National Institutes of Health

Scientific Management Review Board

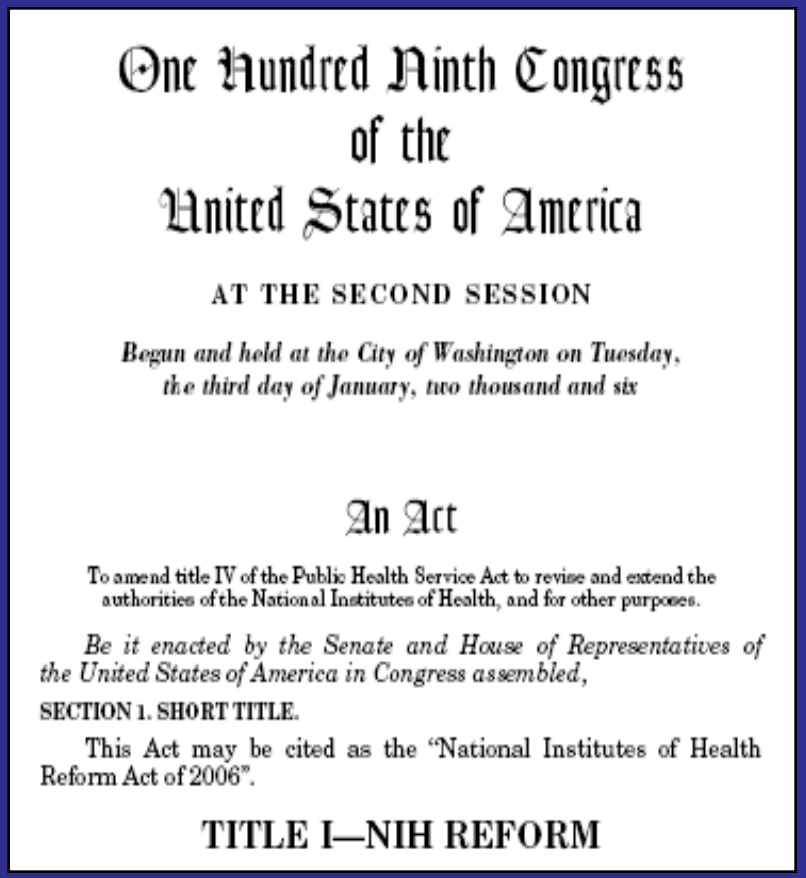
Raynard S. Kington, M.D., Ph.D.

Acting Director, NIH

NIH Reform Act of 2006

- Reauthorization bill passed Congress with unanimous support, affirming importance of NIH and its vital role in advancing biomedical research to improve the health of the Nation

- Signed into law by the President (1/07)



One Hundred Ninth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the third day of January, two thousand and six

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institutes of Health Reform Act of 2006".

TITLE I—NIH REFORM

Scientific Management Review Board

Mission:

- Advise the NIH Director
- Conduct continuous comprehensive organizational reviews of NIH and reports findings to DHHS and Congress at least every seven years

Scientific Management Review Board: Composition

- **NIH Director**
  - permanent *ex officio*, nonvoting member
- **Voting Members**
  - Odd number of additional voting members, not to exceed 21 members, overlapping terms of 5 years
    - 9 Institute and Center Directors
    - 12 Non-federal members
  - Chair—2 year term, selected from non-federal members

Scientific Management Review Board: Members

- **Norman Augustine** (Chairman), Lockheed Martin
- **Jeremy Berg**, NIGMS
- **Josephine Briggs**, NCCAM
- **William Brody**, Salk Institute for Biological Studies
- **Gail Cassell**, Eli Lilly and Company
- **Anthony Fauci**, NIAID
- **Dan Goldin**, Intellisis Corporation
- **Richard Hodes**, NIA
- **Stephen Katz**, NIAMS
- **Thomas Kelly**, Sloan-Kettering Institute
- **Elizabeth Nabel**, NHLBI

Scientific Management Review Board: Members *(cont…)*

- **John E. Niederhuber,** NCI
- **Deborah Powell**, University of Minnesota Medical School
- **Griffin Rodgers**, NIDDK
- **William Roper**, University of North Carolina
- **Arthur Rubenstein**, University of Pennsylvania School of Medicine
- **Solomon Snyder**, Johns Hopkins University
- **Lawrence Tabak**, NIDCR and OD/NIH
- **Eugene Washington**, University of California, San Francisco
- **Huda Zoghbi**, Baylor College of Medicine

Scientific Management Review Board: Consultations

- **Members of the Board are expected to consult:**
  - Institute and Center Directors not on the SMRB
  - NIH scientific leaders not on the SMRB
  - Institute and Center advisory councils
  - Scientific organizations
  - Patient organizations

Scientific Management Review Board: Activities

Issue report not less than once every 7 years

- **Activities include:**
  - Evaluating NIH research portfolio
  - Determining scientific opportunities and public health needs relevant to the NIH mission
  - Assessing organizational issues, including:
    - Use of organizational authorities, including reorganizing and restructuring areas within NIH
    - Budgetary and operational consequences of any proposed changes
    - Recommendations on allocation of resources among the Institutes and Centers

Scientific Management Review Board Legislation: Meetings and Forums

- **Meetings**
  - Meet at the call of the Chair or NIH Director
  - Not fewer than 5 times with respect to issuing any particular Report
  - Summary of meetings must be posted on the NIH website
- **Forums for Reports on Organizational Issues**
  - With scientific community: needs and opportunities related to proposal for organizational changes (1 or more)
  - With consumer organizations: needs and opportunities of patients and their families related to proposals for organizational changes (1 or more)

Scientific Management Review Board: Inaugural Meeting Goals

- Receive briefing on NIH policies and ethics
- Gain general understanding of NIH mission, structure, budget, and central services
- Understand perspectives on science and structure of NIH from former NIH Directors
- Contemplate organizational change
  - Substance Use, Abuse, and Addiction
  - NIH Intramural Research Program and Clinical Center

Scientific Management Review Board: Public Website

- http://smrb.od.nih.gov/

Goals of Meeting

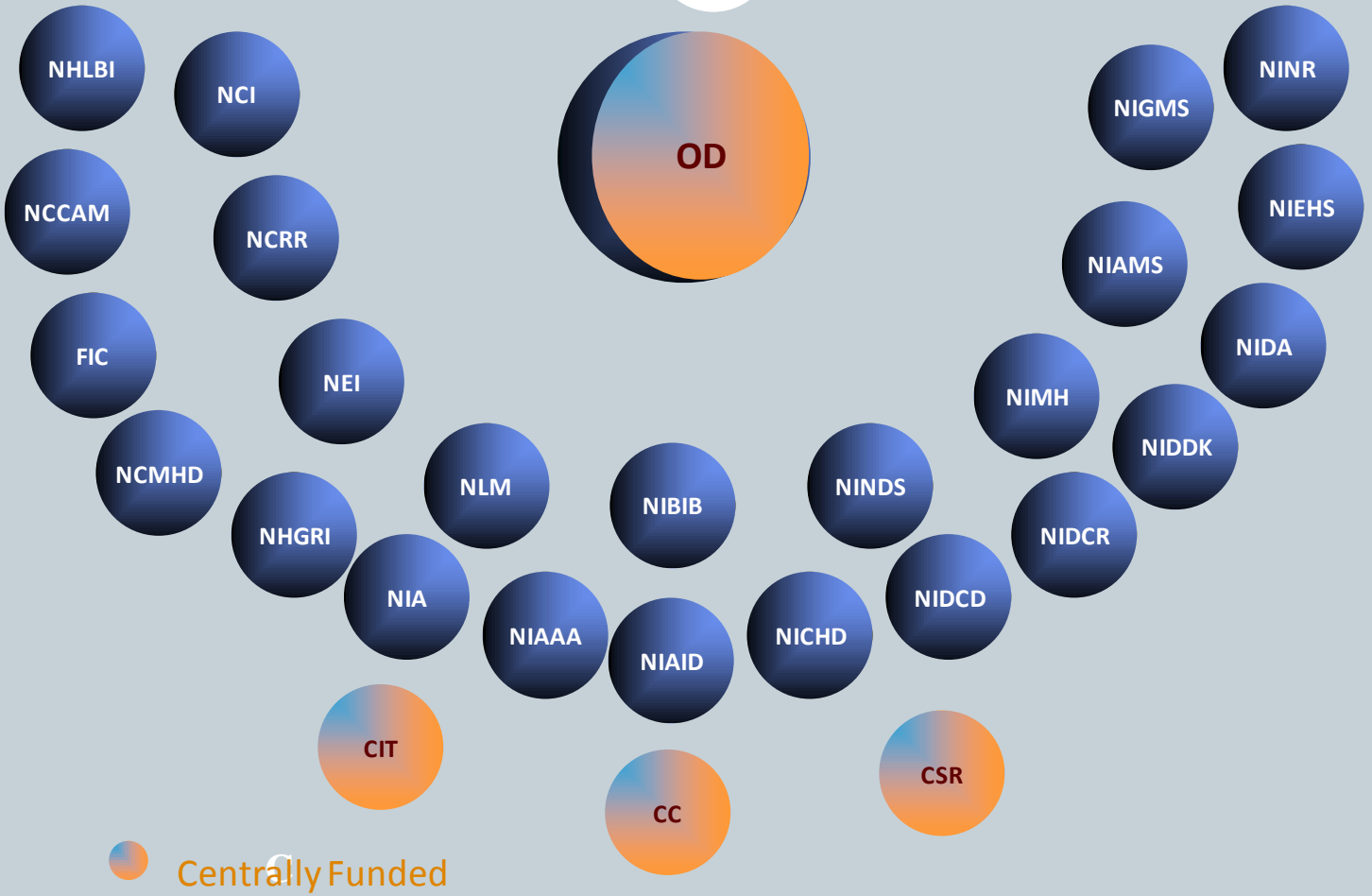
- Be briefed on NIH mission and structure by current NIH staff
- Hear perspectives from a National Academies committee and two former NIH Directors
- Consider taking up specific matters:
  - Whether organizational change within NIH could further optimize research into substance use, abuse, and addiction
  - Whether organizational change within the NIH Clinical Center and/or the NIH Intramural Research Program could further optimize the opportunities available to a central research program at NIH

NIH Central Services, Cost Drivers and the Role of the Clinical Center

PRESENTATION TO THE SMRB

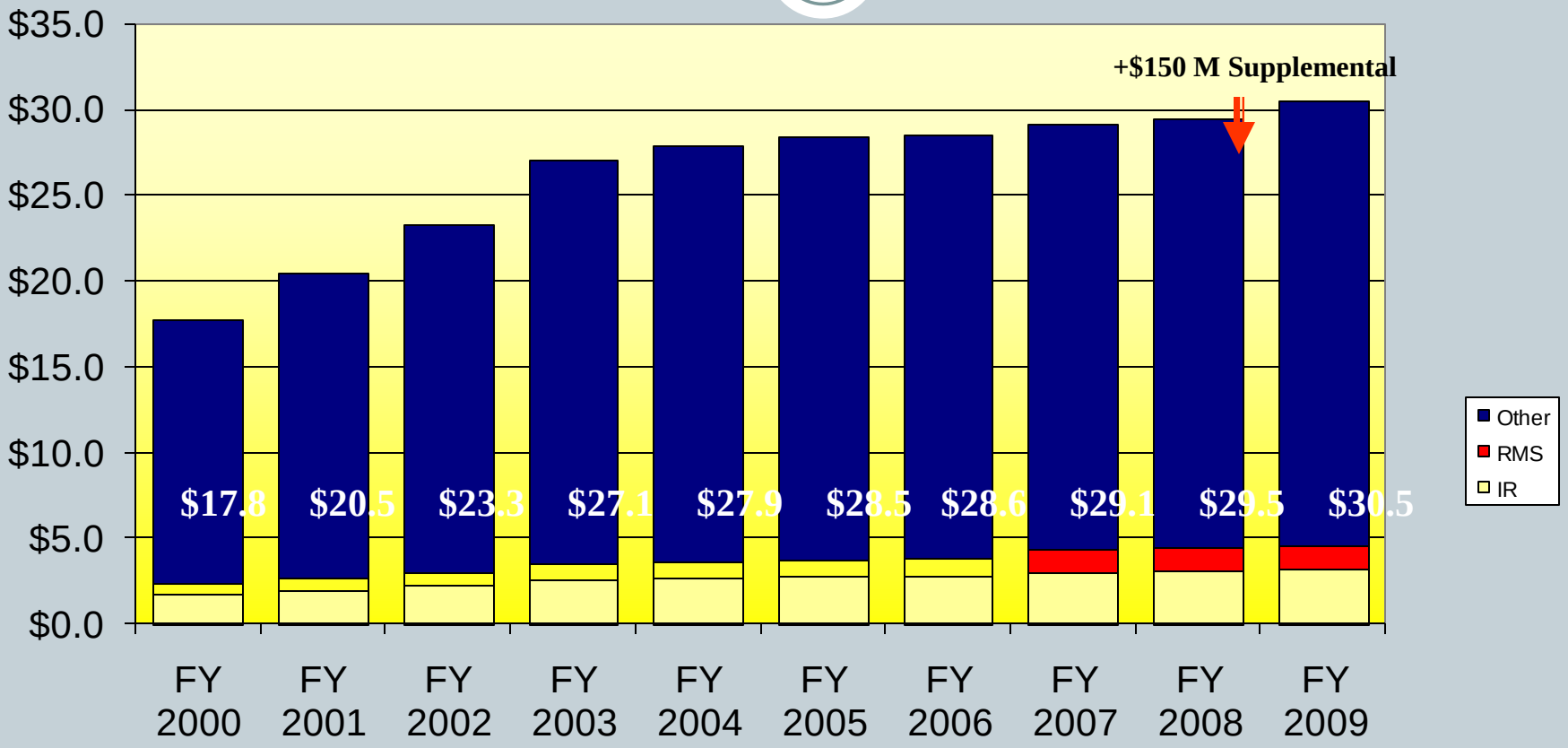
APRIL 27, 2009

NIH – 27 Institutes and Centers



NIH Appropriations, FY2000- FY2009

(Dollars in Billions)



Does not include $10.4 billion appropriated to NIH in FY 2009 for the American Reinvestment and Recovery Act of 2009.

NIH Appropriations by IC, FY 2008-2009

(Dollars in Thousands)

	FY 2008 Enacted with Supplemental	FY 2009 Conference	Difference
IC	**Amount**	**Amount**	**Amount**
NCI	$4,830,647	$4,968,973	$138,326
NHLBI	2,937,654	3,015,689	78,035
NIDCR	392,233	402,652	10,419
NIDDK (excludes Type 1perm)	1,715,761	1,761,338	45,577
NINDS	1,552,113	1,593,344	41,231
NIAID	4,583,344	4,702,572	119,228
NIAID less Global HIV/AIDS Transfer (non-add)	*4,288,585*	*4,402,572*	*113,987*
NIGMS	1,946,104	1,997,801	51,697
NICHD	1,261,381	1,294,894	33,513
NEI	670,664	688,480	17,816
NIEHS	645,669	662,820	17,151
NIA	1,052,830	1,080,796	27,966
NIAMS	511,291	524,872	13,581
NIDCD	396,234	407,259	11,025
NIMH	1,412,951	1,450,491	37,540
NIDA	1,006,022	1,032,759	26,737
NIAAA	438,579	450,230	11,651
NINR	138,207	141,879	3,672
NHGRI	489,368	502,367	12,999
NIBIB	300,233	308,208	7,975
NCRR	1,155,560	1,226,263	70,703
NCCAM	122,224	125,471	3,247
NCMHD	200,630	205,959	5,329
FIC	66,912	68,691	1,779
NLM	322,212	330,771	8,559
OD	1,111,735	1,246,864	135,129
Common Fund Included in OD (non-add)	*498,244*	*541,133*	*42,889*
B&F	118,966	125,581	6,615
Total Labor/HHS	**$ 29,379,524**	**$ 30,317,024**	**$ 937,500**
Interior-Superfund	**$ 77,546**	**$ 78,074**	**$ 528**
Total Discretionary B.A.	**$ 29,457,070**	**$ 30,395,098**	**$ 938,028**

Funding of Central Services

$30.5B

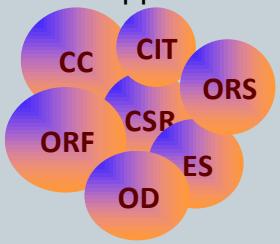
24 ICs/OD

Grants and Contracts- $25.9B

RMS-$1.4B

IRP-$3.2B

Steering Committee Approval



$1.7B

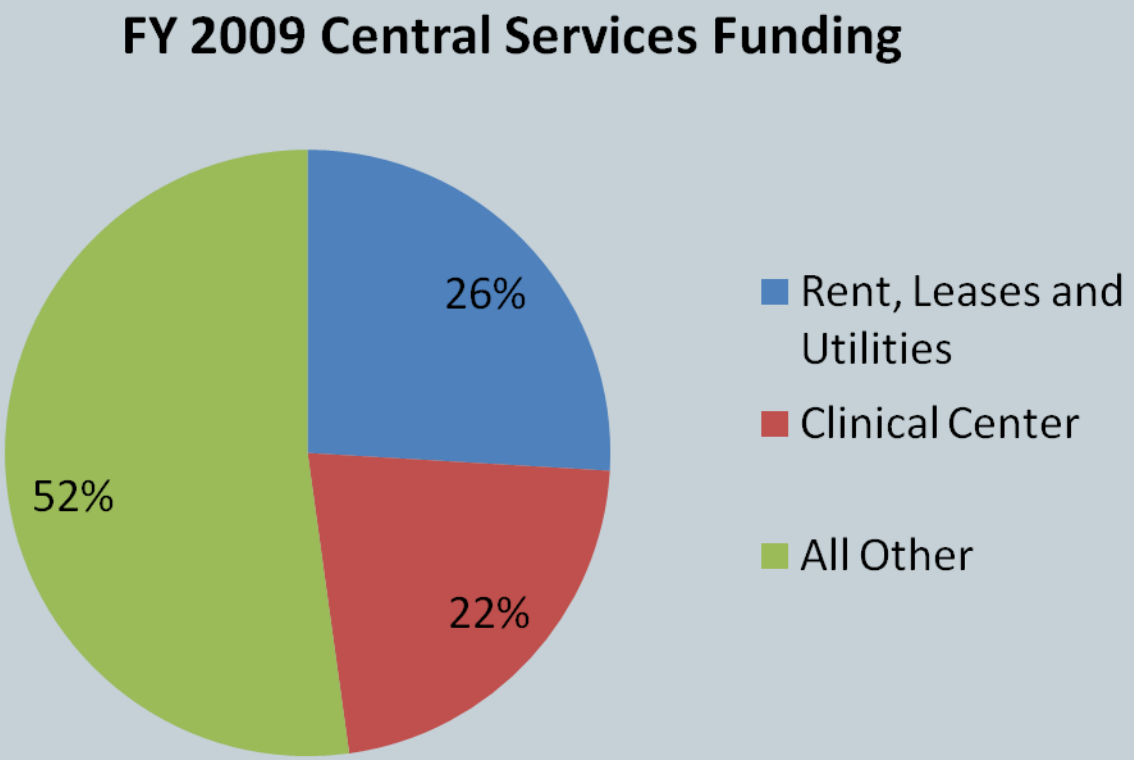
Governance Structure – Working Groups

- The NIH Steering Committee has governance purview for all corporate functions, resources, or policies other than the setting of corporate scientific direction and priorities.
- Individual Steering Committee Working Groups and the OD Central Services Advisory Committee provide oversight for Central Service Organizations and make annual budget recommendations.
- Each Working Group is co-chaired by a Steering Committee Member and the senior OD functional head.
  - Extramural – Provides oversight for the Center for Scientific Review.
  - Intramural – Provides oversight for the Clinical Center and the Office of Research Services.
  - Facilities – Provides oversight for the Office of Research Facilities.
  - Information Technology – Provides oversight for the Center for Information Technology and NIH's Enterprise Systems.
  - Management and Budget – Provides an integrated set of recommendations for Central Services organizations to the Steering Committee.
- Central Services costs have been increasing faster than the growth of RMS/IR between FY 2005-2009 – 15.3% vs. 9.3%.

Partial Listing of Centrally Funded Services

- Scientific Review
- Clinical Center
- Enterprise IT Systems
- Help Desk Services
- Networking and Telecommunications Services
- Computing Services
- IT Procurement Policy
- IT Applications Development
- Bioengineering Services
- Veterinary Resources
- Travel Management
- Cafeteria Services
- Trans-Share Program
- Relocation Services
- Scientific Equipment Fabrication and Rental
- Radiation Safety
- Postal Services
- Personnel Security
- Campus Security
- Police
- Fire Prevention
- Emergency Preparedness
- Parking Services
- Occupational Health
- Laboratory Safety
- Radiation Safety
- Medical Arts and Printing
- Library Services
- International Services
- Conference Services
- Courier Services
- Space Management
- Child Care
- Shuttle Services
- Fitness Centers
- Pest Management
- Printing and CD production
- Interpreting Services
- CPR Training
- Immunizations
- Capital Projects Management
- Building Maintenance
- Custodial Services
- Loading Dock Management
- Leasing Program
- Utilities Management
- Environmental Management
- Grounds Maintenance
- Property Management
- Acquisitions Services
- Warehouse
- Motor Pool
- Loan Repayment Program
- Technology Transfer Services
- NIH Intern Programs
- NIH Training Center
- NIH Transition Center
- NIH Academy
- Financial Services
- HR Services
- EEO Services
- Ethics Services
- Conflict Resolution
- A-76 analyses
- OGC Services
- Graduate Program Partnership
- NRSA
- Extramural Research Reports and Analyses
- Records Management
- Extramural Administrative Support

Major Components of Central Services Budget



• Almost half of Central Service costs are for space (rent, leases and utilities) and the Clinical Center.

Space Costs

(Dollars in Millions)

	Amount	% Increase
FY 2005	$298.8	N/A
FY 2006	334.9	12.1%
FY 2007	363.3	8.5%
FY 2008	422.8	13.4%
FY 2009	429.5	1.6%

- Until this year, space costs (rent, leases, and utilities have been the principal driver of Central Service costs.
- Cost increases in FY 2005-2008 driven by increasing prices and consumption of utilities and growth of off-campus rental space.
- Lower cost growth in FY 2009 is the result of stable square footage, lower energy unit costs and implementation of numerous conservation measures, and other program and administrative efficiencies.
- For the future, increases predicted in the 3% range:
  - Lease costs will continue to be actively managed (lease consolidations, relocating functions to owned space, assigning lower space/person).
  - However, predicting energy prices is uncertain.

Clinical Center Costs

(Dollars in Millions)

CC Central Services Budget

	Amount	% Increase
FY 2005	$333.7	N/A
FY 2006	335.9	0.7%
FY 2007	344.8	2.7%
FY 2008	351.9	2.1%
FY 2009	362.3	2.9%

CC Budget with Cost Shifts

	Amount	% Increase
FY 2005	$333.7	N/A
FY 2006	338.3	1.4%
FY 2007	350.8	3.7%
FY 2008	366.8	4.6%
FY 2009	378.8	3.3%

- Clinical Center costs are assessed to ICs in proportion to the size of their intramural program regardless of their utilization of the CC ("school tax").
- Historically the CC budget increases have been a concern but are low by hospital standards.
- To date, rate of growth constrained by administrative efficiencies and cost shifting of specific services to ICs where a direct charge is more appropriate, e.g., research nurses.
- It is unclear if opportunities to continue this strategy can extend into the future.

Clinical Center – Long Range Implications

	IRP Budget	CC @ +3.2%/yr.	% of IRP Budget		CC @ +6%/yr.	% of IRP Budget
FY 2009	$3,171.3	$378.8	11.9%		$378.8	11.9%
FY 2010	3,218.9	390.9	12.1%		401.5	12.5%
FY 2011	3,267.2	403.4	12.3%		425.6	13.0%
FY 2012	3,316.2	416.3	12.6%		451.1	13.6%
FY 2013	3,365.9	429.6	12.8%		478.2	14.2%
FY 2014	3,416.4	443.4	13.0%		506.9	14.8%

- Assumptions :
  - IRP grows at 1.5% per year (FY 2005/9 Ave.).
  - CC grows at 3.2%/year (FY 2005/9 Ave.) or 6%/yr. (closer to hospital rate of inflation).
- By FY 2014, costs as percentage of IRP increase to 13.0% and 14.8% respectively.
- In the absence of fundamental change, costs will outpace resources available to finance it – costs will continue to increase even if utilization is stable or declines.

