

NSTITUTES

ATIONAL

Deputy Director, NIH

Scientific Management Review Board

HEALTH

NIH Reform Act of 2006 Charge to the SMRB

"With respect to a specific contemplated organizational issue:

- 1.Review NIH research portfolio to determine progress, effectiveness, and value of the portfolio and of the allocation of NIH resources among the activities that comprise the portfolio
- 2. Determine pending scientific opportunities and public health needs with respect to the research within NIH's jurisdiction"

SMRB Charge, continued

3. "For any proposal for organizational change

- Analyze budgetary and operational consequences
- Take into account historical funding and support for research activities at national research institutes and centers established recently relative to those in existence for more than two decades
- Estimate levels of resources needed to implement change(s)
- Make recommendation for allocating NIH resources among institutes and centers
- Analyze consequences for the progress of research in areas affected"

SMRB Charge → This Presentation

Review and assess NIH research portfolio

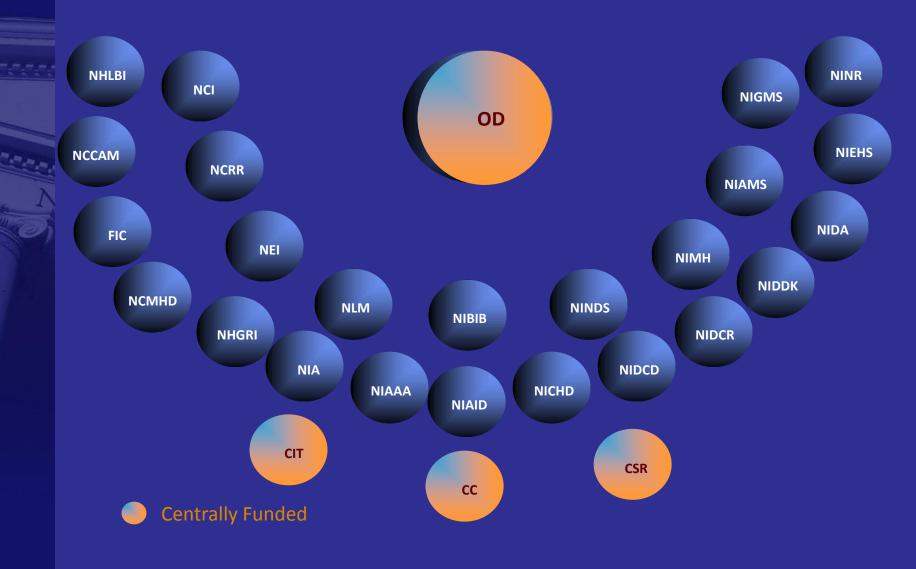
Determine scientific opportunities & public health needs

Priority Setting at NIH

Topics

- NIH organizational governance
- NIH priority setting: principles, imperatives, current initiatives and future directions

NIH Organizational Structure



Governance: NIH Steering Committee

- Established in July 2004 in response to growth in the size of NIH, complexity of its mission, and the requisite resources
- Has governance purview for all corporate functions, resources, or policies other than the setting of corporate scientific direction and priorities
- Brings operational issues of highest significance to all IC Directors

NIH Organizational Governance

Steering Committee Management & Budget Extramural Working **Intramural** Groups **Facilities**

Information Technology

Governance: Membership of the Steering Committee

- 10 Members
- Chaired by NIH Director
- 3 permanent members: Directors of NCI, NHLBI, and NIAID
- 7 rotating members from other small to mid-size institutes and centers
- NIH Deputy Director is ex-officio member

Governance: Membership of the Working Groups

Each working group is co-chaired by a Steering Committee member and a corresponding senior functional head in the Office of the Director:

- 1. Management and Budget
- Extramural
- 3. Intramural
- 4. Facilities
- Information Technology

Governance: Purposes of the Working Groups

- Provide oversight for—but not manage—functions common to ICs
- Make corporate policy and resource recommendations to the Steering Committee
- Issues coordinated by NIH Deputy Director and brought directly to Steering Committee:
 - Science Policy
 - Legislation
 - Communication

