

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2014 Budget Request

Statement for the Record

Senate Subcommittee on Labor-HHS-Education Appropriations

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Director, National Institute of Allergy and Infectious Diseases

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Mr. Chairman and Members of the Committee:

I am pleased to present the President's Budget request for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The fiscal year (FY) 2014 NIAID budget of \$4,578,813,000 includes an increase of \$96,444,000 over the comparable FY 2012 level of \$4,482,369,000.

NIAID conducts basic and clinical research with the ultimate goal of improving human health through the development of diagnostics, therapeutics, and vaccines for infectious diseases; and to increase our understanding of the immune system, how it protects us from infection and disease, and its role in immune-mediated diseases. NIAID also addresses the scientific challenges that arise from emerging and re-emerging infectious diseases, including influenza, HIV/AIDS, tuberculosis, and malaria.

INFECTIOUS DISEASES RESEARCH

HIV/AIDS. Through more than 30 years of supporting and conducting basic and clinical research, NIAID has provided the scientific foundation for groundbreaking interventions and strategies to treat and prevent HIV/AIDS, including combination antiretroviral therapy (ART), pre-exposure prophylaxis (PrEP), medical male circumcision, prevention of mother-to-child transmission (PMTCT), microbicides, and antiretroviral treatment as prevention. It is an exciting time in the domestic and global fight against HIV/AIDS, and NIAID continues to support research critical to a goal now within our reach: an AIDS-free generation. The NIAID-funded HPTN-052 clinical trial—the *Science* magazine 2011 Breakthrough of the Year—conclusively demonstrated that treatment of the HIV-infected person in a stable heterosexual relationship with an uninfected partner dramatically reduces the likelihood of

transmitting HIV to the uninfected partner. Recently, based upon results of the NIAID-funded iPrEx study and other research, the Food and Drug Administration (FDA) approved the ART combination drug Truvada[®] as a prevention tool for uninfected adults at high risk of acquiring HIV. Ongoing NIAID studies of PrEP, microbicides, and PMTCT are exploring new strategies to limit HIV transmission in various populations; one study (TLC-Plus) is evaluating the feasibility of a community-level “testing, link to care, and treatment” strategy; and the new population-based ART study (PopART) will determine the effects of universal testing and immediate ART on HIV transmission.

NIAID continues its longstanding efforts to develop an effective HIV vaccine. NIAID is currently investigating the reasons for the modest efficacy (31% protection) of the HIV vaccine candidates used in the RV-144 clinical trial conducted in Thailand several years ago, and will seek to achieve significantly better results with future vaccine candidates. In this regard, NIAID has funded two new HIV vaccine initiatives and also is moving into Phase I clinical trials to determine if passively transferred neutralizing antibodies can protect against HIV infection.

Tuberculosis and Malaria. Drug-resistant forms of tuberculosis (TB) are emerging worldwide, and co-infection with TB and HIV is a major cause of morbidity and mortality in the developing world. NIAID is helping to bring TB research into the 21st century by applying microbial genomic sequencing technologies, investing in the basic science underlying point-of-care diagnostics, supporting research to develop vaccine candidates, and engaging in public-private partnerships for drug development. These efforts are bearing fruit: NIAID researchers showed the potential of linezolid (originally developed for staphylococcal infections) as a treatment for extensively drug-

resistant TB, and FDA recently approved the first new TB drug (bedaquiline) in decades.

NIAID continues its work to combat malaria. To counter the emerging resistance to artemisinin, a first-line malaria drug, NIAID scientists have identified a region in the genome of the parasite linked to artemisinin resistance. NIAID is pursuing its promising efforts to develop candidate malaria vaccines, including studies conducted at the NIH Clinical Center.

