

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Budget Request for FY 2010

Witness appearing before the
Senate Subcommittee on Labor-HHS-Education Appropriations

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National Institute of Allergy and Infectious Diseases

May 21, 2009

Mr. Chairman and Members of the Committee:

I am pleased to present the President's Fiscal Year 2010 Budget request for the National Institute of Allergy and Infectious Diseases (NIAID), of the National Institutes of Health (NIH). The FY 2010 budget includes \$4,760,295,000, which is \$57,723,000 more than the FY 2009 appropriation of \$4,702,572,000.

NIAID conducts and supports biomedical research to understand, treat, and prevent infectious and immune-mediated diseases of domestic and global concern, including HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, emerging and re-emerging infectious diseases. NIAID's budget request and its research projects are consistent with the President's multi-year commitment for Cancer and Autism. As economies and societies around the world have become increasingly interdependent, responding to emerging infectious diseases, such as the 2009-H1N1 influenza virus, as well as to long-established health challenges such as neglected tropical diseases, has taken on new urgency. As we address infectious diseases in a global context, we have the added benefit of contributing to preparedness against the threat of bioterrorism and naturally occurring disease outbreaks. Meanwhile, our ongoing research on domestic health challenges such as HIV/AIDS, influenza, and asthma, allergies, and other immune-mediated diseases continues to yield important advances. Using a multidisciplinary approach that engages academic, industry, governmental, and non-governmental partners, NIAID remains committed both to basic immunology and infectious disease research and the application of this knowledge to the development of strategies to detect, prevent, and treat these diseases.

The research activities of NIAID will become more important than ever, as current and as-yet unrecognized health threats, particularly in the context of the inevitability of emerging and re-emerging infectious diseases, will require new diagnostic, preventive, and therapeutic interventions. These new tools promise to have a great impact on the public health over the next two decades.

We have long known that the threats posed by infectious microbes do not remain static, but change over time as new microbes emerge and familiar ones re-emerge with new properties or in new settings. This will not change in the coming decades. Addressing these global threats requires that we consider infectious diseases not through the lens of individual diseases, infections, or microbes in a vacuum, but by understanding how diseases interact in people with multiple health issues. Only then can we develop the tools for a comprehensive and practical approach to global health.

Tuberculosis (TB) is a prototypic example of a re-emerging threat as an increase in the prevalence of drug-resistant forms of TB presents major challenges to the control of this disease. TB also is an example of a disease that often occurs with other infectious diseases such as HIV/AIDS—people co-infected with TB and HIV appear to have a more rapid and deadly disease course. Recently, NIAID-supported clinical trials have shown that mortality among TB patients co-infected with HIV is remarkably reduced when antiretroviral (ARV) therapy is provided at the same time as TB therapy. Additional studies are under way to determine optimal strategies for the prevention, treatment and diagnosis of TB in the setting of HIV infection. NIAID continues to conduct and support research to create a foundation of knowledge for the discovery of new diagnostics, drugs and vaccines for TB, including drug-resistant TB. The Institute's support for public-private partnerships has been instrumental in linking research across sectors to build a robust pipeline of tools to combat TB.

Malaria continues to exact a devastating toll on individuals worldwide, mostly among children in sub-Saharan Africa. Compounding the problem is the emergence of drug-resistant malaria parasites and insecticide-resistant mosquito vectors. In 2008, the Institute released the *NIAID Strategic Plan for Malaria Research* and the *NIAID Research Agenda for Malaria*. The *Plan* and *Agenda* outline our efforts to accelerate control and move toward eradication of malaria through biomedical research, including the development of prevention modalities, promising drugs and vaccine candidates. Accomplishing these goals will require the support and cooperation of malaria researchers and other organizations to build on the foundation of NIAID's basic

research program in malaria. Over the next two decades, we hope to have a major impact on global TB and malaria burden through the development of vaccines that protect against these infectious killers.

Seasonal influenza, which changes slightly every year, is the classic example of a re-emerging infectious disease. Influenza viruses also can undergo more drastic genetic changes that periodically enable them to evade pre-existing immunity and cause a pandemic, such as the deadly influenza pandemic in 1918 that killed more than 50 million people worldwide. NIAID has seen significant progress in its influenza research program, particularly in the area of pandemic influenza preparedness. This progress has prepared the Institute to respond rapidly to the newly identified 2009-H1N1 influenza virus, which has emerged as a public health threat in the United States, Mexico, and throughout the world. NIAID-funded researchers have responded quickly to this new threat, characterizing the virus and preparing for the development of a vaccine and other countermeasures.

