Attachment – Additional Questions for the Record
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"Examining the Public Health Response to the Ebola Outbreak"
Before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
October 16, 2014

The Honorable Michael C. Burgess

1. **We have learned a great deal about the difficulty of cleaning a room that has been utilized by an Ebola patient. What are the current standards for sterilizing a room in a healthcare or hospital facility?**

    a. **When were these regulations last updated?**

    b. **Will additional steps be taken to sterilize a room with an Ebola patient?**

    c. **Will you be updating these guidelines to better reflect the realities of an Ebola case?**

    d. **Some Veterans Affairs facilities and other hospitals are currently using pulsing xenon UV light to disinfect rooms – are any of you familiar with this technology?**

        i. **If yes, do you believe this may have a higher success rate in disinfecting rooms and preventing further infection?**

        ii. **Do you believe that this technology could be useful if deployed more widely in the United States?**

        iii. **What about in combating the outbreak in Africa – would it be possible to utilize this technology to fight the outbreak?**

        iv. **Will you please have someone on your staff review the position of the NIH on this technology and whether it will be helpful?**

NIAID Response: The National Institutes of Health (NIH) Clinical Center follows Centers for Disease Control and Prevention (CDC) guidelines for environmental cleaning of an isolation room that has been used by an Ebola virus-infected patient, including terminal cleaning and disinfection using an Environmental Protection Agency-registered hospital disinfectant.

CDC has published Interim Guidance for Environmental Infection Control in Hospitals for Ebola

Virus on its website.[1] These CDC guidelines are updated periodically and were last updated on October 3, 2014. For additional information about these guidelines, you may wish to contact CDC.

With respect to use of ultraviolet (UV) radiation as a disinfectant, in certain circumstances, this technology can effectively kill a variety of microorganisms, including viruses such as Ebola. UV radiation has been used widely to disinfect hospitals and clinics in the United States. There are many technologies for generating UV radiation. The method of generating UV radiation capable of killing microorganisms, such as pulsating xenon UV light, is less important to its effectiveness in killing microorganisms than the conditions under which it is used.

UV radiation does not penetrate objects. For this reason, the use of UV technology is limited to the destruction of airborne organisms or inactivation of microorganisms on clean, smooth, non-porous surfaces. In addition, the effectiveness of UV radiation is dependent on several factors, including: the specific wavelength of UV radiation being used; the removal of dirt, grease, and organic material from surfaces prior to UV treatment; and the duration of UV exposure.

The Ebola virus is shed from patients into the surrounding environment through vomit, feces, blood, and other body fluids that are not completely penetrated by UV radiation. Therefore, UV radiation would not be completely effective in killing Ebola virus in these infectious body fluids. For this reason, UV radiation technologies would be of limited use in addressing the Ebola outbreak in West Africa. Studies have shown that proper, routine cleaning of patient areas and surfaces eliminates the Ebola virus from the environment

The Department of Veterans Affairs has issued detailed guidance to its health care facilities on the implementation of standard, effective disinfection practices for environments potentially contaminated with Ebola virus. This guidance references the use of UV radiation only as an adjunct to these standard practices.

2. Is NIH concerned about the potential infection among janitors, city employees, or waste disposal employees who come in contact with Ebola medical waste?

NIAID Response: NIH is committed to taking every precaution to ensure the safety of our patients, NIH staff, and the public. The NIH Clinical Center in Bethesda, Maryland, is equipped and fully prepared to treat and observe patients with Ebola virus disease. All waste coming from the patient's room, including all personal protective equipment used by Clinical Center staff to provide care, is sterilized and incinerated before being deposited in a landfill. Janitors, city employees, and other waste disposal employees will not come in contact with any waste that is potentially contaminated with Ebola virus. Additional information about safe handling, treatment, transport, and disposal of Ebola-contaminated waste is available from the Occupational Safety and Health Administration.[2]

[1] http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html
[2] https://www.osha.gov/Publications/OSHA_FS-3766.pdf

3. **Mr. Duncan's family was forced to stay in their apartment because officials had no way to quarantine the area or dispose of medical waste – did NIH provide any information or guidance on the dangers of this? If not, why?**

NIAID Response: CDC makes resources available to state and local governments with regard to preventing, preparing for, and managing cases of Ebola virus disease in the United States. NIH was not involved in the treatment of Mr. Duncan or matters involving his family, quarantine, or disposal of medical waste. NIH did not provide information or guidance to any state or local official in this case.

