September 16, 2014

JOINT FULL COMMITTEE HEARING - EBOLA IN WEST AFRICA: A GLOBAL CHALLENGE AND PUBLIC HEALTH THREAT

U.S. SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS AND THE SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES, COMMITTEE ON APPROPRIATIONS

ONE HUNDRED AND THIRTEENTH CONGRESS, SECOND SESSION

HEARING CONTENTS:

WEBCAST: [Duration: 3:29:53] ***[view complete hearing with Adobe Flash Player]***

WITNESS STATEMENTS:

PANEL ONE:

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Senate Committees on Appropriations

and

Health, Education, Labor and Pensions

Ebola in West Africa: A Global Challenge and Public Health Threat

September 16, 2014

Statement of Beth Bell, MD, MPH, Director, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention

Good afternoon Chairman Harkin, Ranking Members Alexander and Moran, and members of the Health, Education, Labor and Pensions and Appropriations Committees. Thank you for the opportunity to testify before you today and for your ongoing support for the Centers for Disease Control and Prevention's (CDC) work in global health. I am Dr. Beth Bell, Director of the National Center for Emerging and Zoonotic Infectious Diseases at the CDC. I appreciate the opportunity to be here today to discuss the current epidemic of Ebola in West Africa, which illustrates in a tragic way the need to strengthen global health security.

We do not view Ebola as a significant public health threat to the United States . It is not transmitted easily, does not spread from people who are not ill, and cultural norms that contribute to the spread of the disease in Africa – such as burial customs – are not a factor in the United States. We know how to stop Ebola with strict infection control practices which are already in widespread use in American hospitals, and by stopping it at the source in Africa. There is a window of opportunity to tamp down the spread of this disease, but that window is closing. CDC is committing significant resources both on the ground in West Africa and through our Emergency Operations Center here at home. But this is a whole

of Government response, with agencies across the United States Government committing human and financial resources.

To date, the United States Government has spent more than $100 million to address the Ebola epidemic, and just last week the U.S. Agency for International Development (USAID) announced plans to make available up to $75 million in additional funding. In addition, we have just proposed that the Congress provide an additional $88 million through the continuing resolution process. This funding would allow us to support development and manufacturing of Ebola therapeutic and vaccine candidates for clinical trials and to send additional response workers from CDC as well as lab supplies and equipment. If the Congress includes this additional funding, it would bring our total commitments to date to over $250 million. Last week, the President indicated that the need to engage the unique logistics and materiel capabilities of the U.S. military on this response.

We need to, and are, working with our international partners, to scale up the response to the levels needed to stop this epidemic.

Ebola is a severe, often fatal, viral hemorrhagic fever. The first Ebola virus was detected in 1976 in what is now the Democratic Republic of Congo. Since then, outbreaks have appeared sporadically. The current epidemic in Guinea, Liberia, and Sierra Leone is the first that has been recognized in West Africa and the biggest and most complex Ebola epidemic ever documented. We have now also seen cases imported into Nigeria and Senegal from the initially affected areas, which is of concern.

Ebola has an abrupt onset of symptoms similar to many other illnesses, including fever, chills, weakness and body aches. Gastrointestinal symptoms such as vomiting and diarrhea are common and severe, and can result in life threatening electrolyte losses. In approximately half of cases there is hemorrhage--serious internal and external bleeding. There are two things that are very important to understand about how Ebola spreads. First, the current evidence suggests human-to-human transmission of Ebola only

happens from people who are symptomatic– not from people who have been exposed to, but are not ill with the disease. Second, everything we have seen in our decades of experience with Ebola indicates that Ebola is not spread by casual contact; Ebola is spread through direct contact with bodily fluids of someone who is sick with, or has died from Ebola, or exposure to objects such as needles that have been contaminated. While the illness has an average 8-10 day incubation period (though it may be as short as two days and as long as 21 days), we recommend monitoring for fever and signs of symptoms for the full 21 days. Again, we do not believe people are contagious during that incubation period, when they have no symptoms. Evidence does not suggest Ebola is spread through the air. Catching Ebola is the result of exposure to bodily fluids, which we are seeing occur in West Africa, for example, in hospitals in weaker health care systems and in some African burial practices. Getting Ebola requires exposure to bodily fluids of someone who is ill from – or has died from – Ebola.

The early recorded cases in the current epidemic were reported in March of this year. Following an initial response that seemed to slow the early outbreak for a time, cases flared again due to weak systems of health care and public health and because of challenges health workers faced in dealing with communities where critical disease-control measures were in conflict with cultural norms. As of last week, the epidemic surpassed 4,400 cumulative reported cases, including nearly 2,300 documented deaths, though we believe these numbers may be under-reported, by a factor of at least two- to threefold. The effort to control the epidemic in some places is complicated by fear of the disease and distrust of outsiders. Security is tenuous and unstable, especially in remote isolated rural areas. There have been instances where public health teams could not do their jobs because of security concerns.

Many of the health systems in these countries are weak or have collapsed entirely, and do not reach into rural areas. Health care workers may be limited (for example, we are aware of one nurse for 90 patients in one hospital in Kenema, Sierra Leone), or may not reliably be present at facilities, and those facilities may have limited capacity. Poor infection control in routine health care, along with local traditions such

as public funerals and cultural mourning customs including preparing bodies of the deceased for burial, make efforts to contain the illness more difficult. Furthermore, the porous land borders among countries and remoteness of many villages have greatly complicated control efforts. The secondary effects now include the collapse of the underlying health care systems resulting for example, an inability to treat malaria, diarrheal disease, or to safely deliver a child, as well as non-health impacts such as economic and political instability and increased isolation in this area of Africa. These impacts are intensifying, and not only signal a growing humanitarian crisis, but also have direct impacts on our ability to respond to the Ebola epidemic itself.

I There are three key things which we need to respond to this epidemic. The first is resources – this epidemic will take a lot of resources to confront. That is why the U.S. Government is putting our resources into this effort and asking the Congress for your assistance. The United Nations believes the cost of getting supplies needed to West African countries to get the Ebola crisis under control will be at least $600 million. I personally believe that to be an underestimate. The second is technical experts in health care and management to assist in country. Last, is a coordinated, global unified approach, because this is not just a problem for Africa. It's a problem for the world, and the world needs to respond.

