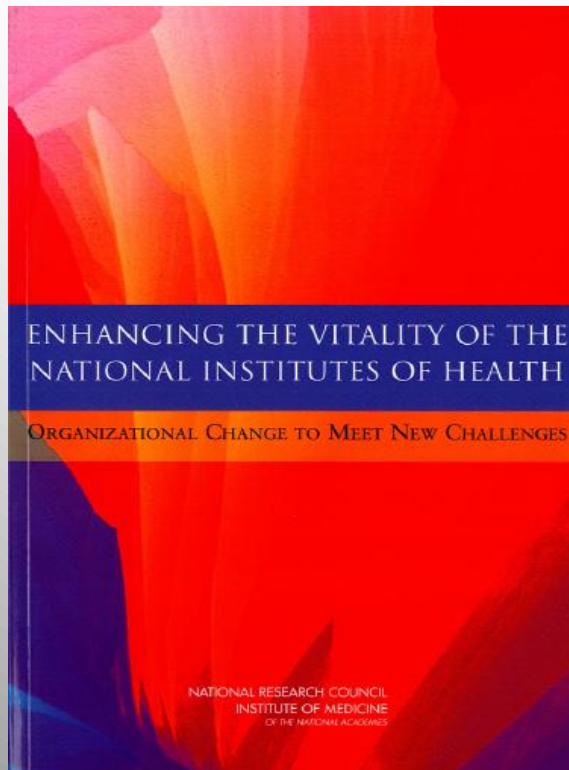


Enhancing the Vitality of the National Institutes of Health

Organizational Change to Meet New Challenges



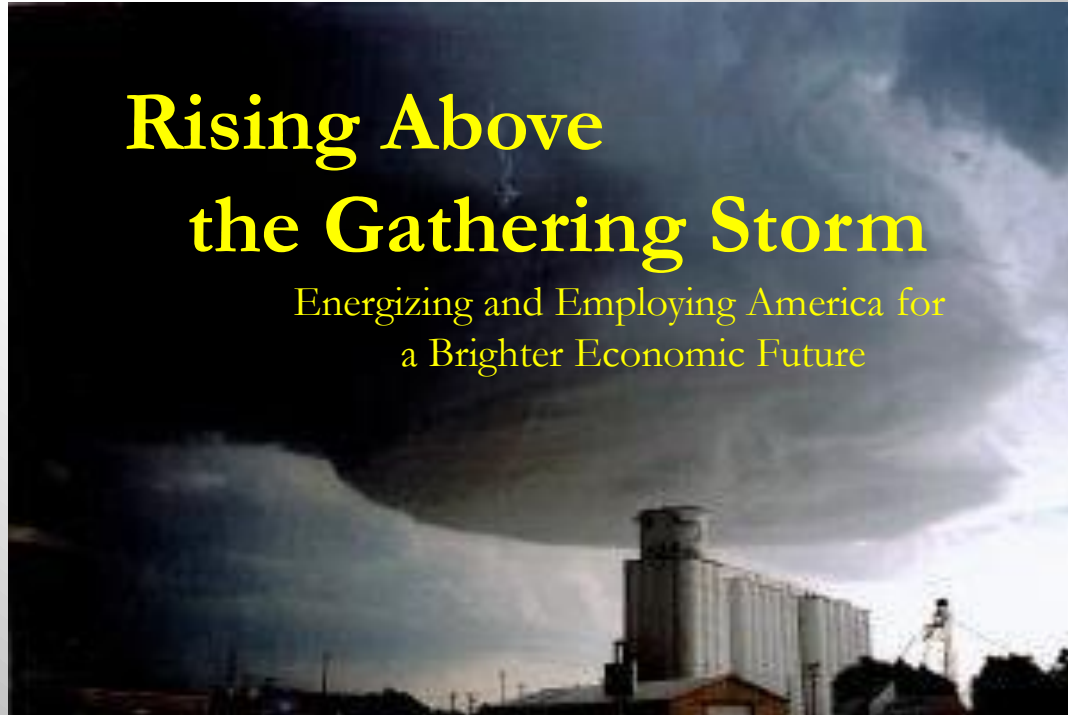
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Senior Vice President

