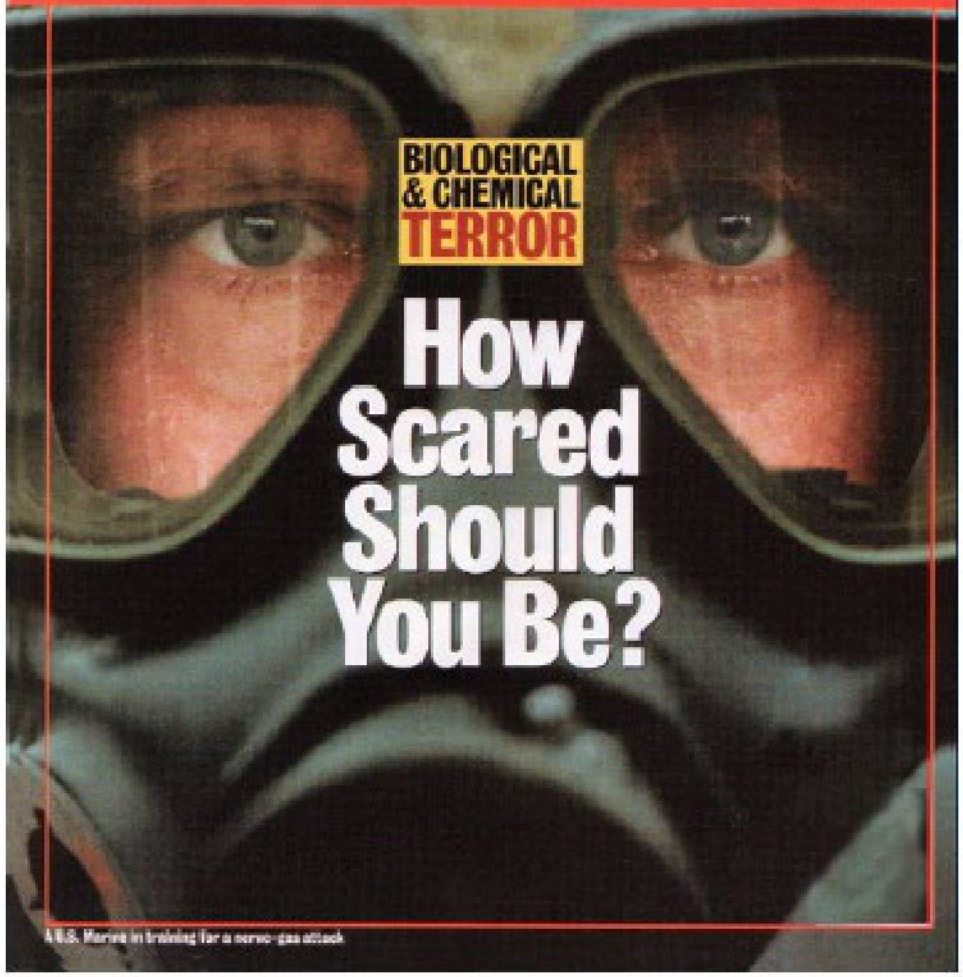
SPYING • COMMANDOS • HIGH-TECH SECURITY

SPECIAL REPORT

Newsweek

October 8, 2001

newsweek.msnbc.com



BIOLOGICAL & CHEMICAL TERROR

How Scared Should You Be?

A U.S. Marine in training for a nerve-gas attack

OCTOBER 8, 2001

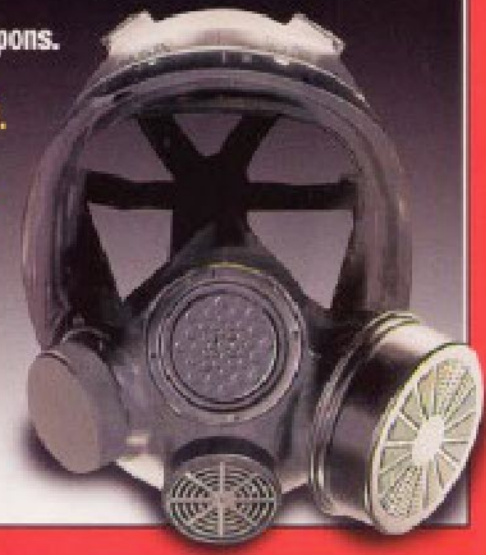
www.time.com AOL Keyword: TIME

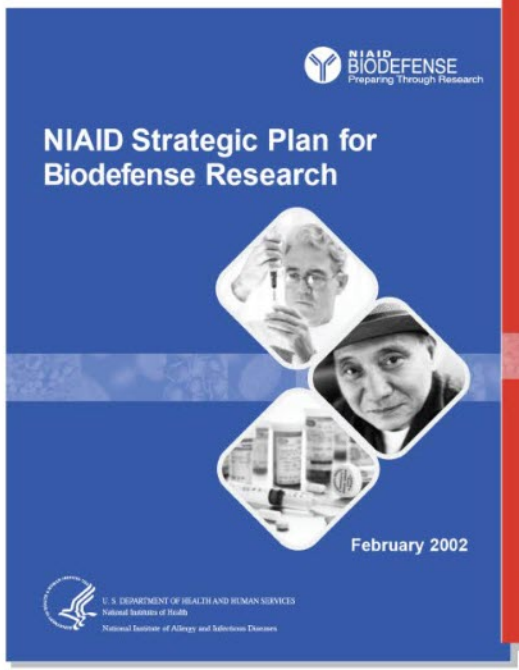
TIME

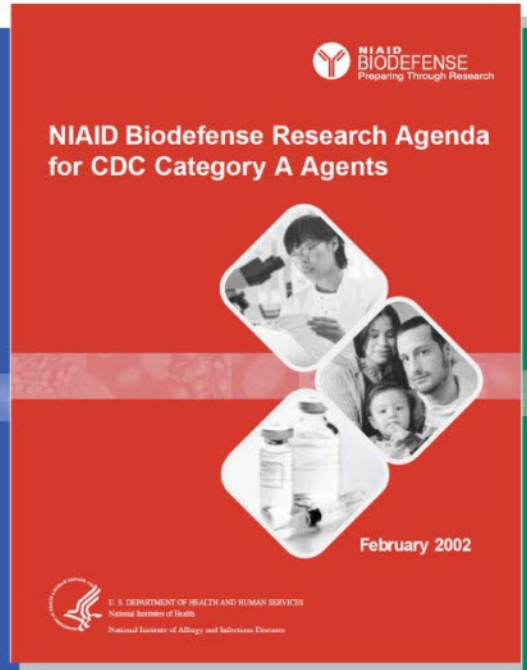
HOW REAL IS THE THREAT?

Germ and chemical warfare. Suicide bombers. Nuclear weapons. A jittery nation needs to separate REALITY from RUMOR. Here are the facts.

