Irector's pdate

Dr. John E. Niederhuber

Director, National Cancer Institute

Clinical Trials Advisory Committee
March 4, 2009

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

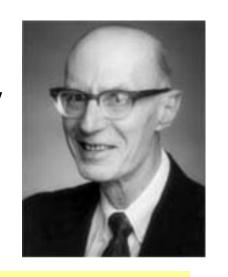
National Institutes of Health

Director's Update

- FY 2009 Omnibus Appropriations Bill
- The American Recovery and Reinvestment Act of 2009
- Priorities of the Obama Administration
- Executive Committee Scientific Retreat

Alan S. Rabson Award

"The NCI is directed to name a Fellowship in Surgical Pathology the 'Alan S. Rabson Award'...
Dr. Rabson had demonstrated unequaled service in his 53



years at NIH...he has made his life passion helping cancer patients and their families come to grips with their cancer diagnosis and locating the medical treatment and provider that will help them most."

FY 2009 Omnibus Appropriations Bill

"National Institutes of Health: \$30.3 billion for lifesaving research into diseases such as Alzheimer's, cancer and diabetes, \$938 million [+3.1%] above last year..."

House Appropriations Committee statement

NCI FY 2009 Operating Budget Development

FY 2008 operating budget (with \$25M supplemental)	\$4,830,647	
FY 2009 Omnibus Appropriations Bill	\$4,968,973	
Difference, FY08 to FY09	\$138,326	
Percent change, FY08 to FY09	+2.9%	

(dollars in thousands)

The American Recovery and Reinvestment Act of 2009

- \$10.4 billion to NIH over two years
- Recognizing the economic and health impact of investing in biomedical and behavioral research
- Impacts more than 3,000 institutions in 50 states

Purposes of Stimulus Legislation

- Preserve and create jobs; promote economic recovery
- Assist Americans most impacted by the recession
- Spur technological advances in science and health
- Invest in transportation; environmental protection, and other infrastructure
- Stabilize state and local government budgets

NIH-OD

- \$8.2 billion to NIH for research, with **\$7.4 billion** to be transferred to ICs and Common Fund in the same proportion as the FY09 budget and used to support additional scientific research
 - -\$1.26 billion to NCI, by current estimate



Sen. Arlen Specter (R-Pa.)

Distribution of Funds

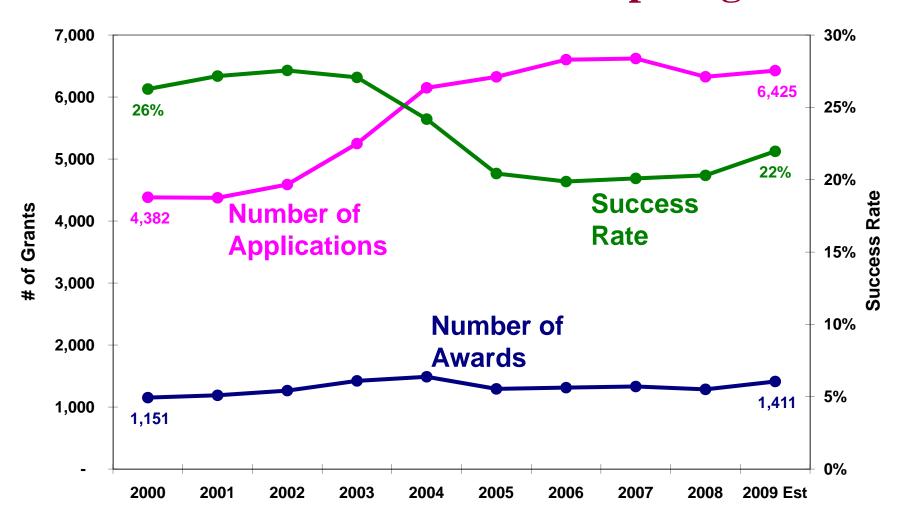
	NIH	NCI est.
NIH facilities - B&F	\$ 500,000	
Office of the NIH Director	8,200,000	
Extramural construction/repair	1,000,000	
NCRR shared instrumentation	300,000	
	\$10,000,000	
Comparative Effectiveness transfer	400,000	
	\$10,400,000	
Office of the Director	8,200,000	
NIH OD, including challenge grants	-800,000	
Transfer to ICs & Common Fund	\$ 7,400,000	\$1,260,000 (16.2%)

Dollars in thousands

Many Types of Funding Mechanisms will be Supported

- Choose from reviewed and new meritorious R01s capable of making significant advances in two years
 - Carefully model out-year challenges
- Accelerate tempo of ongoing science through carefully targeted supplements
- Explore new and innovative activities that fit ARRA goals
 - NIH and NCI RFAs
 - -NIH challenge grant program