Fortunately, we know what we must do. In order to stop an Ebola outbreak, we must focus on three core activities: find active cases, respond appropriately, and prevent future cases. The use of real-time diagnostics is extremely important to identify new cases. We must support the strengthening of health systems and assist in training healthcare providers. Once active cases have been identified, we must support quality patient care in treatment centers, prevent further transmission through proper infection control practices, and protect healthcare workers. Epidemiologists must identify contacts of infected patients and follow up with them every day for 21 days, initiating testing and isolation if symptoms emerge. And, we must intensify our use of health communication tools to disseminate messages about effective prevention and risk reduction. These messages include recommendations to report suspected

cases and to avoid close contact with sick people or the deceased, and to promote safe burial practices. In Africa, another message is to avoid bush meat and contact with bats, since "spillover events", or transmission from animals to people, in Africa has been documented through these sources.

Many challenges remain. While we do know how to stop Ebola through meticulous case finding, isolation, and contact tracing, there is currently no cure or vaccine shown to be safe or effective for Ebola. We need to strengthen the global response, which requires close collaboration with WHO, additional assistance from our international partners, as well as a coordinated United States Government response. At CDC, we activated our Emergency Operations Center to respond to the initial outbreak, and are surging our response. One of the surge objectives was initial deployment of fifty disease-control experts in thirty days to the region to support partner governments, WHO, and other partners working in the region. We surpassed that goal, and as of last week, CDC has over 100 staff in West Africa, and more than 300 staff in total have provided logistics, staffing, communication, analytics, management, and other support functions. CDC will continue to work with our partners across the United States Government and elsewhere to focus on five pillars of response:

- Effective incident management – CDC is supporting countries to establish national and sub-national Emergency Operations Centers (EOCs) by providing technical assistance and standard operating procedures and embedding staff with expertise in emergency operations. All three West African countries at the center of the epidemic have now named and empowered an Incident Manager to lead efforts.
- Isolation and treatment facilities – It's imperative that we ramp up our efforts to provide adequate space to treat the number of people afflicted with this virus.
- Safe burial practices – Effectively shifting local cultural norms on burial practices is one of the keys to stopping this epidemic. CDC is providing technical assistance for safe burials.

- Health care system strengthening – Good infection control will greatly reduce the spread of Ebola and help control future outbreaks. CDC has a lead role in infection control training for health care workers and safe patient triage throughout the health care system, communities, and households.
- Communications – CDC will continue to work on building the public's trust in health and government institutions by effectively communicating facts about the disease and how to contain it, particularly targeting communities that have presented challenges to date.

The public health response to Ebola rests on the same proven public health approaches that we employ for other outbreaks, and many of our experts are working in the affected countries to rapidly apply these approaches and build local capacity. These include strong surveillance and epidemiology, using real-time data to improve rapid response; case-finding and tracing of the contacts of Ebola patients to identify those with symptoms and monitor their status; and strong laboratory networks that allow rapid diagnosis.

CDC's request for an additional $30 million for the period of the Continuing Resolution will support our response and to allow us to ramp up efforts to contain the spread of this virus. More than half of the funds are expected to directly support staff, travel, security and related expenses. A portion of the funds will be provided to the affected area to assist with basic public health infrastructure, such as laboratory and surveillance capacity, and improvements in outbreak management and infection control. Should outbreaks recur in this region, they will have the experience and capacity to respond without massive external influx of aid, due to this investment. The remaining funds will be used for other aspects of strengthening the public health response such as laboratory supplies/equipment, and other urgent needs to enable a rapid and flexible response to an unprecedented global epidemic. CDC will continue to coordinate activities directly with critical federal partners, including USAID and non-governmental organizations.

Though the most effective step we can take to protect the United States is to stop the epidemic where it is occurring, we are also taking strong steps to protect Americans here at home. For example, it is possible that infected travelers may arrive in the United States, despite all efforts to prevent this; therefore we need to ensure the United States' public health and health care systems are prepared to rapidly manage cases to avoid further transmission. We are confident that our public health and health care systems can prevent an Ebola outbreak here, and that the authorities and investments provided by your Committees have put us in a strong position to protect Americans. To make sure the United States is prepared, as the epidemic in West Africa has intensified, CDC has:

- Assisted with extensive screening and education efforts on the ground in West Africa to prevent ill travelers from getting on planes.
- Developed guidance for monitoring and movement of people with possible exposures, and guidance and training for partners (including airlines, Customs and Border Protection officers, and Emergency Medical Systems personnel)
- Provided guidance for travelers, humanitarian organizations, and students/universities
- Advised United States' health care providers to consider Ebola if symptoms present within three weeks of a traveler returning from an affected area
- Provided guidance for infection control practices in hospitals to prevent further spread to United States health care workers and communities
- Developed response protocols for the evaluation, isolation and investigation of any incoming individuals with relevant symptoms.

- Expanded the capacity of our Laboratory Response Network to rapidly test suspected cases so that appropriate measures can be taken.

Working with our partners, we have been able to stop every prior Ebola outbreak, and we will stop this one. It will take meticulous work and we cannot take short cuts. It's like fighting a forest fire: leave behind one burning ember, one case undetected, and the epidemic could re-ignite. For example, in response to the case in Nigeria, 10 CDC staff and 40 top Nigerian epidemiologists rapidly deployed, identified, and followed 1,000 contacts for 21 days. Even with these resources, one case was missed, which resulted in a new cluster of cases in Port Harcourt.

Ending this epidemic will take time and continued, intensive effort. The FY 2015 President's Budget includes an increase of $45 million to strengthen lab networks that can rapidly diagnose Ebola and other threats, emergency operations centers that can swing into action at a moment's notice, and trained disease detectives who can find an emerging threat and stop it quickly. Building these capabilities around the globe is key to preventing this type of event elsewhere and ensuring countries are prepared to deal with the consequences of outbreaks in other countries. We must do more, and do it quickly, to strengthen global health security around the world, because we are all connected. Diseases can be unpredictable – such as H1N1 coming from Mexico, MERS emerging from the Middle East, or Ebola in West Africa, where it had never been recognized before – which is why we have to be prepared globally for anything nature can create that could threaten our global health security.

There is worldwide agreement on the importance of global health security, but as the Ebola epidemic demonstrates, there is much more to be done. All 194 World Health Organization Member States have adopted the International Health Regulations (IHR). Progress has occurred over the past years, but 80 percent of countries did not claim to meet the IHR capacity required to prevent, detect, and rapidly

respond to infectious disease threats by the June 2012 deadline set by WHO. No globally linked, inter-operable system exists to prevent epidemic threats, detect disease outbreaks in real-time, and respond effectively. Despite improved technologies and knowledge, concerning gaps remain in many countries in the workforce, tools, training, surveillance capabilities, and coordination that are crucial to protect against the spread of infectious disease, whether naturally occurring, deliberate, or accidental. The technology, capacity, and resources exist to make measurable progress across member countries, but focused leadership is required to make it happen. If even modest investments had been made to build a public health infrastructure in West Africa previously, the current Ebola epidemic could have been detected earlier, and it could have been identified and contained. This Ebola epidemic shows that any vulnerability could have widespread impact if not stopped at the source.