PLUS: The Hunt for Bin Laden




NIAID BIODEFENSE
Preparing Through Research
NIAID Strategic Plan for Biodefense Research
February 2002
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Allergy and Infectious Diseases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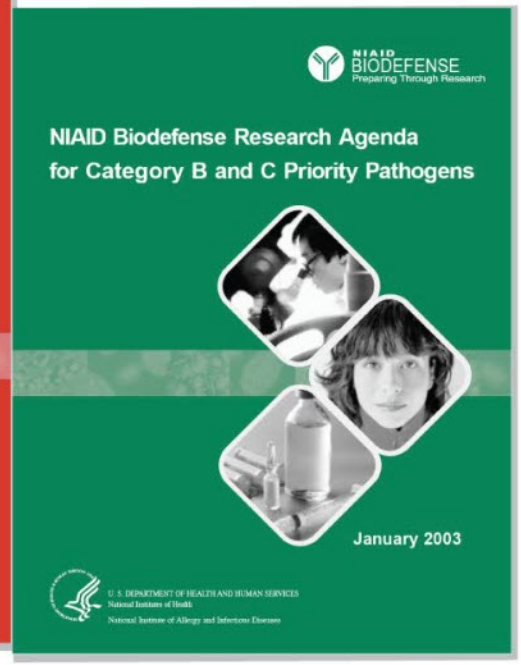
NIAID BIODEFENSE
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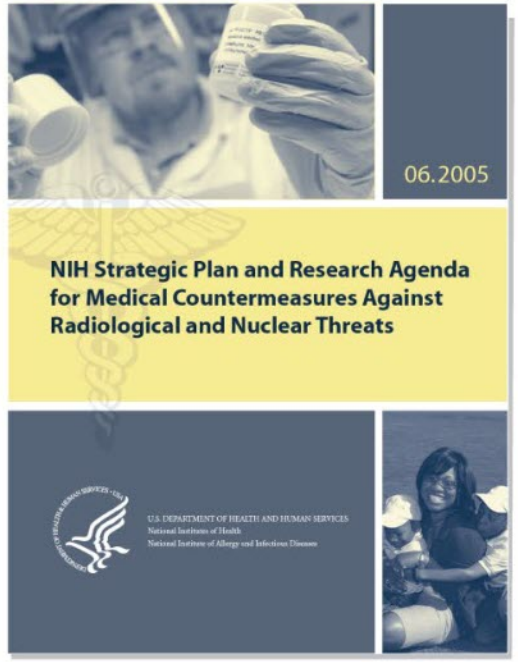
National Institutes of Health
National Institute of Allergy and Infectious Diseases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NIH Strategic Plan and Research Agenda for Medical Countermeasures Against Radiological and Nuclear Threats
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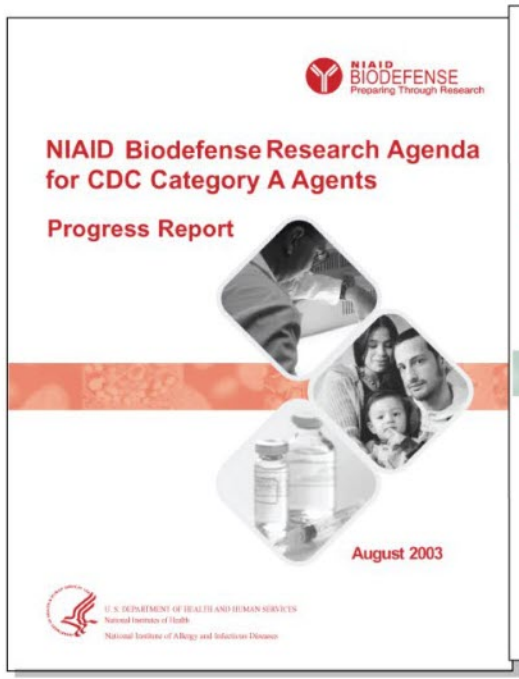
National Institutes of Health
National Institute of Allergy and Infectious Diseases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Progress Report
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National Institutes of Health
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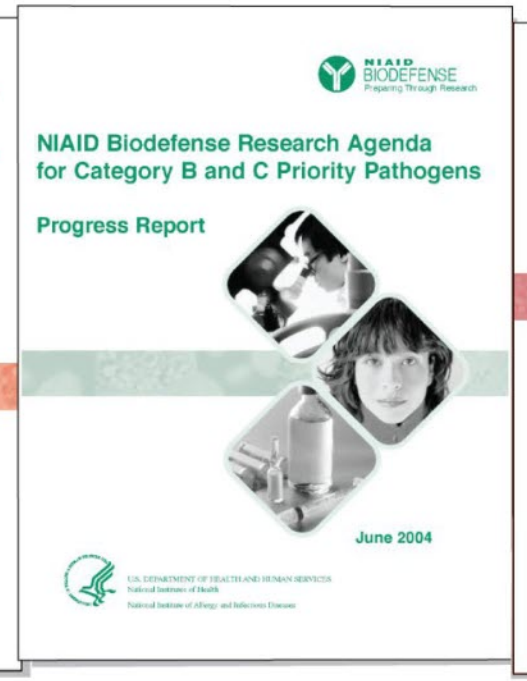
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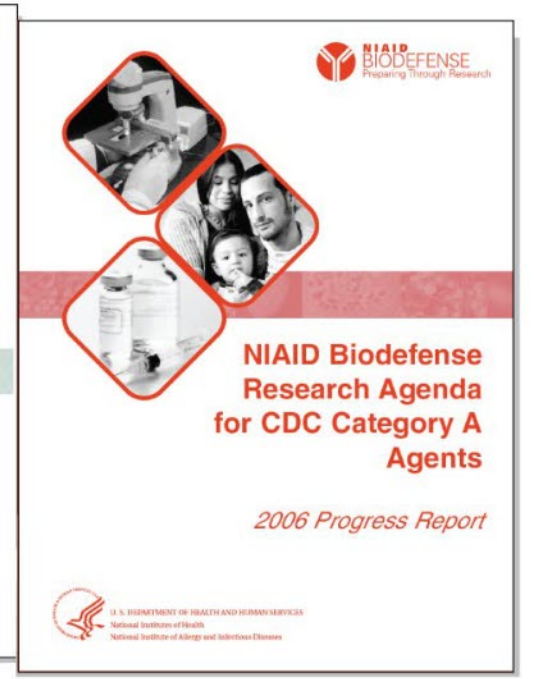
National Institutes of Health
National Institute of Allergy and Infectious Diseases


NIAID BIODEFENSE
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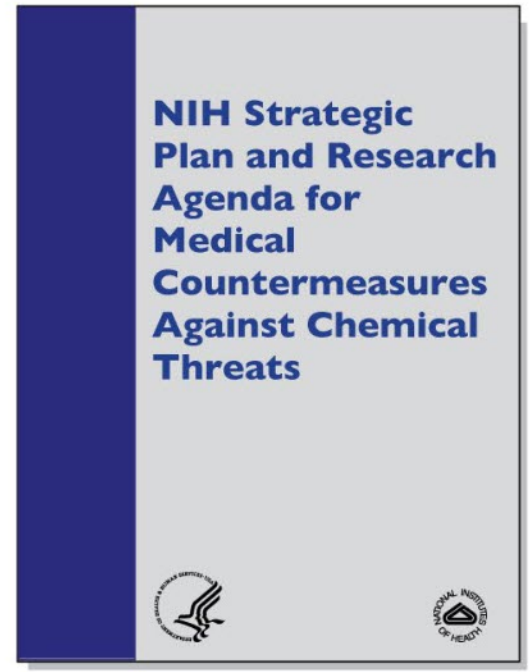
2006 Progress Report
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Allergy and Infectious Diseases

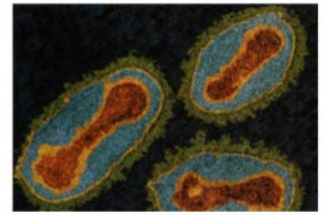
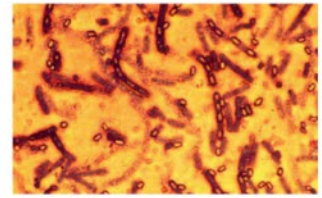
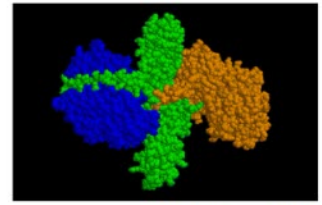
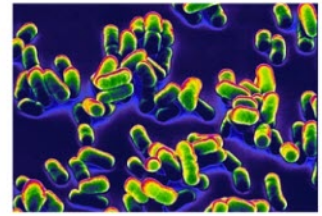
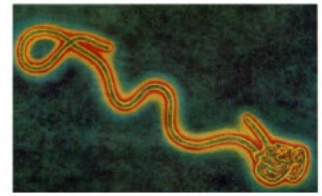

NIH Strategic Plan and Research Agenda for Medical Countermeasures Against Chemical Threats
NATIONAL INSTITUTES OF HEALTH

"At the end of several years, I don't want you coming back and merely saying, 'we've learned a lot' – we need countermeasures."