FY 2008 Report on Financing of the Clinical Center

- Director, NIH convened a committee of senior NIH officials to provide a recommendation on how best to finance the Clinical Center in the context of the current budget environment and its current role.
- Recommendations endorsed by the Management and Budget and Intramural Working Group co-chairs and presented to the NIH Steering Committee.
- Options examined were a separate appropriation, the current "school tax" methodology, or a hybrid model assessing some portion by utilization and the remainder by the current methodology.
- Recommendations:
  - Continue current methodology for the short term.
  - For the longer term, undertake a fundamental review of the mission of, and opportunities for, the NIH Clinical Center and its role in NIH's overall program of Clinical Research.

NIH Scientific Managment Review Board

Scientific Opportunities and Emerging Public Health Issues at the NIH: A View from NIAID

Anthony S. Fauci, M.D.

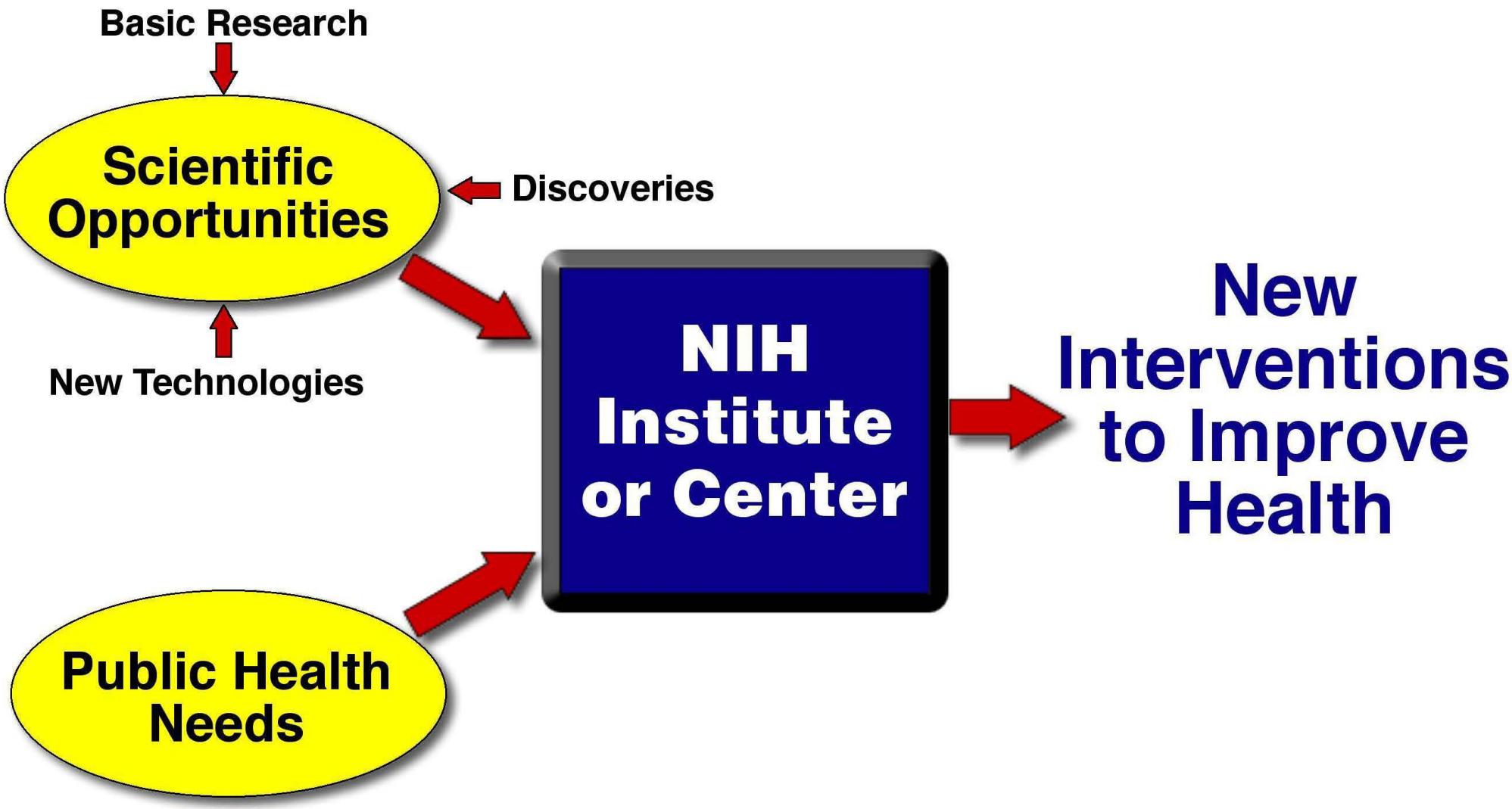
Director

National Institute of Allergy and Infectious Diseases

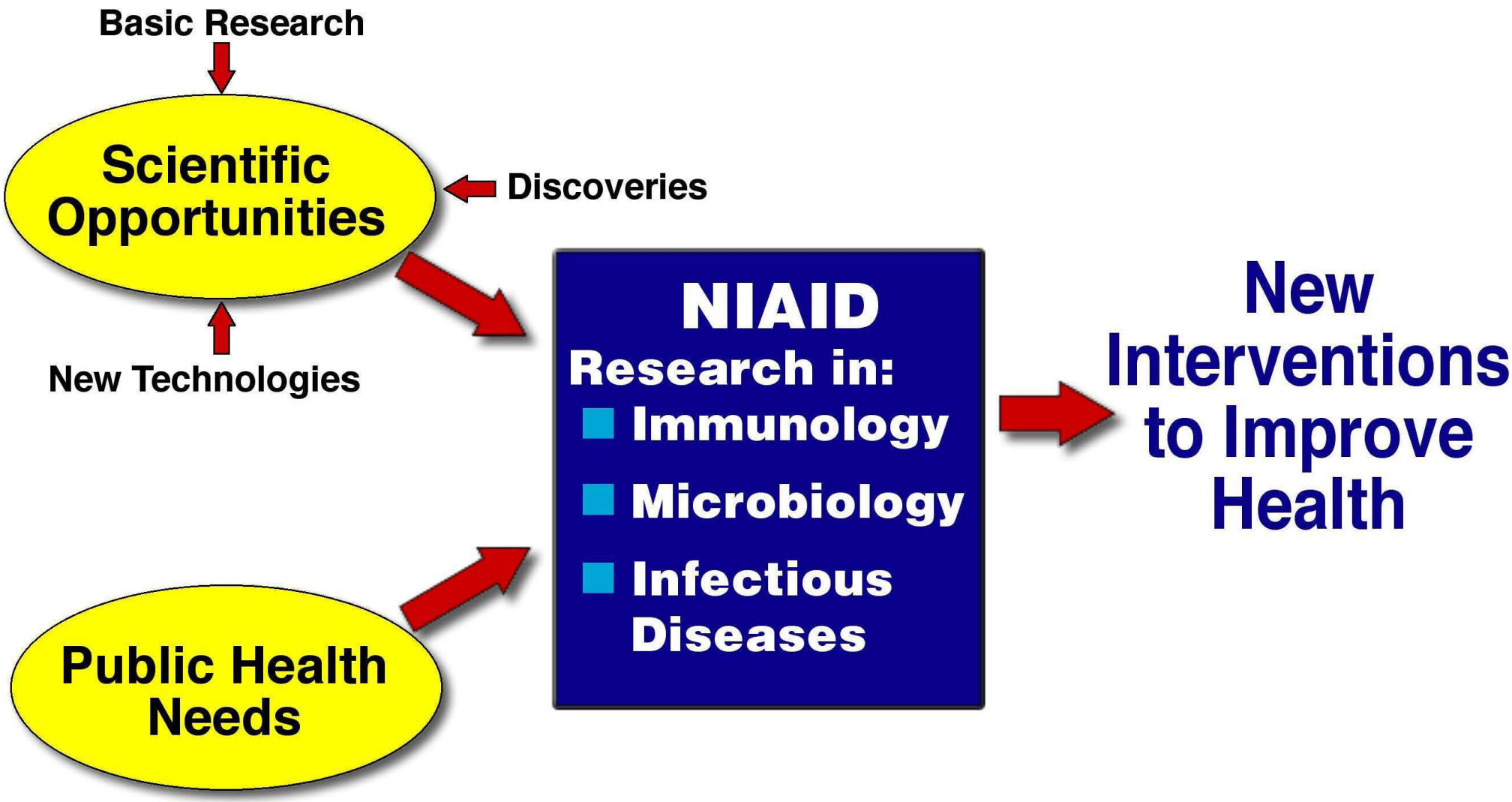
National Institutes of Health

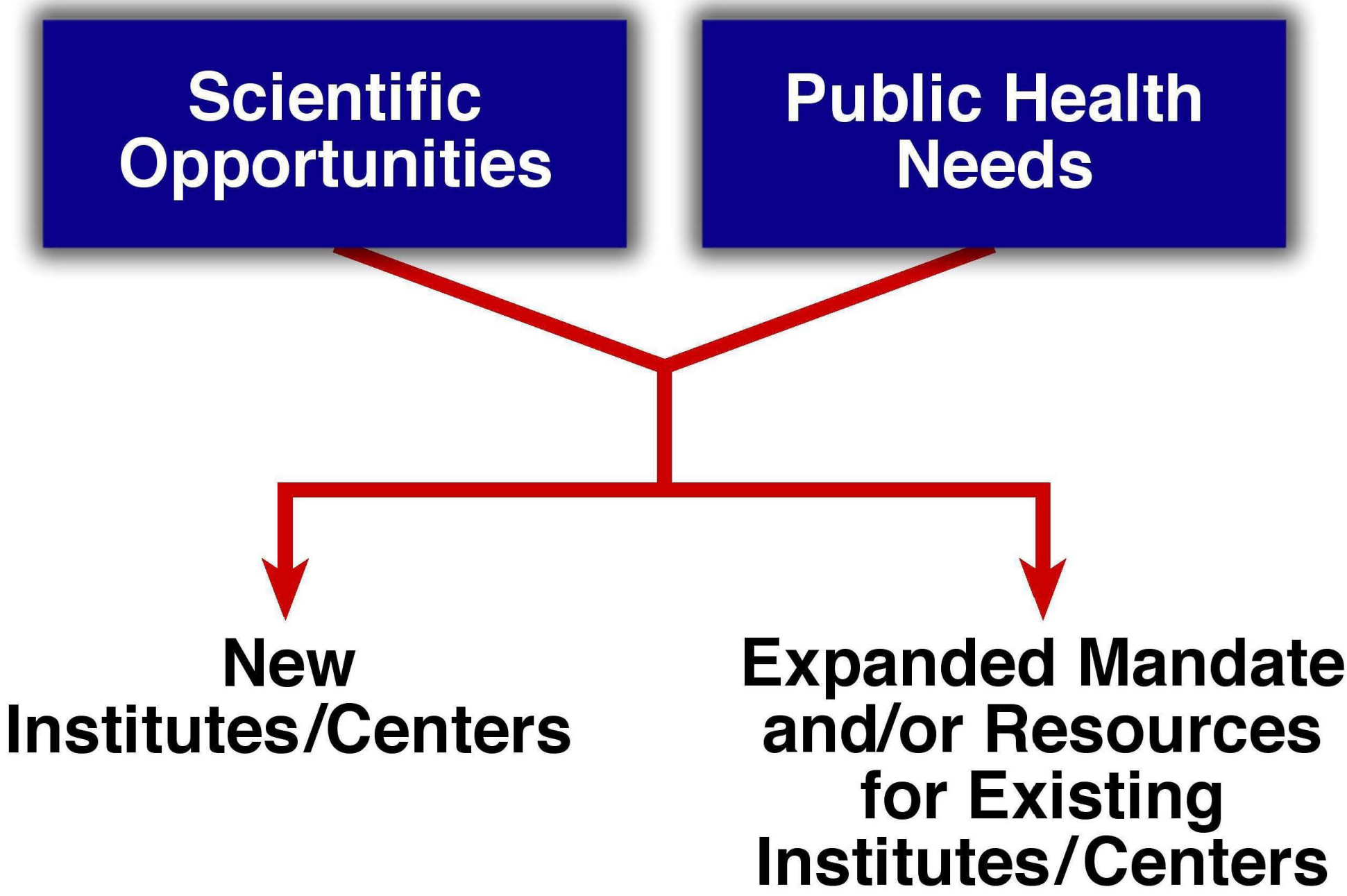
April 27, 2009

Paradigm for NIH Research



Paradigm for NIAID Research




Scientific Opportunities
Public Health Needs
New Institutes/Centers
Expanded Mandate and/or Resources for Existing Institutes/Centers

Evolving Public Health Challenges

Shift from Acute to Chronic Conditions

Aging Population

Health Disparities

Emerging and Re-emerging Infectious Diseases

Emerging Non-communicable Diseases - Obesity

Examples of Key Issues that Have Shaped Individual ICs

NIDDK	Obesity epidemic
NHLBI	Discovery of modifiable risk factors for heart disease
NCI	Genomics to understand molecular basis of cancer
NIAMS	Arthritis in an aging population
NIA	Alzheimer's disease
NINR	Increase in chronic diseases and need for improved symptom management
NICHD	Understanding early developmental processes
NIBIB	Convergence between engineering and life sciences
FIC	Global Health
NIDCR	Relationship of oral health to overall health and well-being
NCRR	Clinical and Translational Science Award program to move research results rapidly from discovery to practice
NINDS	Identification of disease genes and their role in pathology
NIDA	Drug abuse treatment in criminal justice settings to improve public health/safety

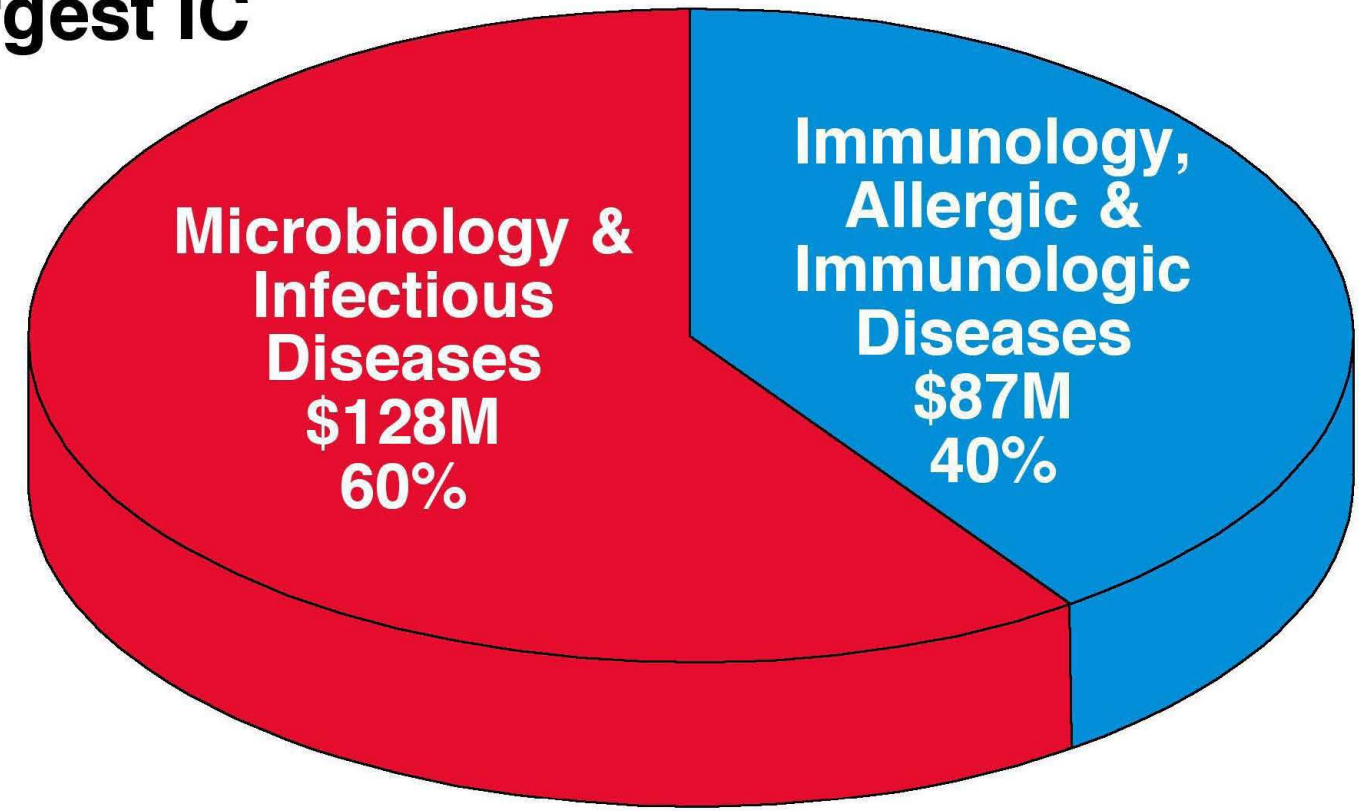
Growth of the National Institutes of Health

- 1948: 6 Institutes
- 1950: 8 Institutes & Divisions
- 1960: 11 Institutes, Centers & Divisions
- 1965: 14 Institutes, Centers & Divisions
- 1975: 20 Institutes, Centers & Divisions
- 1990: 22 Institutes, Centers & Divisions
- 2009: 27 Institutes & Centers

National Institute of Allergy and Infectious Diseases

NIAID in 1980

- Budget: ~$215 million
- Sixth largest IC



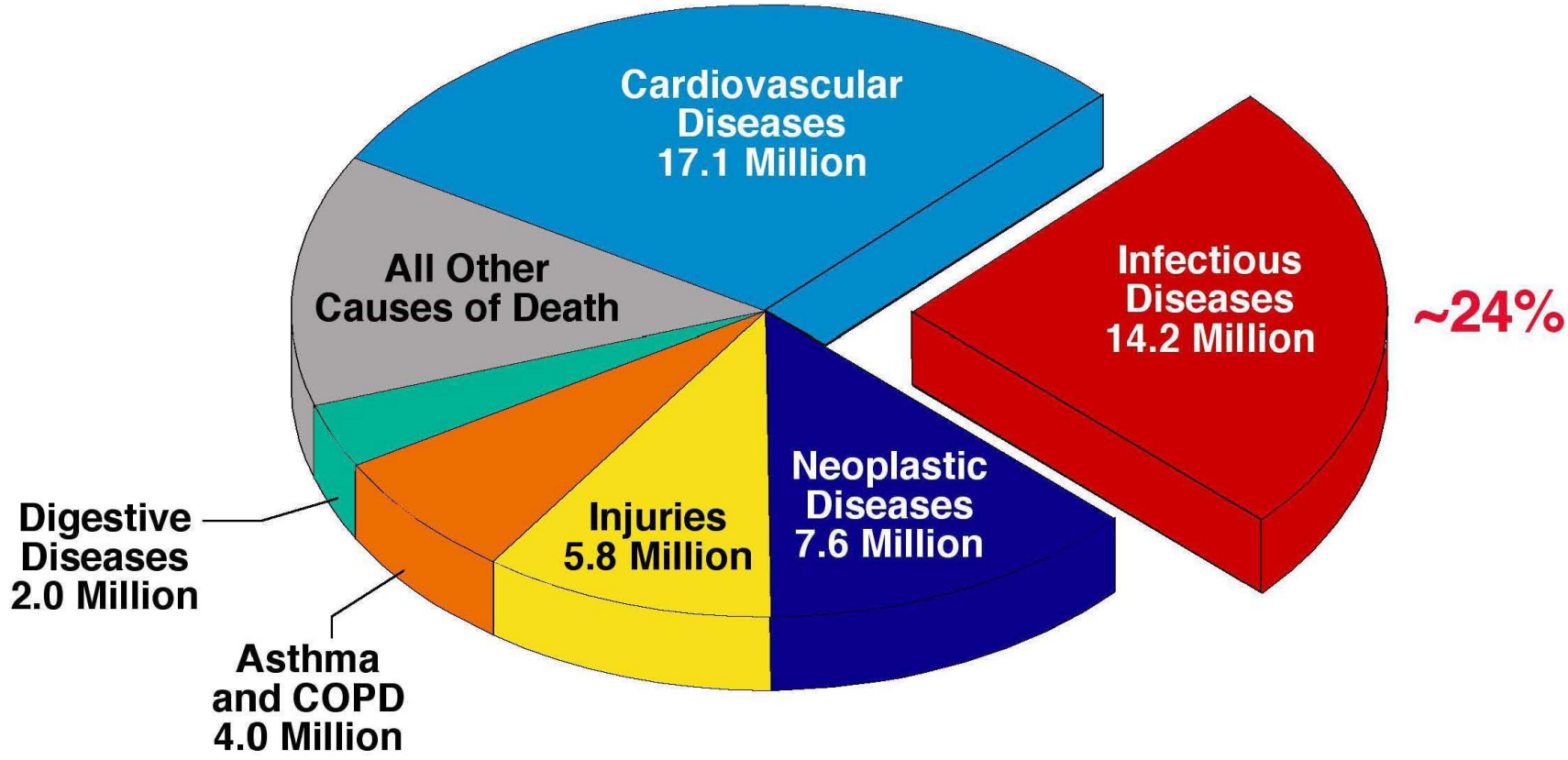
Total Budget: $215M

A Premature Declaration of Victory Over Infectious Diseases

"We can look forward with confidence to a considerable degree of freedom from infectious diseases at a time not too far in the future. Indeed... it seems reasonable to anticipate that within some measurable time... all the major infections will have disappeared."

- Aidan Cockburn, *The Evolution and Eradication of Infectious Diseases*, 1963.