4. **What have NIH efforts been in developing a diagnostic test that provides early detection, possibly before the development of symptoms? Financially, what role is BARDA playing in fostering this development of new technologies? How are you ensuring all diagnostic options are being considered?**

    a. **Please describe all efforts in this area to date.**

NIAID Response: Accurate and accessible diagnostics for Ebola virus infection are needed for the early detection and treatment of patients in the current Ebola outbreak because the symptoms of Ebola can be easily mistaken for other common causes of fever in West Africa, such as malaria. Point-of-care, or on-site, Ebola virus diagnostics would be particularly valuable as they allow caregivers to quickly identify infected patients in order to isolate them, initiate treatment, and minimize additional potential exposures to the virus.

NIAID provides resources for investigators developing medical countermeasures against Ebola, including early detection diagnostics. With NIAID support, Corgenix Medical Corporation is developing rapid immunodiagnostics for Ebola virus using genomic technology to produce recombinant viral proteins. NIAID is advancing development of additional diagnostics, including those using novel technologies such as microfluidics, optofluidics and nanophotonics, which are capable of detecting multiple viruses including Ebola. In addition, intramural scientists from NIAID's Rocky Mountain Laboratories in Hamilton, Montana, and NIAID's Integrated Research Facility in Frederick, Maryland, have responded to the ongoing epidemic in West Africa by establishing and staffing laboratory field sites in Monrovia, Liberia, in coordination with CDC and the Department of Defense (DOD) to identify the presence or absence of Ebola virus in clinical samples. These real-time data are critical to patient care and monitoring of the epidemic. NIAID and CDC researchers also have established collaborations with Malian public health institutes, providing training in laboratory testing for identification of Ebola and other fever-causing viruses.

NIAID is fully committed to engaging its resources to identify and evaluate promising Ebola diagnostics. NIAID employs a multifaceted and interdisciplinary approach to ensure a robust pipeline of candidate medical countermeasures for Ebola virus. Currently NIAID is actively engaging scientists around the world who have come forward to discuss their candidate Ebola diagnostics. NIAID also makes resources available to academic and industry researchers, such as in vitro and in vivo screening, to help evaluate potential medical countermeasures. If candidate countermeasures show promise, NIAID transitions them to the Biomedical Advanced

Research and Development Authority (BARDA) for advanced development. BARDA's role is to facilitate the development and acquisition of medical countermeasures and the domestic manufacturing capacity to prepare for and respond to an emergency.

5. **Please discuss the linkage between ongoing Ebola drug and vaccine development projects at NIH/NIAID and planned advanced research and development projects for Ebola at BARDA.**

NIAID Response: NIAID supports a broad portfolio of intramural and extramural basic research to better understand Ebola virus and applied research to develop diagnostics, therapeutics, and vaccines against Ebola virus. NIAID coordinates with its partners in government, academia, and industry to ensure that the results of NIAID-supported research can be translated rapidly into safe and effective medical countermeasures for high-priority pathogens such as Ebola virus. If candidate medical countermeasures show promise in proof-of-concept animal studies or early human testing, NIAID transitions these candidates to BARDA for advanced development.

NIAID is an active participant in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), an interagency effort led by the Department of Health and Human Service's (HHS's) Office of the Assistant Secretary for Preparedness and Response (ASPR) that coordinates Federal activities to increase preparedness against chemical, radiological, nuclear, and biological threats, including Ebola virus. As an active member, NIAID participates in multiple teams and committees to ensure coordination of scientific activity with PHEMCE partners, including BARDA, the Food and Drug Administration (FDA), and DOD. In addition, NIAID participates in the Ebola Medical Countermeasures Senior Steering Group, coordinated by the White House Office of Science and Technology Policy (OSTP). Senior staff from all agencies participating in the Ebola response meet twice weekly to discuss medical countermeasures for Ebola virus in the context of the U.S. response to the Ebola epidemic.

In partnership with BARDA and others, NIAID is working to accelerate the development of medical countermeasures for Ebola virus to respond to the current outbreak in West Africa. For example, NIAID is partnering with the DOD and BARDA to advance the development and testing of the Ebola therapeutic candidate ZMapp. ZMapp, developed by Mapp Biopharmaceutical, Inc., with support from NIAID and DOD, is a combination of three antibodies that has been shown to protect monkeys from death due to Ebola virus when administered up to five days after infection. NIAID's preclinical services are being used to provide preliminary safety data to support the use of ZMapp for clinical trials in humans. BARDA currently is accelerating manufacturing of ZMapp so that clinical safety and efficacy testing can begin as soon as possible. NIAID and DOD also are collaborating with the biomedical research company NewLink Genetics on an investigational recombinant vesicular stomatitis virus (VSV)-based vaccine candidate developed by the Public Health Agency of Canada and licensed to NewLink Genetics. NIAID worked with the FDA to enable this candidate to begin Phase 1 safety studies in October 2014 at Walter Reed Army Institute of Research in Silver Spring, Maryland, and at the NIH Clinical Center. NIAID is coordinating with BARDA, which is collaborating with NewLink Genetics to manufacture this candidate on a commercial scale. NIAID also is working with BARDA and industry partner GlaxoSmithKline to accelerate development of Ebola candidate vaccine cAd3 through additional vaccine

manufacturing and clinical trials to further determine safety and immune response.