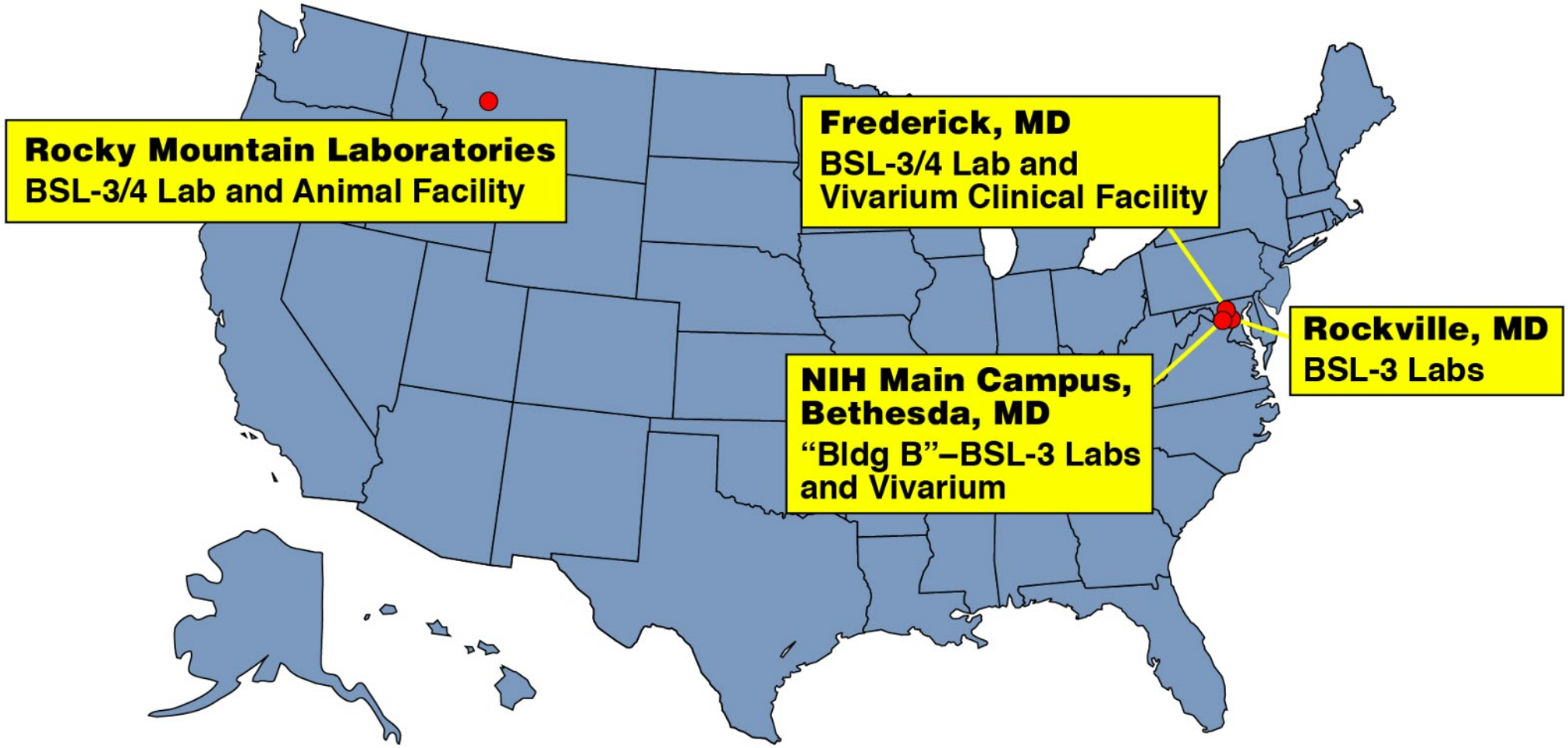
-- President George W. Bush
2002

Category A Select Agents: Key Achievements

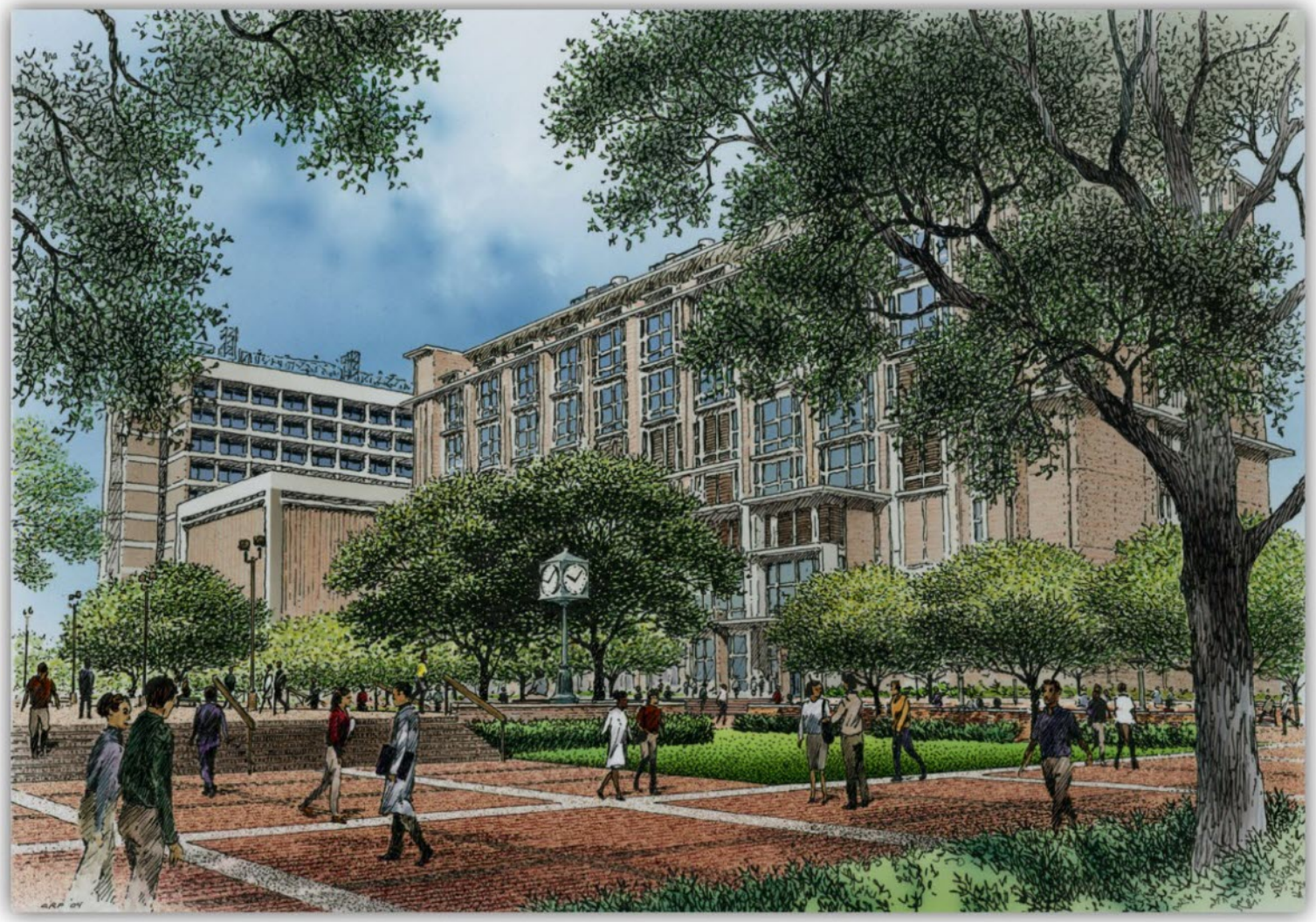
- **Smallpox**
  - Dryvax; MVA; antiviral drug
- **Anthrax**
  - Next-generation 2-dose vaccine; antitoxins
- **Botulinum**
  - Antitoxins; mAbs
- **Plague**
  - Antibiotics
- **Ebola**
  - First human vaccine trials; therapeutics; diagnostics

2002: Immediate Expansion of Federally Funded Facilities to Study Agents of Bioterrorism



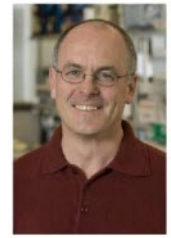
Construction of Galveston National Laboratory