Infectious Diseases Cause ~24% of All Deaths Worldwide



Total Deaths: ~58.8 Million

Source: WHO, 10/2008

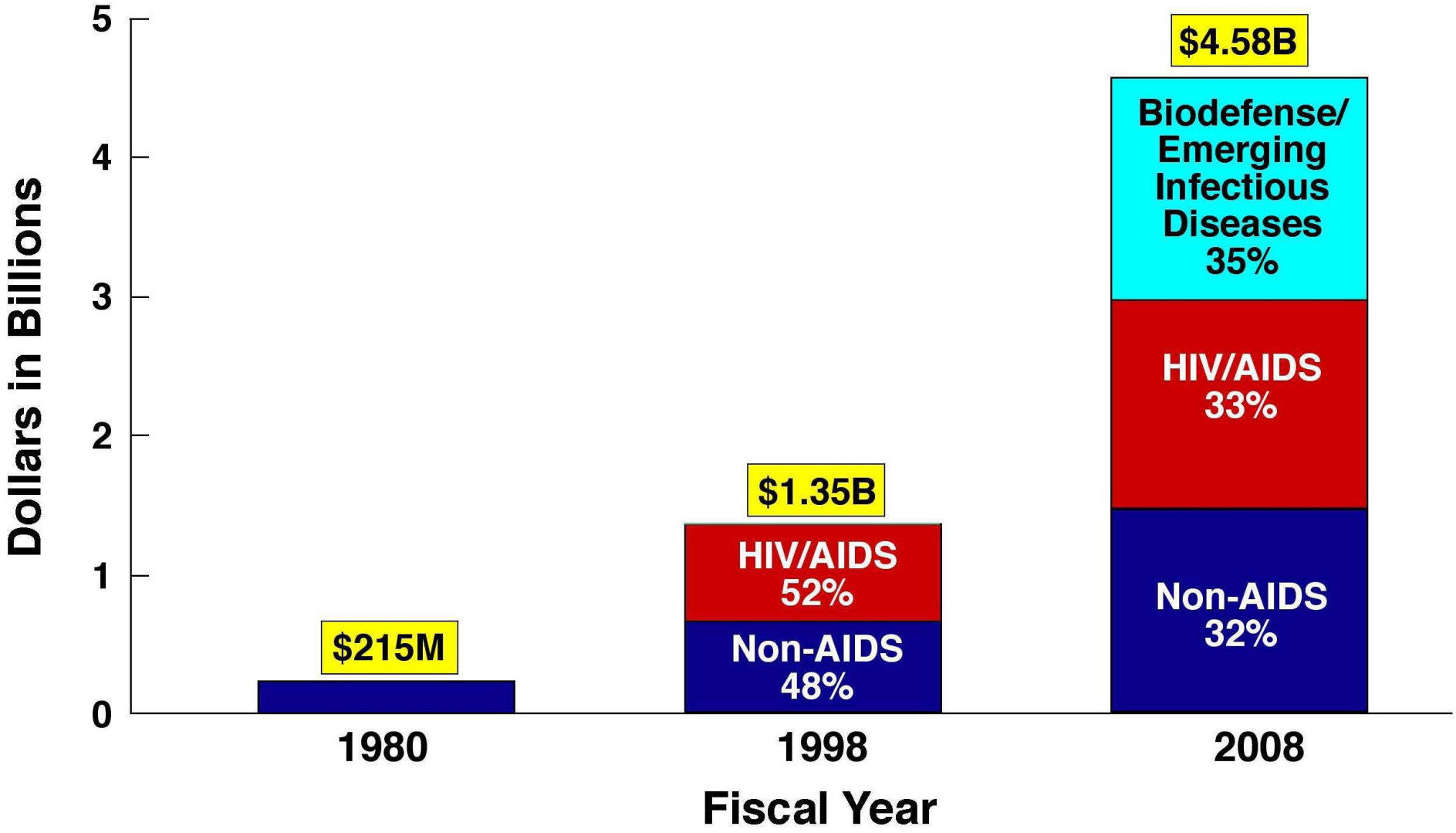
NIAID: Transforming Issues Since 1980

- HIV/AIDS
- Global Health
- Biodefense
- Other emerging/re-emerging infectious disease issues

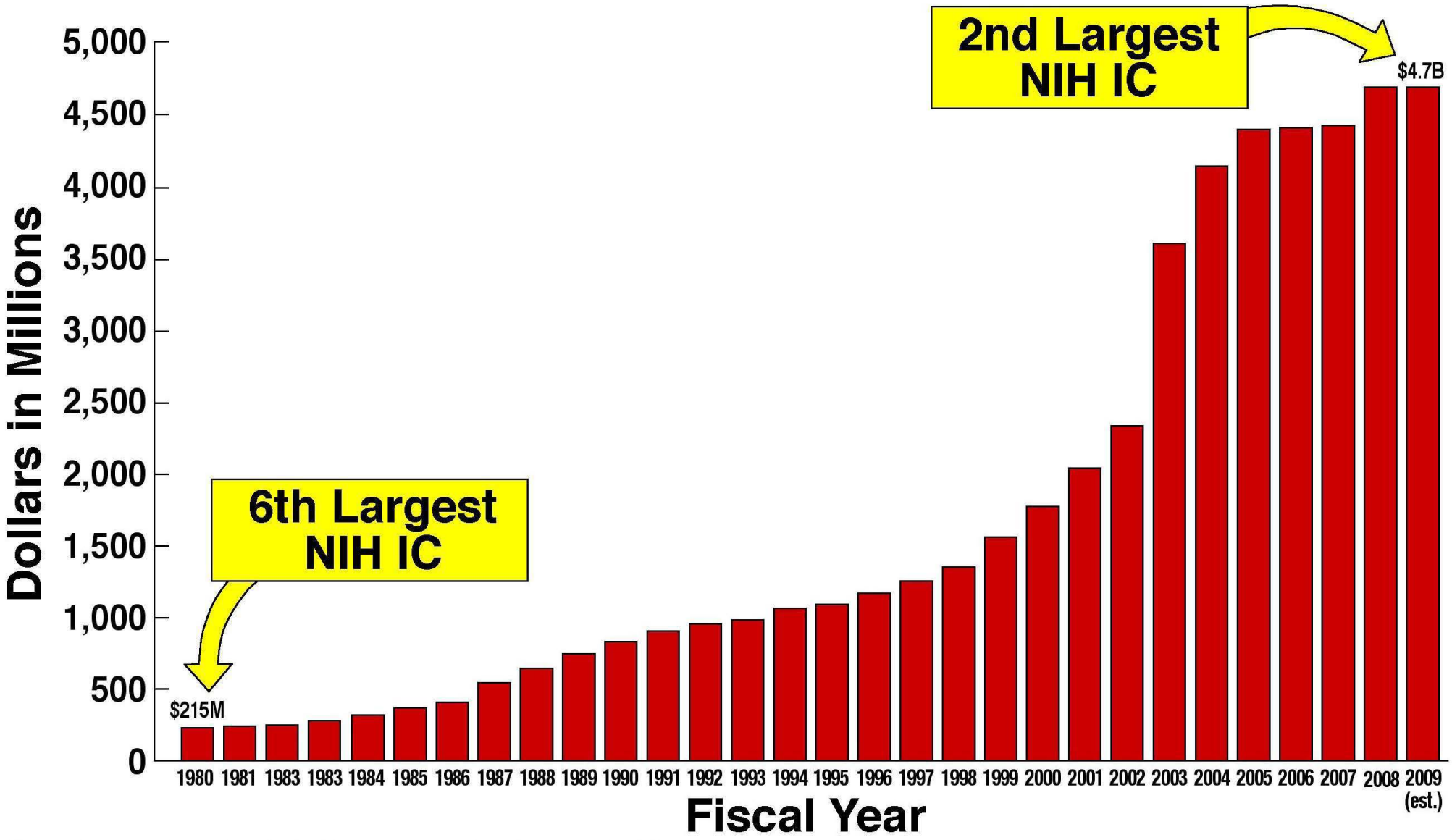
Examples of Technologies and Disciplines that Have Transformed Infectious and Immunological Disease Research

- Genomics and other "omics"
- Array technologies
- Nanotechnology
- Synthetic chemistry
- Robotics
- Computer modeling
- Imaging
- Molecular and genetic epidemiology
- Monoclonal antibodies/fusion proteins/recombinant cytokines
- MHC tetramers
- FACS analysis/cell surface markers/CD antigens
- Systems biology
- Bioinformatics

Evolution of the NIAID Budget



NIAID Funding History, 1980-2009 (est.)



Note: FY 2008 includes $22M Emergency Supplement for NIAID.

CENTERS FOR DISEASE CONTROL

MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

June 5, 1981

Pneumocystis Pneumonia – Los Angeles

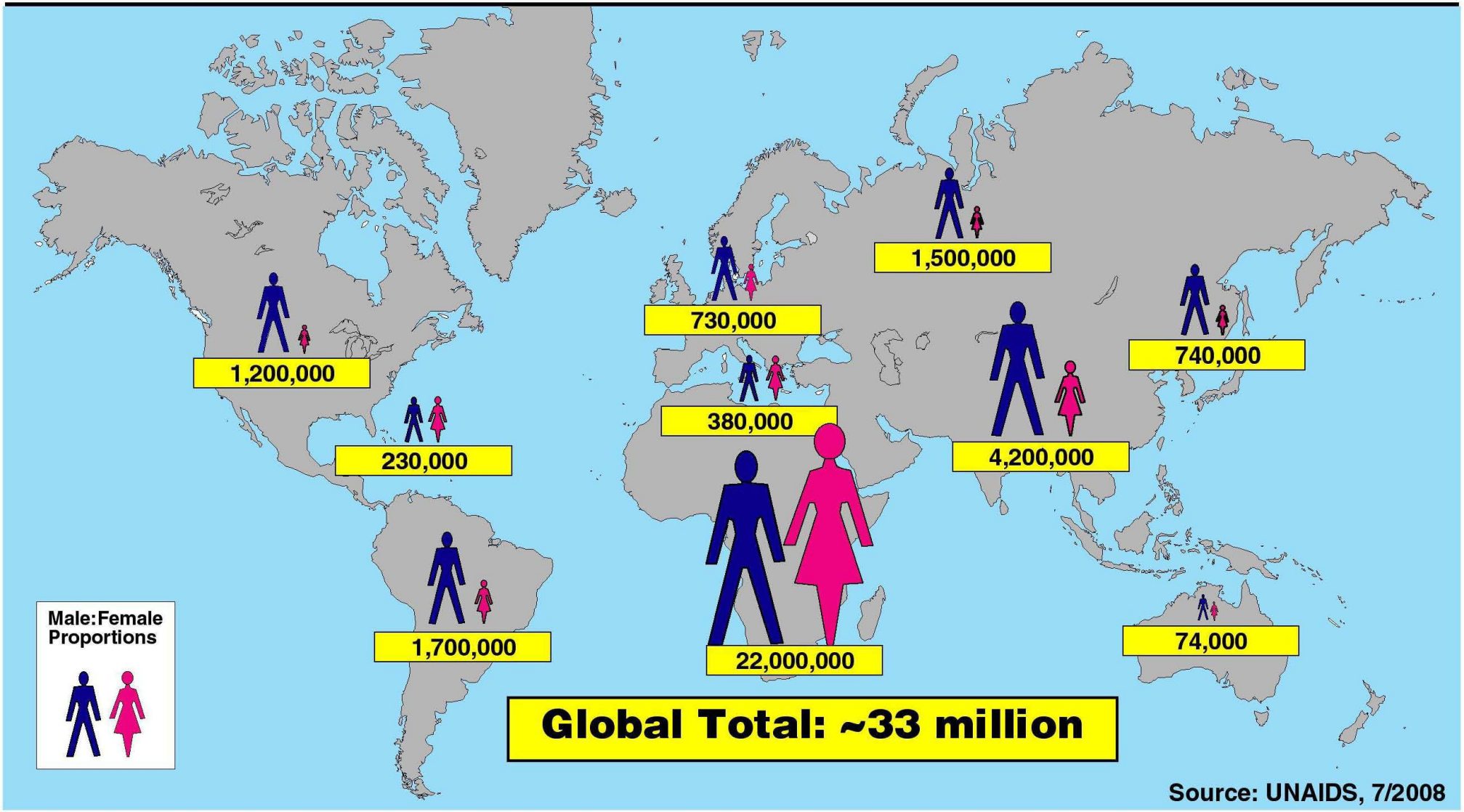
In the period October 1980 - May 1981, 5 young men, all active homosexuals, were treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had laboratory-confirmed previous or current cytomegalovirus (CMV) infection and candidal mucosal infection. Case reports of these patients follow.

July 4, 1981

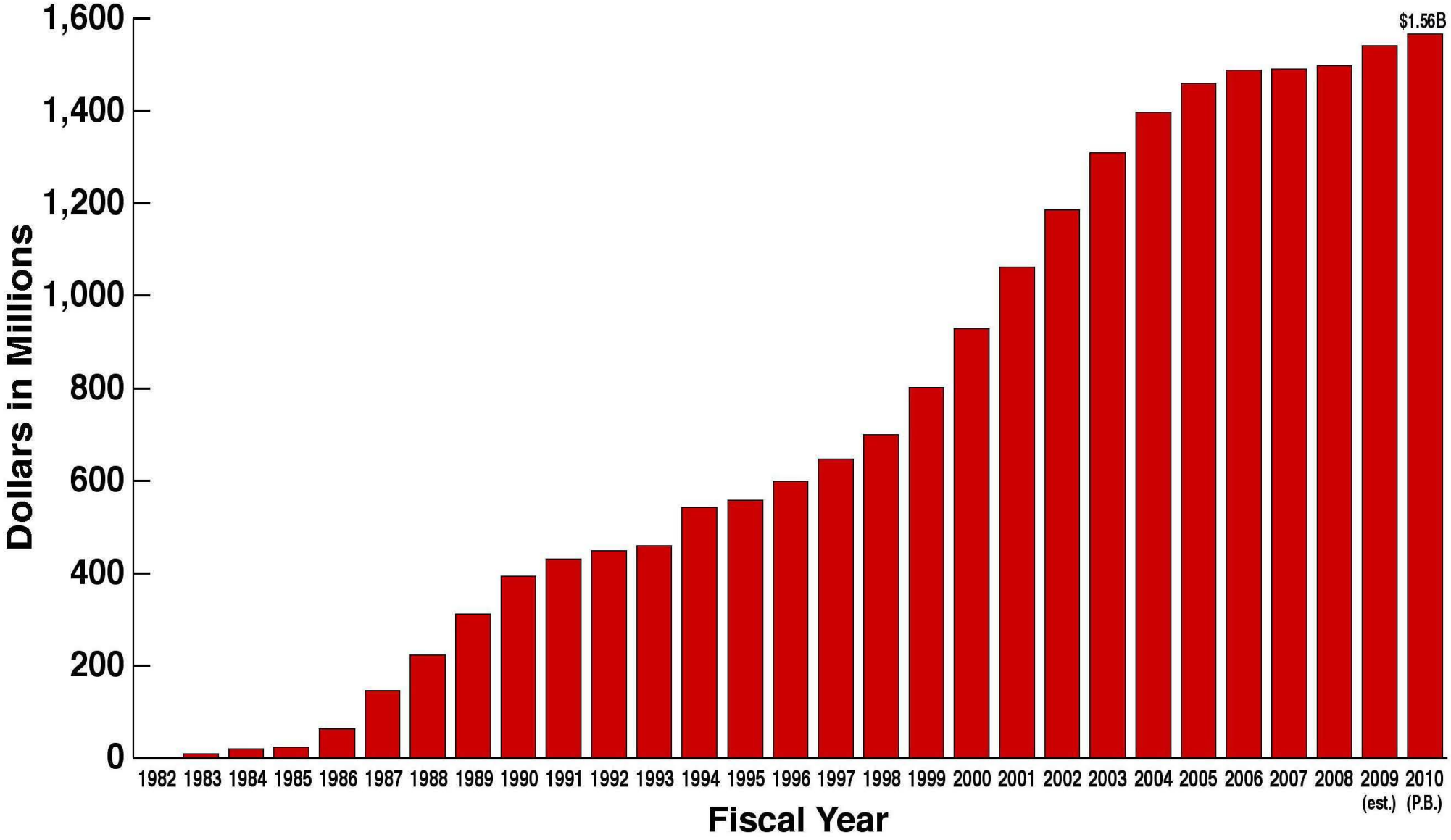
Kaposi's Sarcoma and *Pneumocystis* Pneumonia Among Homosexual Men – New York City and California

During the past 30 months, Kaposi's sarcoma (KS), an uncommonly reported malignancy in the United States, has been diagnosed in 26 homosexual men (20 in New York City (NYC), 6 in California). The 26 patients range in age from 26-51 years (mean 39 years). Eight of these patients died (7 in NYC, 1 in California) - all 8 within 24 months after KS was diagnosed.

Adults and Children Estimated to be Living with HIV, 2007

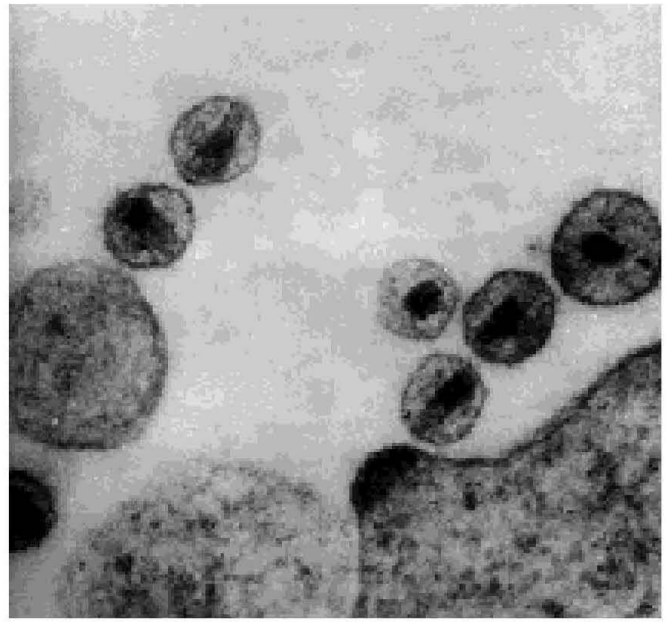


NIAID HIV/AIDS Research Funding



Advances in AIDS Research, 1981-2009

- Etiology
- Diagnosis
- Molecular Virology and Epidemiology
- Pathogenesis
- Natural History
- Treatment
- Prevention
- Vaccine Development



FDA-Approved Antiretroviral Drugs

NRTI

- Zidovudine
- Didanosine
- Zalcitabine
- Stavudine
- Lamivudine
- Abacavir
- Tenofovir
- Emtricitabine

NNRTI

- Nevirapine
- Delavirdine
- Efavirenz
- Etravirine

PI

- Saquinavir
- Ritonavir
- Indinavir
- Nelfinavir
- Amprenavir
- Lopinavir
- Atazanavir
- Fosamprenavir
- Tipranavir
- Darunavir

Fusion Inhibitor

- Enfuvirtide (T-20)

Entry Inhibitor

- Maraviroc

Integrase Inhibitor

- Raltegravir

Combinations

- 6 available, combining 2 or 3 drugs

Antiretroviral Therapy Dramatically Increases Life Expectancy for HIV-Infected Individuals

THE LANCET

Volume 372 Number 9635 Founded 1823 Published weekly July 26, 2008

Life Expectancy of Individuals on Combination Antiretroviral Therapy in High-Income Countries: a Collaborative Analysis of 14 Cohort Studies

Antiretroviral Therapy Cohort Collaboration

- An HIV-infected 20-year-old appropriately treated with ART can expect to live to >69 years in high-income countries

Number of Antiviral Drugs Approved by FDA

1960s	3
1970s	1
1980s	5
1990s	30
2000s	24
Total	63

JAMA®
The Journal of the American Medical Association
July 25, 2001

The AIDS Research Model
Implications for Other Infectious Diseases of Global Health Importance

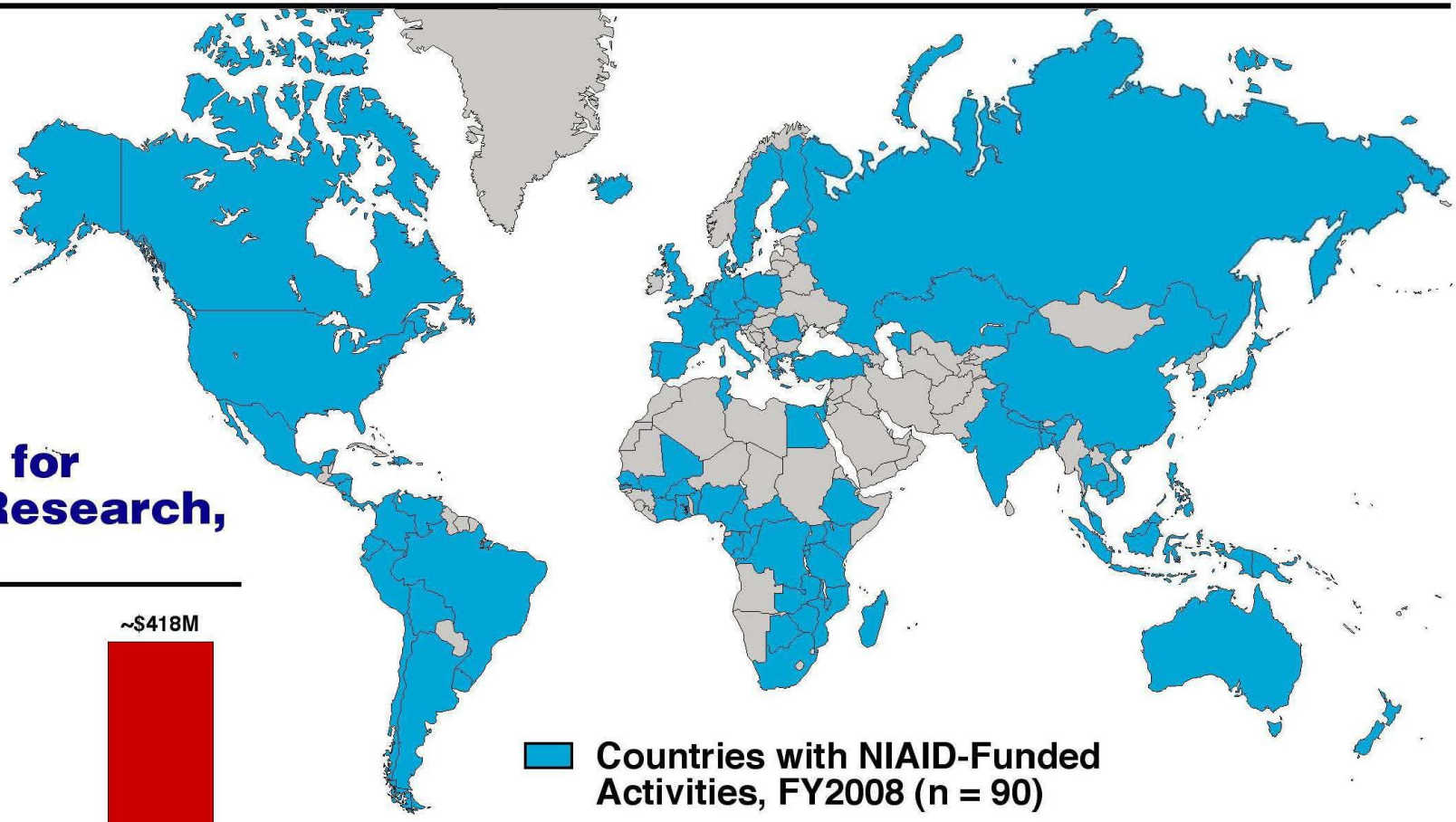
Gregory K. Folkers, MS, MPH and Anthony S. Fauci, MD

Selected Infectious Diseases of Global Public Health Importance

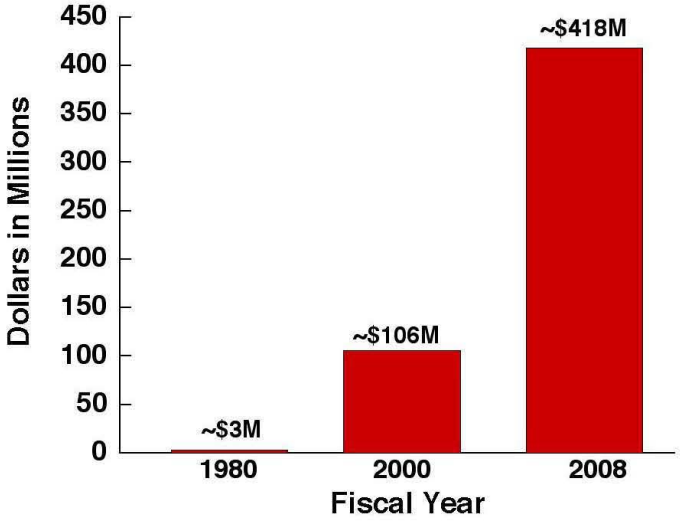
	Estimated Annual Deaths
Respiratory Infections	4.3 million
Diarrheal Diseases	2.2 million
HIV/AIDS	2.0 million
Tuberculosis	**1.7 million**
Malaria	**881,000**
Vaccine Preventable Childhood Diseases (measles, pertussis, tetanus, etc.)	847,000
"Neglected" Tropical Diseases (schistosomiasis, hookworm infection, leishmaniasis, trypanosomiasis, etc.)	530,000

Sources: WHO, 2008; NEJM 357:1018, 2007.