Governance:Review and Revision

- Two reviews completed to date
- Conclusions of internal evaluation of Working Groups:
 - Overall governance structure has improved the decisionmaking process
 - Potential areas for improvement:
 - Unclear role of Legacy Committees, particularly Scientific Directors
 - Enhancing coordination among working groups for cross cutting issues
 - Unclear scope of "authority" for Working Groups
- NIH Director currently reviewing governance

Background on NIH Research Priority Setting

- Focus on extramural research
- Peer review to drive decision-making
- Importance of investigator-initiated research: the "Invisible Hand" in the free market of scientific ideas
- Congress defers to the rigorous process driven by the scientific community
 - "... the day we decide which grants are going to be approved... is the day we will ruin science research in this country. We have no business making political judgments about those kinds of issues."

~ Representative David Obey House Appropriations Committee Chairman July 11, 2003

Priority Setting: Current Processes

Multi-leveled, multi-focal

Priority setting occurs within every institute/center

Priority setting occurs within the Office of the Director

Priority setting occurs beyond NIH in the executive and legislative branches of the federal government

Priorities reflected in resource allocations, especially budget

Priority Setting: Current Processes

Multiple "inputs": stakeholders, data, and information

Health professionals

Basic & clinical scientists

Scientific opportunities

Patients & advocacy groups

Professional societies

Voluntary organizations

Data and information on the burden of disease and disability

General public

Advisory Councils

Scientific Review Committee

Investigatorinitiated research proposals Process and outcomes of priority setting

Setting Research Priorities – Many Stakeholders



Boards of Scientific Counselors

Patients & Their Advocacy Groups

Voluntary Organizations

Scientific Review **Committees**

U.S. President

Scientists

NIH Staff

Congress

Scientist Council **Members**

Ad Hoc Advisors

Physicians & Other

Health Professionals

Public Members of Advisory Councils

Professional Societies

Foreign Governments

Industry

Priority Setting: Current Processes

... complex and multifaceted ...

"Some of the variables in choosing resource allocations include public health needs such as the burden of disease, new scientific opportunities, the quality of research proposals, the experience of applicants, and the ability to sustain research through adequate staffing and infrastructure..."

~ Dr. Elias Zerhouni
Testimony before the Committee on Energy and Commerce,
Subcommittee on Health, United States House of
Representatives
March 17, 2005

Priority Setting: Current Processes Executive and Legislative Branches

U.S. Congress

- NIH authorization and appropriations
- Sets NIH and IC funding levels and directs NIH attention to particular areas of research interest or emphasis
- Historically influential in organizational change at NIH, e.g., through creation of new ICs
- Executive Branch, White House, OMB, HHS
 - NIH appropriations process
 - Establishes priorities for improving health, e.g. Healthy
 People 2010

Priority Setting: Current Processes Institutes and Centers

- Primary locus of research priority setting
- Priorities partially driven by scientific community through investigator-initiated research applications
- Two-tiered peer review process:
 - Assessment of scientific and technical merit
 - Review by Advisory Councils

Priority Setting: Current Processes IC Advisory Councils

- Comprised of senior scientific experts and members of the public
- Advise and recommend programmatic relevance of applications and areas of science to emphasize to the ICs
- Vet ideas for scientific initiatives that receive setaside funds
- Advise ICs on scientific priorities

Priority Setting: Current Processes Trans-NIH Planning

- Creation of the Division of Program Coordination,
 Planning and Strategic Initiatives (DPCPSI) in 2007
 - In the Office of the NIH Director
 - Created to identify important areas of emerging scientific opportunity, rising public health challenge, and gaps in knowledge that deserve special emphasis
 - Home of the NIH Roadmap and Common Fund

Priority Setting: Current Processes Trans-NIH Planning – Roadmap and Common Fund

- Programs are developed via highly dynamic strategic planning process
- Provides NIH with flexibility to respond quickly to new ideas, challenges, and gaps
- Involves broad stakeholder input from multiple scientific and public sources as well as NIH leadership