Groundbreaking of the Galveston National Laboratory - August 10, 2005

NIAID Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases

PI – Dr. Samuel Miller
University of Washington
Seattle, WA



PI – Dr. John Belisle
Colorado State University
Fort Collins, CO

PI – Dr. Olaf Schneewind
University of Chicago
Chicago, IL

PI – Dr. Dennis Kasper
Harvard Medical School
Boston, MA

PI – Dr. W. Ian Lipkin
Columbia University
New York, NY

PI – Dr. Jay A. Nelson
Oregon Health & Science
University
Portland, Oregon

PI – Dr. Myron Levine
University of Maryland
Baltimore, MD

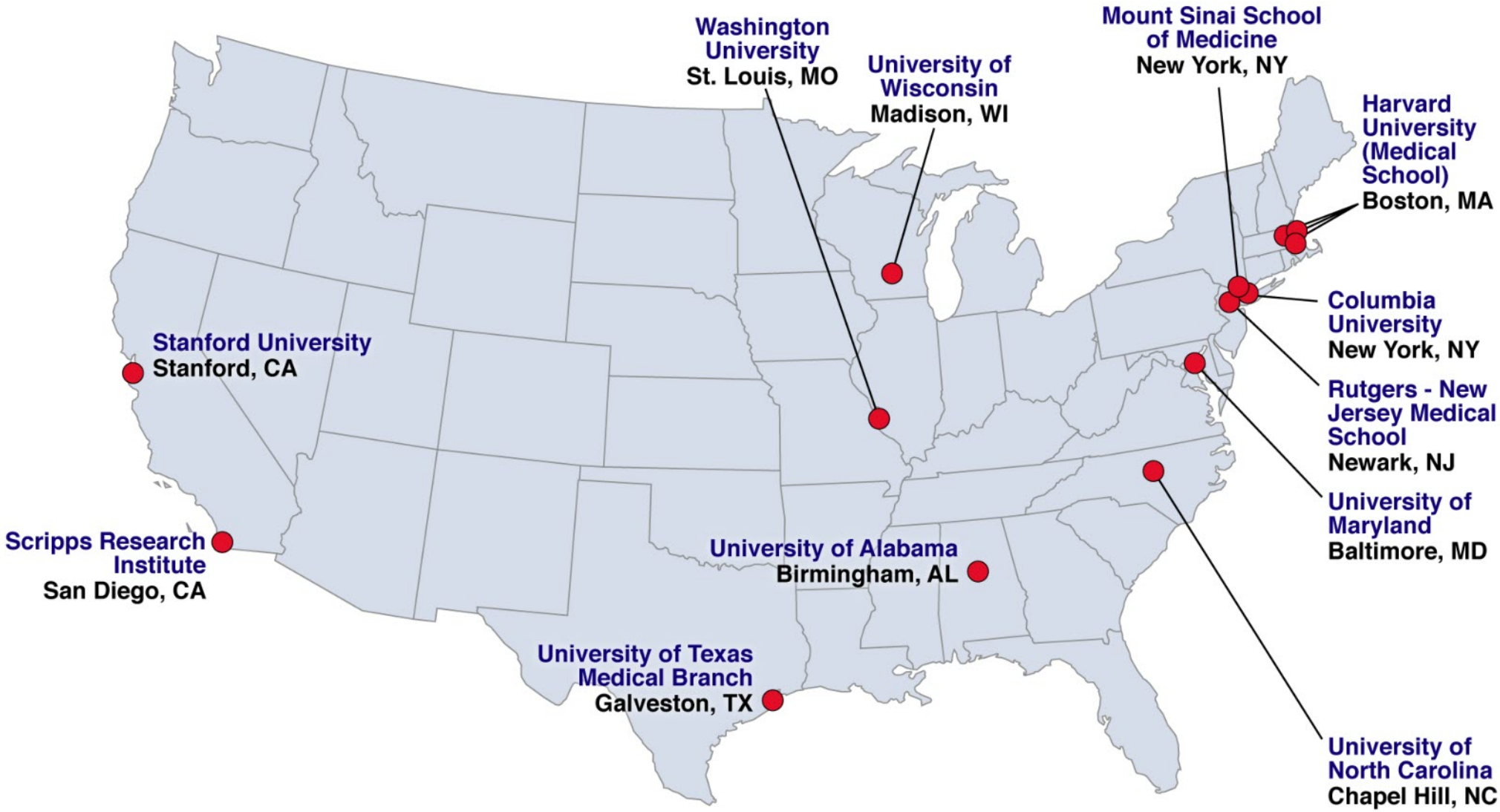
PI – Dr. Alan G. Barbour
University of California
Irvine, CA

PI – Dr. David Walker
University of Texas Medical Branch
Galveston, TX

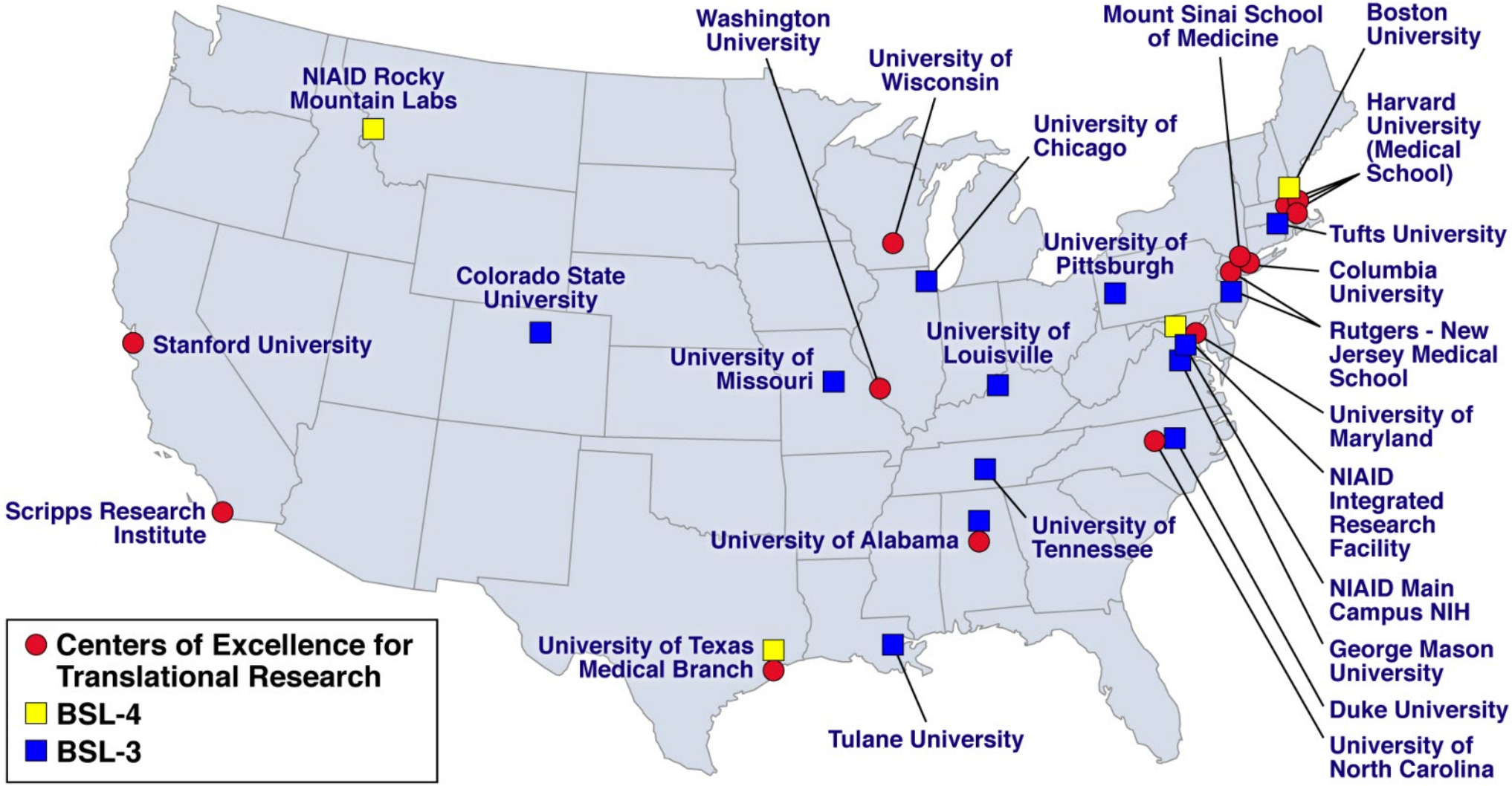
PI – Dr. Samuel Stanley
Washington University
St. Louis, MO