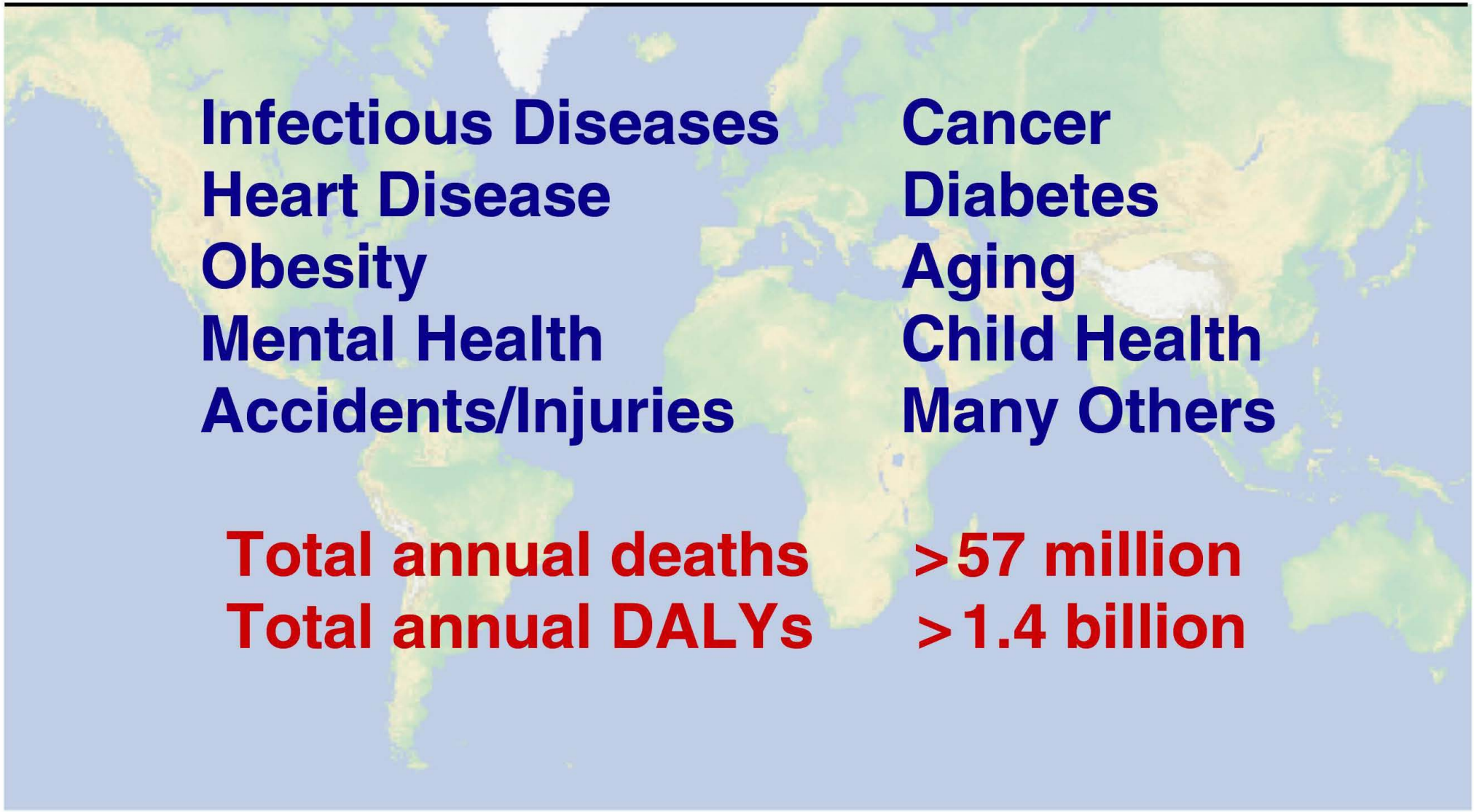
Global Health Research at NIAID



NIAID Funding for International Research, 1980-2008

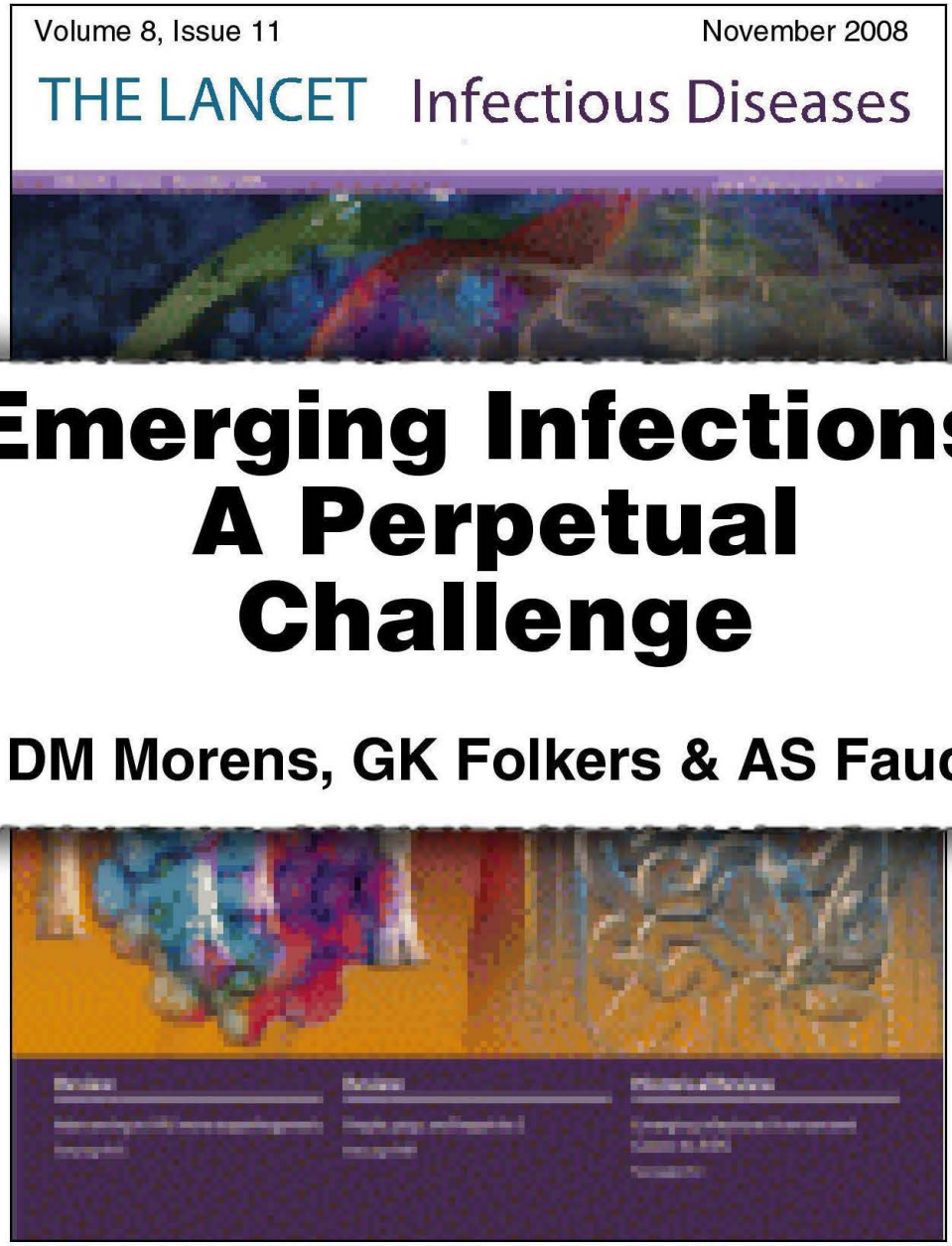


The Global Community is Faced with Numerous Health Challenges



Infectious Diseases	Cancer
Heart Disease	Diabetes
Obesity	Aging
Mental Health	Child Health
Accidents/Injuries	Many Others

Total annual deaths	>57 million
Total annual DALYs	>1.4 billion

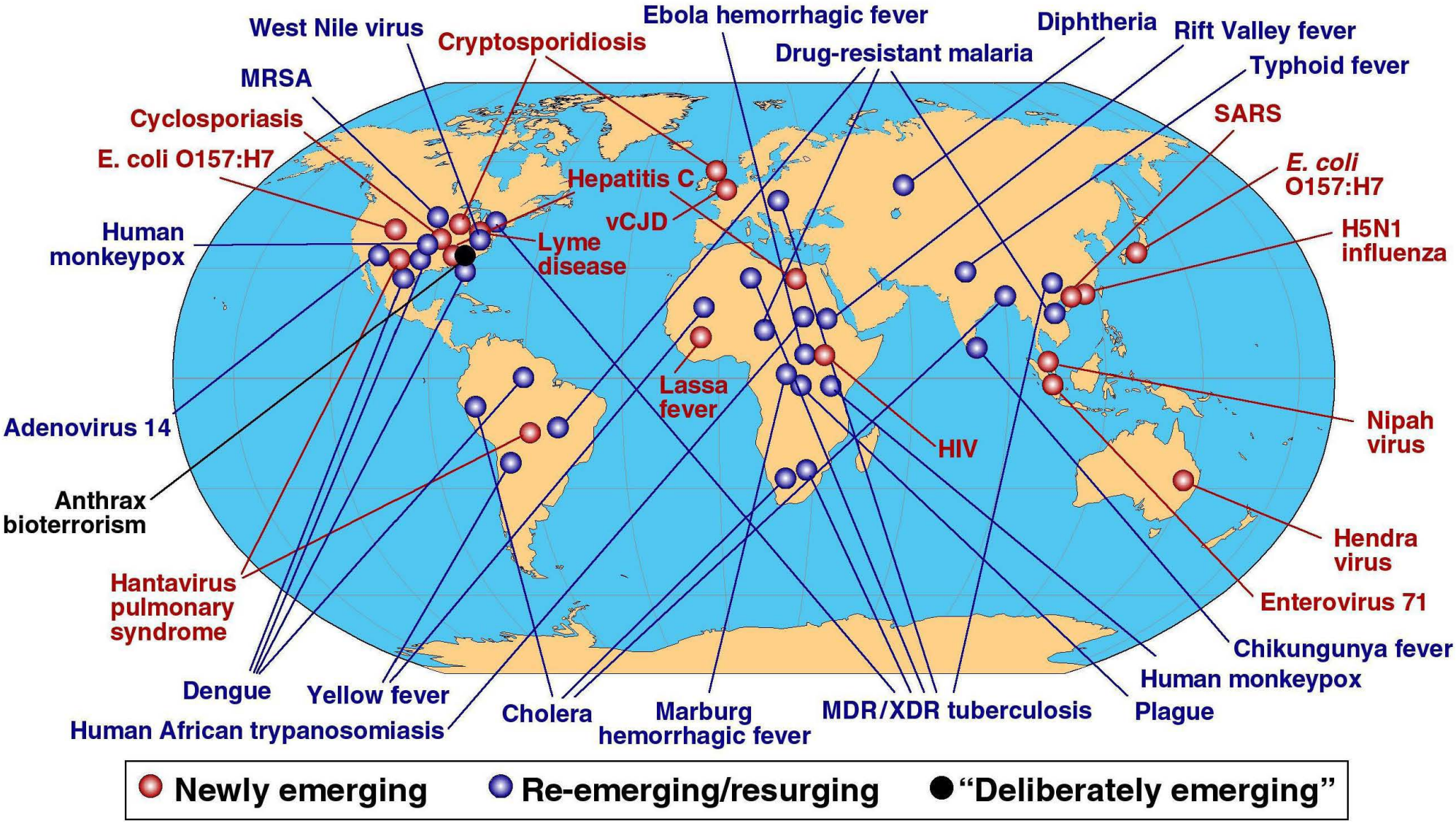


Emerging Infections: A Perpetual Challenge

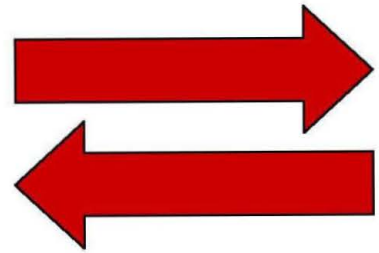
DM Morens, GK Folkers & AS Fauci

"For centuries a fundamental challenge to the existence and well-being of societies -- as reflected by scientific attention, as well as in art, religion, and culture -- emerging infections remain among the principal challenges to human survival."

Global Examples of Emerging and Re-Emerging Infectious Diseases



Naturally Occurring Infectious Disease Threats



Bioterror Threats

4TH GRADE
GREENDALE SCHOOL
FRANKLIN PARK NJ 08852

SENATOR DASCHLE
509 HART SENATE OFFICE
BUILDING
WASHINGTON D.C. 20510-4103

4TH GRADE
GREENDALE SCHOOL
FRANKLIN PARK NJ 08852

SENATOR LEAHY
433 RUSSELL SENATE OFFICE
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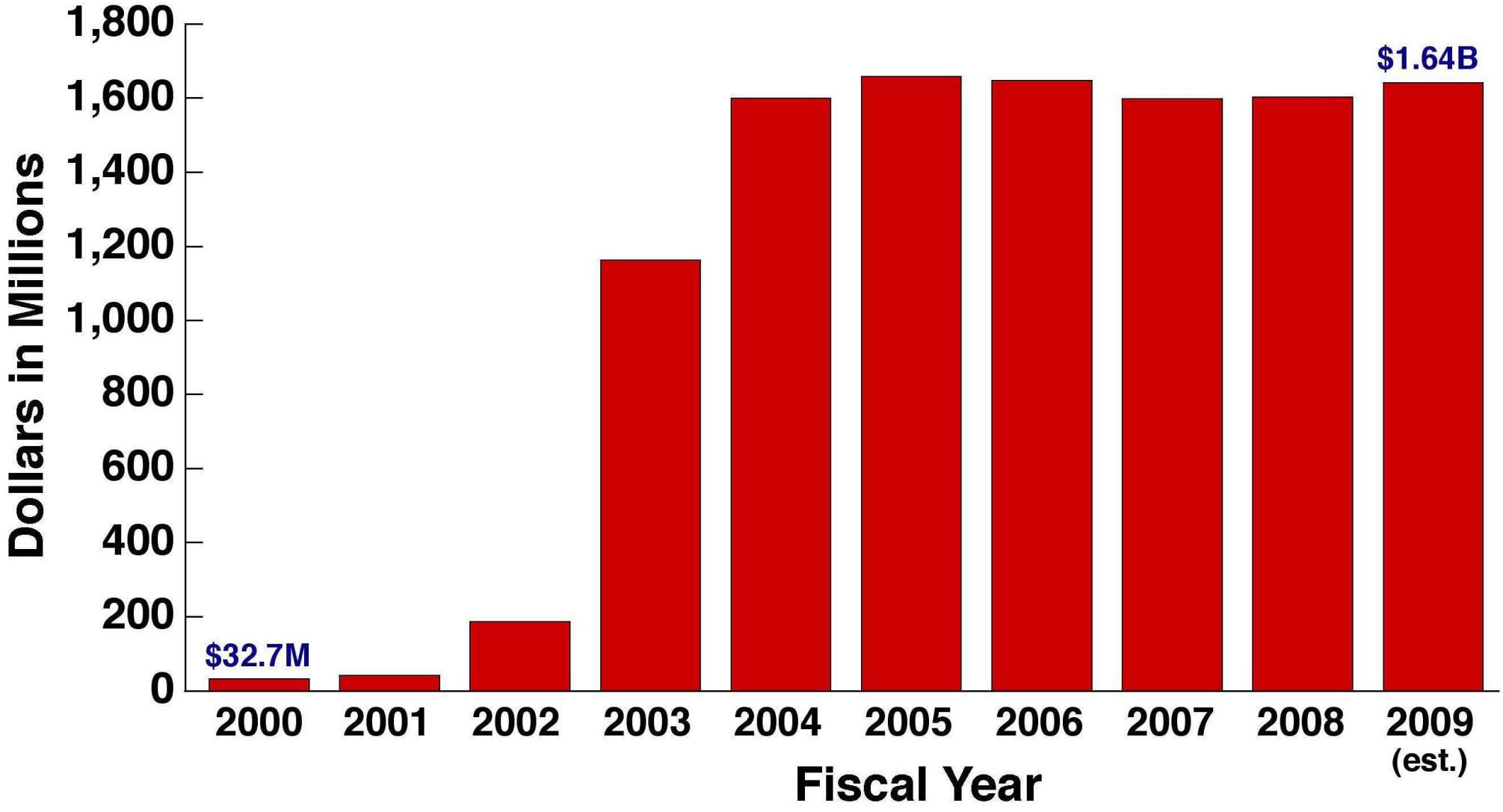
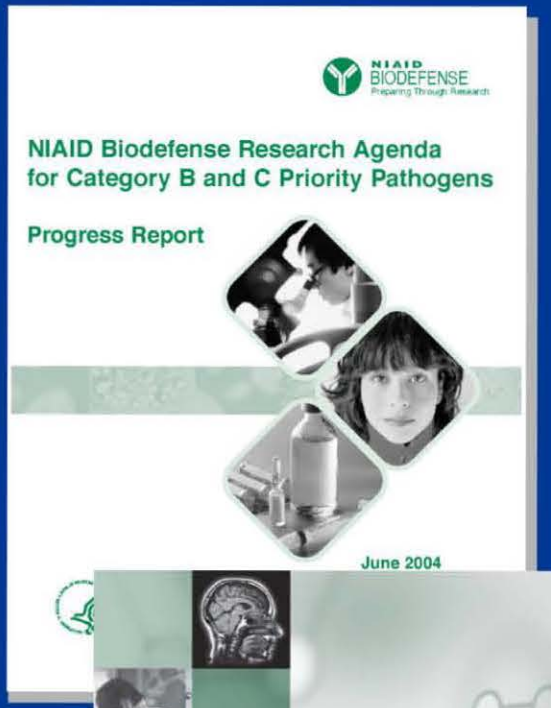
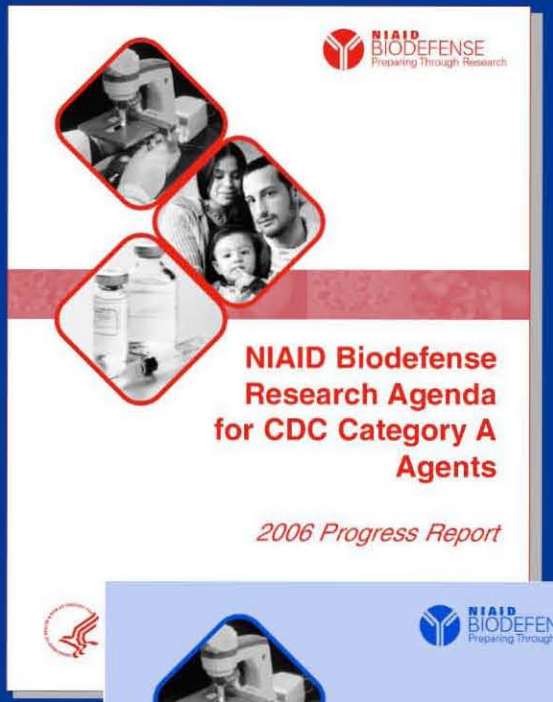
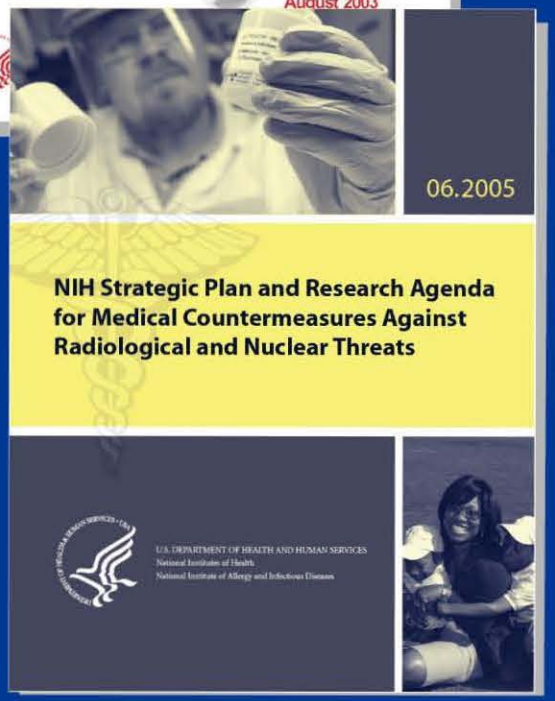
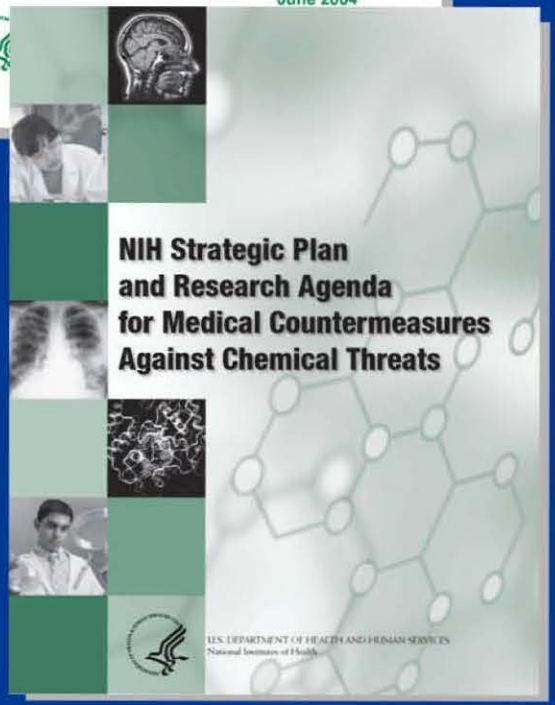
NIAID Funding for Biodefense and Emerging Infectious Diseases Research, 2000-2009

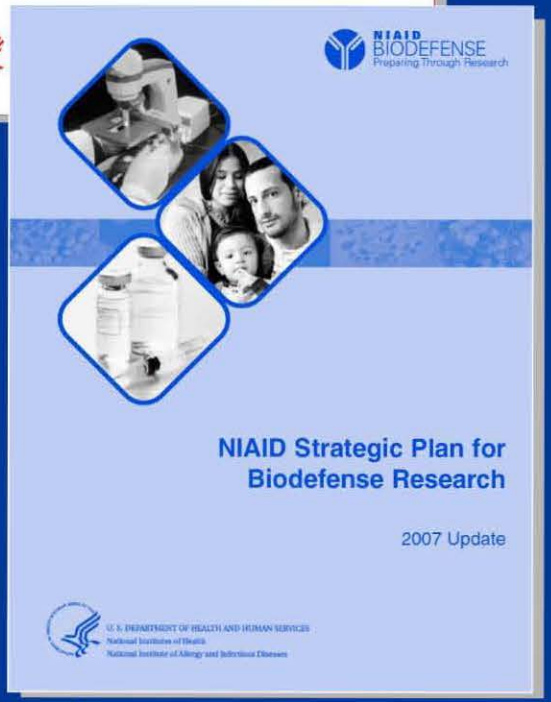




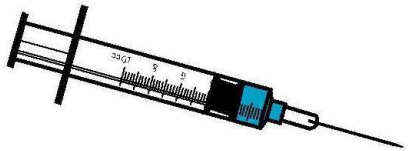






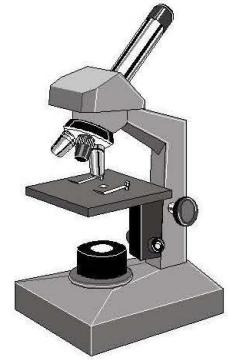


http://www.niaid.nih.gov/biodefense



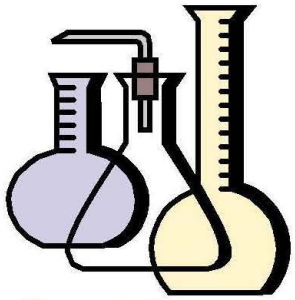
Vaccines

Therapeutics



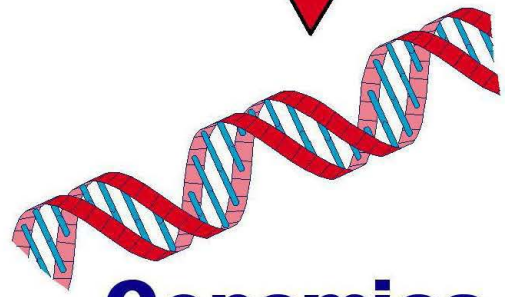
Diagnostics

Biodefense and Emerging Infectious Diseases (EID) Research Priorities



Basic Research

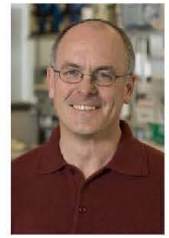
Expansion of Research Capacity



Genomics

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. Alan G. Barbour
University of California
Irvine, CA

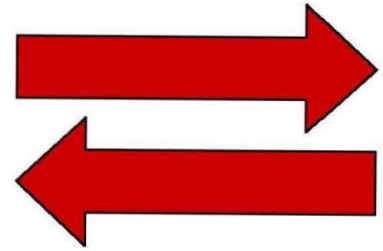
PI – Dr. David Walker
University of Texas Medical Branch
Galveston, TX

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

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

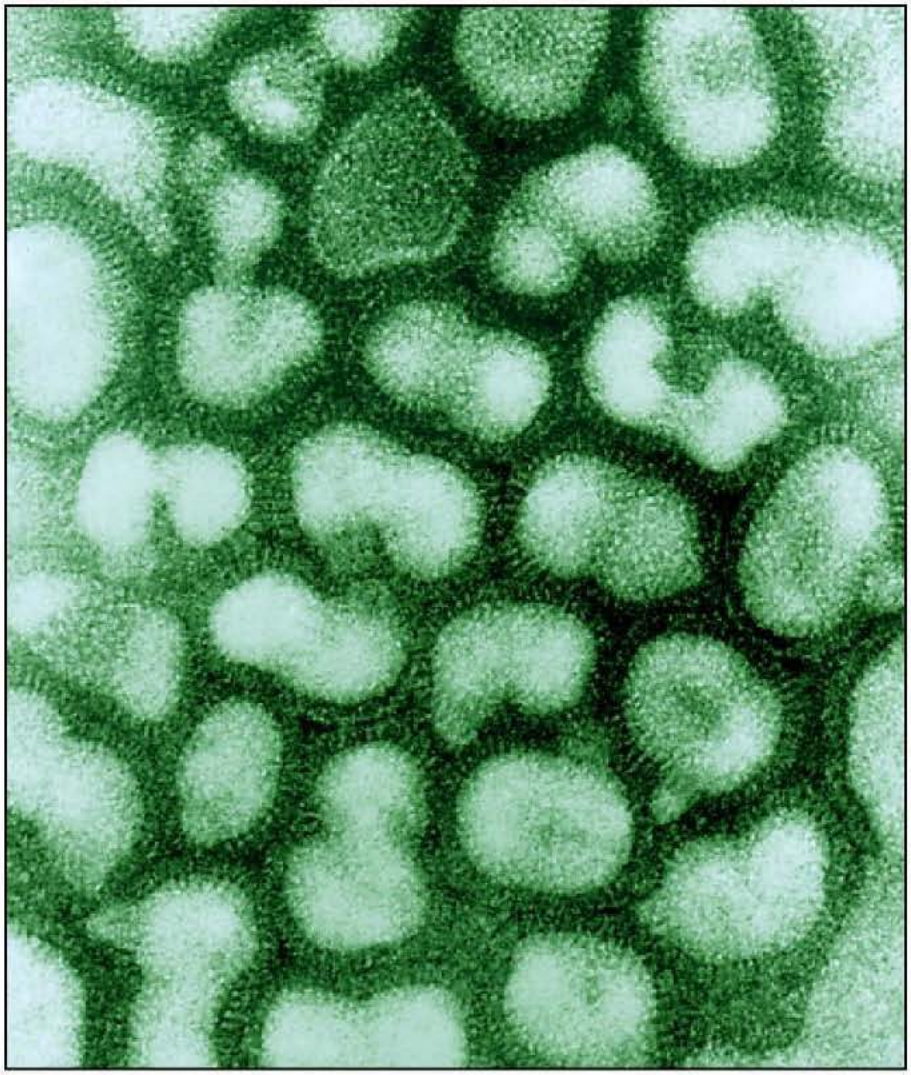
PI - Dr. Fred Sparling
University of North Carolina
Chapel Hill, NC