Earlier this year, the United States Government joined with partner governments, WHO and other multilateral organizations, and non-governmental actors to launch the Global Health Security Agenda. Over the next five years, the United States has committed to working with at least thirty partner countries (with a combined population of at least four billion people) to improve their ability to prevent, detect, and effectively respond to infectious disease threats - whether naturally occurring or caused by accidental or intentional release of pathogens. As part of this Agenda, the President's FY 2015 Budget includes $45 million for CDC to accelerate progress in detection, prevention, and response, and we appreciate your support for this investment. The economic cost of large public health emergencies can be tremendous – the 2003 Severe Acute Respiratory Syndrome epidemic, known as SARS, disrupted travel, trade, and the workplace and cost to the Asia-Pacific region alone $40 billion. Resources provided for the Global Health Security Agenda can improve detection, prevention, and response and potentially reduce some of the direct and indirect costs of infectious diseases.

Improving these capabilities for each nation improves health security for all nations. Stopping outbreaks where they occur is the most effective and least expensive way to protect people's health. While this tragic epidemic reminds us that there is still much to be done, we know that sustained commitment and the application of the best evidence and practices will lead us to a safer, healthier world. With a focused effort and resources proposed in the FY 2015 President's Budget, we can stop this epidemic, and leave behind strong system in West Africa and elsewhere to prevent Ebola and other health threats in the future.

Thank you again for the opportunity to appear before you today. I appreciate your attention to this terrible outbreak and I look forward to answering your questions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

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

Testimony before the

Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

and Senate Health, Education, Labor, and Pensions Committee

Anthony S. Fauci, M.D.

Director

National Institute of Allergy and Infectious Diseases

September 16, 2014

Mr. Chairman and Members of the Committees:

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 virus infection.

For over six decades, NIAID has made important contributions to advancing the 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 partnerships with academia, pharmaceutical companies, international organizations such as the World Health Organization, and collaborations with other Federal entities, particularly the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA), the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DOD).

OVERVIEW OF EBOLA VIRUS DISEASE

Viral hemorrhagic fevers are severe illnesses that can be fatal and are caused by a diverse group of viruses including Marburg virus, Lassa virus, and Ebola virus. Infection with Ebola virus typically causes fever, severe vomiting, diarrhea, rash, profound weakness, electrolyte loss, impaired kidney and liver function, and in some cases internal and external bleeding. Since the

discovery of Ebola virus in 1976, outbreaks of hemorrhagic fever caused by Ebola virus have had fatality rates ranging from 25 percent to 90 percent, depending on the species of virus and the availability of medical facilities to care for infected patients. West Africa is currently experiencing the most severe Ebola epidemic ever recorded. As of last week, the epidemic surpassed 4,400 cumulative reported cases, including nearly 2,300 documented deaths according to CDC. The ongoing Ebola epidemic in Guinea, Liberia, Sierra Leone, Nigeria, and Senegal has generated more cases and deaths than the 24 previous Ebola outbreaks combined.

The ongoing public health crisis in West Africa demands a major amplification of efforts to identify and isolate infected individuals, perform contact tracing, and provide personal protective equipment for healthcare workers involved in the treatment of infected individuals. This still remains the time-proven approach to controlling and ultimately ending the epidemic. However, there is also a critical need to develop improved diagnostics, as well as safe and effective therapeutics and vaccines for Ebola since there are no such FDA-approved interventions available at this time. In this regard, NIAID has a longstanding commitment to advancing research to combat Ebola while ensuring the safety and efficacy of potential medical countermeasures such as treatments and vaccines.

HISTORY OF NIAID EBOLA VIRUS RESEARCH: RELATIONSHIP TO BIODEFENSE RESEARCH

The ability to safely and effectively prevent and treat Ebola virus infection is a longstanding NIAID priority. Since the 2001 anthrax attacks, NIAID has vastly expanded its research portfolio in biodefense and naturally emerging and re-emerging infectious diseases. This research targets pathogens that pose high risks to public health and national security. NIAID

has designated pathogens with high mortality such as anthrax, plague, smallpox, and Ebola virus as NIAID Category A Priority Pathogens to highlight the need for medical countermeasures against these dangerous microbes.

NIAID's expanded efforts in biodefense and emerging and re-emerging infectious diseases were undertaken with specific objectives. The first is to advance basic and translational research and facilitate development of effective products to combat deadly diseases such as Ebola. The second is to employ innovative strategies, such as broad spectrum vaccines and therapeutics, to prevent and treat a variety of related infectious diseases. The third is to strengthen our partnerships with biotechnology and pharmaceutical companies to help accelerate the availability of needed products for affected and at risk individuals.

Since 2001, NIAID's biodefense research has supported the development and testing of numerous candidate products to prevent or treat viral hemorrhagic fevers, including those caused by Ebola and other related viruses. The progress we have made with candidate vaccines, therapeutics, and diagnostics for Ebola virus would not be possible had we not made this important investment.

DEVELOPMENT AND TESTING OF EBOLA MEDICAL COUNTERMEASURES

In response to the Ebola public health emergency in West Africa, NIAID is accelerating ongoing research efforts and partnering with governments and private companies throughout the world to speed the development of medical countermeasures that could help control the current epidemic and future outbreaks. NIAID research on Ebola virus focuses on basic research to

understand how Ebola virus causes illness in animals and in people as well as applied research to develop diagnostics, vaccines, and therapeutics.

Diagnostics

Accurate and accessible diagnostics for Ebola virus infection are needed for the rapid identification and treatment of patients in an outbreak because the symptoms of Ebola can be easily mistaken for other common causes of fever in affected areas, such as malaria. NIAID continues to provide resources to investigators attempting to develop Ebola diagnostics. With NIAID support, Corgenix Medical Corporation is developing diagnostics for Ebola virus using recombinant DNA technology. NIAID also is advancing development of diagnostics, including those using novel technologies, which are capable of detecting multiple viruses including Ebola. Such innovative approaches can provide information critical to the creation of point-of-care diagnostics that could be distributed and used in areas where Ebola virus outbreaks occur. Intramural scientists from NIAID's Rocky Mountain Laboratories (RML) in Hamilton, Montana, and Integrated Research Facility in Frederick, Maryland, have responded to the epidemic by providing technical diagnostic support in Liberia.