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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

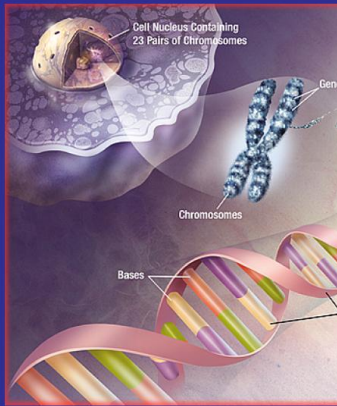
1. *Are there general principles by which NIH should be organized?*
2. *Does the current structure reflect these principles, or should NIH be restructured?*
3. *If restructuring is recommended, what should the new structure be?*
4. *How will the proposed new structure improve NIH's ability to conduct 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

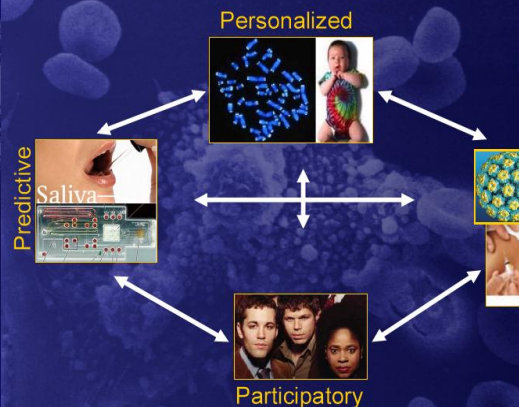
“The Congressional request for this study set a goal of determining the optimal organizational structure for NIH in the context of 21st century biomedical research science.”

- *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*

Toward a New Era in Medicine



The Future Paradigm: The 4 P's *Transform Medicine from Curative to Preemptive*





Guiding Wisdom - *STRUCTURE*

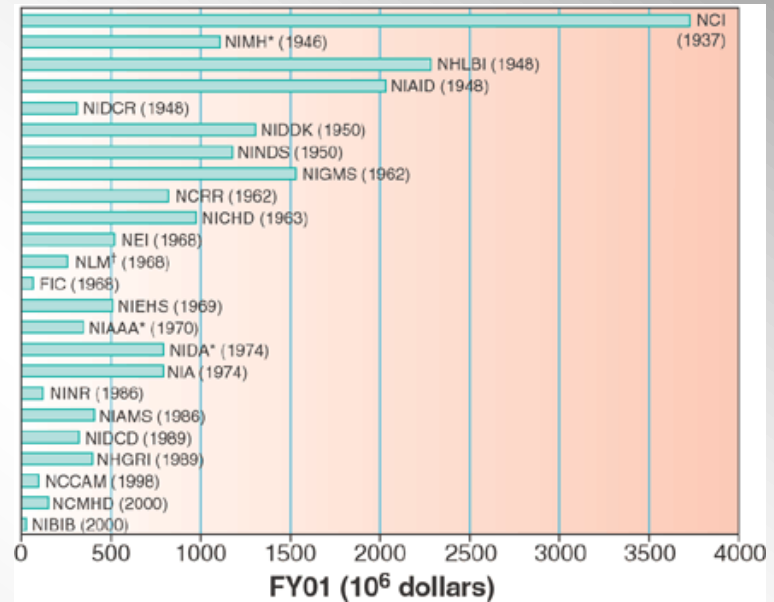
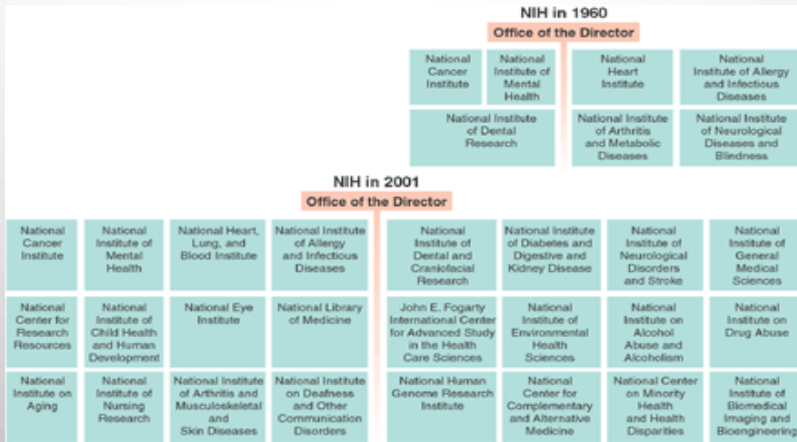
- *“The current situation is not only imperfect but is certainly not one that either the Congress or the scientific community would designate ab initio.”*
- The Committee conducted a thorough review the history of NIH; the accretion of ICs (*an organic system with no “programmed cell death”*)
- The Committee 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*



