

ONE HUNDRED ELEVENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

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**MEMORANDUM**

**June 11, 2010**

**To: Members of the Subcommittee on Health**

**Fr: Democratic Staff of the Subcommittee on Health**

**Re: Subcommittee Hearing on “NIH in the 21st Century: The Director's Perspective”**

On Tuesday, June 15, 2010, at 1:00 p.m. in room 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled “NIH in the 21st Century: The Director's Perspective.” The hearing will examine the National Institutes of Health’s research activities and priorities.

**I. BACKGROUND**

The National Institutes of Health (NIH) is the principal federal agency that conducts and supports biomedical and behavioral research. NIH’s stated mission is “to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.”<sup>1</sup> The agency’s four primary goals are to: (1) foster creative discoveries, innovative research strategies, and their applications to ultimately protect and improve health; (2) develop, maintain, and renew scientific resources that will enable the Nation to prevent disease; (3) expand the scientific knowledge base to enhance the Nation's economic well-being and ensure a continued return on the public investment in research; and (4) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility.

NIH’s research focuses on the causes, diagnosis, prevention, and cure of disease; human growth and development processes; biological effects of environmental contaminants; and understanding of mental, addictive, and physical disorders. The agency’s research spans the continuum of scientific discovery – from “bench to bedside.” These steps include: (1) making

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<sup>1</sup> National Institutes of Health, *About the National Institutes of Health: NIH Mission* (May 18, 2010) (online at [www.nih.gov/about/mission.htm](http://www.nih.gov/about/mission.htm)).

discoveries in a laboratory (basic research); (2) building on this research to develop innovations to prevent, detect, diagnose, and treat disease (translational research); and (3) testing the safety and efficacy of these innovations (clinical research).

NIH's work is conducted through its 27 institutes and centers. The Office of the Director is responsible for setting NIH's policy and planning, managing, and coordinating all programs and activities across the agency.<sup>2</sup>

Beginning in FY2011, NIH plans to continue to strengthen its translational and clinical research.<sup>3</sup> In testimony earlier this year, NIH identified four opportunities to further this strategy.<sup>4</sup> The first opportunity is through NIH's Therapeutics for Rare and Neglected Diseases (TRND) program, which seeks to bridge the gap in time and resources between basic research discoveries and human testing of new treatments by advancing promising compounds through initial clinical trials and generating data for an Investigational New Drug (IND) application. Second, NIH will invest in its Clinical and Translational Sciences Award Program, which funds interdisciplinary clinical teams that work to improve the efficiency and quality of clinical and translational research. The agency identified leveraging its proximity to the largest research hospital in the country, the Mark O. Hatfield Research Center (part of the NIH complex), as a third strategy. Fourth, the newly-formed Joint Leadership Council between NIH and the Food and Drug Administration (FDA) will allow for improved collaboration between biomedical research planning that occurs within NIH's purview and the regulatory review process overseen by FDA.

## **II. THE NATIONAL INSTITUTES OF HEALTH BUDGET**

President Obama's FY 2011 Budget requests \$32.2 billion for NIH, an increase of \$1.0 billion (or 3.2 percent) over FY 2010 enacted funding.<sup>5</sup> The total budget reflects funding for all NIH institutes and centers. The American Recovery and Reinvestment Act of 2009 (P.L. 111-5) allocated \$10.4 billion in supplemental NIH funding for FY 2009 and FY 2010. Approximately half of this funding (\$5.0 billion) was obligated in FY 2009.

## **III. RECENTLY-ENACTED LEGISLATION**

### **A. National Institutes of Health Reform Act of 2006**

NIH was most recently reauthorized in the NIH Reform Act of 2006 (P.L. 109-

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<sup>2</sup> National Institutes of Health, *NIH Organization* (May 18, 2010) (online at [www.nih.gov/about/organization.htm](http://www.nih.gov/about/organization.htm)).

<sup>3</sup> House Labor, Health and Human Services Subcommittee of the Committee on Appropriations, *Hearing on NIH FY2011 Budget*, 111th Cong. (Apr. 28, 2010).

<sup>4</sup> *Id.*

<sup>5</sup> National Institutes of Health Office of Budget, *Institute/Center Submissions: National Cancer Institute* (2010) (online at [officeofbudget.od.nih.gov/insti\\_center\\_subs.html](http://officeofbudget.od.nih.gov/insti_center_subs.html)).