Nearly 28 years since the first cases of AIDS were documented, the terrible burden of HIV/AIDS continues to grow. The 2.7 million new infections worldwide in 2007 underscore the continuing urgency of the global AIDS pandemic, and sobering HIV/AIDS statistics in the District of Columbia remind us that the AIDS epidemic here in the United States demands our strongest efforts. Over the past two decades, NIH and NIAID—supported by Congress and by this Committee—have devoted substantial resources to the fight against HIV/AIDS.

Worldwide, for every two people who receive antiretroviral (ARV) treatment, five others are newly infected. Therefore, our first priority in the fight against HIV/AIDS is prevention. NIAID-supported investigators have made great strides in advancing our understanding of the modalities of effective prevention, including those that prevent mother-to-child transmission of HIV. NIAID-supported research recently determined that medically supervised circumcision of adult males markedly reduces the risk of HIV acquisition through heterosexual intercourse for at least 3.5 years after the

procedure, demonstrating long-term efficacy of male circumcision as a prevention tool. Research conducted by our Microbicide Trials Network found the microbicide gel PRO 2000 to be safe and showed the first suggestion of potential efficacy among several clinical trials with other products. Of course, the most powerful prevention tool would be a safe and effective HIV vaccine. In response to the significant challenges that U.S. and international vaccine investigators have experienced in HIV vaccine development, NIAID has expanded our basic vaccine discovery research portfolio to provide the knowledge necessary to identify a viable HIV vaccine candidate. Our hope is that these advances in HIV prevention research will become part of a comprehensive HIV prevention “toolkit” that will markedly decrease new infections over the next two decades.

In addition to these prevention modalities, NIAID is boldly advancing three new approaches to HIV prevention. Together with government and nongovernmental partners, the Institute is investigating the feasibility of pre-exposure prophylaxis (PrEP) for HIV prevention, which involves providing ARVs to HIV-negative individuals who are at high risk of HIV infection. Second, recent modeling data have shown that aggressive HIV testing and treatment potentially could reduce the number of new HIV cases by 95 percent in the next decade; NIAID is evaluating critical research questions that underpin the validity of this voluntary “test and treat” approach. Finally, NIAID is expanding its efforts to find a cure for HIV/AIDS. Through research to improve our basic understanding of HIV viral latency, we hope to achieve long-term HIV remission following discontinuation of effective therapy – a “functional” cure – or, ultimately, a complete eradication of residual virus.

Since the acceleration of our biodefense research program in FY 2003, NIAID has achieved major successes in the development of countermeasures against significant bioterrorism threats. Some countermeasures have been fully developed and are stockpiled or available for use in an emergency; others in the pipeline have been transferred to the HHS Biomedical Advanced Research and Development Authority for advanced development. Promising candidate countermeasures in development include

ST-246, a smallpox drug candidate that has protected animals from an otherwise lethal exposure to live poxviruses.

Equally important, NIAID has developed a physical and intellectual research infrastructure that has been critical to our ability to respond to new and re-emerging infectious diseases. This year, the Institute recompeted the Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), which comprise a network of 11 regionally based, multi-institutional centers engaged in interdisciplinary research to develop vaccines, therapeutics, adjuvants and diagnostics for biodefense and emerging infectious diseases.

Autoimmune diseases, allergic diseases, asthma, rejection of transplanted organs, and other immune-mediated disorders are significant causes of chronic disease and disability in the United States and throughout the world. NIAID-supported research in immunology and immune-mediated diseases has led to significant advances in our understanding of the mechanisms underlying these diseases and in the development of strategies to detect, prevent, and treat them.

For example, food allergies affect the health and quality of life of many Americans, particularly young children. NIAID remains committed to basic research and clinical studies to advance the understanding of food allergy and food allergy-associated anaphylaxis. In June 2008, NIAID awarded 12 two-year grants, totaling \$2.5 million, to investigators to lead high-impact, innovative studies of food allergy under the *Exploratory Investigations in Food Allergy* initiative. Cosponsored with the Food Allergy and Anaphylaxis Network (FAAN), the Food Allergy Project, and the U.S. Environmental Protection Agency, this program supports innovative pilot studies on the mechanisms of food allergy, with a goal of attracting new investigators to the field of food allergy research. We plan to renew this program in FY 2010.

NIAID also continues to support clinical trials to prevent the development of food allergies and to reverse established allergy to milk, eggs, and peanut. Lastly,

NIAID, in collaboration with professional societies, advocacy groups, and other federal agencies, is developing clinical guidelines to provide guidance to medical practitioners on the diagnosis, management, and treatment of food allergies.