PI - Dr. Fred Sparling
University of North Carolina
Chapel Hill, NC

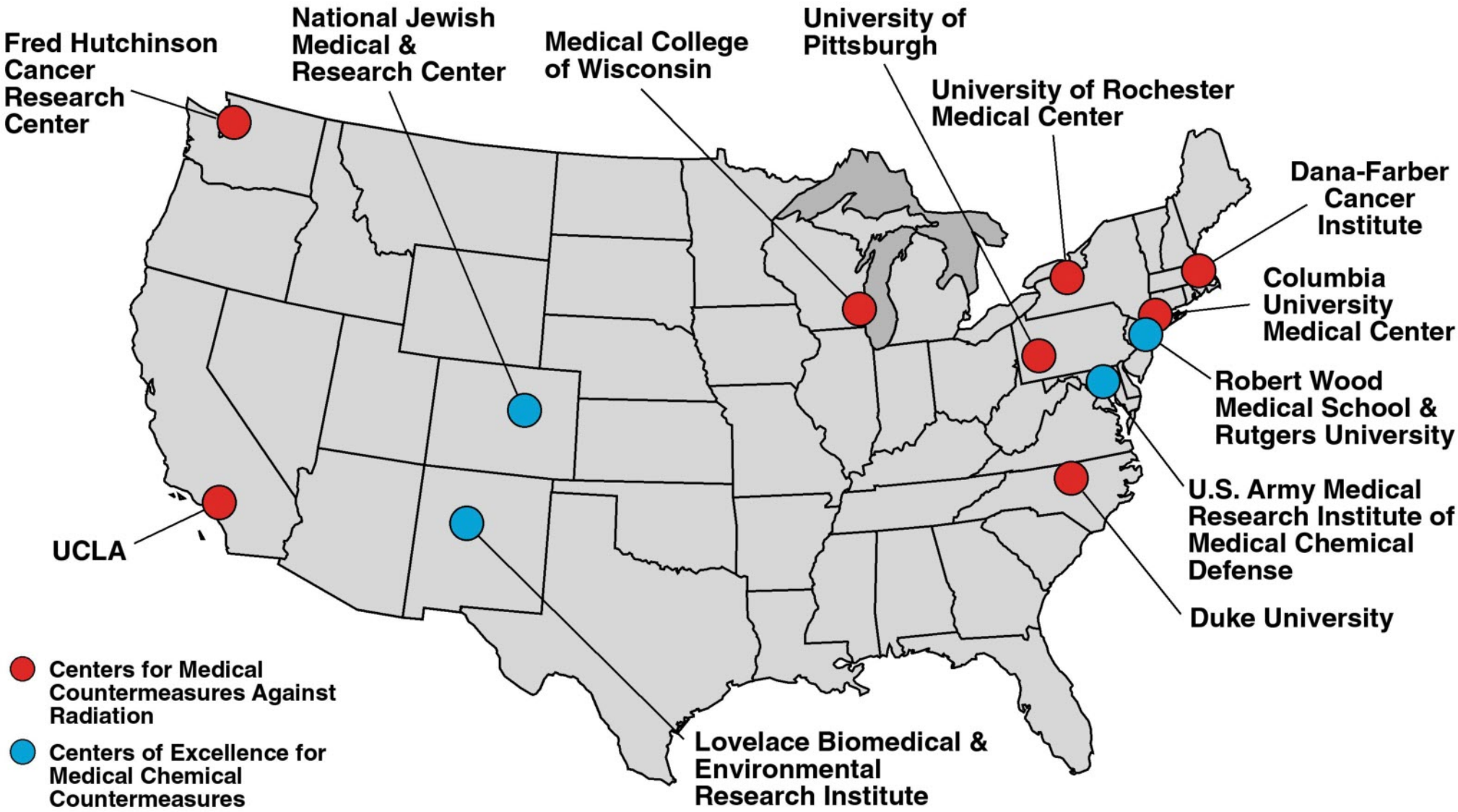
Centers of Excellence for Translational Research, 2017



NIAID-Supported Biodefense Research Infrastructure, 2017



Centers of Excellence for Medical Countermeasures Against Radiological and Chemical Threats



February 5, 2002

President GW Bush: "Tony, what scares you the most among potential microbial threats that a terrorist might use?"

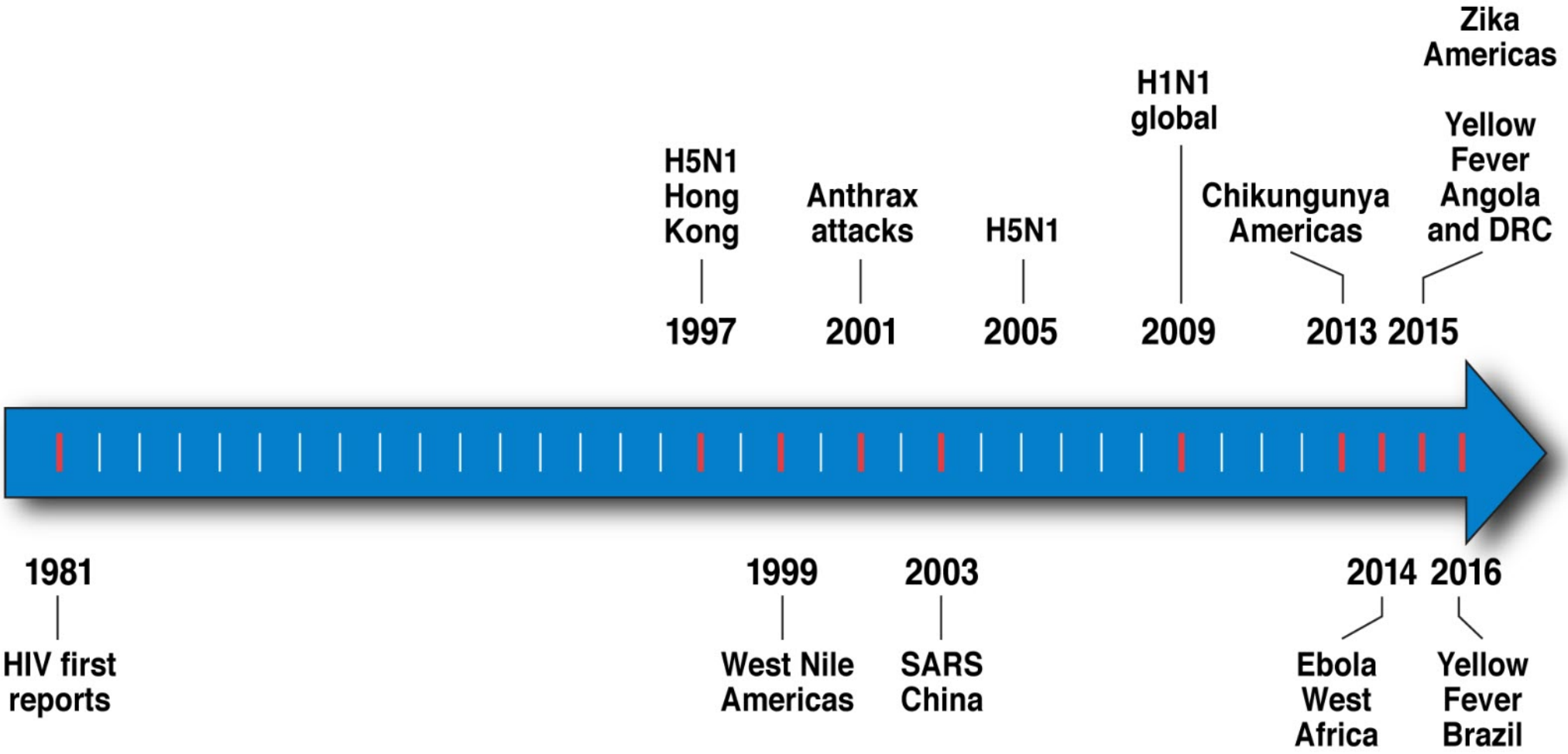
Fauci: "Mr. President, I worry more about the natural occurrence of an influenza pandemic and the ongoing plague of HIV than I do about a bioterror attack."

