



# THE COMMITTEE ON ENERGY AND COMMERCE

## INTERNAL MEMORANDUM

June 19, 2012

To: Members of the Subcommittee on Health

From: Health Subcommittee Staff

Re: Hearing on “The National Institutes of Health – A Review of Its Reforms, Priorities, and Progress”

On Thursday, June 21, 2012 at 10:00 a.m., the Subcommittee on Health will hold a hearing in room 2123 of the Rayburn House Office Building entitled “The National Institutes of Health – A Review of Its Reforms, Priorities, and Progress.” The hearing will review the implementation of the 2006 NIH Reform Act, the progress of the National Center for Advancing Translational Sciences, and the determination of NIH funding and research priorities.

### I. WITNESSES

*Francis S. Collins, M.D., Ph.D.*  
Director  
National Institutes of Health (NIH)

### II. BACKGROUND

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services (HHS), is the nation’s medical research agency. NIH is the largest source of funding for medical research in the world. NIH is made up of 27 Institutes and Centers (ICs), each with a specific research agenda, often focusing on particular diseases or body systems. NIH leadership plays an active role in shaping the agency's research planning, activities, and outlook.

Dr. Francis Collins was sworn in on August 17, 2009, as the sixteenth Director of NIH. The Office of the Director is the central office at NIH, responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components. The NIH Director is responsible for providing leadership to the Institutes and for constantly identifying needs and opportunities, especially for efforts that involve multiple Institutes.

More than 80 percent of the NIH \$30 billion budget goes to more than 300,000 research personnel at over 2,500 universities and research institutions. In addition, about 6,000 scientists work in NIH’s own Intramural Research laboratories, most of which are on the NIH main campus in Bethesda, Maryland. The main campus is also home to the NIH Clinical Center, the largest hospital in the world totally dedicated to clinical research.

### **III. NIH REFORM ACT OF 2006**

NIH was most recently reauthorized via the NIH Reform Act of 2006. The Act caps the number of Institutes and Centers at 27, provides the Director of NIH with expanded authority to manage the agency, encouraged ICs to collaborate on trans-NIH research, and reforms the agency's reporting system so that Congress can evaluate the NIH research portfolio.

Specific provisions of the law include:

- **Office of the Director (OD):** The law provides the Director of NIH with new oversight and coordination responsibilities across ICs. The Director of NIH, in consultation with Directors of the ICs, is responsible for program coordination, including conducting priority-setting reviews, to ensure that the NIH research portfolio is balanced, free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research.
- **Reorganization:** The law reaffirms the Secretary of HHS's authority to reorganize. ICs will be authorized to reorganize their divisions, centers, or other administrative units, including adding, removing, or transferring the functions of such units, following a series of public hearings and approval of the Director of NIH.
- **Scientific Management Review Board:** The law establishes a Scientific Management Review Board to conduct periodic organizational reviews. The Board is required to examine the use of NIH organizational authorities at least every 7 years, provide a report on its review, and make recommendations regarding the use of such authorities.
- **Division of Program Coordination, Planning, and Strategic Initiatives:** The law establishes a new Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director. The following program offices are moved within the Division: the Office of AIDS Research, Office of Research on Women's Health, Office of Behavioral and Social Sciences Research, Office of Disease Prevention, Office of Dietary Supplements, and Office of Rare Diseases.
- **Common Fund:** The Director of NIH has the authority to allocate Common Fund money to the ICs to fund trans-NIH research. Common Fund amounts will be reserved by the Director and subject to appropriations, but the percentage constituted by the amount reserved relative to the total appropriation in any fiscal year (FY) may not be less than the percentage from the preceding fiscal year.
- **Coding System:** The law requires the establishment of an electronic system to uniformly code research grants and activities.
- **Reporting:** ICs are required to annually report to the Director of NIH the amount of the IC budget made available for trans-NIH research. Most reports pertaining to NIH in current law were deleted and replaced with one biennial report to Congress, with instructions on the information that must be included. Additional reports with respect to collaboration with other HHS agencies, clinical trials, human tissue samples, whistleblowers, and experts and consultants are required. Reports also are required from

each institution receiving an NIH award for the training of graduate students for doctoral degrees.

- **Demonstration Programs:** The Director of NIH is authorized, in consultation with the Director of the National Science Foundation, the Secretary of the U.S. Department of Energy, and other agency heads as necessary, to allocate funds for ICs to make grants for interdisciplinary demonstration projects designed to improve public health.
- **Clinical and Translational Science Awards (CTSAs):** The Director of NIH is required to establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers in administering CTSAs.

#### **IV. SCIENTIFIC MANAGEMENT REVIEW BOARD**

NIH Reform Act of 2006 created a Scientific Management Review Board (SMRB). As the reform act provides the Director with much more discretion to change the administrative structure of NIH, the SMRB exists to study and report on the best way to use the new organizational authority. The board consists of NIH research institute heads in addition to individuals working for outside organizations, either private entities or academic institutions, that receive NIH funding. The SMRB provides a report at least every 7 years to the Director which includes a review of the existing research portfolio and analysis of its effectiveness, potential scientific opportunities, and, for any proposed organizational changes, stakeholder input and an estimate of the the budgetary and operational consequences.

#### **V. NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES**

In 2011, NIH abolished the National Center for Research Resources (NCRR) and created the National Center for Advancing Translational Science (NCATS) with the aim of improving the ease and rate by which scientific discoveries are utilized for new diagnostics and treatment advances and facilitate new drug development. NCATS was given a budget of \$575 million in FY2012, redirected from other NIH programs. The creation of NCATS was controversial due to the elimination of NCRR. The formation of NCATS caused concerned over whether the NIH was expanding its mission from medical research to drug development. The NIH has stated the mission of NCATS is to “catalyze the next generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions”. A pilot program, Discovering New Therapeutic Uses for Existing Molecules, has been established as a collaborative designed to develop partnerships between pharmaceutical companies and the biomedical research community to advance therapeutic development.

#### **VI. CONCLUSION**

This hearing will provide Members on the Health Subcommittee an opportunity to question Dr. Collins about the NIH budget, research priorities, organizational structure, Scientific

Management Review Board, and National Center for Advancing Translational Sciences, as well as other provisions of the 2006 NIH Reform Act.

**VII. STAFF CONTACTS**

For further information or questions about this hearing, please contact Brenda Destro or Ryan Long at (202) 225-2927.