NIAID's longstanding and successful collaborations with BARDA and other partners are critical to accelerating efforts to develop treatments and vaccines for Ebola virus disease. As additional medical countermeasures for Ebola virus show promise in early-stage testing, NIAID will continue to coordinate closely with BARDA to transition these candidates for advanced development.

The Honorable Ben Ray Luján

1. **The appearance of a handful of Ebola cases in the United States demonstrates the importance of robust investments in our nation's public health infrastructure. Unfortunately, the National Institutes of Health's budget has been largely flat for years. In addition, we've seen cuts to the Center for Disease Control and the Department of Health and Human Services' Hospital Preparedness program. Can each of you discuss if budget cuts have had any impact on our response to the Ebola outbreak in West Africa or impacted the handling of the cases here in the United States?**

NIAID Response: The loss of purchasing power at NIH, especially with sequestration, has reduced NIH's ability to fund biomedical research in virtually all areas. NIAID cannot predict with certainty the extent of progress that would have been made with more funding. However, funding that has not kept pace with inflation and sequestration have slowed the process of developing vaccines, therapeutics, and diagnostics against deadly infectious diseases, including Ebola viruses.

NIAID will continue to prioritize research on Ebola viruses within its current budget. NIAID is committed to using available funds to respond rapidly to the ongoing outbreak in West Africa by accelerating research to develop diagnostics, vaccines, and therapeutics for Ebola viruses.

The Honorable Paul Tonko

1. **During the hearing, you indicated that the NIH had a grand total of two beds in a special bio containment unit to handle potential Ebola patients. How many of these specialized beds are there across the country and would this number be sufficient to handle an outbreak in the United States?**

NIAID Response: NIH operates and maintains a Special Clinical Studies Unit, a four-room inpatient unit at NIH's Clinical Center in Bethesda, Maryland, that has the capacity to deliver high-level care in containment. When operating at the highest level of containment it can handle a total of two patients. The Special Clinical Studies Unit is specifically designed to provide high-level isolation capabilities and is staffed by specialists trained in strict infection control practices optimized to prevent spread of potentially transmissible agents such as Ebola.

For details regarding the use and number of specialized beds to treat Ebola patients in the country, you may wish to contact CDC.

2. **What is the NIAID doing to help accelerate the development of an Ebola vaccine? Are additional resources needed?**

NIAID Response: NIAID supports and conducts basic, translational, and clinical research on novel vaccines targeting emerging and re-emerging infectious diseases, including Ebola virus. The ongoing NIAID response to the current Ebola outbreak focuses on working with non-profit, private industry, and government partners around the world to advance the development of medical countermeasures against the disease. This approach has led to the generation of multiple vaccine candidates across the different stages of the product development pipeline.

For example, NIAID has worked closely with FDA to advance testing of the cAd3Ebola vaccine candidate developed by NIAID in partnership with GlaxoSmithKline (GSK). This candidate uses a chimpanzee adenovirus as a carrier to introduce Ebola virus genes into the body in order to stimulate an immune response. NIAID is currently conducting Phase 1 clinical trials of the cAd3candidate vaccine at the NIH Clinical Center in Bethesda, Maryland, the University of Maryland, and Emory University. Proactive communication and partnership allowed FDA to review the NIAID Vaccine Research Center's Investigational New Drug application in less than one week, leading to acceleration of the clinical study start date. NIH also provided doses of a related version of this vaccine candidate to partners in the UK who are evaluating the candidate in clinical studies both in the UK and the West African country of Mali. In October 2014, GSK and WHO partners began an additional, larger clinical study of this vaccine in Lausanne, Switzerland. The data from the current Phase 1 trials will help demonstrate whether these candidate Ebola vaccines are safe in humans and are capable of generating an immune response. If successful, these candidates will be advanced to efficacy testing in larger numbers of people in West Africa.

