

PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D.
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DISEASES

Mr. Chairman and Members of the Subcommittee: I am pleased to present the President's fiscal year (FY) 2016 budget request for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The FY 2016 budget request for NIAID is \$4,614,779,000, which is \$197,221,000 more than the FY 2015 level.

For decades, NIAID has made important contributions to the development of diagnostics, therapeutics, and vaccines for infectious and immune-mediated diseases.

INFECTIOUS DISEASES RESEARCH

HIV/AIDS. NIAID's long-term investment in HIV/AIDS research has revolutionized HIV prevention and treatment, including the development and refinement of antiretroviral therapies to treat and prevent HIV infection. NIAID also is pursuing several promising approaches in HIV vaccine development. For example, NIAID is building on the findings from RV144, the first HIV vaccine trial to show modest efficacy. New Phase I/II trials will use improved adjuvant and booster shot strategies in an attempt to increase the protective effect observed in RV144. NIAID Vaccine Research Center (VRC) scientists and grantees also are advancing HIV vaccine design by studying how certain antibodies neutralize HIV and how vaccines could induce the most powerful of these antibodies. In addition, NIAID is supporting research on alternatives to long-term antiretroviral treatment for HIV, such as passive transfer of anti-HIV antibodies as well as gene therapy approaches that may make an HIV-infected person's cells resistant to HIV infection.

Ebola. NIAID was well-positioned to respond rapidly to the Ebola outbreak in West Africa as a result of its longstanding investment in biodefense research. NIAID VRC scientists, with government and industry partners, developed and conducted early-stage clinical testing of an experimental Ebola vaccine called cAd3-EBOZ. This candidate and another product, VSV-ZEBOV, supported in part by NIAID, entered large-scale clinical trials in Liberia in February. These trials are led by a Liberia-U.S. clinical research partnership and will examine safety and efficacy of the vaccines. In late February, the research partnership also launched a trial in Liberia and the United States to test the investigational drug ZMapp, a combination of three monoclonal antibodies against Ebola. In addition, NIAID conducts Ebola clinical research at the Special Clinical Studies Unit in the NIH Clinical Center. The Unit is designated to provide state-of-the-art care in a research setting to U.S. citizens who become infected with infectious diseases requiring high containment such as Ebola.

Influenza. During the current influenza season, we have observed a mismatch between circulating influenza strains and this season's influenza vaccine. The mismatch and resulting low vaccine effectiveness have highlighted the importance of NIAID efforts to develop a universal influenza vaccine that could generate long-lasting protection against multiple influenza strains without the need to frequently reformulate the vaccine. NIAID, in collaboration with the Biomedical Advanced Research and Development Authority (BARDA) and the Centers for Disease Control and Prevention, is planning a Phase I clinical trial to investigate the human immune response to universal influenza vaccine candidates. In addition, VRC scientists at NIAID are developing a ferritin nanoparticle influenza vaccine that may improve the potency and durability of seasonal influenza vaccination.

Malaria. NIAID continues to make research progress against malaria. An early-stage trial at the NIH Clinical Center showed that an NIAID-supported vaccine candidate composed of weakened malaria sporozoites was safe and protected against malaria. NIAID has begun trials in Africa to test this candidate against naturally occurring malaria infections. In addition, NIAID scientists have identified genetic mutations that make malaria parasites resistant to artemisinin, a key drug for treating the disease.

Other Infectious Diseases of Domestic and Global Health Importance. NIAID-supported researchers are combating emerging and re-emerging infectious diseases worldwide. Recent advances include clinical studies of candidate vaccines for the mosquito-borne viruses dengue and chikungunya, progress in understanding the emergence of Middle East Respiratory Syndrome (MERS) coronavirus, and new genetic clues to illness caused by enterovirus D68. NIAID also is working to address hepatitis C virus (HCV). Novel HCV antiviral drugs have greatly improved therapeutic options. NIAID scientists have pioneered shorter courses of treatment with these novel drugs, finding in some cohorts that triple-drug regimens can cure 90 to 100 percent of HCV patients in just 6 weeks.

In addition, NIAID is playing an important role in the White House's initiative on Combating Antibiotic-Resistant Bacteria. Key NIAID efforts in antibacterial resistance (AR) research include sequencing bacterial genomes for a national database; co-sponsoring a monetary prize with BARDA to encourage development of rapid diagnostics; and supporting an AR-targeted clinical research network. NIAID also is supporting the discovery of new antimicrobial treatments. The novel drug teixobactin, identified from soil bacteria by NIAID grantees, is effective against several antibiotic-resistant bacteria in laboratory testing, and similar approaches could yield additional drug candidates.

RESEARCH ON IMMUNOLOGY AND IMMUNE-MEDIATED DISORDERS

NIAID continues to make important advances in the treatment and prevention of immune-mediated disorders. NIAID's Immune Tolerance Network recently showed that early introduction of peanut into the diets of infants at high risk for peanut allergy was safe and led to an 81-percent reduction in subsequent peanut allergy. NIAID is convening clinicians, professional groups, and other stakeholders to revise current clinical practice guidelines to implement this groundbreaking finding.

Multiple sclerosis (MS) is a chronic autoimmune disease and one of the most common neurological disorders of young adults. NIAID-funded researchers found that autologous stem cell transplants after high-dose immunosuppression halted progression of the most common form of MS in nearly 80 percent of participants.

CONCLUSION

NIAID research on infectious and immune-mediated diseases has spurred the development of vaccines, therapeutics, and diagnostics to improve the health of millions globally and has enhanced our ability to respond rapidly to emerging and re-emerging infectious diseases such as Ebola virus disease and influenza.