For more than six decades, NIAID has conducted and supported basic research on infectious and immune-mediated diseases that has underpinned the development of vaccines, therapeutics, and diagnostics. These, in turn, have improved health and saved millions of lives in the United States and around the world. Through partnerships with academic, industry, governmental, and non-governmental partners, the Institute will continue to leverage these fundamental discoveries into the tools needed to achieve a healthy world.

BIOGRAPHY DR. ANTHONY S. FAUCI

Dr. Anthony S. Fauci, a native of Brooklyn, New York, received his M.D. degree from Cornell University Medical College in 1966. He then completed an internship and residency at The New York Hospital-Cornell Medical Center. In 1968, Dr. Fauci came to the National Institutes of Health (NIH) as a clinical associate in the Laboratory of Clinical Investigation (LCI) at the National Institute of Allergy and Infectious Diseases (NIAID). In 1980, he was appointed Chief of the NIAID Laboratory of Immunoregulation, a position he still holds. In 1984, Dr. Fauci became Director of NIAID, where he oversees an extensive research portfolio of basic and applied research to prevent, diagnose, and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies. The NIAID budget for fiscal year 2008 is approximately \$4.4 billion. Dr. Fauci serves as one of the key advisors to the White House and Department of Health and Human Services on global AIDS issues, and on initiatives to bolster medical and public health preparedness against emerging infectious disease threats such as pandemic influenza.

Dr. Fauci has made many contributions to basic and clinical research on the pathogenesis and treatment of immune-mediated and infectious diseases. He has pioneered the field of human immunoregulation by making a number of basic scientific observations that serve as the basis for current understanding of the regulation of the human immune response. In addition, Dr. Fauci is widely recognized for delineating the precise mechanisms whereby immunosuppressive agents modulate the human immune response. He has developed effective therapies for formerly fatal inflammatory and immune-mediated diseases such as polyarteritis nodosa, Wegener's granulomatosis, and lymphomatoid granulomatosis. A 1985 Stanford University Arthritis Center Survey of the American Rheumatism Association membership ranked the work of Dr. Fauci on the

treatment of polyarteritis nodosa and Wegener's granulomatosis as one of the most important advances in patient management in rheumatology over the previous 20 years.

Dr. Fauci has made seminal contributions to the understanding of how the AIDS virus destroys the body's defenses leading to its susceptibility to deadly infections. He also has delineated the mechanisms of induction of HIV expression by endogenous cytokines. Furthermore, he has been instrumental in developing highly effective strategies for the therapy of patients with this serious disease, as well as for a vaccine to prevent HIV infection. He continues to devote much of his research time to identifying the nature of the immunopathogenic mechanisms of HIV infection and the scope of the body's immune responses to the AIDS retrovirus.

In 2003, an Institute for Scientific Information study indicated that in the twenty year period from 1983 to 2002, Dr. Fauci was the 13th most-cited scientist among the 2.5 to 3 million authors in all disciplines throughout the world who published articles in scientific journals during that time frame. Dr. Fauci was the world's 10th most-cited HIV/AIDS researcher in the period 1996-2006.

Through the years, Dr. Fauci has served as Visiting Professor at major medical centers throughout the country. He has delivered many major lectureships all over the world and is the recipient of numerous prestigious awards for his scientific accomplishments, including the Presidential Medal of Freedom, the National Medal of Science, the George M. Kober Medal of the Association of American Physicians, the Mary Woodard Lasker Award for Public Service, the Albany Medical Center Prize in Medicine and Biomedical Research, and 34 honorary doctorate degrees from universities in the United States and abroad.

Dr. Fauci is a member of the National Academy of Sciences, the American Academy of Arts and Sciences, the Institute of Medicine (Council Member), the American Philosophical Society, and the Royal Danish Academy of Science and Letters, as well as a number of other professional societies including the American College of Physicians, the American Society for Clinical Investigation, the Association of American

Physicians, the Infectious Diseases Society of America, the American Association of Immunologists, and the American Academy of Allergy Asthma and Immunology. He serves on the editorial boards of many scientific journals; as an editor of Harrison's Principles of Internal Medicine; and as author, coauthor, or editor of more than 1,100 scientific publications, including several textbooks.

Department of Health and Human Services
Office of Budget
Richard J. Turman

Mr. Turman is the Deputy Assistant Secretary for Budget, HHS. He joined federal service as a Presidential Management Intern in 1987 at the Office of Management and Budget, where he worked as a Budget Examiner and later as a Branch Chief. He has worked as a Legislative Assistant in the Senate, as the Director of Federal Relations for an association of research universities, and as the Associate Director for Budget of the National Institutes of Health. He received a Bachelor's Degree from the University of California, Santa Cruz, and a Masters in Public Policy from the University of California, Berkeley