Bioterror Threats



Naturally Occurring Infectious Disease Threats

Influenza



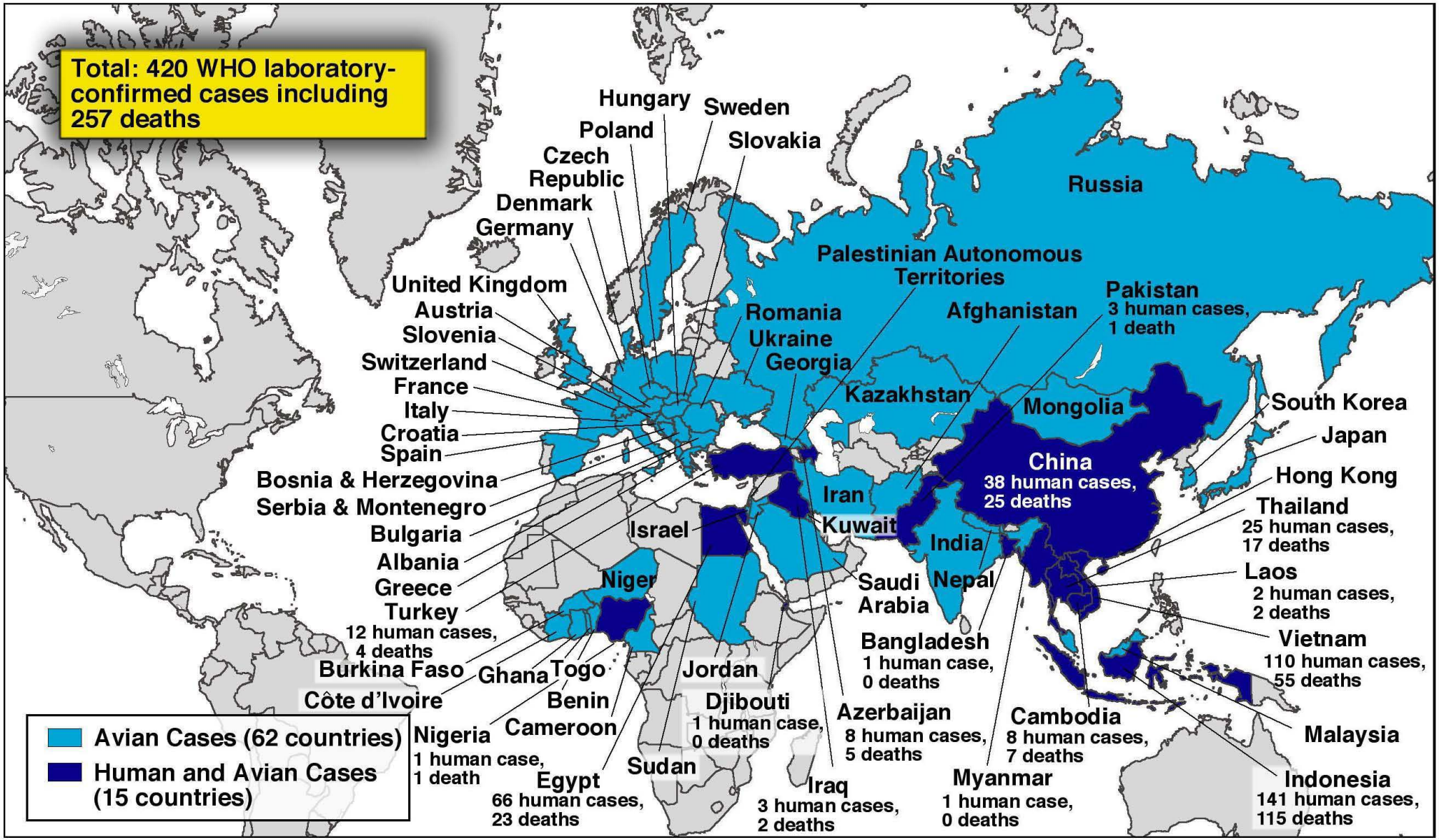
- Re-emerging disease (seasonal flu)
- Newly emerging disease (potential pandemic flu)

The Burden of Seasonal Influenza

- 250,000 to 500,000 deaths globally/yr
- 36,000 deaths and >200,000 hospitalizations/yr in U.S.
- $37.5 billion in economic costs/yr in U.S. related to influenza and pneumonia

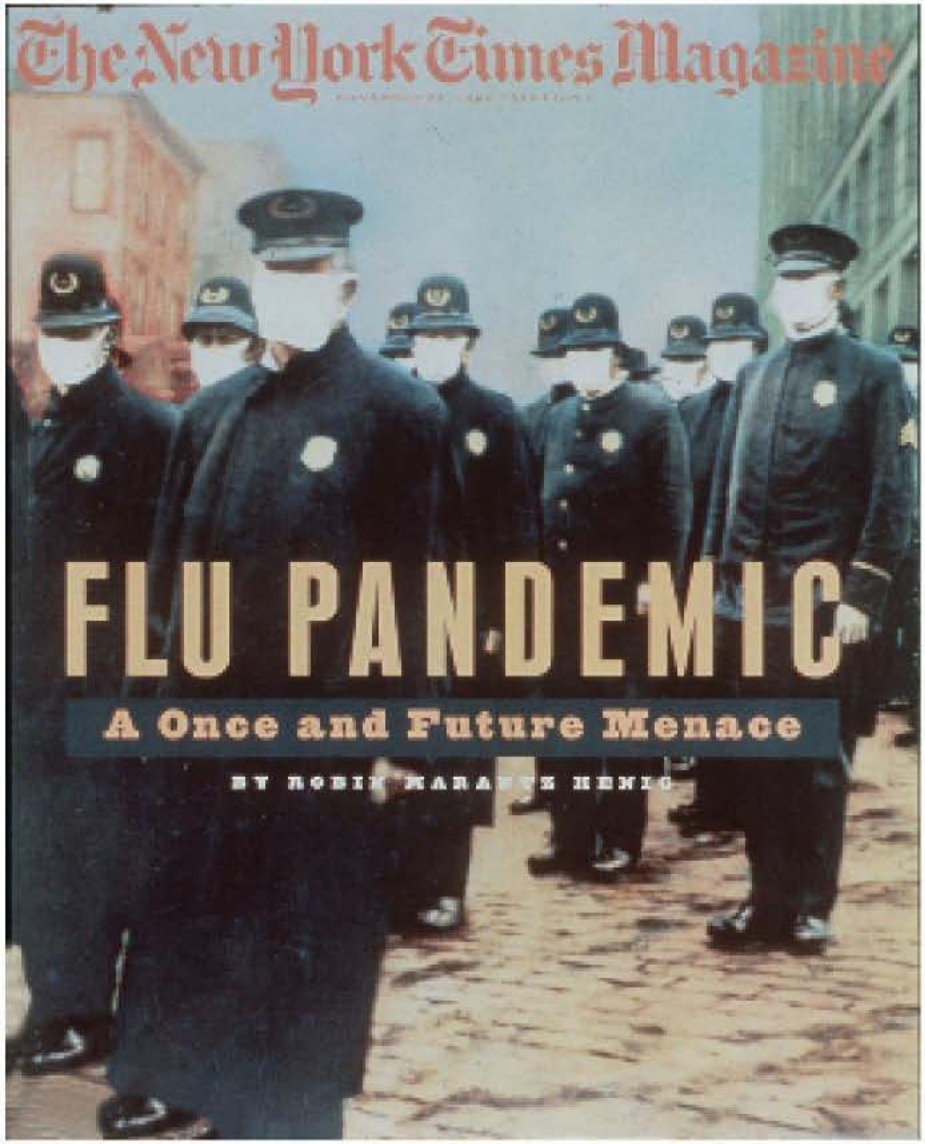
Sources: CDC, WHO, Am. Lung. Assoc.

H5N1 Influenza Cases, 2003-2009



Source: WHO and OIE (World Organization for Animal Health), 4/21/2009

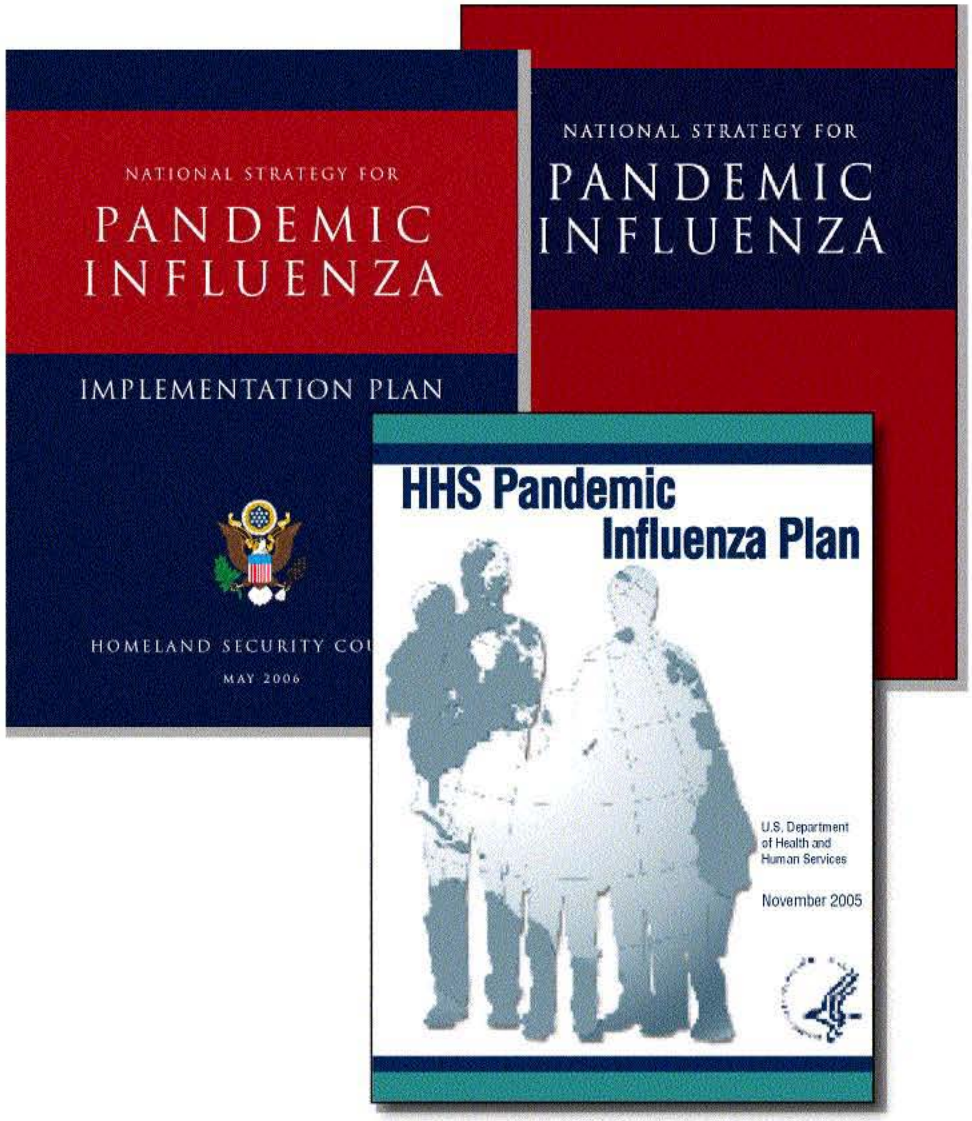
The Influenza Pandemic of 1918-1919



- 25-30% of world's population (~500 million people) fell ill
- >50 million deaths worldwide; ~60 percent in people ages 20-45
- >500,000 deaths in United States; 196,000 in October, 1918 alone

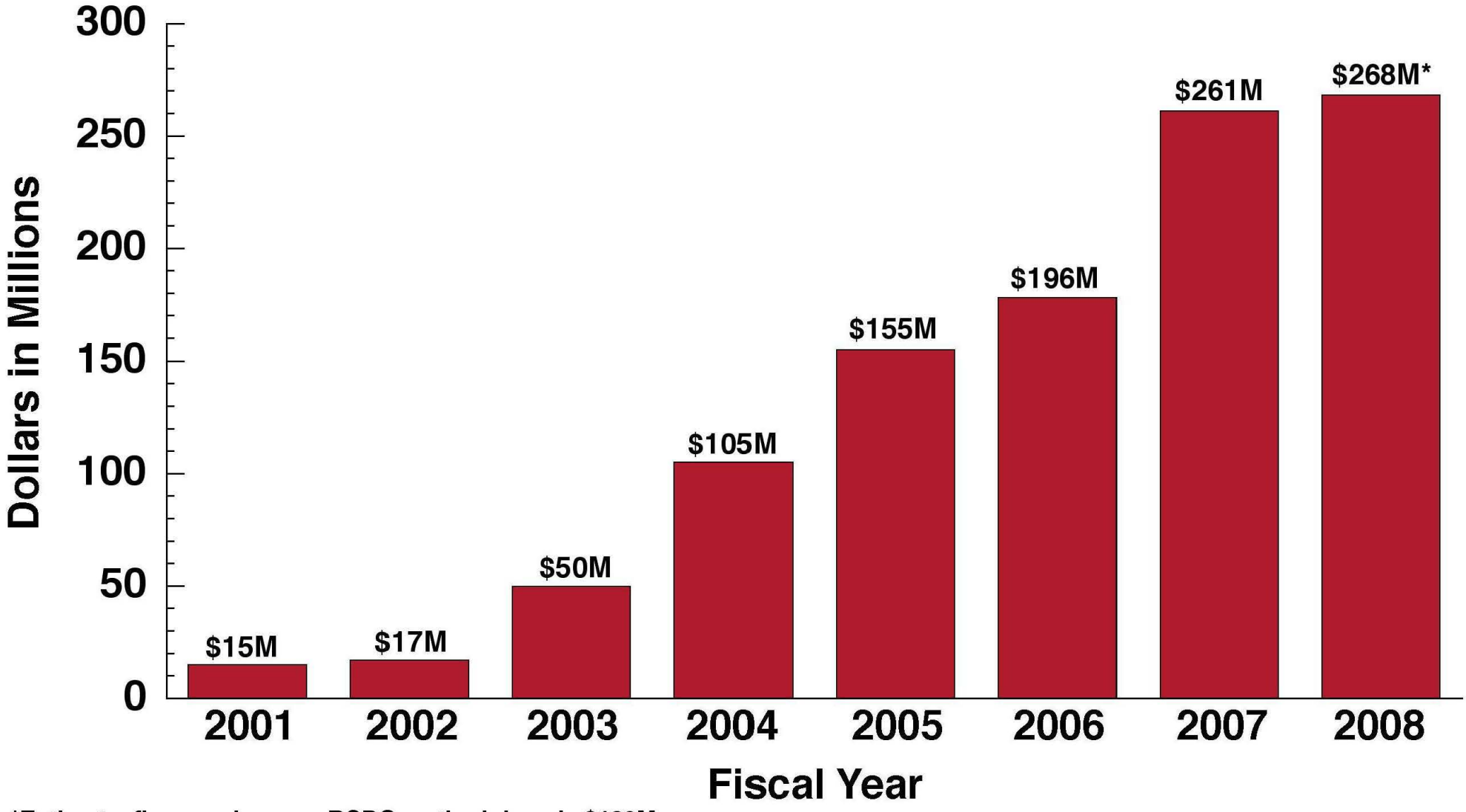
Source: WHO, 1/2005

Pandemic Influenza Preparedness
Strategy and Implementation

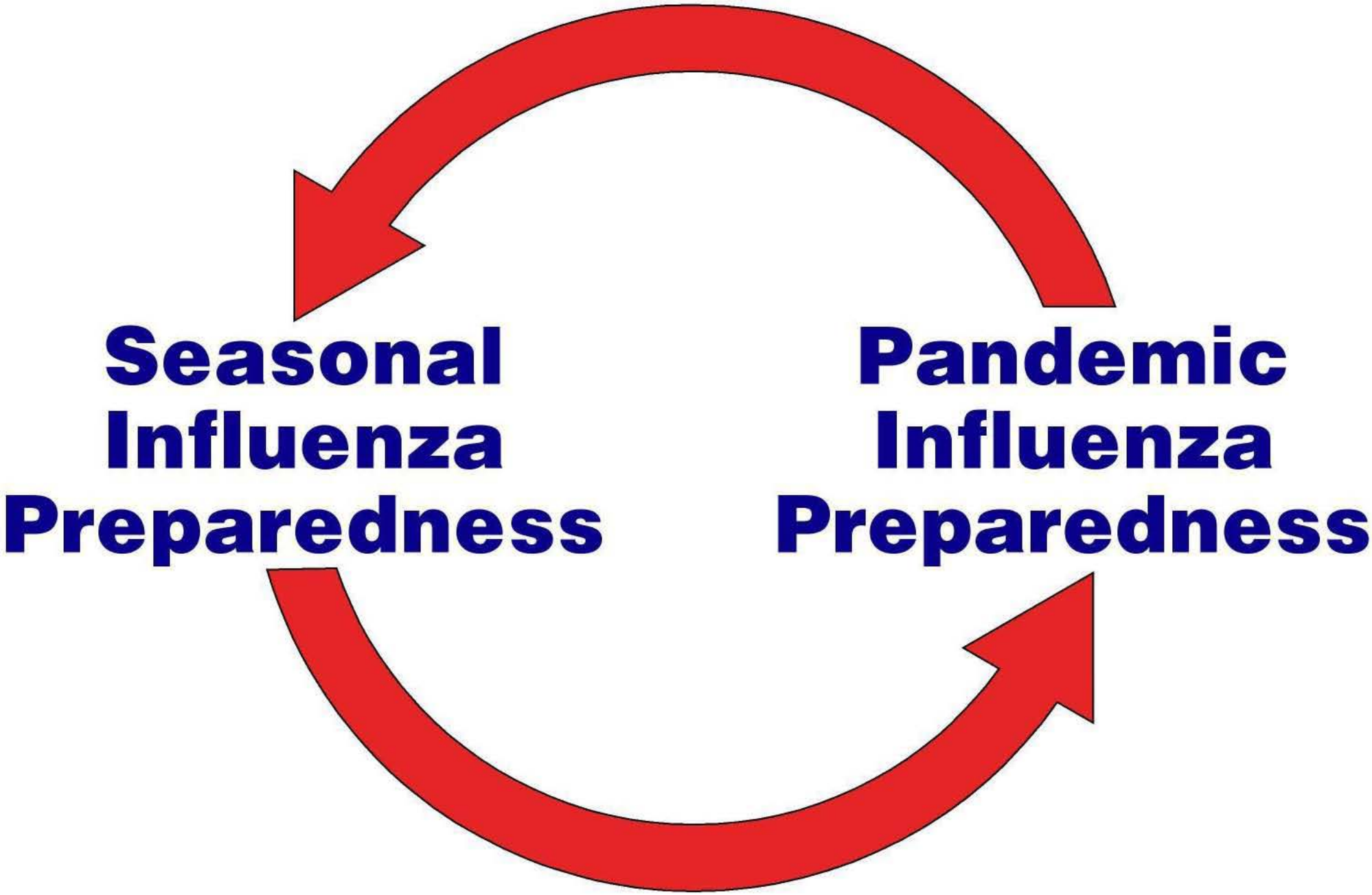


- International Surveillance
- Domestic Surveillance
- Vaccines
- Antivirals
- Communications
- State and Local Preparedness

NIAID Influenza Research Funding

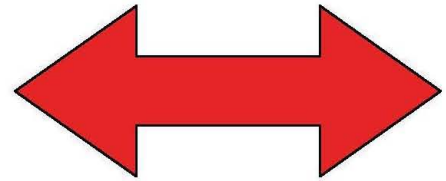


*Estimate; figure using new RCDC methodology is $186M.