Newsday

November 18, 2001

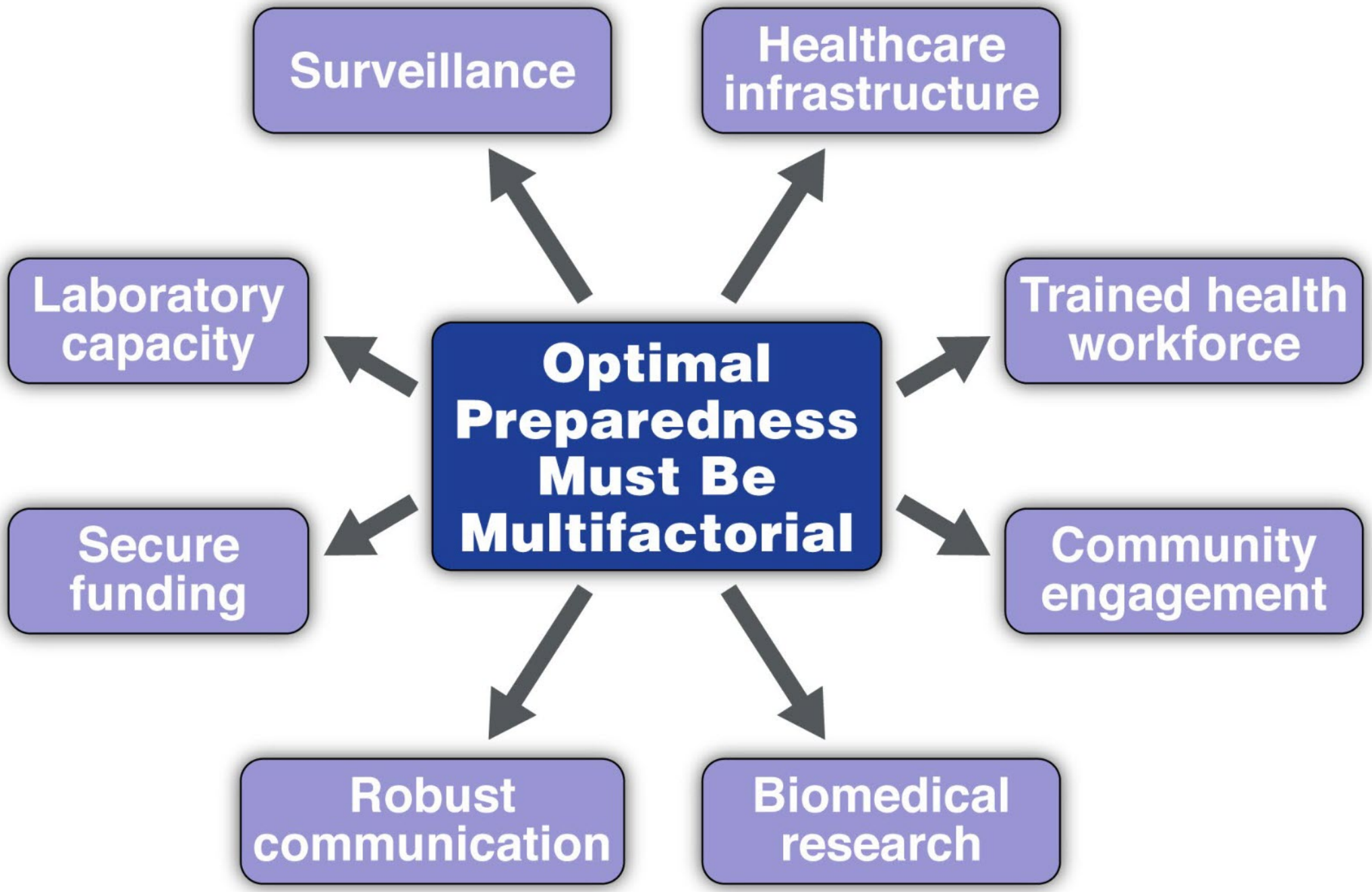
The Worst Bioterrorist May Be Nature Itself

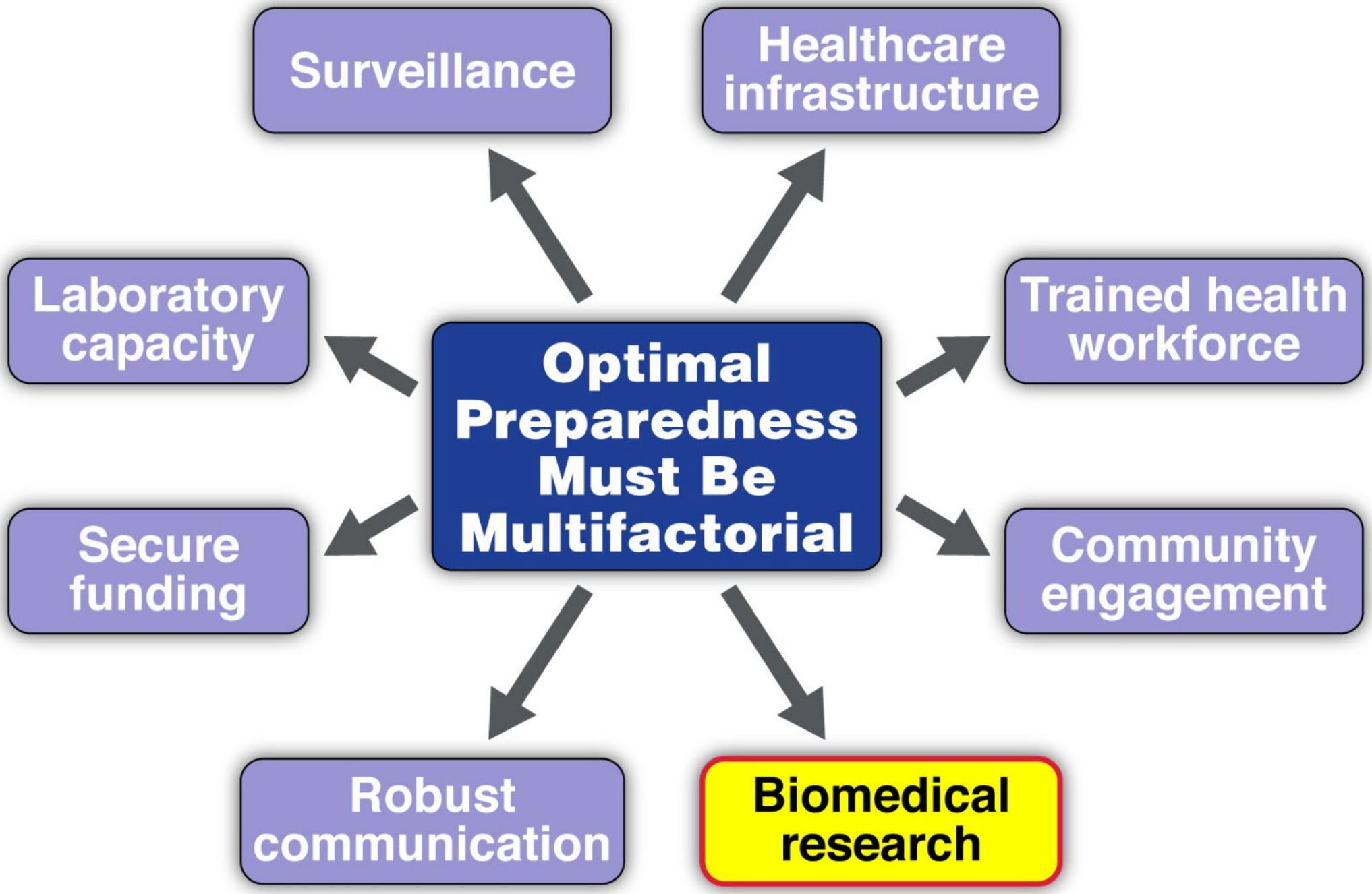
Recent Landmark Events in Emerging Infectious Diseases



Lessons Learned from Previous Pandemics

- Global surveillance
- Transparency and communication
- Infrastructure and capacity building
- Coordinated and collaborative basic and clinical research
- Adaptable platform technologies for vaccines, diagnostics and therapeutics
- Stable funding mechanism – “Public Health Emergency Fund”


Surveillance
Healthcare infrastructure
Laboratory capacity
Trained health workforce
Optimal Preparedness Must Be Multifactorial
Secure funding
Community engagement
Robust communication
Biomedical research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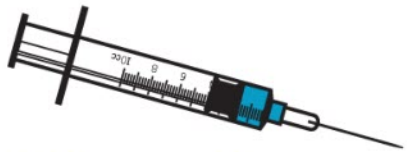
Published online
October 4, 2017

JAMA
The Journal of the
American Medical Association

The Critical Role of Biomedical Research in Pandemic Preparedness

HD Marston, CI Paules and AS Fauci

Biodefense and Emerging Infectious Diseases (EID) Research Priorities



Vaccines

Therapeutics

Diagnostics

Basic Research

Genomics

Expansion of Research Capacity

Therapeutics

Diagnostics

Biodefense and Emerging Infectious Diseases (EID) Research Priorities

Basic Research

Expansion of Research Capacity

Genomics

Vaccine Development for Pandemic Preparedness

- Priority-Pathogen Approach
- Platform Approach
- Prototype-Pathogen Approach

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- Priority-Pathogen Approach
- Platform Approach
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AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS

PLAN OF ACTION
MAY 2016

World Health Organization

The Blueprint aims to reduce the time between the declaration of a public health emergency of international concern and the availability of effective tests, vaccines and medicines that can be used to save lives and avert crisis.

