



Vision for the NIH and the Role of the SMRB

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NIH Director

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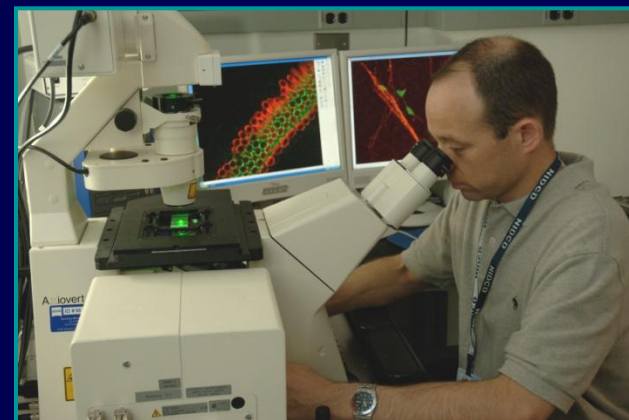
My first 94 days as NIH Director.....



NIH: Steward of Medical and Behavioral Research for the Nation



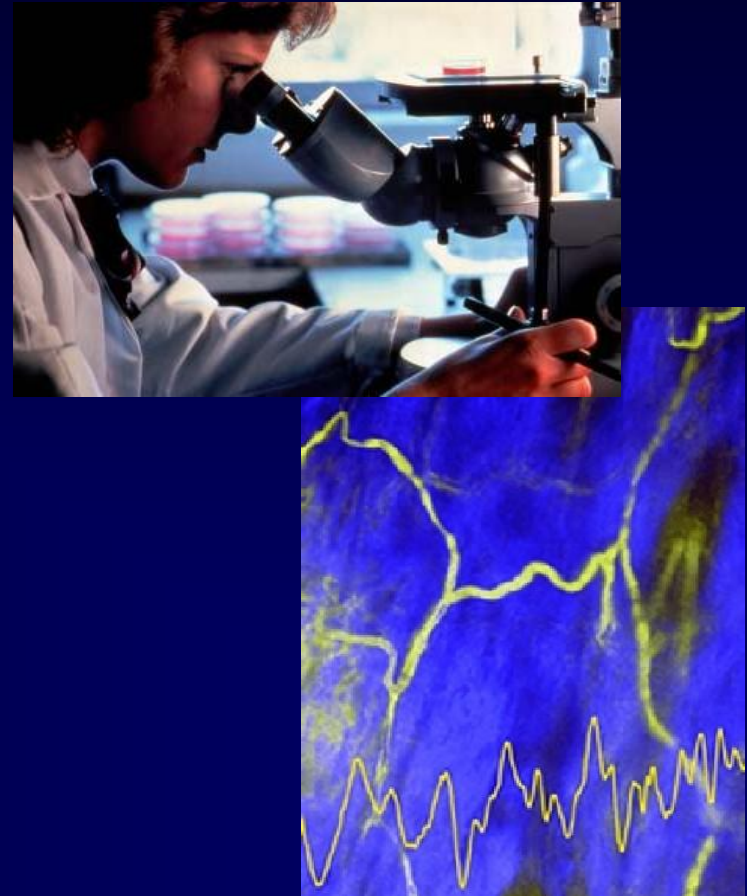
“Science in pursuit of **fundamental knowledge** about the nature and behavior of living systems... and the **application of that knowledge** to extend healthy life and reduce the burdens of illness and disability.”



Investigator-Initiated Research: *The Foundation of Biomedical Advances*

“... the hope of major advances lies in sustaining broad and free-ranging inquiry into all aspects of the phenomena of life, limited only by the criteria of excellence, the scientific importance, and the seriousness and competence of the investigator.”

**– James A. Shannon, M.D.
8th Director of NIH**



Opportunities in Biomedical Research

- **Opportunity #1:**
Applying unprecedented opportunities in genomics and other high throughput technologies to understand fundamental biology, and to uncover the causes of specific diseases



Opportunities in Biomedical Research

- **NextGen DNA sequencing and beyond**
- **Nanotechnology**
- **Small molecule screening**
- **New imaging modalities**
- **Emphasis on comprehensive approaches**
- **Computational biology is critical**
- **Examples that are ripe for expanded effort**
 - Cancer
 - Autism
 - Microbiome
 - Many more....

Opportunities in Biomedical Research

- Opportunity #2:

Translating basic science discoveries into new and better treatments

- Moving from...



Opportunities in Biomedical Research

- To...



Opportunities in Biomedical Research

- **Stage set for NIH to play an expanded role in translation**
 - New discoveries about the fundamental basis of disease
 - Resources empowering academic investigators to develop lead compounds and “de-risk” projects
 - Opportunity for public-private partnerships
- **Small molecules**
 - Roadmap provides HTS capabilities that now exceed that of most pharmaceutical companies
 - Many ICs are ramping up investments
 - Therapeutics for Rare and Neglected Diseases (TRND) program now explicitly tackles the Valley of Death
 - Common diseases are increasingly seen as a collection of rare diseases, so they fit this model too
- **Stem cells (including hESC and iPSC)**
 - Explosion of new information likely with new NIH policy
 - Therapeutic uses uncertain but urgent to pursue

Opportunities in Biomedical Research

- Opportunity #3:
Putting science to
work for the benefit of
health care reform



Opportunities in Biomedical Research

- **Comparative effectiveness research**
- **Prevention and personalized medicine**
 - Behavioral research
- **Health disparities research**
- **Pharmacogenomics**
- **Large scale prospective studies**
 - National Children's Study
 - Study of adult onset diseases?
- **Health IT**
- **Health research economics**
 - Going beyond clinical trials to studying health care delivery in the real world?
 - What payment incentives actually work to reduce costs and improve outcomes?