Priority Setting: Current Processes Trans-NIH Planning – Roadmap and Common Fund

- NIH solicited ideas for new initiatives from intramural and extramural scientific community, health professionals, patient advocates, and general public
 - (RFI in NIH Guide: http://grants.nih.gov/grants/guide/notice-files/NOT-RM-08-014.html)
- Programmatic review of submitted ideas, assessment in light of current NIH portfolio, vetting by Council of Councils, and final review by NIH leadership

Priority Setting: Current Processes Trans-NIH Planning – Roadmap and Common Fund

Proposed initiatives must:

- 1. Be truly transforming
- 2. Promote and advance the individual missions of the Institutes and Centers (IC) to benefit health
- 3. Require participation from NIH as a whole and/or address an area(s) of science that does not clearly fall within the mission of any one IC or program office
- 4. Be unique

Priority Setting: Current Processes Trans-NIH Planning – DPCPSI

- Coordinate development of tools to enhance portfolio analysis and priority setting
 - Create better information systems to analyze the entire NIH portfolio of research and provide modern decision support systems to all Institutes and Centers
 - Research, Condition, and Disease Categorization (RCDC) system
 - Portfolio Analysis Pilot Projects
 - Institute and Center-developed efforts, e.g., NIAID electronic Scientific Portfolio Assistant (eSPA)

Priority Setting: Current Processes Trans-NIH Planning – DPCPSI

- Enhance efforts to report on outputs, outcomes, and return on investment
 - Research Portfolio Online Reporting Tool (RePORT)
 - Expand measures of Scientific Opportunity vs. Public Health burden and societal demands within each IC and across NIH

Priority Setting: Current Processes

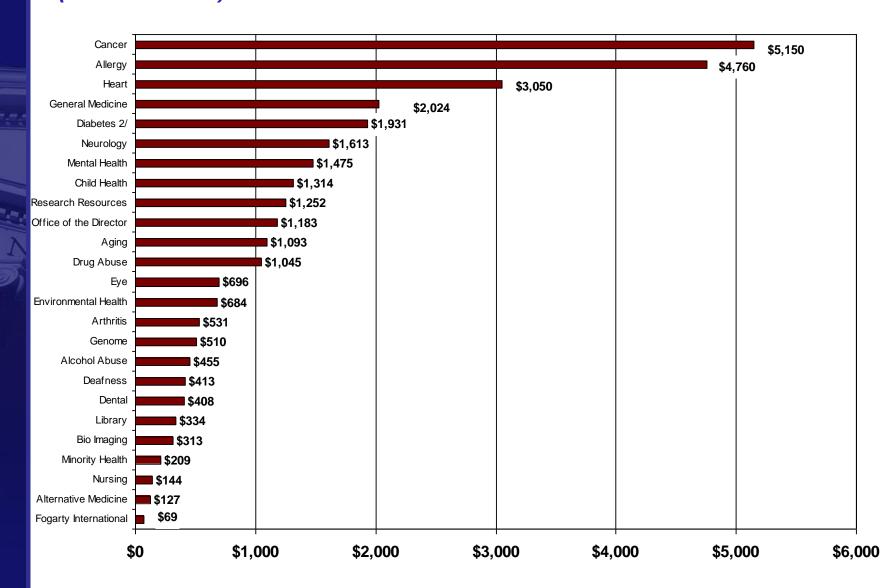
"Some of the variables in choosing resource allocations include public health needs such as the burden of disease, new scientific opportunities, the quality of research proposals, the experience of applicants, and the ability to sustain research through adequate staffing and infrastructure. These factors are often lost in the public debate about NIH funding, in which the discussion is sometimes simplified by focusing attention on apparent differences between the toll of certain diseases and the amount spent on research about those diseases." ~ Dr. Elias Zerhouni

Testimony before the Committee on Energy and Commerce,
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Budgets and Funding as Reflections of NIH's Priorities: Differing Perspectives