Diseases to Be Urgently Addressed under the R&D Blueprint, as of May 2016

- Crimean-Congo Hemorrhagic fever virus
- Filovirus diseases (i.e., EVD & Marburg)
- Highly pathogenic emerging coronaviruses relevant to humans (MERS Co-V & SARS)
- Lassa fever virus
- Nipah virus
- Rift Valley fever virus
- A new severe infectious disease

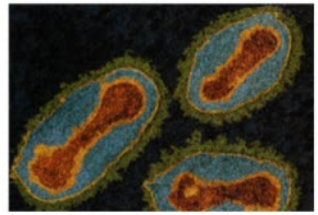
Serious Diseases Necessitating Further Action as Soon as Possible, as of May 2016

- Chikungunya virus
- Severe fever with thrombocytopenia syndrome
- Congenital abnormalities and other neurological complications associated with Zika virus

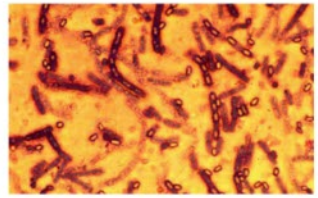
Source: WHO

Category A Select Agents: Key Achievements

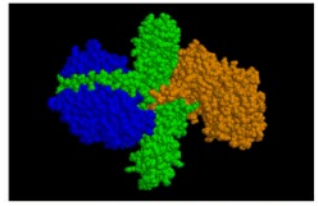
- **Smallpox**
  - Dryvax; MVA; antiviral drug



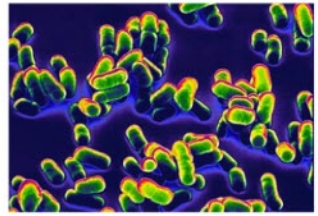
- **Anthrax**
  - Next-generation 2 dose vaccine; antitoxins



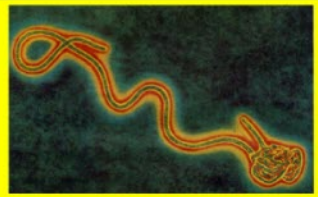
- **Botulinum**
  - Antitoxins; mAbs



- **Plague**
  - Antibiotics



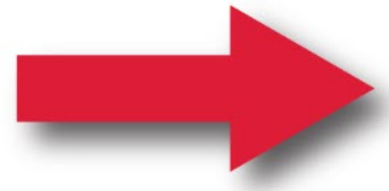
- **Ebola**
  - First human vaccine trials; therapeutics; diagnostics



Vaccine Development for Pandemic Preparedness

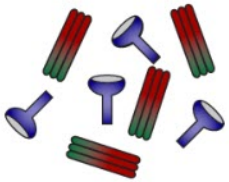
- Priority-Pathogen Approach
- **Platform Approach**
- Prototype-Pathogen Approach

Priority Pathogen



Platform

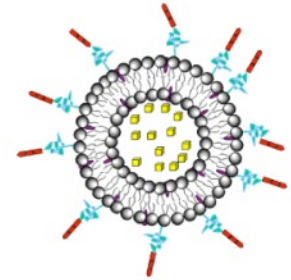
Novel Vaccine Platforms



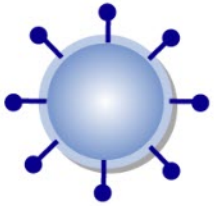
Recombinant subunit

Synthetic peptide

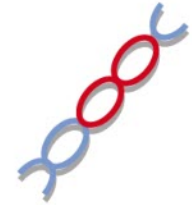
Microbial vector



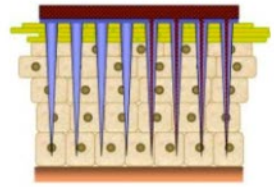
Nanoparticle-based



Virus-like particles (VLPs)



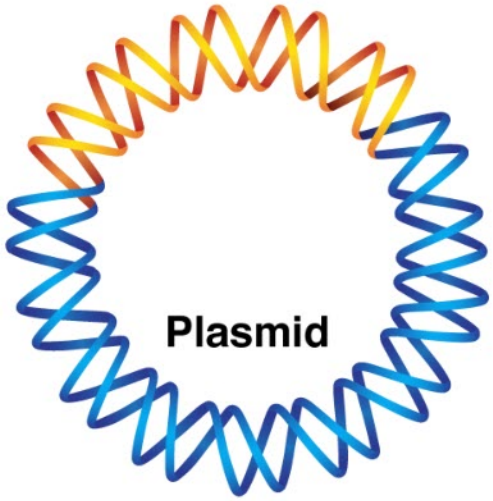
DNA-based



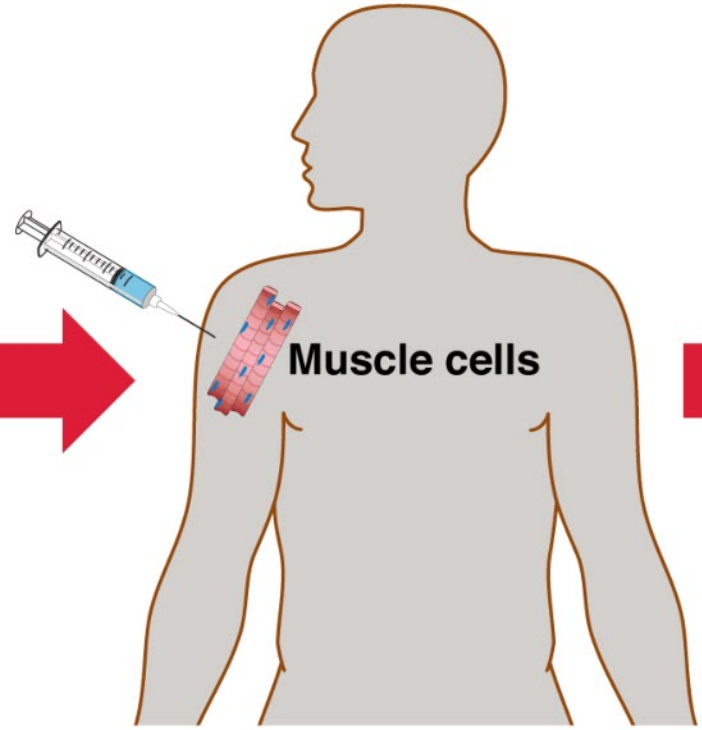
Novel delivery systems (e.g., microneedles)

DNA Vaccine Approach

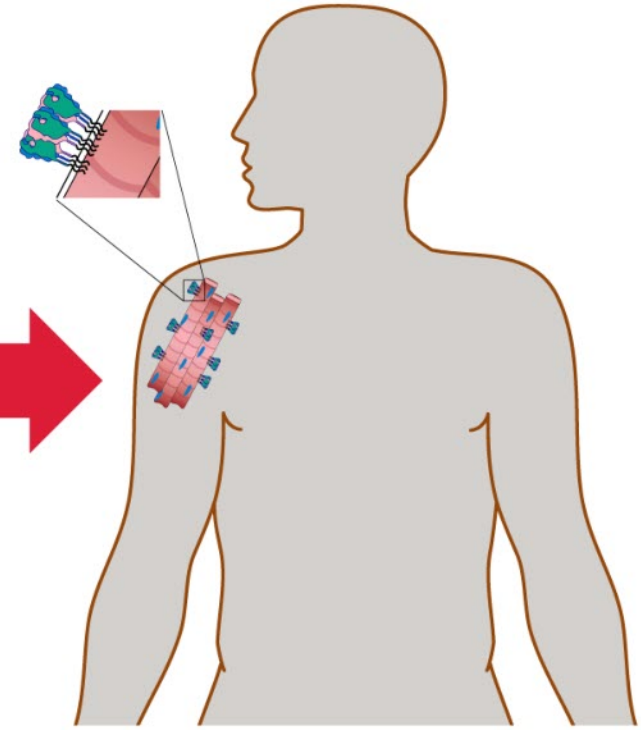
Gene encoding surface glycoprotein from SARS virus



