DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

The Role of the National Institutes of Health in Preparing for Emerging Infectious Disease Threats

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

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March 14, 2019

Mr. Chairman, Ranking Member Murray, and members of the Subcommittee, thank you for the opportunity to discuss the role of the National Institutes of Health (NIH) in the research response to emerging and re-emerging infectious diseases. I direct the National Institute of Allergy and Infectious Diseases (NIAID), the lead NIH institute for conducting and supporting infectious disease research. Infectious pathogens are a perpetual challenge to human health because of their diversity and inherent capacity to adapt and evolve, allowing them to emerge and re-emerge in different populations, different circumstances, and new geographic locations. NIAID addresses this ongoing challenge with basic research to better understand mechanisms of pathogenesis and immunity, as well as applied and clinical research to evaluate candidate diagnostics, therapeutics, and prevention strategies, including vaccines. NIH funding for emerging infectious disease research was approximately $2.8 billion in fiscal year 2018.

PANDEMIC PREPAREDNESS: A MULTIFACETED APPROACH

Preparedness for emerging and re-emerging diseases and the potential epidemic and pandemic threats they pose requires a multifaceted approach. A critical component of preparedness is biomedical research to develop medical countermeasures that could be rapidly

PANDEMIC PREPAREDNESS: BUILDING INFRASTRUCTURE

NIAID advances its research through a robust research infrastructure that includes long-term partnerships with individual scientists, scientific organizations, and governments worldwide. NIAID has prioritized research on pathogens with known or suspected pandemic potential in cooperation with international organizations such as the World Health Organization (WHO) and the Coalition for Epidemic Preparedness Innovations (CEPI). NIAID is poised to leverage its existing research investments to develop and test candidate vaccines and therapeutics. Critical to these efforts are longstanding NIAID clinical research networks such as the NIAID Vaccine and Treatment Evaluation Units (VTEUs), which conduct clinical trials on candidate interventions, and the Centers of Excellence for Influenza Research and Surveillance (CEIRS), which advance our understanding of influenza viruses and support early identification of emerging viruses with pandemic potential.

PANDEMIC PREPAREDNESS: RESPONSE TO SELECTED EMERGING DISEASES

Ebola. Ebola was first identified in the Democratic Republic of the Congo (DRC) in 1976, and 27 additional Ebola outbreaks have subsequently occurred. The largest Ebola outbreak occurred in West Africa from 2014 - 2016, with more than 28,600 infections and 11,300 deaths. NIAID built upon biodefense research investments made after the 2001 anthrax attacks to rapidly launch a robust research response to the West African Ebola outbreak. A critical component of that response was the Partnership for Research on Ebola Virus in Liberia (PREVAIL), an agreement between HHS and the government of Liberia that enabled the evaluation of candidate vaccines and therapeutics during the outbreak. These NIAID-supported

Ebola studies showed the feasibility of conducting scientifically and ethically sound clinical research during a major public health emergency.

NIAID has incorporated the lessons learned in conducting research during the West African outbreak into its response to the most recent re-emergence of Ebola in the DRC. The current outbreak began in August 2018 and already is the second largest in history. Many Ebola cases are occurring in an area of armed conflict and tenuous security, which is hindering response efforts. Data from prior NIAID-supported studies, including large-scale vaccine trials conducted by PREVAIL, have provided evidence supporting the use of candidate Ebola countermeasures during the current outbreak. NIAID has entered a memorandum of understanding with the WHO to facilitate a research response to emerging infectious diseases; this collaboration underpins the Institute's efforts in the DRC.

Safe and effective Ebola vaccines will be crucial tools in the response to future Ebola outbreaks, especially for situations in which conflict or other factors limit the healthcare response. The rVSV-EBOZ Ebola vaccine candidate evaluated by the PREVAIL 1 study currently is being used in a ring vaccination campaign in the DRC

the investigational monoclonal antibody cocktail ZMapp™ that showed signs of efficacy in NIAID-supported testing during the West African outbreak. The three additional investigational therapeutics being evaluated in the DRC are the broad-spectrum antiviral remdesivir, a cocktail of monoclonal antibodies known as REGN-EB3, and mAb114. The monoclonal antibody mAb114 was isolated from a survivor of the 1995 Ebola outbreak in Kikwit, DRC, and further developed by scientists at the NIAID Vaccine Research Center (VRC) in partnership with the DRC's INRB and the U.S. Department of Defense. The isolation and development of mAb114 as an Ebola therapeutic highlights the future promise of strategic deployment of monoclonal antibodies to prevent and treat emerging infectious diseases and potentially alter the course of epidemics. These advances are made possible by investments in pathogen-specific research that have improved our ability to identify precisely tailored monoclonal antibodies to combat infectious diseases.

For example, NIAID has supported several natural history studies to better understand the long-term consequences of Zika virus infection. This includes the Zika in Infants and Pregnancy (ZIP) study, which has enrolled women throughout the Americas to follow the effects of Zika virus during pregnancy on the growth and development of affected infants. NIAID scientists also used Zika virus genetic information to rapidly develop a vaccine candidate using a DNA vaccine platform that moved from sequence selection to a first-in-human trial in less than four months. A Phase II/IIb clinical trial of the vaccine candidate has completed enrollment in several countries in the Americas, and analysis of the vaccine's safety and ability to prompt an immune response is ongoing. The NIAID Zika vaccine was developed with a readily deployable DNA vaccine platform that was previously used by NIAID to develop a candidate vaccine for West Nile virus. Using this broadly applicable platform technology, NIAID was able to accelerate its response to a previously unrecognized public health threat.

Influenza. NIAID has a longstanding research program to address the constant threat of seasonal and pandemic influenza, including studies to understand influenza pathogenesis and develop effective antiviral treatments. Influenza poses a challenge to vaccine developers because the virus can undergo significant mutational changes to its surface proteins (the target of current influenza vaccines). This phenomenon was highlighted by recent experience with H7N9 influenza, which was identified as a potential pandemic strain when it first emerged in China in 2013. HHS preparations to address the possibility of a pandemic included the development and stockpiling of an H7N9 vaccine. In 2017, a new H7N9 strain was detected and studies showed that the stockpiled 2013 H7N9 vaccine did not provide adequate protection against the new 2017 strain. NIAID has sought to avoid such challenges in the future by developing broadly protective