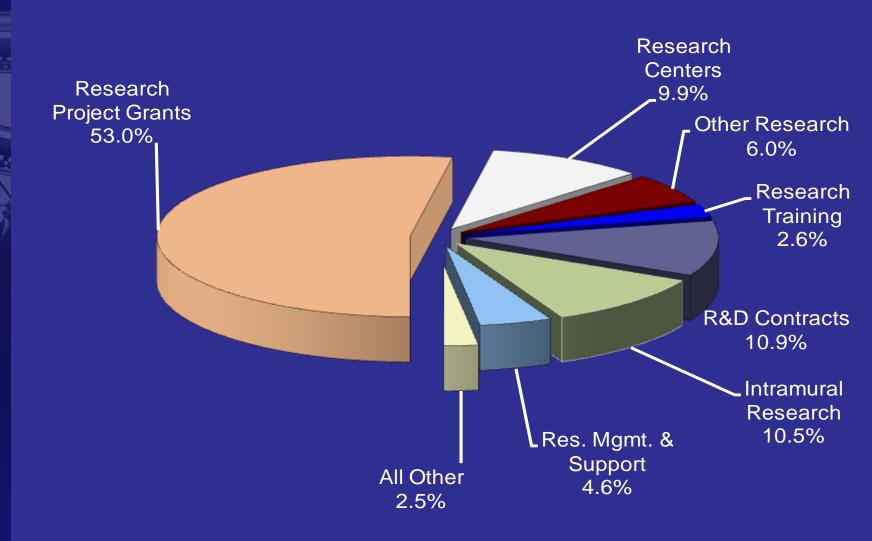
- By Institute, Center, Office
- By Mechanism
- By Spending at and to Entities Outside NIH
- By Research/Disease Areas
- By Likelihood of Application Being Funded
- By Disease Burden

FY 2010 President's Budget NIH Funding By Institute/Center¹ (\$ in Millions)