Therapeutics

Currently, supportive care, including careful attention to fluid and electrolyte replacement, is the only effective medical intervention for patients with Ebola virus disease; no drugs are available specifically to treat Ebola virus infection. Experts are now evaluating whether drugs licensed or approved for the treatment of other diseases should be reevaluated for potential treatment of patients with Ebola in the current epidemic on an emergency basis. In parallel,

NIAID is supporting the development of novel therapeutics targeting Ebola virus. These investigational candidate therapeutics could possibly be used in clinical trials in the current epidemic and hopefully will prove to be safe and effective; if so, such treatments could be more widely available for future outbreaks. It is important to note that NIAID-supported candidate therapeutics are in early development and are currently available only in limited quantities.

NIAID has provided support to and collaborated with Mapp Biopharmaceutical, Inc., to develop MB-003, a combination of three antibodies that prevents Ebola virus disease in monkeys when administered as late as 48 hours after exposure. An optimized product derived from MB-003, known as ZMapp, has shown to be substantially more effective in animal models than earlier combinations and protected monkeys from death due to Ebola virus up to five days after infection, according to Mapp Biopharmaceutical, Inc. NIAID's preclinical services are now being used to provide pivotal safety data to support the use of ZMapp for clinical trials in humans. Mapp Biopharmaceutical, Inc., has announced that ZMapp was recently administered to humans for the first time as an experimental treatment to several Ebola-infected patients, including two Americans. It is not possible at this time to determine whether ZMapp benefited these patients. NIAID is working closely with partners at DOD, BARDA, and FDA to advance development and testing of ZMapp to determine whether it is safe and effective. BARDA has recently announced plans to optimize and accelerate the manufacturing of ZMapp so that clinical safety testing can proceed as soon as possible.

NIAID also has funded BioCryst Pharmaceuticals to develop and test BCX4430, a novel drug that interferes with the reproductive process of the virus and has activity against a broad spectrum of viruses. According to BioCryst, BCX4430 has protected animals against infection

by Ebola virus and the related Marburg virus. BioCryst has announced that a Phase 1 clinical trial of this drug is expected to begin in late 2014 or early 2015.

In related work, NIAID intramural scientists at RML are working on therapeutics that might be effective against all hemorrhagic fever viruses including the filoviruses Ebola and Marburg and the arenavirus Lassa. Ribavirin, a drug currently used to treat hemorrhagic fever viruses such as Lassa virus, is being examined for its potential use in combination therapy to treat Ebola virus infection. NIAID scientists also are studying human interferons as Ebola therapies. Other therapeutics being examined by scientists at RML are in early stages of study and if successful, will advance to animal model testing.

Vaccines

A safe and effective Ebola vaccine could be a critically important tool to help prevent Ebola virus disease and help contain future outbreaks. The hope is that such a vaccine could be licensed and used in the field to protect frontline healthcare workers and individuals living in areas where Ebola virus exists. Two Ebola vaccine candidates are entering Phase 1 clinical testing this fall. NIAID will play a critical role in advancing these Ebola vaccine candidates. The results of these Phase 1 studies will inform essential discussions about whether and how such vaccines could be of use in the current epidemic or future Ebola outbreaks.

The NIAID Vaccine Research Center (VRC) has a robust viral hemorrhagic fever vaccine development program. Since 2003, the VRC has evaluated three early-generation Ebola vaccine candidates and one Marburg vaccine candidate in Phase 1 clinical trials at the NIH campus. An additional Phase 1 clinical trial was conducted in Kampala, Uganda, in collaboration with DOD. None of the early-generation candidates raised safety concerns in these small trials; however,

they did not elicit the level of immune response thought to be needed to provide protection against exposure to the virus. The data from those trials have contributed directly to the VRC's current Ebola vaccine collaboration with the pharmaceutical company GlaxoSmithKline (GSK). VRC and GSK have developed an experimental vaccine that uses a chimpanzee virus (similar to the common cold virus), Chimp Adenovirus 3 (CAd3), as a carrier, or vector, to introduce Ebola virus genes into the body; these genes code for Ebola proteins that stimulate an immune response. The vaccine candidate has shown promising results in animal models against two Ebola virus species, including the Zaire Ebola species responsible for the current epidemic in West Africa. A small Phase 1 study to examine the safety and ability of this candidate to induce an immune response in humans began on September 2, 2014, at the NIH Clinical Center in Bethesda, Maryland. Results from the study are anticipated by the end of this calendar year, and will help inform future development of the vaccine.

Additional Phase 1 clinical trials of Ebola vaccine candidates are expected to launch before the end of 2014. In October, testing will begin in the United States on a vaccine candidate derived from the CAd3-vector designed to protect against a single Ebola virus species, the Zaire Ebola virus. NIAID and GSK also will donate doses of this vaccine candidate to enable testing by NIAID partners in the United Kingdom and the West African country of Mali, where existing NIAID research infrastructure will support the vaccine trial. Also this fall, NIH is collaborating with DOD and NewLink Genetics Corporation on Phase 1 safety studies of an investigational Ebola vaccine based on vesicular stomatitis virus (VSV). The VSV vaccine will serve as a vector or carrier for an Ebola gene similar to how the Chimp adenovirus served as a vector or carrier as described above for the NIAID/GSK vaccine. This vaccine candidate was developed by and licensed from the Public Health Agency of Canada.

In addition to these Ebola candidates entering Phase 1 trials in 2014, NIAID supports a broad portfolio of Ebola vaccine research, including partnering with biopharmaceutical companies. NIAID also makes preclinical services such as animal testing to advance product development available to researchers in academia and industry. More than 30 different filovirus vaccine formulations have been evaluated through NIAID's preclinical services since 2011 using animal models and assays that NIAID has developed over many years.

NIAID has supported the biopharmaceutical company Crucell to develop a recombinant adenovirus-vectored Ebola vaccine. In animal studies, this vaccine candidate protected against filovirus infection, including Ebola virus. NIAID has played an instrumental role in the recent announcements by Johnson & Johnson (parent company of Crucell) and Bavarian Nordic that they will collaborate on a two dose (prime-boost) vaccination regimen that will begin Phase 1 testing in 2015.