Re-engineering the Clinical Research Enterprise

People

- Promote interdisciplinary research and training
- Sunset the current system of general clinical research centers by 2012
- Stimulate creation of new academic entities dedicated to translational and clinical science (CTSAs).
- Re-invent translational sciences

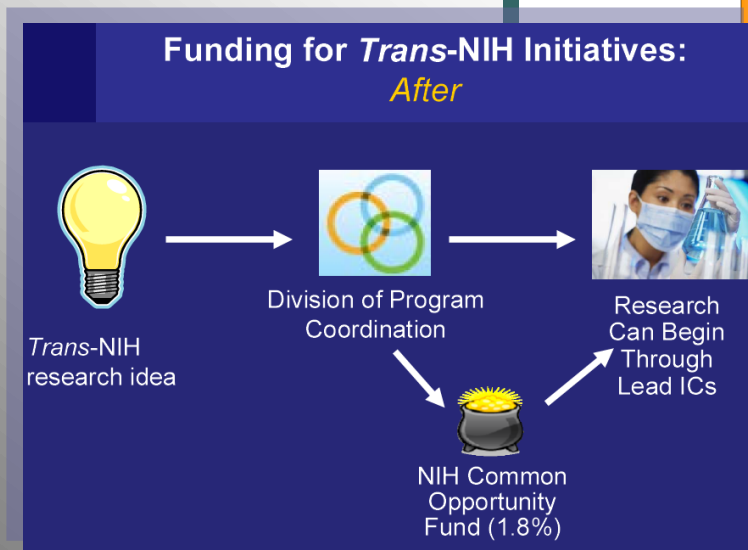
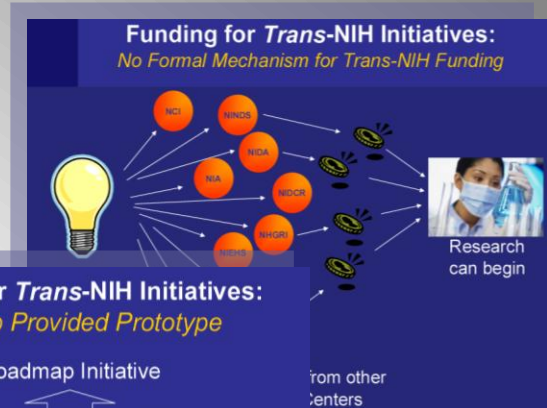
Science

Elias A. Zerhouni, M.D. Director, NIH January 2006

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

Opportunities for Tomorrow:
NIH Investing in New, Transformative Ideas



NIH will commit \$1 Billion over next 5 years to investigator-initiated high risk, high impact transformative research

- ✓ NIH Director's Pioneer Award
- ✓ New Innovator Award
- EUREKA Awards
- ✓ Transformative R01



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



**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 must 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*



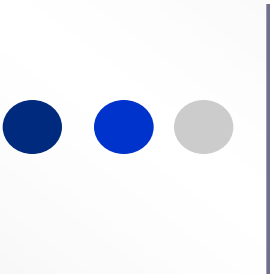
Specific Guidance on Key Issues Before SMRB

- *NIDA – NIAAAA merger?*
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- *Intramural Research at NIH?*
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- *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*

NIH Must be Able to Adapt its
Structure to Fulfill its Mission

Short-term → Streamlined Governance



NIH Reform Act Establishes:

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

Composition:

- 21 Members
 - 9 Institute and Center Directors
 - 12 external research and management experts



DISCUSSION

