

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

The Role of the National Institute of Allergy and Infectious Diseases in Research Addressing
Ebola Virus Disease

Testimony before the
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Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
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Mr. Chairman, Ranking Member DeLauro, and Members of the Subcommittee: Thank you for the opportunity to discuss the National Institutes of Health (NIH) response to the global health emergency of Ebola virus disease. I direct the National Institute of Allergy and Infectious Diseases (NIAID), the lead institute of the NIH for conducting and supporting research on infectious diseases, including viral hemorrhagic fevers such as those caused by Ebola. In fiscal year (FY) 2014, NIH funding for Ebola was approximately \$77 million. In FY 2015, the President requested and Congress appropriated \$238 million to NIAID to prevent, prepare for, and respond to Ebola domestically and internationally.

For more than six decades, NIAID has made important contributions to advancing our understanding of infectious, immunologic, and allergic diseases, from basic research on mechanisms of disease to applied research to develop diagnostics, therapeutics, and vaccines. NIAID has a dual mandate that balances research addressing current biomedical challenges with the capacity to respond quickly to newly emerging and re-emerging infectious diseases, including bioterror threats. Critical to these efforts are NIAID's collaborations with other Federal

entities, particularly the Centers for Disease Control and Prevention (CDC); the Food and Drug Administration (FDA); the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response, including the Biomedical Advanced Research and Development Authority (BARDA); the HHS Office of Global Affairs; and the Department of Defense (DOD); as well as with academia, industry, and international organizations. NIAID has a longstanding commitment to advancing research to combat Ebola virus disease while ensuring that potential medical countermeasures are rigorously tested for safety and efficacy.

OVERVIEW OF EBOLA VIRUS DISEASE

Ebola virus disease presents typically with

prevent or treat viral hemorrhagic fevers, including those caused by Ebola. NIAID was well-positioned to respond rapidly to the crisis in West Africa because of its longstanding investment in biodefense and emerging infections research. NIAID research on Ebola focuses on understanding how Ebola virus causes illness and on developing and testing new diagnostics, vaccines, and therapeutics.

Diagnostics

Symptoms of Ebola can easily be mistaken for other common causes of fever in affected areas, such as malaria. A rapid diagnostic for Ebola is critical so that isolation and treatment strategies can be implemented without delay. With NIAID support, Corgenix Medical Corporation developed the ReEBOV™ Antigen Rapid Test, which detects the presence of an Ebola virus protein in about 15 to 25 minutes. FDA recently authorized the test for emergency use in the presumptive detection of the Ebola Zaire virus in symptomatic individuals in appropriate circumstances; it was the first rapid diagnostic test for the Ebola virus to receive such a designation. The test represents a new tool allowing rapid isolation of Ebola patients to limit spread of the disease. NIAID also is advancing the development of other rapid point-of-care diagnostics that use novel technologies to detect multiple pathogens, including Ebola.

Rapid and accurate Ebola diagnostics are critical to monitor the outbreak, rapidly diagnose patients, and provide appropriate patient care. NIAID scientists, in coordination with CDC and DOD, have established and staffed laboratory sites to identify the presence or absence of Ebola virus in clinical samples in Monrovia, Liberia. In addition, NIAID scientists and grantees are analyzing genomic sequences of Ebola virus isolated from patients in West Africa to better understand the origin and transmission of the virus. NIAID scientists recently reported that the

NIAID Vaccine Research Center (VRC) has pursued multiple early-generation Ebola vaccine candidates, culminating in a vaccine candidate currently in large-scale clinical trials. VRC scientists, in collaboration with GlaxoSmithKline, developed an experimental vaccine that uses the chimpanzee adenovirus type 3 (cAd3) as a carrier, or vector, to express an Ebola virus protein designed to stimulate protective immune responses. An NIAID-sponsored Phase II/III clinical trial of cAd3-EBOZ is now underway in Liberia as part of the Partnership for Research on Ebola Vaccines in Liberia (PREVAIL) study. The study also is testing an additional vaccine candidate, rVSV-EBOV, developed with support from DOD and NIAID. Interim findings in more than 600 people enrolled in the PREVAIL study indicate that the two experimental Ebola vaccines appear to be safe. Given these findings, the study should be able to advance to Phase III