1. Includes funding for Type 1 Diabetes.

FY 2010 President's Budget Request NIH Budget Authority \$30,759M



NIH Funding by Mechanism FY 2010: \$30.759 B

Spending at NIH

\$5.3 B

18%

- \$3.2 B Intramural Research = 10.4%

\$2.0 B Research Management & Support and OD (w/o Common Fund) = 6.7%

\$134 M B&F = 0.4%

Spending Outside NIH

\$25.5 B

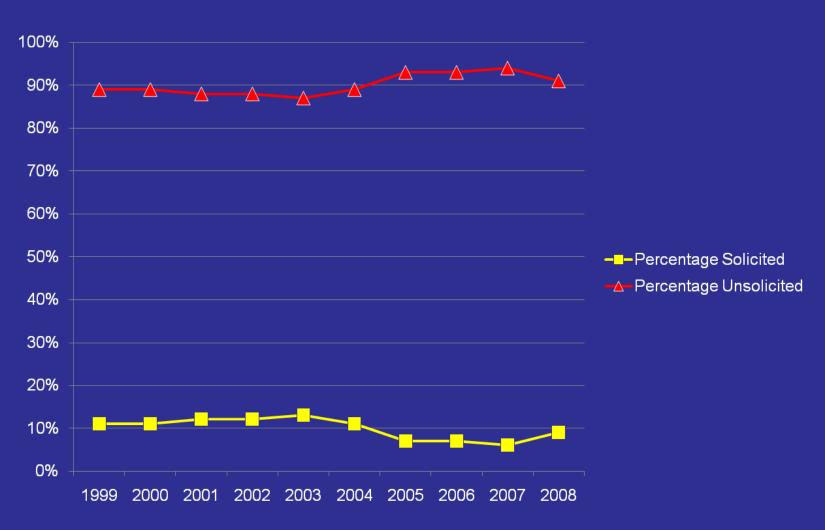
82%

Supports over 325,000 Scientists &

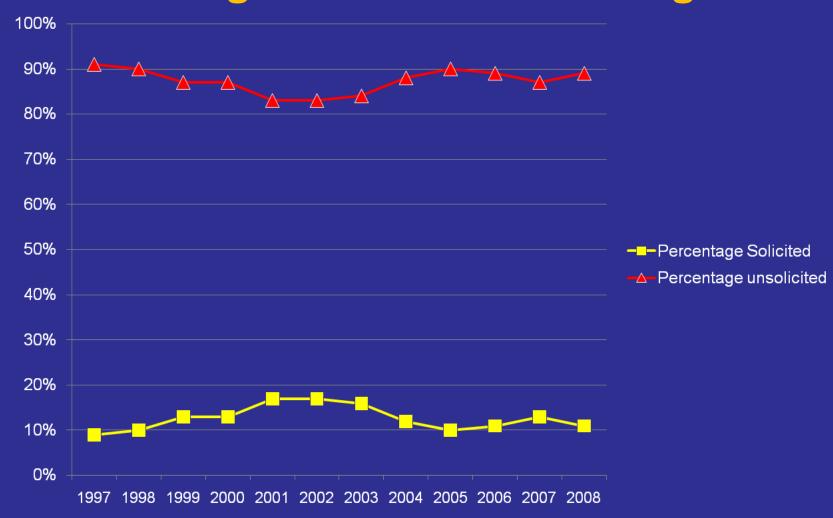
Research Personnel

Supports over 3,000 Institutions

Trends in investigator-initiated (RO-1 equivalents) vs. NIH targeted research funding



Trends in investigator-initiated (Research Project Grants) vs. NIH targeted research funding

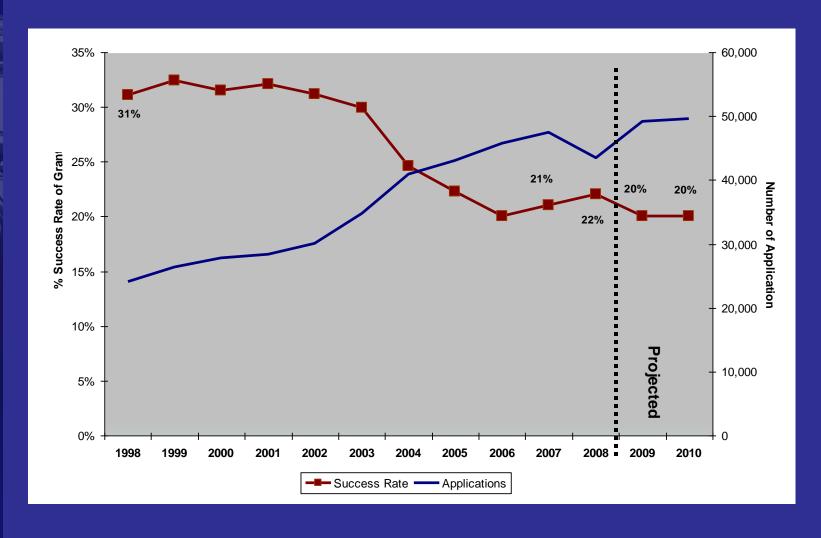


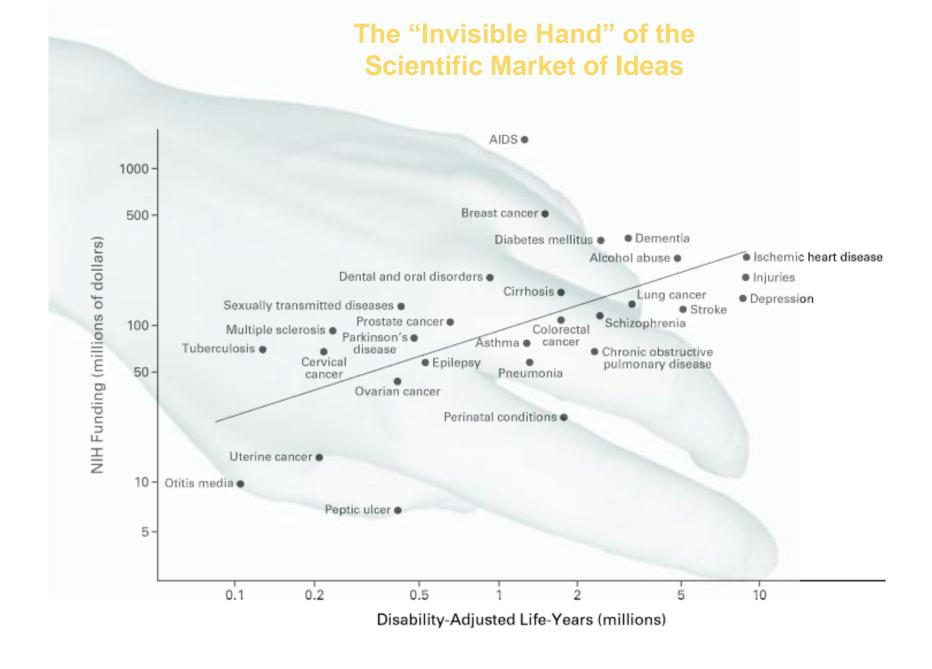
NIH Funding in 2008-2010: Sample of Disease/Research Area