NCI Applications, Awards & Success Rates FY 2000 to FY 2009 Estimate: Competing RPGs



Note: FY 2008 & beyond RPGs include R01s, U01/19s previously funded from Cancer Prevention & Control budget mechanism

Challenge Grants

- Challenge Grants will come out of the money that OD retains; likely \$100 to \$200 million in grants - capped \$500K
 - RFA out in next week or two
 - Applications expected by end of March
 - Reviewed May/June by special study panels
 - First year \$ for grants to be distributed by end of Sept. 2009

NIH's NCRR

- \$1 billion to construct, renovate, or repair existing non-federal research facilities
- \$300 million for shared instrumentation and other capital equipment to recipients of grants and contracts

Other Funds of Interest

- Office of the Secretary: \$2 billion to Office of National Coordinator for Health Information Technology (section specifies that funds "remain available until expended")
- Prevention and Wellness Fund: \$1 billion
 administered through Office of Secretary;
 \$650 million to carry out evidence-based
 clinical and community-based prevention and
 wellness strategies that deliver specific,
 measurable health outcomes that address
 chronic disease rates

NIH's Working Plan for Allocating Stimulus Funds

- Support the best scientific opportunities
- Projects with the broadest impact
- Work that can be accomplished in two years

Accountability and Transparency

"Administration is committed to investing ARRA of 2009 with an unprecedented level of transparency and accountability."

- Accountability for every dollar spent
- Unprecedented level of required reporting
- Recovery.gov and NCI websites

Obama Administration

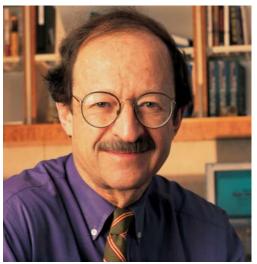


Kathleen Sebelius, nominee, Secretary of Health and Human Services

- Steven Chu, Energy Secretary
- John Holdren, Science Advisor



Eric Lander
co-chair of the
President's
Council of
Advisors on
Science and
Technology



Harold Varmus
co-chair of the
President's
Council of
Advisors on
Science and
Technology

Priorities of New Administration

- Healthcare coverage and affordability
- Access and quality of care
- Innovation through science
- Attracting and training the next generation
 - Cancer Centers network
 - NCCCP network
 - BIG Health[™] Consortium and IT history with (caBIG[®])
 - Biology to translation infrastructure
 - Clinical applications based on evidence



Cancer Community

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health

Meeting with Mark McClellan

Follow-on to Sept. 26, 2008 Brookings Institution Conference on Clinical Cancer Research

- Cancer can serve as a model: clinical applications based on evidence, IT infrastructure, basic biology, etc.
 - We must continue chipping away at barriers to clinical research and build a new model for development of targeted therapies
- It will be important to talk about the changes required in biomedical research within in the context of the new administration's priorities

Meeting with Mark McClellan

- Cancer is the arena for the investigation of molecular medicine
 - No other disease type has the necessary expertise and infrastructure
- Need to build partnerships to develop knowledge around molecular medicine in real-time situations
- Partnerships with CMS should be developed, to pay for diagnostic tests within a set of identified circumstances to allow for further study
- The opportunity to co-develop diagnostic and preventive interventions should be further explored – including effective biomarker validation

EC Scientific Retreat



Build interdisciplinary teams

2009 EC Retreat

Integrate all 'omics'

Study individuals
who are at high

Identify predictive

Create a

who are risk for d cancer are ar resista deve

 Real time assays of the stressors and responses that initiate and sustain cancer invent the icademic pproach to science eers/change vard systems

Measure and Measur

 Model the evolution of cancer with a focus on alterations in the stroma/niche/microenvironment

mprove realime imaging of cancer

Supplement high risk projects Understand the epigenetic changes that control the type and number of cancer cells

rect gene ronmental eractions with mechanisms of cancer

analy assets of asset populations based cohort studies

actual/real translational projects

NCI's Challenges

- Anticipate science: know where science and technology are leading us
- Improve our portfolio: fill the gaps and strengthen by soliciting and incentivizing
- Conduct science at the intersection of disciplines
- Facilitate our ability to maximally work across divisions
- Optimally use precious resources
- Ultimately, translate our findings

Two Cancer Leaders Lost

Dr. Stephen Williams

Founding director of Indiana University's Melvin and Bren Simon Cancer Center



BSC member and former vice president of epidemiology at the American Cancer Society