Opportunities in Biomedical Research

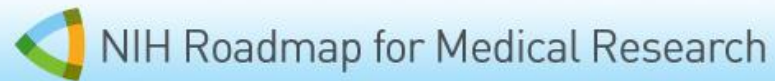
- Opportunity #4:
Encouraging a
greater focus on
global health



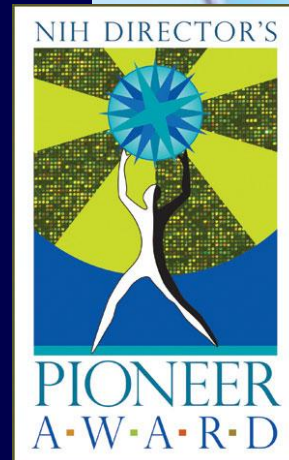
Opportunities in Biomedical Research

- **Emphasis on global health fits with U.S. emphasis on “soft power”**
- **Scientific advances make an attack on infectious diseases more feasible than ever**
 - RNAi
 - Small molecule screening
 - Genomics
 - Vaccine development
- **Push beyond AIDS, malaria, TB to long list of neglected tropical diseases (NTDs) affecting hundreds of millions of people worldwide**
- **Include chronic noncommunicable diseases and injuries, responsible for more 50% of deaths in developing world**

Opportunities in Biomedical Research



- Opportunity #5:
Reinvigorating and
empowering the
biomedical research
community



Opportunities in Biomedical Research

- **Strive to avoid the post-ARRA cliff**
- **Emphasis on innovation**
 - Pioneer awards
 - New Innovator awards
 - Transformative RO1s
- **Assessing results of current innovations in peer review**
- **Reinvigorating the Common Fund**
- **Training programs**
 - Seek to reduce age at first grant award
 - Underrepresented minority programs
 - Work force analysis – what's the right answer?

Advisory Committees

- **Four key external committees advise the NIH director:**
 - **Advisory Committee to the NIH Director**
(NIH Director co-Chairs)
 - **Council of Councils**
 - **Council of Public Representatives**
(NIH Director co-Chairs)
 - **Scientific Management Review Board**
(NIH Director is ex officio)

**“A committee is a cul-de-sac
down which ideas are lured and
then quietly strangled.”**

**Sir Barnett Cocks
(1907 -1989)**

**“It is better to give than to
receive – especially advice.”**

**Mark Twain
American Author and Lecturer
(1835 – 1910)**

Advisory Committee to the NIH Director

- **Focus:**
 - Program development
 - Resource allocation
 - NIH administrative regulation and policy
 - Other aspects of NIH policy
- **Specific Activity:**
 - Advises on grant applications and cooperative agreements for research and training



Council of Councils

- **Focus:**
 - **Policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives**
- **Specific Activities:**
 - **Advise on research responsive to emerging scientific opportunities, public health challenges, and knowledge gaps**
 - **Advise the IC Directors during review process for trans-NIH initiatives**

Council of Public Representatives

- **Focus:**
 - Public participation in NIH activities
 - Outreach and public communication efforts
 - Other matters of public interest
- **Specific Function:**
 - Provides a formal mechanism for public input into the research decision-making and priority-setting process



Scientific Management Review Board

- **Focus:**
 - Ensuring the optimal organizational structure and function for the fulfillment of NIH mission
- Recommendations are provided to NIH, HHS, and Congress



Unique Role of the SMRB

- **Statutorily-mandated committee to advise on the effective alignment of the Agency structure and function to achieve its goals**
- **SMRB recommendations will be relevant to the work of the other advisory committees**
 - **Periodic updates both to and from the ACD, CoC, and COPR**
 - **SMRB member also serves as ACD member**

Key Considerations for the SMRB

- **NIH as the “crown jewel” of the Federal government**
- **Any proposed changes require thorough evaluation and cautious consideration**
- **Principal driver of change:**
 - **NIH mission and the Agency’s ability to support the best science and address public health needs**

Specific Requests to the SMRB

- **Working groups:**

- **Deliberating Organizational Change and Effectiveness**

- Develop framework for assessing the need for change and develop principles for implementing recommended change*

- **NIH Intramural Research Program**

- Consider changes enabling the IRP to maximize human health and patient well being*

- **Substance Use, Abuse, and Addiction Research**

- Evaluate current organization in light of science and public health*

Looking Forward

- **SMRB recommendations that enhance NIH's ability to:**
 - **Maximize scientific discovery and innovation using new research technologies**
 - **Translate research into new diagnostics and therapeutics**
 - **Provide a scientific foundation for health care reform**
 - **Encourage a focus on global health**
 - **Reinvigorate and empower the research community**

Not failure, but low aim, is a crime.

— *James Russell Lowell*