Other Infectious Diseases of Domestic and Global Health Importance. Events in the news remind us almost on a daily basis of the global threat of emerging and re-emerging infectious diseases. Paramount among these are seasonal influenza and potential pandemic influenza threats, such as the H7N9 influenza emerging in China. NIAID conducts research on the pathogenesis and transmissibility of influenza, and the emergence of epidemics and pandemics, with the goal of furthering the development of influenza diagnostics, therapeutics, and vaccines. We have made significant strides toward developing a universal influenza vaccine, which would obviate the need for annual influenza vaccination and enhance our ability to respond to the emergence of influenza pandemics. Though it will be years before this goal is achieved, NIAID grantees and scientists, including those at NIAID's Vaccine Research Center, have demonstrated success in animal models, and have begun Phase I trials in humans. In addition, the NIAID Human Immunology Project Consortium is characterizing human immune responses to improve vaccines and immunotherapeutics for a variety of infectious diseases, including influenza.

NIAID scientists have developed an animal model to study the novel coronavirus recently identified in Saudi Arabia, and to evaluate potential treatments and vaccines. They have shown recently that a combination of two antiviral drugs, ribavirin and interferon, can inhibit replication of the virus in cell culture.

Common microbial infections are increasingly becoming resistant to the drugs generally used to treat them. Methicillin-resistant *Staphylococcus aureus* (MRSA) has been a longstanding problem. Of particular concern is the recent emergence of other antibiotic-resistant organisms such as the carbapenem-resistant Enterobacteriaceae (CRE) including *Klebsiella pneumoniae*. To address the challenge of antimicrobial resistance, NIAID continues its efforts in the development and testing of vaccines to prevent these infections, and in the evaluation of new and repurposed drugs to treat antimicrobial-resistant organisms. This year, NIAID will establish a leadership group for a national network to conduct clinical research on antibacterial resistance.

We are witnessing rapid changes in the treatment of hepatitis C virus (HCV), a major cause of chronic liver disease and a common co-infection with HIV. Promising new HCV protease inhibitor drugs recently approved by FDA were developed with the help of NIAID and other NIH Institutes. NIAID also is collaborating with industry to develop new HCV therapeutics and vaccines, and to test approved drugs in individuals with HCV/HIV co-infection.

NIAID biodefense research continues to build on our fundamental understanding of the biology of and immune response to microbes. Recent successes include FDA approval of a monoclonal antibody to treat anthrax and progress on vaccines against Ebola and other hemorrhagic fever viruses. NIAID biodefense research also addresses

the global threat of emerging and re-emerging diseases, including the development of vaccines for dengue fever and animal models to study West Nile virus.

RESEARCH ON IMMUNOLOGY AND IMMUNE-MEDIATED DISORDERS

NIAID remains committed to basic and clinical research on the immune system and immune-mediated diseases, including the development and testing of adjuvants to enhance the immune response to vaccination. NIAID also supports groundbreaking studies in the treatment of food allergy, a significant concern for many Americans. Recently, NIAID-funded scientists found that oral egg immunotherapy can reduce and even eliminate allergic responses for extended periods in certain children. Similarly promising results showed that peanut immunotherapy given under the tongue can reduce the allergic response in adolescents and adults.

CONCLUSION

NIAID conducts critical research on infectious and immune-mediated diseases that ultimately will enable interventions to improve health domestically and worldwide. Understanding and developing countermeasures against microbes that threaten our public health is central to NIAID's mission. NIAID will continue to fund meritorious basic and clinical research with the ultimate goal of translating these discoveries into global public health benefits.

Anthony S. Fauci, M.D.

Director, National Institute of Allergy and Infectious Diseases

Dr. Fauci was appointed Director of NIAID in 1984. 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 request for fiscal year 2014 is approximately \$4.6 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. He was one of the principal architects of the President's Emergency Plan for AIDS Relief (PEPFAR), which has already been responsible for saving millions of lives throughout the developing world.

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 20-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 delivered many major lectures 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, the Robert Koch Gold Medal and 38 honorary doctoral 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 Sciences 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 & 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 1,200 scientific publications, including several textbooks.