NIAID intramural scientists are collaborating with Thomas Jefferson University investigators to produce a vaccine candidate based on an existing rabies vaccine. The researchers aim to generate immunity to Ebola, Marburg, and rabies viruses, important diseases in certain regions in Africa. The investigators plan to pursue a version of the vaccine for human and veterinary use as well as a version for use in African wildlife. The wildlife vaccine could help prevent transmission of Ebola virus from animals to humans. The vaccine candidate for use in humans is undergoing preclinical testing and has demonstrated protection against infection by rabies and Ebola viruses in animal models. NIAID is currently partnering with DOD to produce sufficient quantities of the vaccine candidate to begin clinical testing in early 2015.

NIAID also is supporting the biotechnology company Profectus BioSciences, Inc., to investigate a second recombinant VSV-vectored vaccine candidate against Ebola and Marburg

viruses. Profectus is pursing preclinical testing of the vaccine in preparation for a future Phase 1 clinical trial. Additionally, NIAID is collaborating with the Galveston National Laboratory & Institute for Human Infections and Immunity at the University of Texas Medical Branch at Galveston to further progress made by NIAID intramural scientists on a paramyxovirus-based vaccine against Ebola and Marburg viruses.

Other NIAID-supported efforts include Ebola virus vaccine candidates in early development, such as a DNA vaccine targeting Ebola and Marburg viruses, an adenovirus-5-based intranasal Ebola vaccine, and a combination virus-like particle/DNA vaccine targeting Ebola and Marburg viruses to be delivered by microneedle patch. Knowledge gained through these studies will further the goal of the ultimate deployment of a safe and effective vaccine that will prevent this deadly disease.

Clinical Trials

It is important to balance the urgency to deploy investigational medical countermeasures in an emergency such as the current Ebola outbreak with the need to ensure the maximal safety and to determine the efficacy of candidate drugs and vaccines for Ebola. We will do this with the strictest attention to safety considerations, established scientific principles, and ethical considerations and compassion for and realization of the immediate needs of the affected populations. The United States government, working in partnership with industry, has an established mechanism for testing and reviewing the safety and efficacy of potential medical interventions. We also have an emergent crisis in West Africa that demands a quick and compassionate response.

NIAID is committed to working with our partners to evaluate candidate drugs and vaccines for safety and efficacy. We are working to generate the evidence to show whether potential interventions are safe and effective to reassure affected communities that we are pursuing the tools needed to prevent and treat this deadly disease. Our partnerships with industry will be critical to move these products expeditiously along the development pipeline into clinical trials. NIAID is currently working to accelerate the vaccines discussed above into Phase 1 clinical trials in healthy volunteers. The data from these trials will help demonstrate whether candidate Ebola vaccines are safe in humans and are capable of generating the desired immune response. Candidate Ebola treatments will be similarly evaluated for safety and markers of potential efficacy. If successful, these candidates will be advanced to further testing in larger numbers of people. As we proceed through clinical testing, we will continue to work with our partners in the FDA to accelerate development of and speed access to the products, while also protecting the safety and rights of study volunteers.

CONCLUSION

While NIAID is an active participant in the global effort to address the public health emergency occurring in West Africa, it is important to recognize that we are still in the early stages of understanding how infection with the Ebola virus can be treated and prevented. As we continue to expedite research while enforcing high safety and efficacy standards, the implementation of the public health measures already known to contain prior Ebola virus outbreaks and the implementation of treatment strategies such as fluid and electrolyte replacement are essential to preventing additional infections, treating those already infected, protecting health care providers, and ultimately bringing this epidemic to an end. We will

continue to work with biopharmaceutical companies and public health agencies throughout the world to develop and distribute medical countermeasures for Ebola virus disease as quickly as possible. NIAID remains committed to fulfilling its dual mandate to balance research on current biomedical challenges with the capability to mobilize a rapid response to newly emerging and re-emerging infectious diseases.

Written Testimony
Committee on Health, Education, Labor and Pensions and the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
United States Senate

"Ebola in West Africa: A Global Challenge and Public Health Threat"

Statement of

Robin A. Robinson, Ph.D.

Deputy Assistant Secretary and BARDA Director
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:30 p.m.
Tuesday, September 16, 2014

Good afternoon. Chairman Harkin, Ranking Members Alexander and Moran, and other distinguished Members of the Committees, thank you for the opportunity to speak with you today about our Government's Ebola epidemic response efforts. I am Dr. Robin Robinson, Director of the Biomedical Advanced Research and Development Authority (BARDA) and Deputy Assistant Secretary to the Assistant Secretary for Preparedness and Response (ASPR) of the Department of Health and Human Services (HHS).

In 2006, the Pandemic and All-Hazards Preparedness Act (PAHPA) created BARDA and its parent organization, ASPR. Two years ago, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). BARDA is the Government agency mandated to support advanced research and development and procurement of novel and innovative medical countermeasures such as vaccines, antimicrobial drugs, diagnostics, and medical devices for the entire nation to address the medical consequences of chemical, biological, radiological, and nuclear agents of terrorism ("biothreats") and naturally-occurring and emerging threats like the H1N1 pandemic, the H7N9 influenza outbreak last year, and the current Ebola epidemic.

BARDA exists to address the medical consequences of these threats and to bridge the gap between early development and procurement of medical countermeasures for novel threats. Ebola is simultaneously a biothreat (with a

Material Threat Determination issued in 2006 by the Department of Homeland Security) and an emerging infectious disease. The current Ebola epidemic is the worst on record. As CDC has said, we do not view Ebola as a significant public health threat to the United States. The best way to continue to protect our country from any domestic threat posed by Ebola is to take action to address the epidemic in Africa.

BARDA works with our PHEMCE partners in HHS and other Federal agencies to transition medical countermeasures from early development into advanced development and ultimately to Food and Drug Administration (FDA) regulatory review and approval. Advanced development includes critical steps needed for a product to be ready to use, such as optimizing manufacturing processes so products can be made in quantity to scale, creating and optimizing assays to assure product integrity, conducting late-stage clinical safety and efficacy studies, and carrying out pivotal animal efficacy studies that are often required for approval. Since 2006, BARDA has managed the advanced development of more than 150 medical countermeasures for chemical, biological, radiological, and nuclear threats and pandemic influenza. Seven of these products have received FDA approval in the last two years alone.

Over the last decade, the PHEMCE has supported basic research and early stage development of numerous Ebola and Marburg virus medical countermeasure candidates. Now, as a result of this work, several promising

Ebola vaccine and therapeutic candidates have matured enough for BARDA to transition them rapidly from early development to advanced development. Our aim is to have products we can use in time to make a difference in the current Ebola epidemic. We seek to have FDA-approved medical countermeasures as soon as it is feasible. Specifically, BARDA is now providing assistance for the development and scaled-up manufacturing of the ZMapp monoclonal antibody therapeutic and two Ebola vaccine candidates, early development of which has been supported by the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) and the Department of Defense's (DoD) Defense Threat Reduction Agency (DTRA).