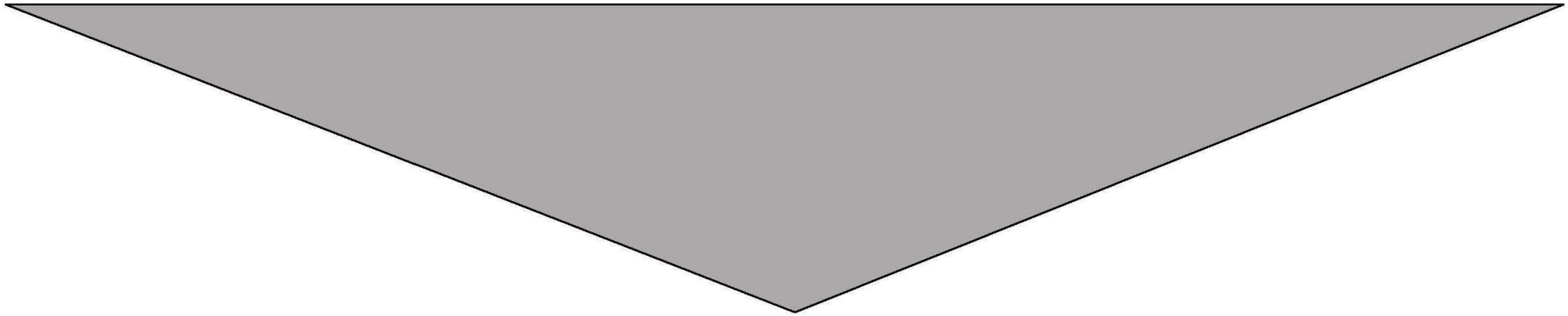

Seasonal
Influenza
Preparedness
Pandemic
Influenza
Preparedness

NIAID Research: A Dual Mandate

Maintain and "grow" a robust basic and applied research portfolio in microbiology, infectious diseases, immunology and immune-mediated diseases

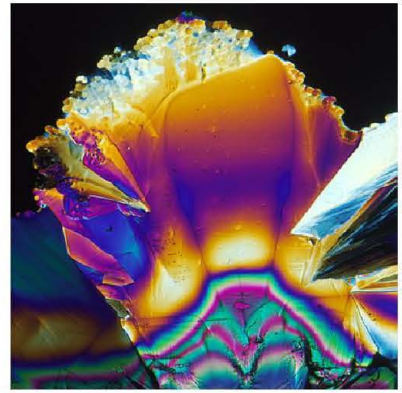


Respond rapidly to new and emerging disease threats

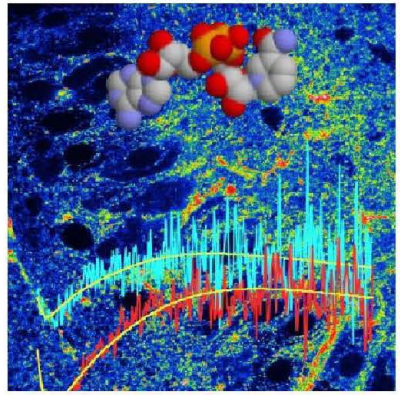
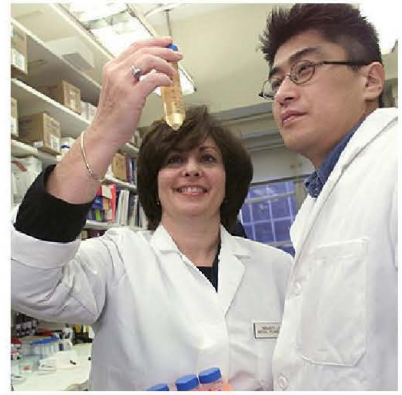


New/Improved Interventions



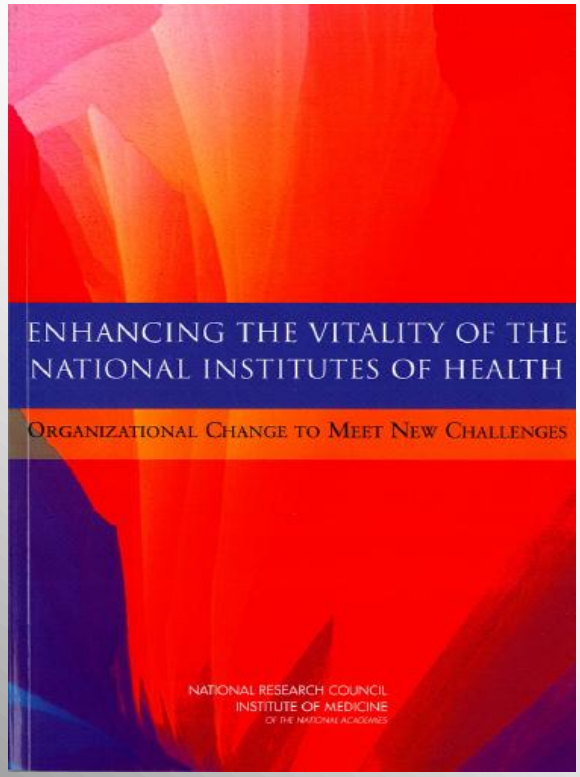



NIH *Transforming medicine and health through discovery*


Enhancing the Vitality of the National Institutes of Health

Organizational Change to Meet New Challenges



Debra R Lappin JD

B&D Consulting

Senior Vice President

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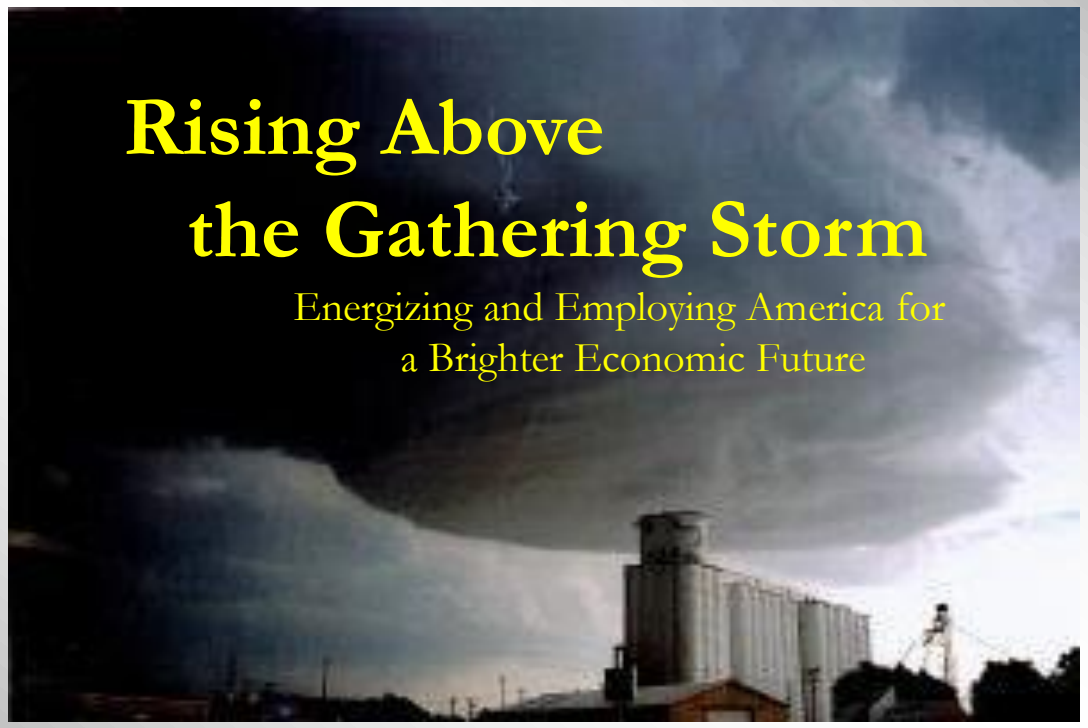
…. Few NAS Reports Have Had This Impact, except….



Today's Presentation

- **Background on NAS Report**
  - *NAS committee*
  - *Drawing from the "Guiding Wisdom" of the NAS report*
  - *Relevance of Charge, Principles and Recommendations to SMRB*
- **Response to the NAS Report**
  - *Areas addressed through NIH and Congressional action*
  - *Areas remaining open for further consideration to inform the work of SMRB*
- **Specific guidance on key issues before SMRB**
  - *NIDA – NIAAA merger?*
  - *"Specter Bill" ~ Institute on Health Disparities*
  - *Intramural Research at NIH?*
  - *Clinical Research and the Clinical Center at NIH?*
  - *Structure versus evolving organizational processes and authorities*

The NAS Committee and Process

- Six formal meetings
- Testimony & written input
- Interviews and/or testimony
- Multiple, hotly debated, report drafts
- Fourteen independent reviewers

- **HAROLD SHAPIRO,** *Chair*, Princeton University
- **NORMAN AUGUSTINE,** Lockheed Martin Corporation
- **MICHAEL BISHOP,** University of California
- **JAMES GAVIN,** Morehouse School of Medicine
- **ALFRED GILMAN,** University of Texas Southwestern Medical Center
- **MARTHA HILL,** Johns Hopkins University School of Nursing
- **DEBRA LAPPIN, Denver, Colorado; member of COPR**
- **ALAN LESHNER,** American Association for the Advancement of Science
- **GILBERT OMENN,** University of Michigan
- **FRANKLYN PRENDERGAST,** Mayo Clinic Cancer Center
- **STEPHEN RYAN**, University of Southern California
- **SAMUEL SILVERSTEIN,** Columbia University College of Physicians and Surgeons
- **HAROLD SLAVKIN,** University of Southern California
- **JUDITH SWAIN,** Stanford University School of Medicine
- **LYDIA VILLA-KOMAROFF,** Whitehead Institute
- **ROBERT WATERMAN,** The Waterman Group
- **MYRL WEINBERG, National Health Council**
- **KENNETH WELLS,** University of California
- **MARY WOOLLEY, Research!America, Alexandria**
- **JAMES WYNGAARDEN,** Duke University
- **TADATAKA YAMADA,** GlaxoSmithKline

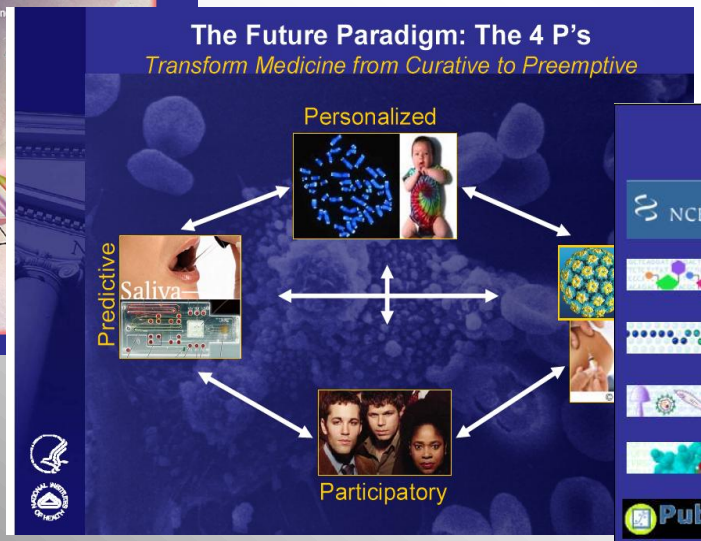
Charge Remains Highly Relevant to Your Work

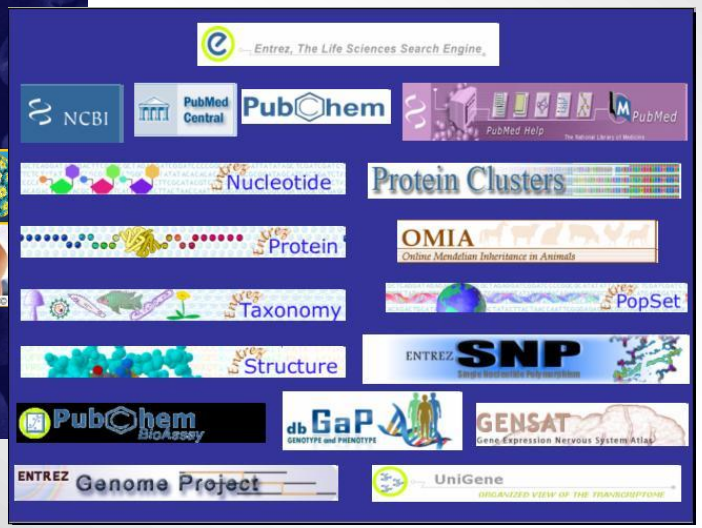
1. *Are there general principles by which NIH should be organized?*
2. *Does the current structure reflect these principles, or should NIH be restructured?*
3. *If restructuring is recommended, what should the new structure be?*
4. *How will the proposed new structure improve NIH's ability to conduct biomedical research and training, and accommodate organizational growth in the future?*
5. *How would the proposed new structure overcome current weaknesses, and what new problems might it introduce?*

Guiding Wisdom

"The Congressional request for this study set a goal of determining the optimal organizational structure for NIH in the context of 21st century biomedical research science."

- ***Clinical research needs***
- ***Increasing urgency in some fields of research***
- ***Health disparities***
- ***Large-scale and discovery driven science***
- ***New resource requirement***
- ***Trends in private sector investments & research collaborations***
- ***International research***





Guiding Wisdom - *STRUCTURE*

- "*The current situation is not only imperfect but is certainly not one that either the Congress or the scientific community would designate ab initio.*"

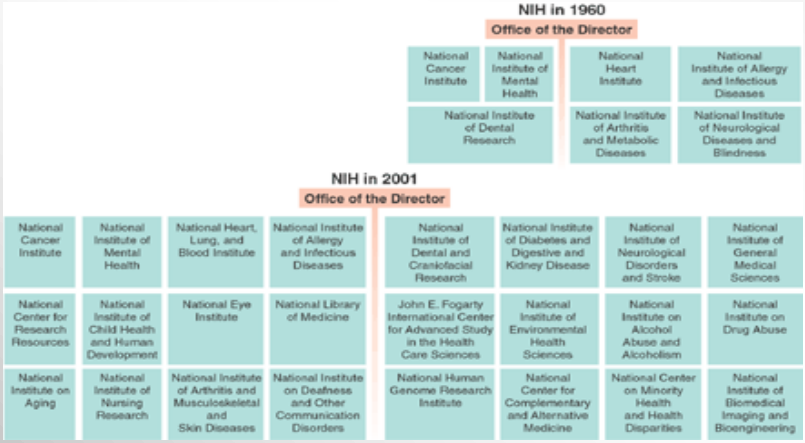
- The Committee conducted a thorough review the history of NIH; the accretion of ICs *(an organic system with no "programmed cell death")*

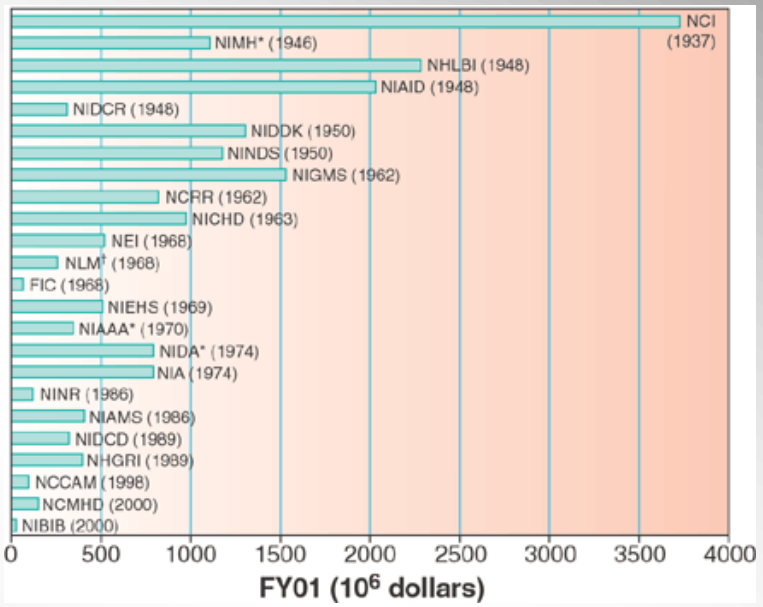
- The Committee examined options driven by experience of prior directors
  - **Clustering….?**
    - Would add a layer of management
    - No ready set of natural dimensions for clustering
      - Scientific discipline? e.g. genomics
      - Disease? e.g., cancer
      - Body systems? e.g. heart, lung, & blood
  - **Consolidation… ? (Varmus 2001)**

Proliferation of National Institutes of Health
Harold VARMUS

Science 9 March 2001:
Vol. 291. no. 5510, pp. 1903 - 1905
DOI: 10.1126/science.1059063
PUBLIC HEALTH

"Is it possible to imagine a reasonable alternative to the current pattern? Here is one proposal for a simpler and arguably better NIH.





" Six units or approximately equal size**…..***Five of these would be categorical institutes, committed mainly to groups of diseases:* ***the National Cancer Institute, the National Brain Institute, the National Institute for Internal Medicine Research, the National Institute for Human Development, and the National Institute for Microbial and Environmental Medicine. The sixth unit, NIH Central, would be led by the NIH director, to whom the directors of five institutes would report."***

Guiding Wisdom: *Structure Versus Processes and Authorities*

Value of organizational theorists who conveyed the distinctions between structure, process and authorities

- *"The goal of the study focused on the organizational structure of NIH, but it was not possible to address this issues satisfactorily without considering the mission of NIH, some of its key process, and the scientific, social and political environment in which NIH activities take place."*

- *"There is more to organization than just structure."* Strategic priorities; Culture; Systems and processes; Multiple and complex constituent relationships

- *"NIH's existing structure is the result of a set of complex evolving social and political negotiations among a variety of constituencies including the Congress, and administration, the scientific community, the health advocacy community, and other interested in research, research training and the public policy related to health. "*

Guiding Wisdom

- Recognition of political realities: *"The Committee does not find the conceptual or practical case for a wholesale reorganization sufficiently compelling to outweigh its potential adverse consequences or risks."*

- Look at the organizational structure… *"Rather, [the Committee] took more general approach, namely to inquire if there were significant organizational changes – including widespread consolidation of [ICs] that would allow NIH to be even more successful in the future."*

- Don't stay frozen…. *"Nevertheless, the Committee did feel that no organization as important as the NIH should remain frozen in organizational space and that some regular, thoughtful and publicly transparent mechanisms is require to allow changes to take place…" p. 27*

NINE Organizational Principles –Remain Relevant to SMRB

1. The NIH research and training portfolio should be broad and integrated, ranging from basic to applied and from laboratory to population-based, in support of understanding health and how to improve it for all populations.
   - *Portfolio should reflect a balance between work in existing highly productive domains or disciplines and high-risk, groundbreaking, potentially paradigm-shifting work;*
   - *Especially responsive whenever scientific opportunity and public health and health care needs overlap.*
2. NIH should support research that cuts across multiple health domains and disease categories.
   - *Might require special efforts to integrate research across NIH components.*
3. The NIH research and training portfolio should make special efforts to address health problems that typically do not attract substantial private sector support, such as prevention, some therapeutic strategies, and many rare diseases.

NINE Organizational Principles

4. The standards, procedures, and processes by which research and training funds are allocated should be transparent to applicants, Congress, voluntary health organizations, and the general public.
   - *Wide variety of constituencies should have input into the setting of broad priorities.*

5. Extramural research should remain the primary vehicle for carrying out NIH-supported research.
   - *Open competitive peer review should be the presumptive mechanism for guiding extramural funding decisions.*

6. The intramural research program (IRP) is a unique federal resource that offers an important opportunity to enhance NIH's capability to fulfill its mission.
   - *Should seek to fill distinctive roles in the nation's scientific enterprise, with appropriate mechanisms of accountability and quality control.*

NINE Organizational Principles

7. As a world-class science institution, NIH should have state-of-the-art management and planning strategies and tools.

    - *Key example is the capability for retrieving comprehensive NIH-wide data related to its various objectives.*

8. There should be appropriate mechanisms to ensure the regular review, evaluation, and appointment of senior scientific and administrative leadership at all levels of NIH.

9. Proposals for the creation, merger, or closure of institutes, centers, and offices should be considered through a process of thoughtful public deliberation that addresses potential costs, benefits, and alternatives.

Adoption and Implementation of the NAS Report

2003

Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges

Published by The National Research Council and the Institute of Medicine of the National Academies, calls for trans-NIH planning, coordination

2003 - 2004

The Director of the NIH launches trans-NIH Roadmap process of strategic planning and research coordination known as the

2005

The NIH Director establishes the Office of Portfolio Analysis and Strategic Initiatives (OPASI) to coordinate trans-NIH planning, funding, reporting, and evaluation.

2006

The NIH Reform Act of 2006 is passed with bipartisan support, mandating the establishment of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), making trans-NIH coordination a legal requirement.

1. Protect Management at NIH
2. Create public process for organizational change

1. Assure that centralization does not undermine NIH

2. Create a public process of considering proposed changes in the number of NIH ICs
   - ***Committee "favors" 2 potential mergers***
     - ***NIDA and NIAAA;***
     - ***NIGMS and NHGRI;***

1. *"One HHS" has been confronted…yes?*

2. *NIH Reform: outlines public process*
   - *ICs : DHHS Secretary send notice to Congress*
   - *OD Offices: public hearing + Sec. approval*
   - *ICs internal: public hearings + Director approval*

3. *SMRB: Examine NIH organizational authorities*
   - *Report every 7 years minimum*
   - *If recommended change, process commences in 100 days; completed in 3 years*

3. *Strengthen Clinical Research*

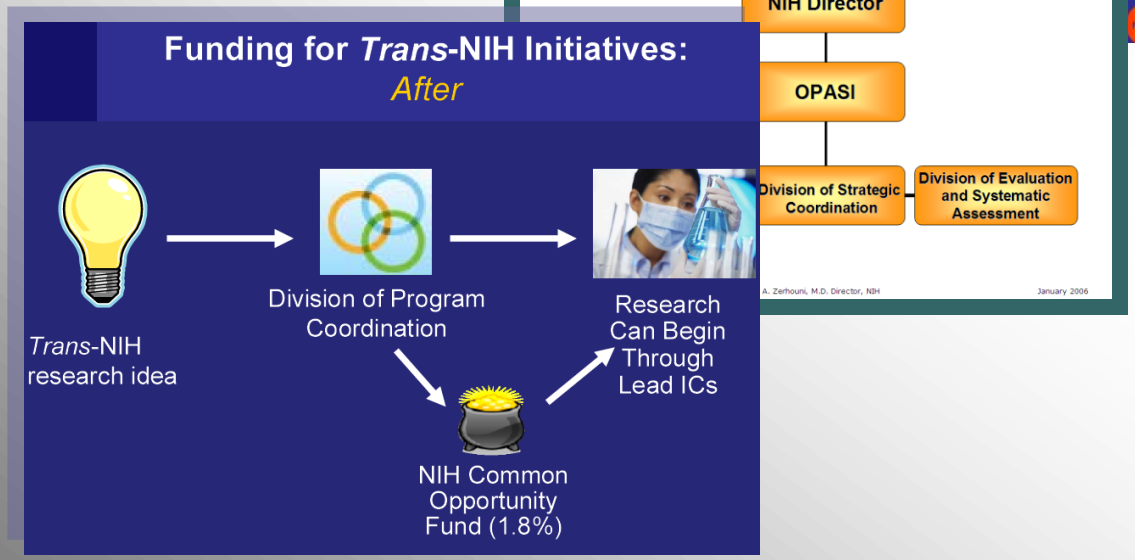
Strengthen overall NIH Clinical research through consolidation of programs and creation of new leadership position

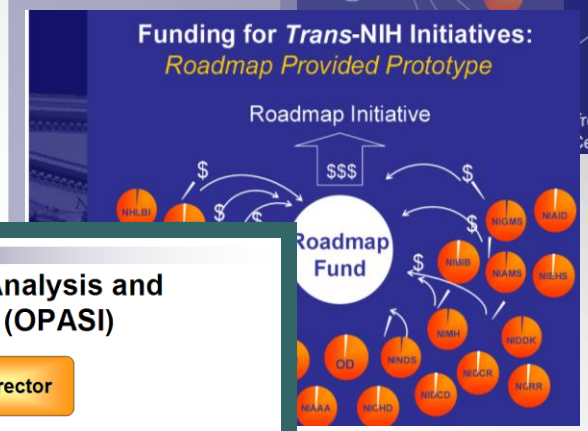
Committee "Recommends"
Creation of NCCRRR

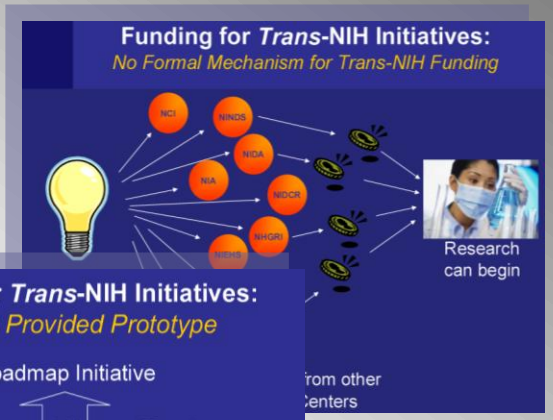
1. *Clinical Center?*
2. *Further action?*

4. Enhance and Increase TRANS-NIH Strategic Planning and Funding

- Congress should charge director to conduct trans-NIH planning process
- Budget based on scientific rationale – at 5%
- Escrow funds at IC level for trans-NIH research
- Provide staff support







5. Strengthen OD
6. Establish Process for New OD Offices

- OD should be given "adequate" budget

… "or" …

- Greater discretionary authority to reprogram
- Amplify budget for trans-NIH planning

NIH Reform gives Director the authority, following public hearings and approval of Secretary of HHS

7. Create a Director's Special Project Program

- High risk, exceptionally innovative research, high potential payoff
- Leader w/ short term staff
- Rapid review
- $100Mto grow to $1B

8. Promote Innovation and Risk-taking in Intramural Research

- Program should 'complement' and be distinguished from EMP, community and private sector
- Special status 'obligates it' to take risks and be innovative
- Regular in-depth review
- Resources should be tied to accomplishments and opps
- Inter/intra IC collaborations should be enhance

FasterCures
The Center for Accelerating Medical Solutions

Task Force on NIH's Intramural Research Program

9. Standardize "Level of Investment" Data and Information Management Systems

- Responsibility for effective management, accountability and transparency
- NIH mush enhance capacity for timely collection, thoughtful analysis and accurate reporting
- Collect these data 'consistently' and 'across ICs'
- Submit to a centralized information management system

NIH Reform

• Assemble accurate data to be used to

•Assess research priorities

•Evaluate scientific opportunity, public health burdens, and progress in reducing health disparities

NIH Reform Act Increases NIH Transparency

Research, Conditions, and Disease Categorization (RCDC) system

- Provides uniform, automated and fully transparent report of NIH funding
- Released spring 2009

NIH Biennial Report

- Consolidated dozens of Congressional reports into single document
- Comprehensive description of research, priorities, and plans of the Institutes and Centers
- Submitted April 2008

Accountability, Administration and Leadership

10. *Set Terms and Conditions for IC Director appointments and Improve IC Director Review Process*
11. *Set Terms and Conditions for NIH Director Appointment*
12. *Reconsider special status of NCI*
13. *Retain integrity in appointments to Advisory Councils and Reform Advisory Council Activity and Membership Criteria*
14. *Increase funding for RMS*

Specific Guidance on Key Issues Before SMRB

- *NIDA – NIAAA merger?*
- *"Specter Bill" ~ Institute on Health Disparities*
- *Intramural Research at NIH?*
  - *Clinical Research and the Clinical Center at NIH?*
- *Structure versus evolving organizational processes and authorities*

NIDA – NIAAA Merger

- Is there a scientific justification for keeping these two Institutes separate?
- Are there shared synergies that support integration?
  - *prevention approaches*
  - *treatment approaches*
  - *share mechanisms of action/patho-physiology*
- Does the lack of consolidation work against integrating the fields of science, aligning the external communities and accelerating scientific progress?

