

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2013 Budget Request

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

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Mr. Chairman and Members of the Committee:

I am pleased to present the President's Fiscal Year (FY) 2013 budget request for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The FY 2013 NIAID budget of \$4,495,307,000 includes an increase of \$10,210,000 over the comparable FY 2012 level of \$4,485,097,000.

NIAID conducts and supports biomedical research to understand, treat, and prevent infectious and immune-mediated diseases, including HIV/AIDS, tuberculosis, malaria, influenza, emerging and re-emerging infectious diseases, asthma and allergic diseases, autoimmune diseases, and the rejection of transplanted organs. I appreciate the opportunity to highlight our recent scientific advances and to describe some of our most promising research aimed at improving public health and quality of life.

INFECTIOUS DISEASES RESEARCH

HIV/AIDS. In the 30 years since AIDS was first recognized in the United States, the substantial NIAID investment in basic, translational, and clinical HIV/AIDS research supported consistently by this Committee has resulted in many groundbreaking discoveries. With this commitment, we have made significant progress, including strengthening HIV prevention efforts and developing nearly 30 antiretroviral drugs to suppress HIV. Thirty years ago, HIV/AIDS was for the most part a death sentence. Today, if a young person enters the clinic with early HIV disease and begins appropriate therapy, he or she can expect to live a near-normal lifespan, a milestone unimaginable at the start of the HIV/AIDS pandemic.

I am pleased to report landmark advances and opportunities in HIV/AIDS research this year. In December 2011, the journal *Science* named an NIAID-funded international HIV prevention study its *Breakthrough of the Year*, reinforcing that the investment in NIH research continues to pay extraordinary dividends for public health. This study, known as HPTN 052, demonstrated that HIV-infected heterosexual individuals who began taking antiretroviral medicines when their immune systems were still relatively healthy, rather than later, were 96 percent less likely to transmit the virus to their uninfected sexual partners. This study convincingly demonstrates that antiretrovirals not only can be life-saving to people infected with HIV, but also can prevent transmission of the virus to their uninfected sexual partners. Other studies have shown that medically supervised adult male circumcision has proven to be highly effective and durable in preventing the acquisition of HIV infection. In addition, pre-exposure prophylaxis of at-risk uninfected individuals may be an important means of preventing HIV infection.

HIV vaccines still represent the best long-term hope for ending the HIV pandemic. Building on the promising results of the U.S. Army-NIAID RV144 HIV vaccine clinical trial, which found a “prime-boost” vaccine candidate to be safe and modestly effective at preventing acquisition of HIV, NIAID is working to understand the immune mechanisms that explain these results, to optimize the protective immune responses elicited by the vaccine candidate, and to develop and evaluate new vaccine candidates. We also are encouraged by the discovery by NIAID-supported scientists of human antibodies that can block a wide range of HIV strains. We are expanding

clinical testing in this area, and insights gained from these studies will guide future HIV vaccine research.

These research advances taken together with the implementation of other evidence-based HIV prevention and treatment strategies make the possibility of an “AIDS-free generation” in the foreseeable future eminently feasible. This July, we will consider strategies to implement these important findings during the International AIDS Society Conference in Washington, D.C.

Tuberculosis and Malaria. NIAID continues to invest in basic and clinical research and collaborate with global partners, including the World Health Organization’s Stop TB Partnership, to combat the co-infections that often accompany HIV infection, including tuberculosis (TB) and malaria. Building on these efforts, we now have a substantial development pipeline of TB treatments and vaccines. NIAID has developed a *Strategic Blueprint for TB Vaccines* that proposes new research pathways for achieving a licensed TB vaccine. For malaria, NIAID supported early-stage basic research that ultimately led to the development by others of the first moderately successful malaria vaccine candidate aimed particularly for children, RTS,S/AS01, a *Science Runner-Up Breakthrough of the Year* in 2011. In addition, the NIAID Vaccine Research Center is partnering with a biotechnology firm to undertake clinical studies of a novel malaria vaccine candidate, PfSPZ. NIAID also plays a leading role in the international Malaria Eradication Research Agenda initiative.

Other Infectious Diseases of Domestic and Global Health Importance. NIAID’s longstanding investments in basic and clinical research have led to many successes in vaccine development for diseases of worldwide public health concern,

including gastroenteritis caused by rotavirus, pneumonia, hepatitis A, and deadly meningitis caused by *Haemophilus influenzae* type b. These are among the vaccines now being delivered to countries around the world; where they have been deployed, substantial reductions in morbidity and mortality have been observed. NIAID has assumed a major leadership role in the “Decade of Vaccines” initiative, a ten-year collaborative effort coordinated by the Bill & Melinda Gates Foundation, to develop and deliver vaccines to the world’s poorest countries. NIAID will continue research on other urgently needed vaccines, including vaccines for Group B *Streptococci*, Epstein-Barr virus, and hepatitis C virus.

Seasonal and pandemic influenzas remain critical global health and economic threats. NIAID has made significant progress in the development and testing of vaccines to protect people from influenza, including the elderly, young children, and those with asthma. Recently, NIAID researchers demonstrated that a “prime-boost” gene-based vaccination strategy could activate the immune system and lead to broadly neutralizing antibody responses against influenza viruses. This finding and those from other researchers signal that we are closer to developing a “universal” vaccine that could protect against multiple strains of seasonal and pandemic influenza viruses.

This year, in response to the growing public health issue of antimicrobial resistance, NIAID will expand our clinical trials networks developed originally for HIV/AIDS to investigate this important concern. In addition, NIAID will support research to determine how to preserve the effectiveness of current antibiotics.

NIAID’s biodefense research has yielded numerous scientific advances as we have moved from a “one bug-one drug” approach to a more flexible, broad-based

product development strategy that utilizes sophisticated genomic and proteomic platforms to address infectious disease outbreaks, whether they are deliberately introduced or naturally occurring. As part of this effort, NIAID has awarded contracts for the development of broad-spectrum therapeutics against emerging infectious disease and biodefense agents.

RESEARCH ON IMMUNOLOGY AND IMMUNE-MEDIATED DISORDERS

NIAID was highly gratified that the 2011 Nobel Prize in Physiology or Medicine was awarded to three NIAID grantees: Bruce A. Beutler, Jules A. Hoffmann, and the late Ralph M. Steinman. Their research has been pivotal in understanding the human immune response, and it is helping to inform the development of new vaccines and vaccine adjuvants that may provide better protection against infectious diseases.

NIAID's commitment to basic immunology research has led to advances in the treatment of immunological conditions such as the rejection of transplanted organs. In 2011, the *Journal of the American Medical Association* published an NIAID Immune Tolerance Network study demonstrating that children who receive liver transplants may not need lifelong anti-rejection therapy to maintain the transplanted organ. Other NIAID-supported investigators demonstrated that some kidney transplant recipients who also received bone marrow from the kidney donor can maintain their kidney grafts without immunosuppressive drugs.

CONCLUSION

NIAID basic and clinical research on infectious and immune-mediated diseases will continue to promote the development of vaccines, therapeutics, and diagnostics to improve health and save millions of lives worldwide. NIAID remains committed to supporting highly meritorious research with the goal of translating fundamental scientific findings into public health advances.

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. 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.

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.

Dr. Fauci 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 36 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 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.