Research/Disease Areas	FY 2008	FY 2009	FY 2010
(Dollars in millions and rounded)	Actual	Estimated	Estimated
Acute Respiratory Distress Syndrome	\$82	\$84	\$85
Agent Orange & Dioxin	\$13	\$14	\$14
Aging	\$1,965	\$2,019	\$2,045
Alcoholism	\$452	\$466	\$473
Allergic Rhinitis (Hay Fever)	\$6	\$6	\$6
ALS	\$43	\$44	\$45
Alzheimer's Disease	\$412	\$423	\$428
American Indians / Alaska Natives	\$142	\$147	\$149
Anorexia	\$7	\$7	\$7
Anthrax	\$134	\$137	\$139
Antimicrobial Resistance	\$228	\$234	\$237
Aphasia	\$22	\$22	\$23
Arctic	\$22	\$23	\$23
Arthritis	\$232	\$238	\$241
Assistive Technology	\$215	\$221	\$224

Full list can be accessed at: http://report.nih.gov/rcdc/categories/

National Research Capacity and Demand for Grants Surges at End of Doubling Period, Success Rates Fall then Flatten





Source: Gross, Cary P., M.D., et al., (1999). The relation between funding by the National Institutes of Health and the burden of disease. New England Journal of Medicine, 340(24); 1881-1887.

Need to Be Able to Prepare for and Respond to Other Important Public Health Issues



Principles and Imperatives for Priority Setting

- Necessary to ensure that the NIH research portfolio:
 - addresses national public health needs,
 - capitalizes on important scientific opportunities,
 - addresses current and potential needs,
 - attends to research needs for rare and neglected diseases,
 - leverages common interests across IC, and
 - uses resources as effectively as possible.
- Processes for planning and priority setting must:
 - Continue to occur at multiple levels within the timeframe needed for progress in every phase and ultimately for implementation.
 - Be transparent and, along with their outcomes, effectively communicated to all necessary stakeholders.

Principles and Imperatives for Priority Setting: Allowing for Serendipity

Planning and priority setting processes must also acknowledge and be responsive to the phenomenon of serendipity in scientific discovery

Fleming's accidental discovery of penicillin

In the quest for an improved smallpox vaccine, Nagano and Kojima discover interferon

1928

1947

1954

1964

Initial synthesis of chlorpromazine as an antihistamine, then observation of its psychiatric potential Initially synthesized as an anticancer drug, two decades later AZT becomes the first approved antiviral for HIV

Improving the Process of Priority Setting: Future Directions

- Key inputs will be better data on the research supported/conducted by NIH and on public health needs.
- Better means for comparing disease and disability burdens (current and anticipated) with information on ongoing scientific efforts and opportunities.
- Comparative analyses utilizing quantitative measures of the quality of science supported across ICs, e.g., range of priority scores, variation in levels of citation of published research.
- Better understanding of what other funders are doing (e.g., foundations, industry)

Improving the Process of Priority Setting: Future Directions

 Trends in and comparisons across ICs in the balance of solicited vs. unsolicited research, use of program projects, center grants, cooperative agreements, contracts.

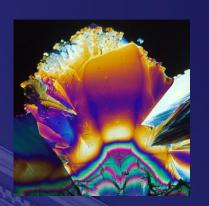
 Systematic analysis and review of the long-term outcomes of research funded by NIH.

Measures of NIH Success

- Discoveries that improve the practice of medicine
- World leadership in science and medicine
- Improved health and life expectancy
- Strength of U.S. universities, medical centers, and industry
- Continued support of Congress and the public









Transforming medicine and health through discovery