"Specter Bill" – Cures Acceleration Network and National Institutes of Health Reauthorization Act of 2009

- *Cures Acceleration Network*
  - *interagency agreement with NCSR*
  - *$15M per award; $1B appropriation*
- ***Institute** on Health Disparities*
- *Enforcement of Conflicts of Interest Policies*
- *$40B Appropriations for NIH*

Intramural Research at NIH
Clinical Research and the
Clinical Center at NIH

- NAS Report:
  - *Program should 'complement' and be distinguished from EMP, community and private sector*
  - *Special status 'obligates it' to take risks and be innovative*

- Task Force on NIH'S Intramural Research Program

1) NIH should articulate an overarching mission for the IRP and strategies for meeting goals over the next five years, focused specifically on advancing translational and clinical research in the interest of public health.

2) The Clinical Center must be fully utilized and the IRP's clinical research program should be expanded.

3) The IRP should be encouraged to systematically and proactively mobilize resources to rapidly and effectively respond to emerging scientific challenges and opportunities.

4) The IRP should be the premier national program for translational and clinical research training.

5) The IRP should play a central role in developing and sustaining large-scale, long-term projects.

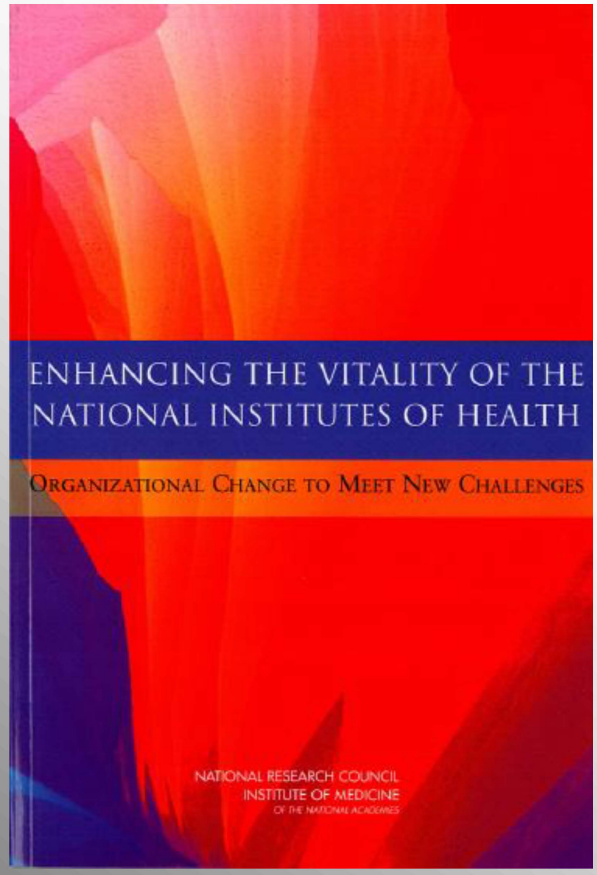
Structure Versus Evolving Organizational Processes and Authorities

SHORT TERM
Steering Committee

MED TERM → ***DPCPSI/ Common Fund***

LONG TERM → ***SMRB***

DISCUSSION


ENHANCING THE VITALITY OF THE NATIONAL INSTITUTES OF HEALTH
ORGANIZATIONAL CHANGE TO MEET NEW CHALLENGES
NATIONAL RESEARCH COUNCIL
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES


NIH
Transforming medicine and health through discovery

The Search for a "Better Way:"
The Evolution Leading to the SMRB

Marc Smolonsky
Associate Director, NIH Office of Legislative Policy and Analysis

April 27, 2009

National Institutes of Health

The 65-Year Mission of NIH

Section 301 of the PHS Act – "The Secretary shall conduct in the Service and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man . . ."

The NIH is the primary Federal agency for conducting and supporting medical research

Key Moments in Legislative History

- March 3, 1879 – National Board of Health to lead first Federal medical research effort
- March 3, 1901 – Hygienic Laboratory to investigate matters pertaining to public health
- August 14, 1912 – Public Health Service created to research “diseases of man.”
- August 5, 1937 – NCI created
- July 1, 1944 – Passage of Public Health Service Act, creates first National Institutes of Health
- June 10, 1993 – NIH Revitalization Act passed
- January 15, 2007 – NIH Reform Act Signed

Evolution of NIH Reauthorization

- 1944 - 1985 – Individual bills amending missions of existing ICs or creating new ICs.
- 1985 – First omnibus reauthorization of NIH.
- 1993 – Second omnibus reauthorization of NIH.
- 1993 – 2004 – Authorization process subsumed by appropriations laws. Some individual bills created new ICs or amended authorities. Failed attempt for omnibus reauthorization in 1996.
- 2004 –2006– Post doubling era, focus on accountability and oversight, passage of NIH Reform Act.
- Today – NIH emerges into new era of hope and vitality. ARRA and FY 2009 budget increase signal upward funding trend.

Public Health Service Act
Key Authorities for NIH

- Prioritizes Research Through Organizational Structure
- Authorizes Biomedical Research
- Provides Grantmaking Authority
- Authorizes Peer Review
- Authorizes Training
- Authorizes Dissemination of Information
- Requires Human Subjects Protections
- Authorizes the Solicitation of Public Advice

External Political Factors Driving Growth and Organizational Design of NIH

- World War II
- Academic Medical Centers
- Advances in Methods of Discovery
- Patient Advocates

Science, The Endless Frontier

- “With particular reference to the war of science against disease, what can be done now to organize a program for continuing in the future the work which has been done in medicine and related sciences?”

Question from President Roosevelt to Vannevar Bush, Director, Office of Scientific Research and Development, July 25, 1945

Establishing the NIH Model

- "The responsibility for basic research in medicine and the underlying sciences, so essential to progress in the war against disease, falls primarily upon the medical schools and universities…the Government should extend financial support to basic medical research in the medical schools and universities."

  - Vannevar Bush's Response to FDR in Science, the Endless Frontier.

Success and Fear Spurs Growth

- Advances in Basic Research, from discovery of design of DNA to Sequencing of Human Genome.
- Remarkable increases in life expectancy.
- The toll of cancer, the shock of the AIDS epidemic, the ability to diagnose and respond.
- Bioterrorism and the threat of global diseases.

Political Lobbying

- Scientists largely apathetic, not a major political force.
- Academic Health Centers and Universities motivated and effective.
- Patient and disease advocates, organized, potent and results oriented – perfected lobbying techniques, spurred the doubling and expansion of Institutes and Centers.

Examples of Congressional Actions Since 1993

- Creation of new offices, Institutes or Centers – NCCAM, NCMHD, NIBIB, Nursing Institute, ORWH, OBSSR, Office of Rare Diseases.

- New programs – IDeA, Parkinson's disease centers, Pediatric Research Initiative, Pain Consortium, Autism Centers and Interagency Autism Committee, Loan Repayment, Muscular Dystrophy Centers.

1993-2003 Appropriations Laws Dominate NIH's Legislative Arena

- 1993 - $10.3 billion
- 2003 - $27.2 billion

Key Period of Doubling

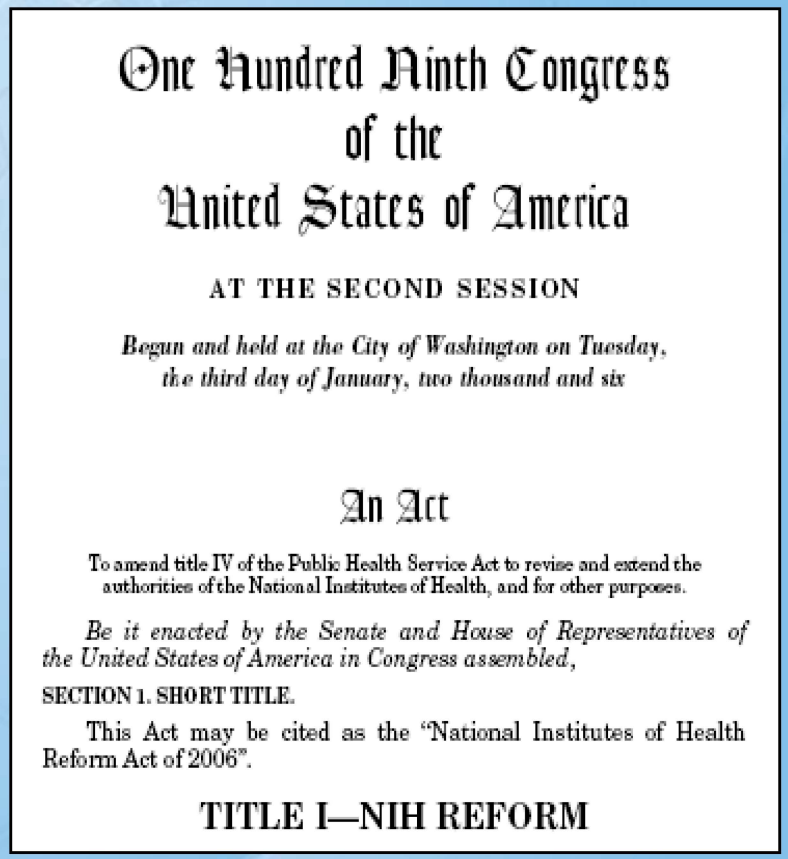
- 1998 - $13.6 billion
- 2003 - $27.2 billion
- Flat Funding 2004-2008

2004

Shift From Appropriations Emphasis To Authorization Process

National Institutes of Health Reform Act of 2006 (P.L. 109-482)

- **Passed Congress with virtually unanimous support (Dec 2006)**
- **Signed into law by the President (Jan 2007)**
- **Key Features of Act:**
  - Institutional mechanism for supporting trans-NIH research
  - Transparent disease reporting
  - Shift from political review to SMRB



One Hundred Ninth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the third day of January, two thousand and six

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

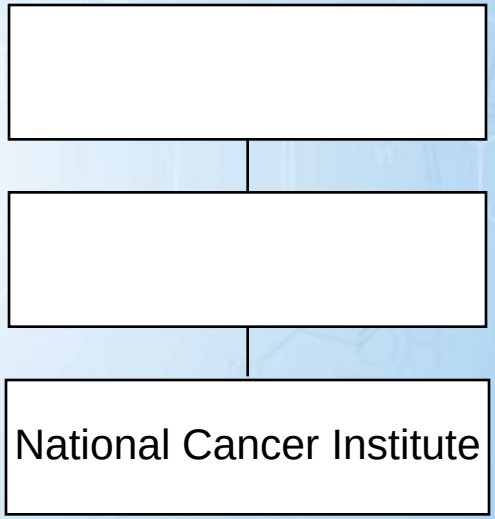
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

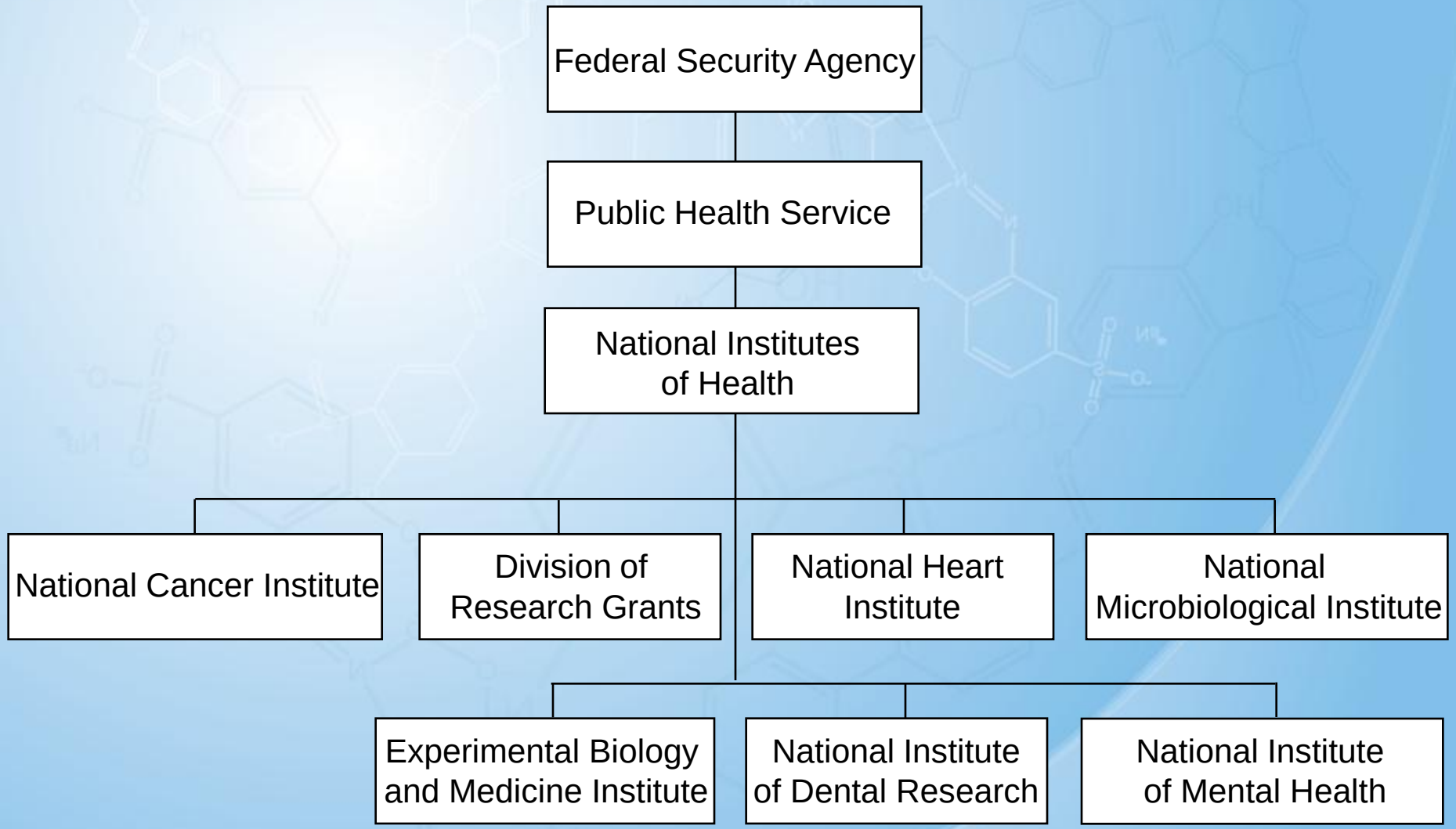
This Act may be cited as the "National Institutes of Health Reform Act of 2006".

TITLE I—NIH REFORM

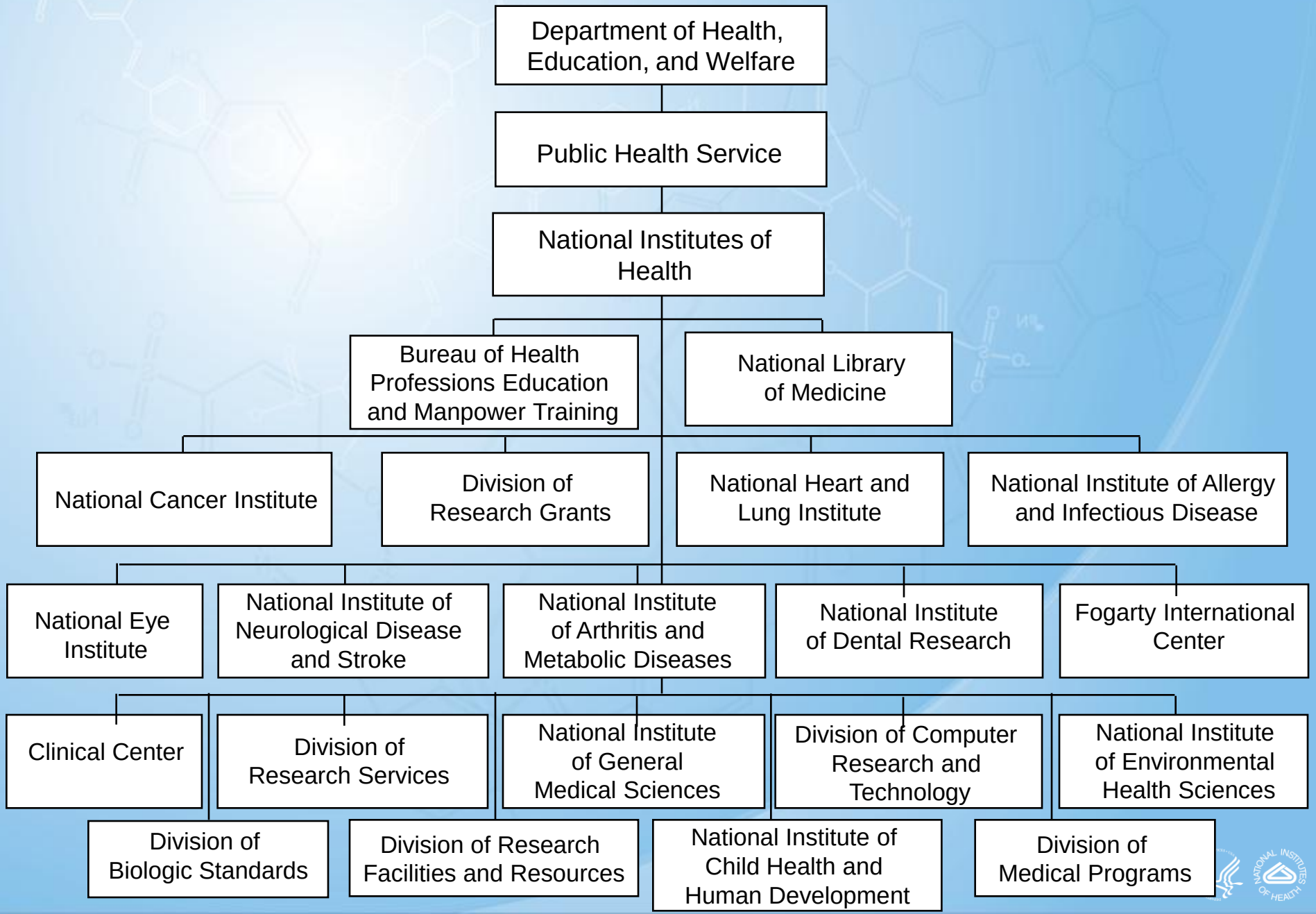
Organizational Evolution of the NIH: 1937



Evolution of the NIH: 1947 - 1949



Evolution of the NIH: 1969



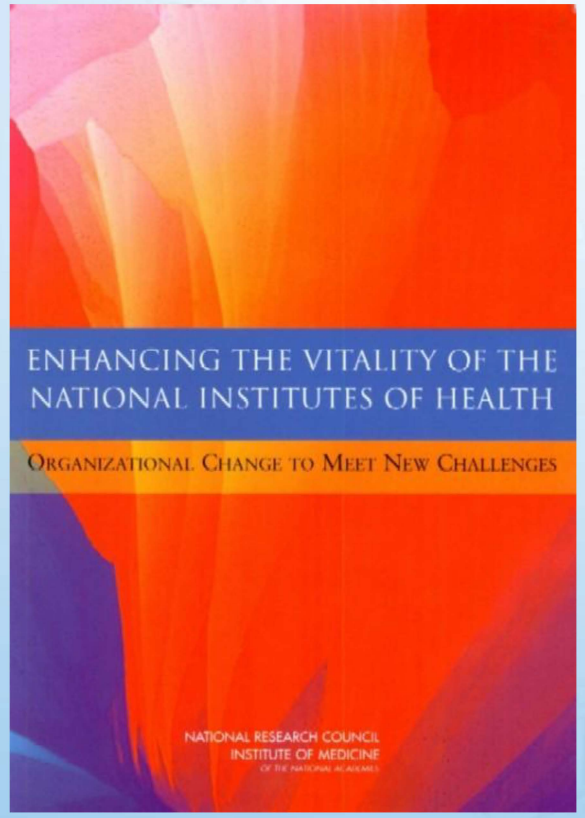
NIH Today

Division of Program Coordination, Planning and Strategic Initiatives
Office of the Director Program Offices
Office of Research on Women's Health
Office of AIDS Research
Office of Behavioral and Social Sciences Research
Office of Disease Prevention

Immediate Office of the Director

Office of the Director Staff Offices
Office of Extramural Research
Office of Intramural Research
Office of Management/Chief Financial Officer
Office of Science Policy
Office of Communications and Public Liaison
Office of Equal Opportunity and Diversity Management
Office of Program Coordination
Office of Legislative Policy and Analysis
Office of Community Liaison
Executive Office
Office of the Ombudsman/Ctr. for Cooperative Resolution
NIH Ethics Office

- National Cancer Institute
- National Eye Institute
- National Heart Lung and Blood Institute
- National Human Genome Research Institute
- National Institute on Aging
- National Institute on Alcohol Abuse and Alcoholism
- National Institute of Allergy and Infectious Disease
- National Institute of Arthritis and Musculoskeletal and Skin Diseases
- National Institute of Biomedical Imaging and Bioengineering
- National Institute of Child Health and Human Development
- National Institute of Deafness and Other Communication Disorders
- National Institute of Dental and Craniofacial Research
- National Institute of Diabetes and Digestive and Kidney Diseases
- National Institute on Drug Abuse
- National Institute of Environmental Health Sciences
- National Institute of General Medical Sciences
- National Institute of Mental Health
- National Institute of Neurological Diseases and Stroke
- National Institute of Nursing Research
- National Library of Medicine
- John E. Fogarty Center for Advanced Study in the Health Sciences
- National Center for Complementary and Alternative Medicine
- National Center for Minority Health and Health Disparities
- National Center for Research Resources
- Clinical Center
- Center for Information Technology
- Center for Scientific Review



"While the NIH is to be celebrated, success alone does not answer fully the question of whether there is a better way to proceed, particularly as one faces a future where the world of biomedical science is being rapidly transformed in virtually all its dimensions."