Working in conjunction with PHEMCE partners, BARDA uses public-private partnerships with industry to ensure that we have the medical countermeasures to protect the emergency health security of the United States. Over the past five years, BARDA—with NIH, CDC, FDA, and industry partners—has built a flexible and rapidly-responsive infrastructure to develop and manufacture medical countermeasures. Last year, for example, in response to the H7N9 influenza outbreaks in China, the PHEMCE mobilized these partnerships to design, develop, manufacture, clinically evaluate, and stockpile several vaccine candidates in record time. In the current Ebola response, the PHEMCE is working with a wider array of partners in addition to our Federal partners. They include other countries, specifically the affected and at-risk African countries; the World Health Organization (WHO); the Bill and Melinda Gates Foundation; and

others. These expanded partnerships are critical to our efforts to address the current Ebola epidemic.

BARDA has established a medical countermeasure infrastructure to assist product developers on a daily basis. The medical countermeasure infrastructure also allows for BARDA to respond immediately in a public health emergency. Today, BARDA is using this infrastructure to respond to the current Ebola epidemic by helping to develop and manufacture several investigational Ebola therapeutics and vaccines. BARDA's Animal Studies Network is conducting critical animal challenge studies for promising investigational Ebola therapeutic candidates. BARDA's Centers for Innovation in Advanced Development and Manufacturing, established in 2012, are positioned to accelerate production of Ebola monoclonal antibodies, like those in ZMapp, in tobacco plants and mammalian cells if clinical trials demonstrate that ZMapp is safe and effective. BARDA will monitor ZMapp throughout the development cycle, and, if necessary, can shift funds to test other candidate therapeutics. Our Fill-Finish Manufacturing Network, established last year for pandemic preparedness, stands ready to formulate and fill Ebola antibody and vaccine products into vials for studies and other uses. The investments we have made to create this infrastructure over the past four years are helping us respond to the current epidemic.

BARDA also supports large-scale production of medical countermeasures as a response measure for public health emergencies. BARDA led the manufacturing of vaccine and antiviral drugs in response to the H1N1 pandemic in 2009 and of vaccines as a preparedness measure for H7N9 in 2013. In the current Ebola epidemic, BARDA is providing assistance to vaccine and therapeutic manufacturers to scale up production from pilot scale, in which a handful of doses can be made, to commercial scale. For ZMapp, we are currently supporting the manufacture of enough doses for clinical safety studies, but we need to start now to expand the number of domestic manufacturers who can produce Ebola monoclonal antibodies using tobacco plants. Therefore, the Administration is requesting funding for this purpose through an anomaly to the Fiscal Year 2015 Continuing Resolution. Additionally, we are looking at alternative Ebola monoclonal antibody production systems, including those used for similar families of products in the commercial market, as a means of further expanding production capacity for this product. With respect to vaccines, BARDA is working with NIH/NIAID, DoD/DTRA, and industry partners to scale up the manufacturing of the two promising investigational Ebola vaccine candidates. To enable the conduct of clinical efficacy studies for investigational Ebola therapeutics and vaccines in Africa throughout the next year, we need appropriations to fund investments in these medical countermeasure candidates now as proposed through the Continuing Resoltion anomaly.

BARDA faces significant challenges in the coming weeks and months with the manufacturing of these medical countermeasures. The major challenge is being able to provide sufficient quantities soon enough to support clinical studies. BARDA is prepared to meet those challenges and provide resources, expertise, and technical assistance for other promising investigational Ebola vaccine and therapeutic candidates. We are working with our United States Government partners, new and existing industry partners, the WHO, non-governmental organizations, African countries, and others to meet these challenges.

In conclusion, BARDA has established a solid track record in developing medical countermeasures. With the rest of the PHEMCE, we are using all of our capabilities to address the Ebola epidemic in Africa, and have identified crucial additional steps that can be supported through the Fiscal Year 2015 Continuing Resolution. BARDA's investments today into Ebola medical countermeasures will address not only the current epidemic and any future Ebola outbreaks, but they will also help the United States to become better prepared for bioterrorism. Again, I would like to thank the Committee and Subcommittee for your generous and continued support, and for the opportunity to testify. I look forward to your questions.

Dr. Kent Brantly

Senate Committee on Health, Education, Labor and Pensions
Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Ebola in West Africa: A Global Challenge and Public Health Threat
September 16, 2014

Chairman Harkin, esteemed Senators, and fellow guests of this committee, I am grateful for the opportunity to testify in front of you today about the unprecedented Ebola virus outbreak that has already claimed thousands of lives in West Africa and threatens to kill tens of thousands more.

On October 16, 2013, I moved to Liberia with my family to serve as a medical missionary at ELWA Hospital in the capital city, Monrovia. I worked as a physician to support the woefully inadequate healthcare system of a country still struggling to recover from a brutal civil war. Resources were limited, and we often saw patients die of diseases that would be easily treatable in the United States. It was a challenging job to provide quality care even before the Ebola virus tore through the country.

In late March, we learned that there were cases of Ebola in our region, and we began preparing our staff and the ELWA facility so that we would be ready to care for patients in the safest way possible should the need arise. Three months later, our hospital had the only available Ebola Treatment Unit, also known as an isolation center, and I was one of two physicians to treat the first Ebola-infected individuals in southern Liberia.

From June 11 to July 20, the number of Ebola patients we saw increased exponentially. During that time, my organization, Samaritan's Purse, took over responsibility for all direct clinical care of those infected with the disease. I was appointed Medical Director of what would become the only isolation unit in the Monrovia area.

We opened a new, larger Ebola Treatment Unit and brought in patients from the government hospital. During that time, the number of cases continued to grow at an incredible rate. Within days, our 20-bed facility was housing 30 patients, and there was no end in sight. The disease was spiraling out of control, and it was clear that we were not equipped to fight it effectively on our own. We began to call for more international assistance, but our pleas seemed to fall on deaf ears.

As the Ebola virus continued to consume my patients, I witnessed the horror that this disease visits upon its victims—the intense pain and humiliation of those who suffer with it, the irrational fear and superstition that pervades communities, and the violence and unrest that now threatens entire nations.