482). It was previously reauthorized in 1993. The NIH Reform Act of 2006 focused on strengthening the Director's role and his/her ability to set an overall direction for NIH and foster increased research collaboration among institutes and centers.<sup>6, 7</sup> The Act also sought to ensure that NIH's research addresses current scientific opportunities and public health burden, and to improve evaluation efforts of the agency's research portfolio.<sup>8</sup> Several provisions within the Act were informed by recommendations of a 2003 Institute of Medicine report, *Enhancing the Vitality of the National Institute of Health: Organizational Change to Meet New Challenges*.<sup>9</sup>

Specific highlights of the 2006 legislation include the following<sup>10 11</sup>:

- Provides the Director with responsibility for coordination and oversight of all institutes and centers within NIH and explicit authority to make organizational changes to improve efficiency of the Director's Office. Requires the Director to ensure that research conducted or supported by NIH is subject to a peer-review process.
- Creates a "Common Fund" to support research activities identified by the newly-created Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director. Research priorities would include emerging scientific opportunities, rising public health challenges, or gaps in current knowledge that warrants special emphasis and would benefit from collaboration among multiple institutes and/or centers or strategic coordination and planning.
- Authorizes total funding levels for FY2007-FY2009 (\$30.33 billion for FY2007, \$32.83 billion for FY2008, and such sums for FY2009). The Act also eliminated institute, center, and program-specific authorization levels.
- Established a Scientific Management Review Board, comprised of institute and center leadership and other scientific experts, to review and provide recommendations on the organizational structure of the agency at least once every seven years.
- Creates an electronic, searchable reporting system to catalogue all NIH research.
- Requires submission of a biennial report to Congress on the agency's biomedical and behavioral research activities.

## **B. Patient Protection and Affordable Care Act (PPACA)**

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<sup>6</sup> House Committee on Energy and Commerce, *National Institutes of Health Reform Act of 2006*, 109th Cong. (2006) (H. Rept. 109-687).

<sup>7</sup> National Institutes of Health Reform Act of 2006, Pub. L. No. 109-482.

<sup>8</sup> *Supra* note 6.

<sup>9</sup> Institute of Medicine, *Enhancing the Vitality of the National Institute of Health: Organizational Change to Meet New Challenges* (2003) (online at [www.nap.edu/catalog.php?record\\_id=10779](http://www.nap.edu/catalog.php?record_id=10779)).

<sup>10</sup> *Supra* note 7.

<sup>11</sup> National Institutes of Health Office of Legislative Policy and Analysis, *National Institutes of Health Reform Act of 2006* (2010) (online at [olpa.od.nih.gov/legislation/109/publiclaws/reformact06.asp](http://olpa.od.nih.gov/legislation/109/publiclaws/reformact06.asp)).

PPACA (P.L. 111-148) includes several provisions that affect NIH authorities.<sup>12</sup> Most notably, PPACA authorizes the Cures Acceleration Network (CAN) program and elevates the National Center on Minority Health and Health Disparities to institute status. NIH will also play an integral role in the implementation of Patient-Centered Outcomes Research provisions. Finally, there are research provisions that encourage NIH to continue current activities, such as: (1) research on the causes and potential treatments of pain, and (2) research on the etiology and causes of and development and evaluation of treatments for postpartum depression or psychosis.

Like TRND, the purpose of CAN is to translate promising discoveries into new, approved therapies by awarding grants and contracts to accelerate their development. However, CAN's scope is broader than rare and neglected diseases and the focus instead is supporting research "to accelerate the development of 'high-need cures'."<sup>13</sup> To achieve this goal, CAN's primary functions include the provision of needed resources to government agencies, researchers, and industry; reduction of barriers between basic scientific discoveries and clinical trials; and facilitation of FDA review. CAN will be administered by the NIH Director and guided by a board comprised of scientific experts, venture capitalists, and patient advocates.

#### **IV. CURRENT LEADERSHIP**

On August 17, 2009, Dr. Francis S. Collins was sworn in as the 16<sup>th</sup> NIH director, succeeding Dr. Elias A. Zerhouni.<sup>14</sup> Dr. Collins was nominated to this position by President Obama on July 8, 2009 and unanimously confirmed by the U.S. Senate on August 7, 2009. He is a physician-geneticist and holds a doctorate in philosophy (Ph.D.) in physical chemistry, in addition to a medical degree (M.D.).

Dr. Collins previously served as director of one of NIH's institutes, the National Human Genome Research Institute (NHGRI) from 1993 to 2008. While Director of NHGRI, he led the Human Genome Project, a comprehensive effort to understand genetic factors in human disease by sequencing all human DNA. This project was completed under budget and more than two years ahead of schedule. Thus far, the Human Genome Project has resulted in the discovery of over 1,800 genes that cause disease.<sup>15</sup>

In addition to his accomplishments while at NHGRI, Dr. Collins' research laboratory has generated discovery of important genes, including those responsible for cystic fibrosis, neurofibromatosis, Huntington's disease, and type 2 diabetes. Dr. Collins is a recipient of both the Presidential Medal of Freedom and National Medal of Science, and he is an elected member of the Institute of Medicine and the National Academy of Sciences.

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<sup>12</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148.

<sup>13</sup> *Id.*

<sup>14</sup> National Institutes of Health, *Biographical Sketch of Francis S. Collins, M.D., Ph.D.* (Mar. 12, 2010) (online at [www.nih.gov/about/director/directorbio.htm](http://www.nih.gov/about/director/directorbio.htm)).

<sup>15</sup> National Institutes of Health, *Human Genome Project* (2010) (online at [www.nih.gov/about/researchresultsforthepublic/HumanGenomeProject.pdf](http://www.nih.gov/about/researchresultsforthepublic/HumanGenomeProject.pdf)).

**V. WITNESSES**

The following witness has been invited to testify:

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