Institute of Medicine
Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges (2003)

Excerpts from Chairman Barton's Hearing Statement – March 17, 2005

- ***Unfortunately, NIH has grown like Topsy.*** *In 1960, NIH was comprised of a director and seven institutes. Now there are 27 Institutes and Centers. While the motivation behind this explosive growth was certainly sincere, the individual organizations were created arbitrarily, usually without benefit of systemic analysis or review of the efficiency of this structure.*

- ***This growth has resulted in an almost random collection of structures*** *in which largely independent institutes and centers are tasked to advance research programs not in cooperation with one another, but according to diseases, organ systems, or stage of life in which they specialize. Thus we study diabetes and aging in separate places, with separate staffs and separate directors overseeing the research. Plainly there is collegiality and professional cooperation, but it defies reason to believe they will produce the efficiencies that can be achieved by logically unified structure.*

- *Furthermore, this "silo" system produces thousands of pages of strategic plans, one for each of the 27 Institutes and Centers comprising the NIH. Read separately, each Institute and Center produces an impressive list of research goals and targets. Realistically,* ***scientific progress can not be accurately measured and strategic plans set by evaluating the research activities of one Institute alone when modern science transcends the research activities at several Institutes and Centers.***

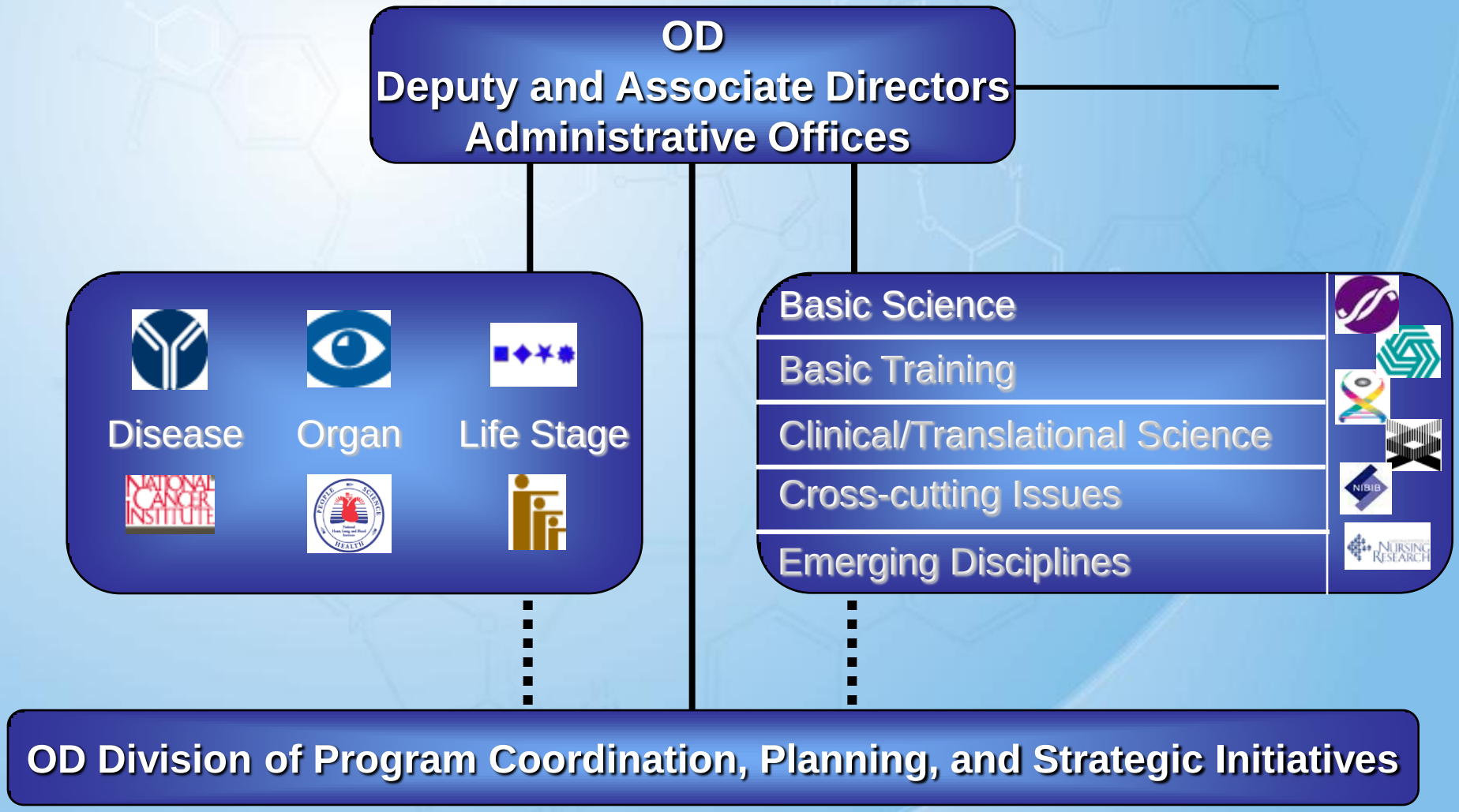
Dr. Harold Varmus

- Many people with influence in Washington view the National Institutes of Health as `the jewel in the crown of the federal government.' Such praise has helped to enhance the value--the number of carats--in this jewel, especially over the past few years. But considerably less attention has been given to its shape than its price. **New facets are being added without much thought to overall design, providing a superficial sparkle that may be pleasing to the few, but threatening to the functional integrity of the entire gem.** With too many surfaces of different sizes, the organization may soon become less able to take advantage of its extraordinary budget increase and more difficult to manage responsibly. **Those who care about the NIH need to think about its form and propose some solutions before the structure becomes even more fragmented and harder to fix.**

Dr. Elias Zerhouni

- Over the years the NIH has had what I call a structural approach to portfolio management. **Anytime there was a need and a vocal constituency, and Congress agrees, a structure was added to the NIH. That structure would get an appropriation that would grow in lockstep with all of the other structures.** The problem here is that no one cares for the entire institution except the director . . . at the end of the day we need a new way to manage the portfolio, and that's what I call functional portfolio management. The director needs the ability to merge the fourteen different tracking systems that have developed to record and code what the NIH does . . . We need to be able to plan across NIH. We need some funds in common. **If you have twenty-seven fingers out there with no palm, you don't have a hand.**

Congressional Conceptual Framework for NIH



Includes the 5 Specific Program Coordination Offices Which Will Continue Their Roles

The Intent for the SMRB

- “In response to the IOM suggestion that there is need for public process when considering proposed changes in the number of NIH institutes and centers, the National Institutes of Health Reform Act of 2006 creates a formal, public process to review the structural organizational design of the agency every seven years. A `scientific management review' group comprised of institute and center directors and other scientific experts would evaluate the structural design of the existing institutes and centers at the NIH, and proposed new institutes, and recommend necessary restructuring plans.” **House Report 109-687**

NIH

Ideas
People
Resources
Leadership

Federal Advisory Committee Act and the Scientific Management Review Board

Jennifer Spaeth
Director, Office of Federal Advisory Committee Policy
April 2009

Review: What is FACA?

- FACA - Federal Advisory Committee Act
  (Public Law 92-463, as amended).

- Defines a Federal advisory committee and establishes a system to govern Federal advisory committees in the Executive Branch of the Federal Government.

- Created to ensure that the public has access to the deliberations of advisory committee meetings and that there is accurate accounting of committee costs, activities, membership, etc.

- Explains the responsibilities of the President, Congress, Agency Heads, and other Federal officials in relation to the establishment and management of functions of Federal advisory committees.

Compliance

- Any advisory group established or utilized by a Federal agency with one or more non-Government members must comply with FACA.

- Most important provisions for you:
  - Compensation and expense reimbursement;
  - Membership balance;
  - Presence of Federal Officer at all meetings;
  - Open and closed sessions; and
  - Public accessibility to information provided to, and generated by, members

Exemptions

- Exemptions from the Government in the Sunshine Act are common at NIH when information discussed is:
  - **Proprietary;**
  - **Subject to the Privacy Act;**

  and rarely when information discussed:

  - **Would frustrate implementation if prematurely disclosed.**

Statistics

- NIH has 151 advisory committees
- Approximately 33,000 committee members and peer reviewers served on advisory committees and peer review study groups at NIH in the past year
- NIH held nearly 3,000 meetings in FY 2008
- NIH spent 150 M on committee related business

SMRB's Scope

- Evaluating NIH research portfolio
- Determining scientific opportunities and public health needs relevant to NIH mission
- Assessing organizational issues
- Meetings, consultations and forums required
- Report on the above to Congress, HHS and NIH at least once every seven years

Outside SMRB's Scope

- Final NIH actions that follow from board's reports, recommendations or approvals
- Internal NIH personnel matters
- Final NIH budget actions
- Official NIH communications

Role of Working Groups

- Gathering information, conducting research and analyzing issues in preparation for an advisory committee meeting
- Drafting position papers for deliberation at an advisory committee meeting

Federal Advisory Committees vs. Working Groups

Issue	Federal Advisory Committee	Working Group
Subject to FACA Laws & Regulations	Yes	No
Provides Direct Advice to the Government	Yes	No
Federal Official Present at all Meetings	Yes	Yes
Reports to a Federal Advisory Committee	No	Yes
Temporary in Nature	No	Yes
Must Have an Open Public Session	Yes	No
Must be Advertised in the Federal Register	Yes	No
Must Contain Members of the Chartered Advisory Committee	Yes	No
Balanced Expertise, Points of View, Geographic, Ethnic, Gender Representation	Yes	Highly Recommended
Must Have a Process for Dealing with Conflict of Interest	Yes	Yes

What's New

- Current Administration's emphasis on transparency and open government

- FACA Amendments of 2009 introduced in the House of Representatives

Proposed FACA Amendments of 2009

- Impact on SMRB
  - Conflicts of interest disclosure
  - Subcommittees/working groups
  - Information requirements
  - Public accessibility
- Status in Congress

Frequently Asked Questions

- May committee business be discussed at social gatherings of advisory committee members?
- Can we vote via e-mail?
- May web technology be used when conducting advisory committee meetings?

For More Information

- **Please contact me:**

Jennifer S. Spaeth
Director, Office of Federal Advisory Committee Policy
Office of the Director, National Institutes of Health
spaethj@od.nih.gov
301-594-5115

- **Refer to Website:**

Office of Federal Advisory Committee Policy Home Page:

http://www1.od.nih.gov/cmo/

American Recovery and Reinvestment Act (ARRA)- Impact of Economic Stimulus on NIH

Lawrence A. Tabak, DDS, PhD.
Acting Deputy Director
National Institutes of Health

One Hundred Eleventh Congress
of the
United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the sixth day of January, two thousand and nine

An Act

Making supplemental appropriations for job preservation and creation, infrastructure investment, energy efficiency and science, assistance to the unemployed, and State and local fiscal stabilization, for the fiscal year ending September 30, 2009, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

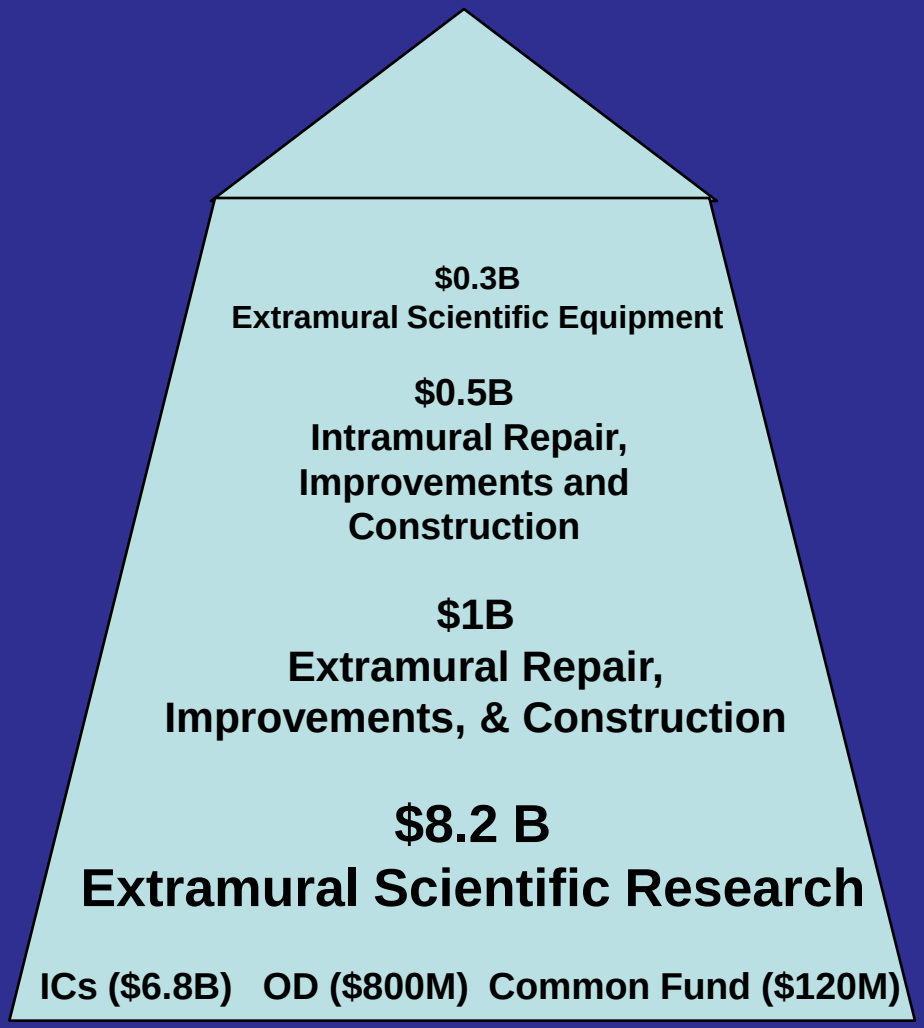
This Act may be cited as the "American Recovery and Reinvestment Act of 2009".

NIH is grateful to President Obama and Congress for the opportunity for NIH to play its part in improving the Nation's health and economy

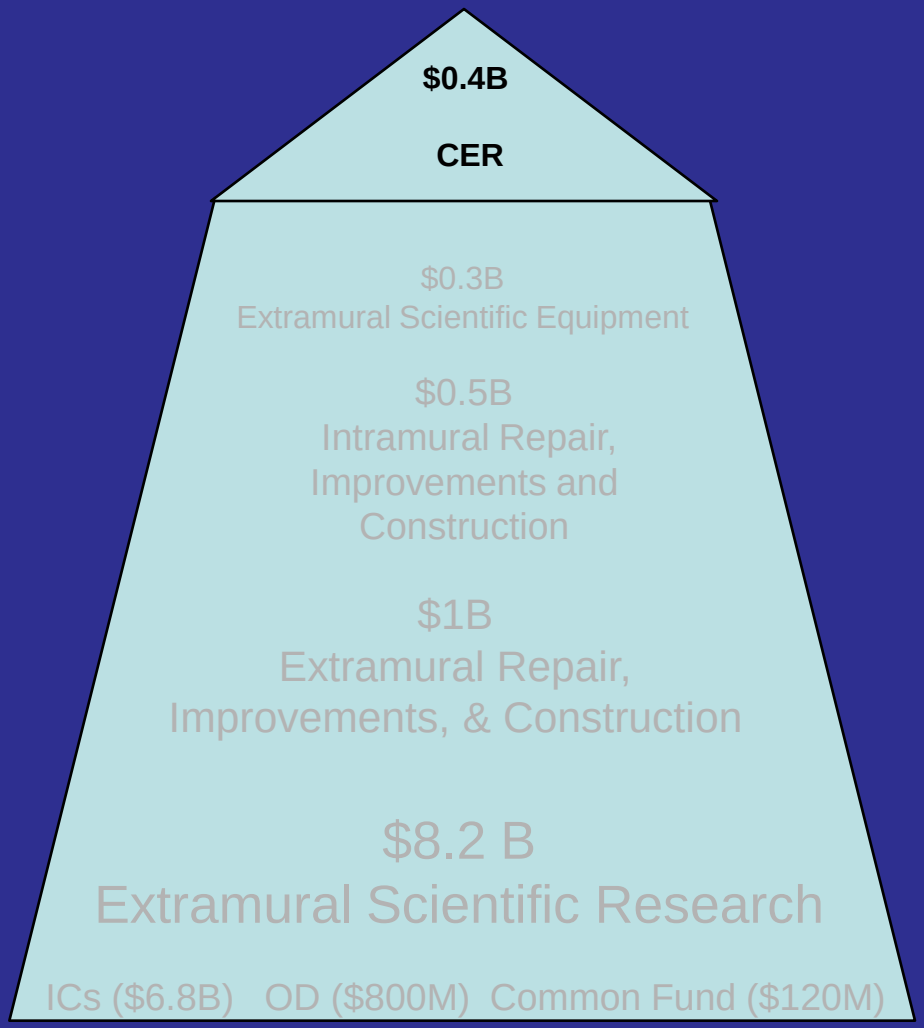
Funding Impact

- Stimulate the economy
- Create and preserve jobs
- Advance biomedical research

ARRA appropriated $10B directly to NIH

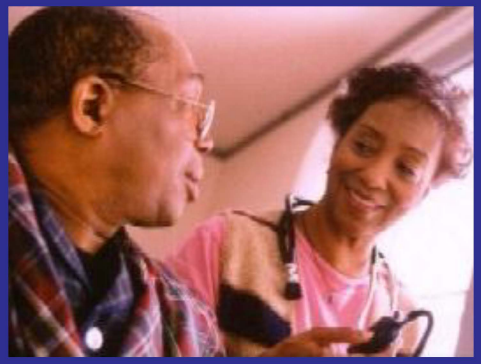


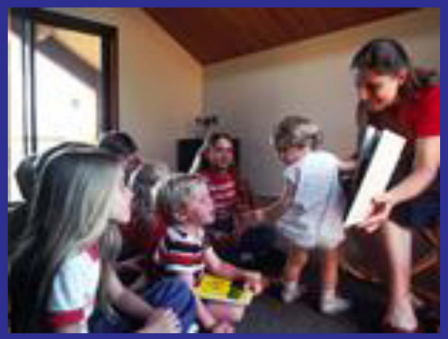
ARRA appropriated $400M to NIH via AHRQ

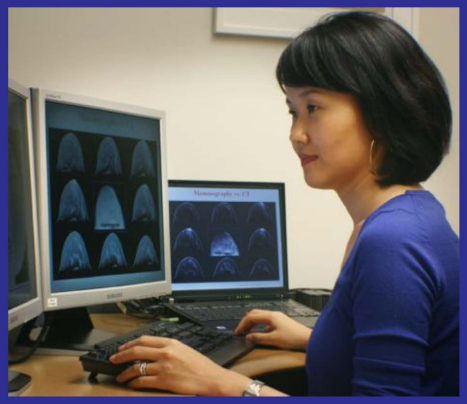


Scientific Research Approach

- Stimulate and accelerate biomedical research with existing mechanisms
  - Funding additional meritorious RO1s, R21s and R03s that have been peer reviewed and approved by IC Councils
  - Administrative supplements to accelerate ongoing research
- Expand science with new programs
  - Revisions to extant programs (“Competitive supplements”)
  - New ARRA NIH-wide programs
  - New ARRA IC-specific programs





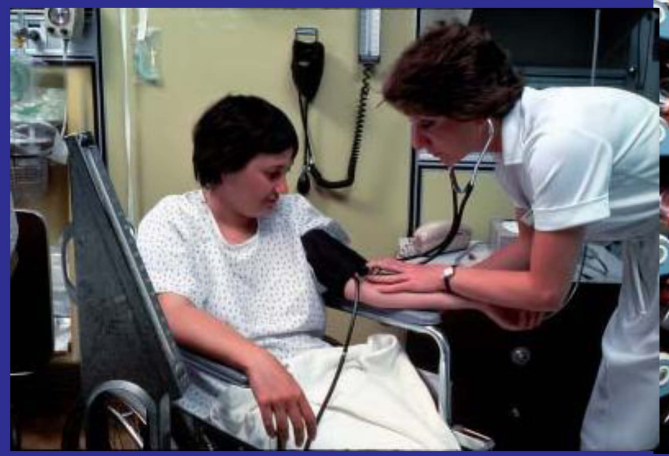


New ARRA NIH-wide Programs

- Challenge Grants
- Grand Opportunities (“GO” Grants)
- Recruit new faculty to conduct research
- Provide summer jobs for high school / college students and teachers to work in science labs
- AREA (R15) Grants

Challenge Grants

- Challenge Grants (at least $200M total) provide:
  - Priority avenues of research
  - Up to $500K total costs/year for up to two years



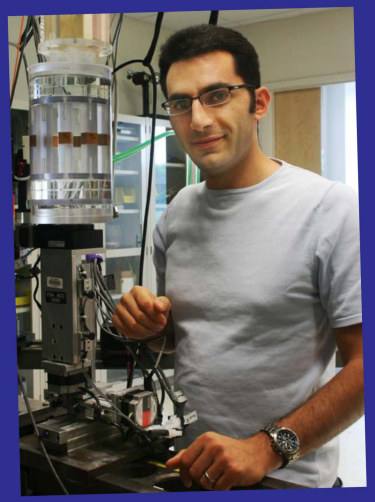
Challenge Grants

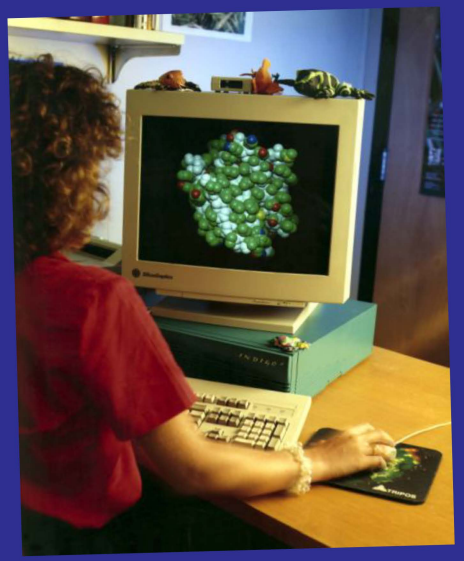
Links to High Priority Topics Within Broad Challenge Areas (PDF - 556 KB):

(01) Behavior, Behavioral Change, and Prevention
(02) Bioethics
(03) Biomarker Discovery and Validation
(04) Clinical Research
(05) Comparative Effectiveness Research (CER)
(06) Enabling Technologies
(07) Enhancing Clinical Trials
(08) Genomics
(09) Health Disparities
(10) Information Technology for Processing Health Care Data
(11) Regenerative Medicine
(12) Science, Technology, Engineering and Mathematics Education (STEM)
(13) Smart Biomaterials – Theranostics
(14) Stem Cells
(15) Translational Science

Grand Opportunity Grants

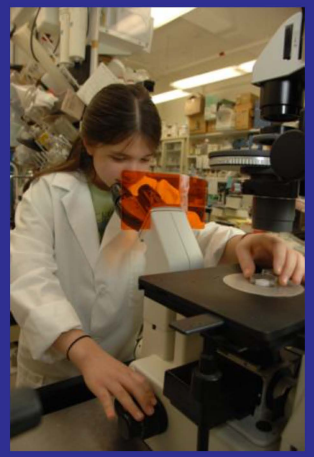
- Grand Opportunity (GO) Grants (at least $200M total):
  - High impact
  - Well defined
  - Large scale





Summer Jobs in Research for Students and Teachers

- Engage students and educators in research
- Encourage students to pursue research careers
- Provide summer internships at NIH-funded laboratories for science teachers



New Faculty

- Core Centers for Enhancing Research Capacity in U.S. Academic Institutions
  - Newly trained scientists
  - Start-up packages
  - Pilot research projects
  - Recruitment of Bioethicists among the priorities

IC-specific RFAs: e.g. $60M Grants for Strategic Autism Research

- Research to Address the Heterogeneity in Autism Spectrum Disorders
  - Develop / test diagnostic screening tools
  - Assess risk from exposures
  - Test early interventions / adapt existing pediatric treatments for older groups

Additional Trans-NIH Supplement Programs

- Revisions (competitive supplements) – Due 4/21/09
- Administrative supplements – Multiple receipt dates

OD ARRA Funds ($800M)

- $328M to be determined
- $472M tentatively allocated as follows:
  - Extramural
    - $200M for Challenge Grants in Health and Science
    - $100M for Grand Opportunities (“GO Grants”)
    - $ 30M for OD-IC Community Signature projects
    - $ 30M for IC-OD Signature projects
    - $ 30M for OD-IC Small Business Program
    - $ 20M for Summer Training for Students/Teachers
    - $ 20M AREA (R15) Grants Program
    - $ 10M for Faculty Recruitment Program (Bioethics Faculty)
  - RMS for OD
    - $ 16M
  - Other OD Requirements
    - $ 15M for CC equipment
    - $ 1M for summer training for students/teachers

Common Fund ARRA Funds (136.8M)

- Stimulate and accelerate biomedical research within existing program areas
  - Fund additional New Innovator Grants that will be peer reviewed in FY2009 and FY2010
  - Administrative supplements to accelerate ongoing research
  - Competitive revisions to expand the breadth of research that can be accomplished
- Challenge grants that address needs identified through the CF planning process
- Grand Opportunity grants

NIH and Comparative Effectiveness Research

- NIH received $400M of the $1.1B appropriated for CER under the American Recovery and Reinvestment Act of 2009
- There is no consistent, HHS-wide, definition of CER at this time
- NIH's involvement has included:
  - Participation on the Federal Coordinating Committee (NIH is represented by Dr. Betsy Nabel, Director, NHLBI)
  - Participation in the March 2009 Stakeholder meeting of the IOM CER Priority Setting Committee (the priority list is to be issued by June 2009)
  - NIH CER Coordinating Committee created to provide advice to the NIH Director on the best use of the CER stimulus funds, implementation of CER rules and definitions, et cetera.
  - NIH-AHRQ CER Subcommittee created to coordinate the CER dialogue with AHRQ
- NIH Fingerprinting Subcommittee

NIH and Comparative Effectiveness Research (cont.)

- NIH CER Opportunities Using ARRA Funds
  - Challenge Grants in Health and Science Research
  - 69 CER-specific submissions in the March 2009 Challenge Grant RFA
  - Research and Research Infrastructure Grand Opportunities ("GO Grants")
  - Deadline: Applications due May 27, 2009
  - Examples
    - NCI: "Centers for Planning and Evaluation for CER in Genomic and Personalized Medicine"
    - NHLBI: Projects that target heart, lung and blood diseases
- Stay Tuned- More to Come!

http://www.nih.gov/recovery

Notes for the Scientific Management Review Board

Gretchen H. Weaver
Senior NIH Ethics Counsel
April 27, 2009

Conflicts of Interest
18 U.S.C. § 208

You may not:

- "personally and substantially participate"
- In a "particular matter"
- In which you have a personal or imputed financial interest
- If the matter will have a "direct and predictable" effect on that interest

Emoluments Clause

- Applies to federal members
- Does not apply to non-federal members –

  Employment and the performance of services for foreign governmental entities under employment-like circumstances is permitted.

Foreign Gifts and Decorations

(not in exchange for services)

You may accept certain things offered gratuitously by foreign governments:

- Medals, badges, honors associated with awards, orders of merit from chivalric codes
- Tangible gift items valued at less than $335 (US)
- Educational scholarship or medical treatment
- Travel or expenses for travel occurring entirely outside of US

Other Rules

- Gifts – given to influence you as an SMRB member, or solely because you are an SMRB member, are generally prohibited
- Testimony – need agency permission before testifying as expert for another in a matter in which you participated as an SMRB member
- Charity – can't use title or position, and can't solicit from entity having interests that could be substantially affected by SMRB activities

Lobbying/Politics

- Appropriated funds cannot be used to “lobby” Congress or encourage others to do so.
- The Hatch Act restricts the “political” activities of SGEs while engaged in the performance of official Government business