Then on July 23, I started to feel ill. Three days later, I learned that I had tested positive for Ebola Virus Disease. I became a patient, and I came to understand firsthand what my own patients had suffered. I was isolated from my family, and I was unsure if I would ever see them again. Even though I knew most of my

caretakers, I could see nothing but their eyes through their protective goggles when they came to treat me. I experienced the humiliation of losing control of my bodily functions and faced the horror of vomiting blood—a sign of the internal bleeding that could have eventually led to my death.

I received the best care possible in Liberia, and I am grateful for the team that worked tirelessly to keep me alive despite a severe lack of medical resources and other limitations. I was then evacuated to Emory University Hospital where I was given world-class medical treatment and eventually beat the odds to become one of the few who recover from Ebola. As a survivor, it is not only my privilege but also my duty to speak out on behalf of the people of West Africa who continue to face unspeakable devastation because of this horrific disease.

This unprecedented outbreak began nine months ago but received very little attention from the international community until the events of mid-July when my friend and colleague, Nancy Writebol, and I became infected. Since that time, there has been intense media attention and therefore increased awareness of the situation on the ground in Liberia, Guinea, Sierra Leone and neighboring countries. The response, however, is still unacceptably out-of-step with the size and scope of the problem now before us.

On September 7, President Obama committed U.S. military support in the fight against Ebola in West Africa. He also is requesting an additional $88 million for the Centers for Disease Control to send in more personnel, equipment, and laboratory supplies. This is great news, and I applaud his willingness to enter into this battle with us. Now it is imperative that these words are backed up by immediate, decisive action. We need more than just a 25-bed Ebola Treatment Unit and training for local security forces. To control this outbreak and save the lives of thousands of West Africans—and possibly even more Americans—we need the U.S. to take the lead in providing large treatment facilities, skilled personnel, medical supplies, logistical support, mobile laboratories, and security. We also need to implement innovative community programs to stop the spread of the virus.

In a recent Washington Post op-ed, the International President of Doctors Without Borders, Joanne Liu, called for “a large-scale deployment of highly trained personnel who know the protocols for protecting themselves against highly contagious diseases and who have the necessary logistical support to be immediately operational.” She went on to say, “Private aid groups simply cannot confront this alone.” I agree with her assessment of the desperate need for medical boots on the ground.

Treating Ebola patients is not like caring for other patients. It is grueling work. The personal protective equipment (PPE) we wore in the Ebola Treatment Unit becomes excruciatingly hot, with temperatures inside the suit reaching up to 115 degrees. It cannot be worn for more than an hour and a half. Because of the elaborate safety protocols involved in treating an Ebola patient, each one takes an average of 30 minutes of time from a team of three to five people. It is easy to see that a significant influx of medical personnel will be needed to adequately care for the thousands of people that epidemiologists now are predicting will fall victim to the disease in the coming weeks.

The U.S. military also must establish an "air bridge" for the delivery of critically needed personnel and supplies. Right now, those who are fighting this disease are forced to rely on commercial airlines even as flights into and out of the affected countries are scarce and unreliable. Our military is the only global force with the capacity to immediately and effectively mobilize this kind of logistical support. We cannot turn the tide of this disease without regular flights of personnel and large cargo loads of equipment and supplies.

The use of our military is a legitimate and defensible request because if we do not do something to stop this outbreak now, it quickly could become a matter of U.S. national security—whether that means a regional war that gives terrorist groups like Boko Haram a foothold in West Africa or the spread of the disease into America. Fighting those kinds of threats would require more from the Department of Defense than what I am asking for today.

A surge in medical treatment capacity also must include the deployment of all available mobile laboratories and increased funding for more to be built as quickly as possible. During my time in Liberia, ELWA Hospital was the only Ebola Treatment Unit for all of Monrovia and the surrounding area—serving a population of more than one million. The laboratory we used to confirm Ebola Virus Disease in patients was 45 minutes away and inadequately staffed. A patient would arrive at our center in the afternoon, and their blood specimen would not be collected until the following morning. We would receive results later that night at the earliest. This means that the turn-around time to positively identify Ebola cases was anywhere from 12 to 36 hours after the blood was drawn. If a patient is not infected with the virus, that can be a life-threatening delay.

I remember one patient who presented with symptoms of Ebola—fever, diarrhea, and vomiting. She was in our unit 36 hours before we received confirmation that she was not infected with the virus. We were then able to determine that she was actually suffering from diabetic ketoacidosis. Her treatment had been delayed for a day and a half because of inadequate laboratory support. Amazingly, she survived, but she was in a coma for three weeks. That didn't have to happen.

These laboratory delays can have an even greater—and deadlier—consequence. The longer it takes to confirm a positive result, the longer an Ebola-infected patient is left in the "suspected" side of the isolation unit. Every precaution is taken to protect people in that part of the facility from cross-contamination, but there is always the potential that those without the disease can become infected if they are in close proximity to an Ebola-positive person.

As you have heard today, I am a strong advocate for sending large numbers of medical personnel and supplies to increase capacity for Ebola treatment. I also believe we must do more to support the Centers for Disease Control and the National Institutes of Health as they research vaccines and drugs that can give patients hope for recovery. I am deeply grateful to the personnel at Mapp Biopharmaceuticals who even before this outbreak had devoted their lives to combatting Ebola. I hope that the devastating impact of the current epidemic will result in new discoveries for treatments and vaccines in the future, but we cannot wait for a magic bullet to halt the spread of Ebola in West Africa. The current

epidemic is beyond anything we have ever seen, and it is time to think outside of the box.

Historically, Ebola outbreaks have been contained through the identification and isolation of suspected cases, and this has worked extremely well to stop the disease. Today, however, the number of cases and rate of transmission are surpassing the ability of these traditional interventions to bring the situation under control. Intensive medical care is important, but it is given only to patients in isolation units. We know that the virus is being spread primarily by those who are unwilling or unable to go to an Ebola Treatment Unit.

Many Ebola-positive people are staying at home and even hiding when they become ill. Because of fear and superstition, their family members either abandon them or lovingly tend to them in ways that almost always result in the infection of the caregivers. We have to consider the role of home care as we seek to stop the transmission of Ebola.

Caregivers must be trained in safety measures and supplied with basic protective equipment—gloves and masks at a minimum—so that they can care for their loved ones while protecting themselves. As the number of survivors increases, these individuals should be mobilized to help educate and support their own communities. They would be a powerful witness that this disease is not 100% fatal and provide much-needed support to those who are trying to do what is best for their loved ones.

Survivors are sometimes unable to return home because of stigma in their communities, but the great majority of them are looking for ways to be useful to society again. They can be given important roles in educating home caregivers and disseminate the facts about Ebola with their communities.