Inject DNA containing SARS gene

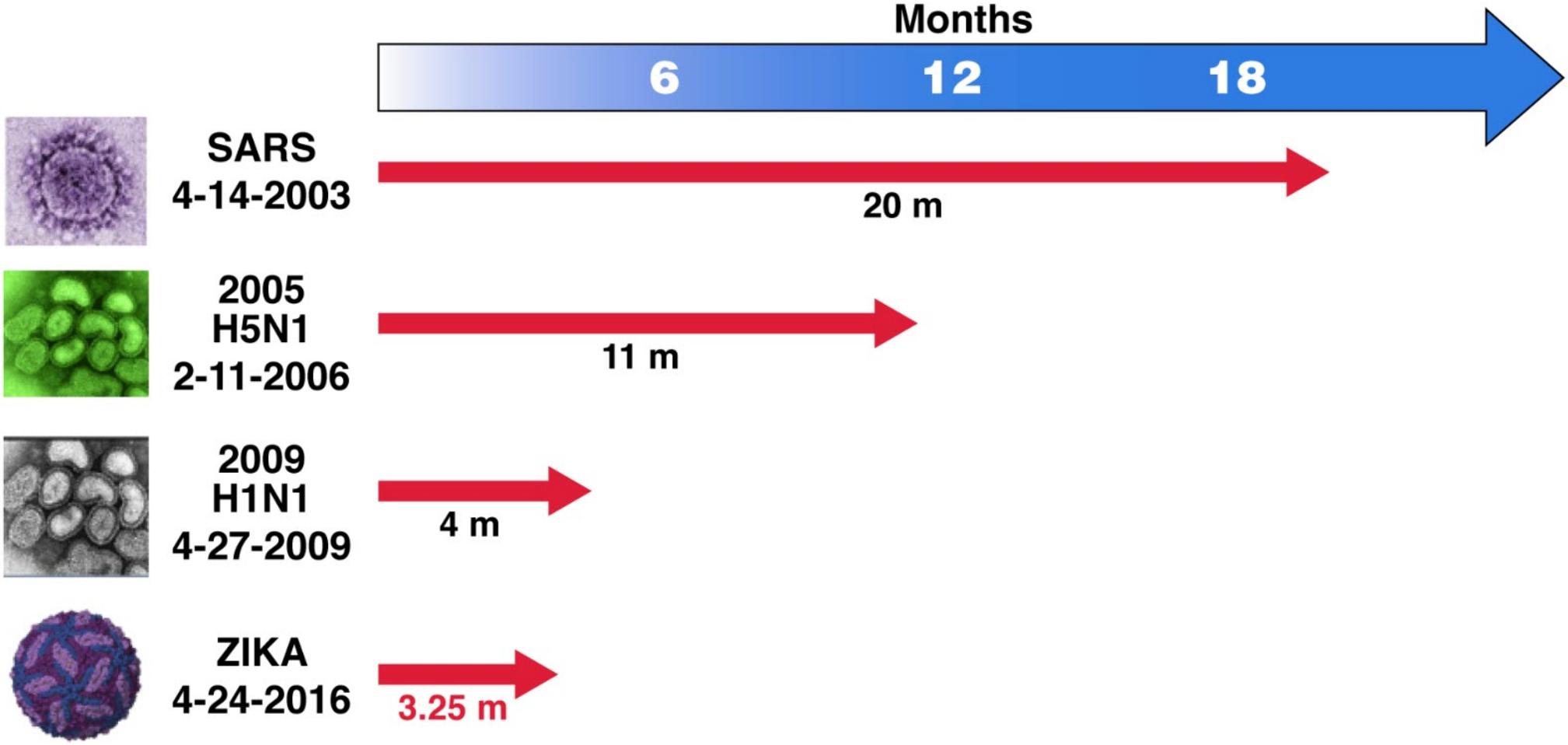


Body's cells produce membrane-anchored spike proteins



VRC DNA Vaccines for Emerging Infections

Sequence Selection to 1st Human Injection



Courtesy: J Ledgerwood/NIAID VRC

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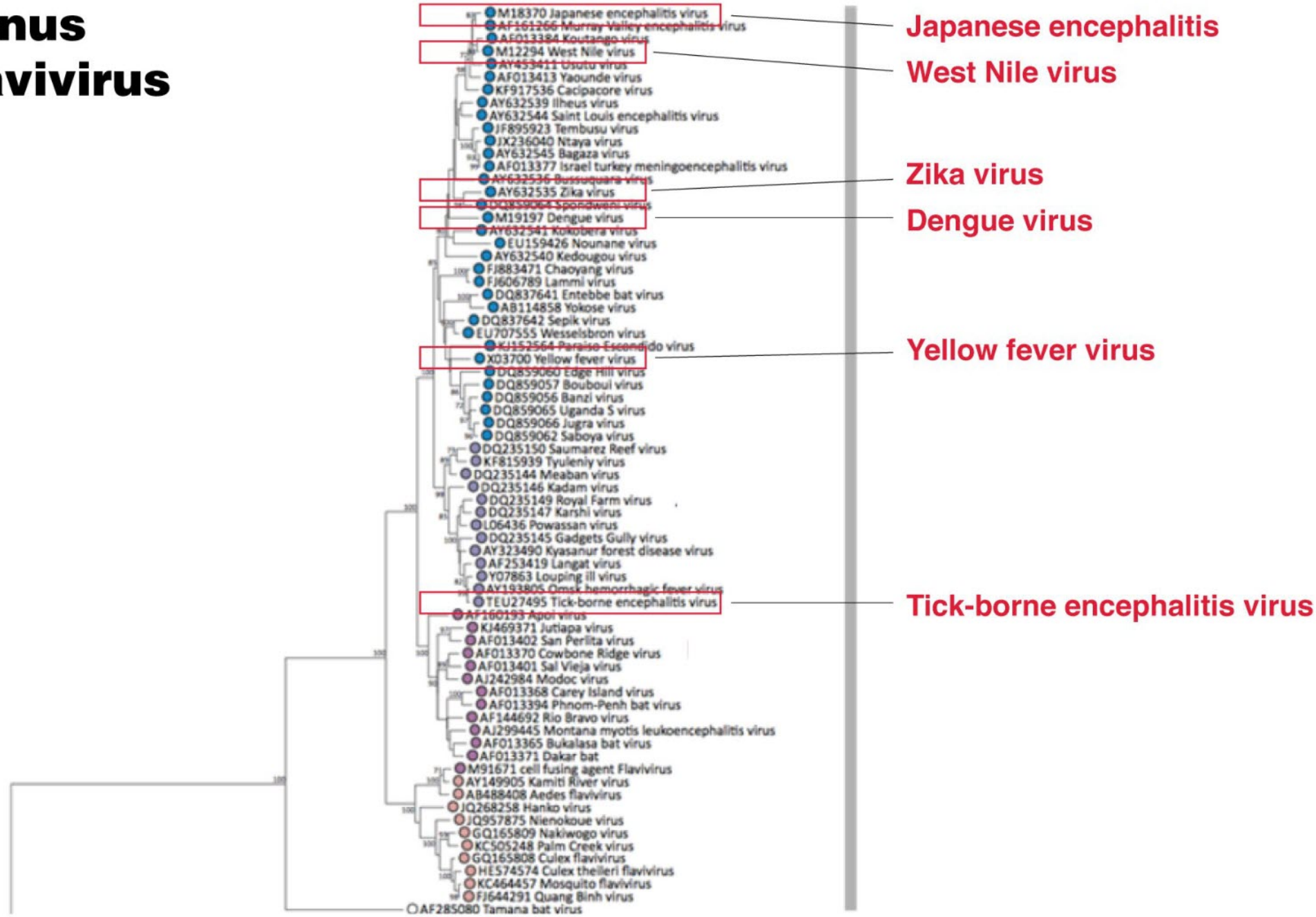
Genus Flavivirus



Applying Strategies and Tools from One Virus to Inform Vaccine Design for Related Viruses

- Basic virology (e.g., neutralization mechanisms)
- Assays for preclinical and clinical settings
- Animal models
- Antigenic targets
- Optimal platforms
- Potential immune correlates
- Manufacturing strategies

A Delicate Balance

The Extraordinary Capability of Microbial Pathogens to Emerge, Re-Emerge, and Persist

Public Health Measures, Biomedical Research, and Countermeasure Development