In addition, NIAID and DOD are coordinating efforts to accelerate the production of two Ebola vaccine candidates. NIAID and DOD are collaborating with NewLink Genetics on an investigational recombinant VSV-based vaccine candidate developed by the Public Health

Agency of Canada and licensed to NewLink Genetics. NIAID has worked with FDA to enable this candidate to begin Phase 1 safety studies. These studies began in October 2014 at Walter Reed Army Institute of Research in Silver Spring, Maryland, and at the NIH Clinical Center in Bethesda, Maryland. Another project aims to produce a vaccine candidate based on an existing rabies vaccine that could protect against Ebola and rabies, important diseases in certain regions in Africa. NIAID and DOD are partnering with researchers at Thomas Jefferson University to produce sufficient quantities of this candidate to begin clinical testing in early 2015. In September 2014, NIH licensed the candidate rabies/Ebola vaccines to Exxell BIO of St. Paul, Minnesota, which aims to advance the products through clinical testing and potential commercialization.

NIAID also is supporting biotechnology company Profectus BioSciences, Inc., to investigate a second recombinant VSV-vectored vaccine candidate against Ebola and Marburg viruses. Profectus is pursuing preclinical testing of the vaccine in preparation for a future Phase 1 clinical trial. Additionally, NIAID is collaborating with the University of Texas Medical Branch at Galveston to further progress made by NIAID intramural scientists on a paramyxovirus-based vaccine against Ebola virus. Production of the paramyxovirus-based vaccine is in progress to enable clinical testing planned for mid-2015.

In addition, NIAID has played an instrumental role in the recently announced collaboration between Johnson & Johnson (parent company of Crucell) and Bavarian Nordic. Crucell will contribute its adenovirus-vectored vaccine and Bavarian Nordic will contribute its modified-vaccinia-virus-Ankara-vectored vaccine for a two-dose (prime-boost) vaccination regimen that will begin Phase 1 testing in early 2015. Additional vaccine candidates are in the early stages of evaluation with NIAID support.

As of November 24, 2014, the President has proposed an emergency appropriations request for Fiscal Year 2015 that includes $6.18 billion to implement a comprehensive strategy to contain and end the Ebola outbreak at its source in West Africa, enhance domestic preparedness, speed the procurement and testing of vaccines and therapeutics, and accelerate global capability to prevent the spread of future infectious diseases. This request would provide support to NIH to accelerate and expand the clinical evaluation of promising medical countermeasure candidates for Ebola virus, including a large Phase 2/3 randomized clinical trial of candidate vaccines in West Africa. Additional supplemental funds would also support discovery, preclinical testing, and clinical evaluation of vaccine and therapeutic candidates.

3. The first Ebola patients brought to the United States were treated with experimental drugs that we have subsequently run out of. Is the NIAID collaborating with the manufacturers of these treatments to produce additional quantities?

NIAID Response: NIAID supports a broad portfolio of intramural and extramural basic research to better understand Ebola viruses and applied research to develop diagnostics, therapeutics, and vaccines against Ebola viruses. NIAID has supported a number of medical countermeasures for Ebola virus disease currently in development and will continue to work with developers to advance promising candidates. It is important to note that products in development have not been shown to be safe and effective for patients with Ebola virus disease, and are not approved

for use against Ebola viruses although they may be considered for limited clinical use in patients with documented or suspected Ebola virus infection in clinical trials or under expanded access mechanisms if situations arise that justify such use.

With respect to experimental drugs for Ebola viruses currently in development, NIAID is partnering with DOD and BARDA to advance the development and testing of the Ebola therapeutic candidate ZMapp. ZMapp, developed by Mapp Biopharmaceutical, Inc., with support from NIAID and DOD, is a combination of three antibodies that has been shown to protect monkeys from death due to Ebola virus when administered up to five days after infection. NIAID is working closely with partners at DOD, BARDA, and FDA to help determine whether ZMapp is safe and effective. NIAID's preclinical services are being used to provide preliminary safety data to support the use of ZMapp for clinical trials in humans. BARDA currently is working with Mapp Biopharmaceutical to accelerate the manufacturing of more ZMapp so that clinical safety and efficacy testing can begin as soon as possible.

NIAID will continue to work closely with industry partners and with BARDA to transition additional therapeutic candidates for advanced development as appropriate. BARDA's role is to facilitate the advanced development and acquisition of medical countermeasures and the domestic manufacturing capacity to prepare for and respond to an emergency.

The Honorable Gene Green

1. **Dr. Fauci, can you discuss the linkage between ongoing Ebola drug and vaccine development projects at the National Institute of Allergy and Infectious Disease and planned advanced research and development projects for Ebola at BARDA?**

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