These are just normal people. Yes, sometimes they are doctors and nurses, but they are also uneducated day laborers and children. Mothers and other respected members of society can play an especially critical role. They have to be trained and given resources.

To effectively execute this strategy, a technical and logistical infrastructure would have to be put in place. The U.S. should provide advisors and experts to train survivors and others and support the delivery of supplies to affected areas. We must also ensure the personal safety of these outreach workers so that they can do this potentially life-saving job confidently. That may require security forces to protect them. I am not suggesting that we have troops staring people down with guns. They have seen too much of that in their recent history. We just need to make sure that these community workers are safe.

Admittedly, homecare is less ideal than the treatment provided in an isolation unit. It would be impossible to administer I.V. fluids and provide other supportive medical interventions. However, there are not enough beds in the Ebola Treatment Units, and many infected people are choosing to suffer and die at home anyway. The least we can do is to try to give their caregivers the information and resources to protect themselves from this deadly virus.

The World Health Organization has laid out a roadmap similar to what I have just described, but they are so bound up by bureaucracy that they have been painfully slow and ineffective in this response. Their recommendations for home

care were made August 28, and I am not aware of any significant progress in the implementation of their plan to date. It is imperative that the U.S. take the lead instead of relying on other agencies.

The U.S. military is highly trained with a clear chain of command. They are experienced in responding to complex international crises such as what we are facing now. I believe they are the only force capable of mounting an immediate, large-scale offensive to defeat this virus before it lays waste to all of West Africa.

All of the interventions needed to stop this horrendous transnational outbreak also require significant funding, and budgets must be adjusted appropriately. This is not simply a matter of providing humanitarian aid, it is very much a national security concern.

One of my patients in Liberia was a man named Francis. Initially, the lab told us that he was positive for Ebola, but the written report we received said "Negative." Everything about his clinical case said that he was infected, so we made plans to retest him. We then received word that there was a typo on the first report and that his test was indeed positive.

Like most patients at first, he was fearful, but he eventually shared the story of how he contracted the disease. "Doc, I remember who the man was," he said. "His condition worsened in his home, and his wife made the decision to take him to the hospital. Everyone around them fled, so I helped his wife carry him to the taxi." On his way to the hospital that man died. Had someone come alongside Francis with training and some basic personal protective equipment, his family might still have their husband, father, and son, and the world might still have this Good Samaritan.

Many have used the analogy of a fire burning out of control to describe this unprecedented Ebola outbreak. Indeed it is a fire—a fire straight from the pit of hell. We cannot fool ourselves into thinking that the vast moat of the Atlantic Ocean will keep the flames away from our shores. Instead, we must mobilize the resources needed to keep entire nations from being reduced to ashes.

Ishmeal Alfred Charles
Testimony September 16, 2014

Good afternoon, my name is Ishmeal Alfred Charles, a resident of Freetown, Sierra Leone, married and a father of two children, 9 months and 10 years. I arrived yesterday morning to share with you what my country is dealing with on a daily basis with the current Ebola outbreak, while still rebuilding after a brutal civil war; unlike the civil war the outbreak creates more fear to the entire population

Today there is a general atmosphere of fear. This is the biggest crisis we have faced since the end of our civil war.

As a former Child soldier, I was able to survive the war, and now I fear, "This is going to be worse than the war."

The Healey International Relief Foundation is based in Lumberton, NJ supports the rebuilding of Sierra Leone's healthcare system and has provided relief services to our country since the end of our civil war, over 12 years ago.

The Foundation Mission is to invest and support families and individuals affected by war, disaster and adverse socio-economic conditions through the delivery of healthcare, clean water, food, training and other programs, hence it mandate is to empower communities and build their capacity to become self-sustaining.

The foundation partners with Caritas Freetown on all its projects in Sierra Leone.

Caritas Freetown whose mission is to eradicate poverty, corruption, injustice; to improve equality, advance good governance, achieve peace and human rights, empower women, youth and the disabled.

As the spokesperson for the Healey International Relief Foundation in Sierra Leone, I feel privileged to share with you our experience. Since the outbreak, we have implemented the "Ebola Outbreak Response Project" in the rural and urban districts of Sierra Leone. We work closely with the Ministry of Health and Sanitation, Ministry of Social Welfare and the Emergency Operation Center.

As part of this project, we have been working in number of communities within the Western Area Districts with a catchment area of about 219,000 people, raising awareness and providing chlorine, soaps and tap buckets to all police stations and posts. In addition we have a strong national media campaign in collaboration with our counterpart Caritas organizations in the other regions.

The growing number of cases recorded on a daily basis has made the situation in Sierra Leone very scary. Each day the situation becomes worse and the effects of the Ebola cannot be over emphasized. When I was about to leave, my 10 years old daughter asked "dad are you leaving us here in this difficult situation with this Ebola, they said there is no Ebola in America, why can't you take us along?" I starred at her

for a minute and said "Maa as I call her, my trip is for the general good of all our family and your future, I will be back in two weeks", she asked again "are you sure when flights are being cut off daily?"

Similarly, my wife said, "dear the money you normally leave when travelling will not be enough as the cost of commodities has tripled", this was another difficult situation.

As I leave, my biggest stress is if anyone gets sick while I am away, the health system is not functional.

The Ebola phobia is increasing. Even people who do not have Ebola are being stigmatized, not to talk about those who are tested positive.

The state is overwhelmed and unable to effectively coordinate the Ebola response and people are losing their confidence. The Ebola crisis has escalated quickly and has led to the widespread fallout the healthcare system.

- Harvests are being cancelled because so many farmers had died;
- In the capital, Freetown, patrons are sparse at hotels and restaurants specially those catering to the expatriates. Hotel occupancy rates have dropped and large hotels have only 4 guests and these hotels are laying off staff daily;

- In a country with 70% illiteracy schools are closed indefinitely;
- Our country high orphan population, is increasing every day;
- People do not have the free will to bury their loved ones, and even the sick ones are deprived of the emotional care from their family needed to recover;
- Many companies are laying off staff amidst the slowdown in commerce, restrictions on travel and decrease in other economic activity.

As a result, households are struggling with food shortages and increase costs due to panic buying.

Families go hungry when the bread winner dies, gets sick or loses his or her jobs.

With the support of the United States, the International Community and the survival spirit of the people of Sierra Leone, I am confident we will defeat this deadly virus. However, a decade of progress will be lost, especially so when the health care was already in bad shape before the outbreak.

I plead not to leave once the crisis is over and help us rebuild our country physically and economically by investing in Sierra Leone to empower our people become self-reliant.

I thank you for your attention.