



STATEMENT OF

SYLVIA BURWELL

SECRETARY

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

**EMERGENCY APPROPRIATIONS REQUEST TO ENHANCE THE U.S.
GOVERNMENT'S RESPONSE TO EBOLA AT HOME AND ABROAD**

BEFORE THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

NOVEMBER 12, 2014

Chairwoman Mikulski, Ranking Member Shelby, Chairman Harkin, Ranking Member Moran, and members of the Committee, thank you for inviting me here today to discuss the Department of Health and Human Services' (HHS) response to the current Ebola epidemic, and our request for emergency funding to invest in these ongoing efforts and further strengthen our response. Since the first cases of Ebola were reported in West Africa in March 2014, the United States has mounted a whole-of-Government response to protect the American people and contain and eliminate the epidemic at its source. At HHS, this response involves close coordination between the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Assistant Secretary for Preparedness and Response (ASPR), the Office of Global Affairs (OGA), and the U.S. Public Health Service Commissioned Corps, among others. I appreciate the opportunity to discuss our role in this critical effort and our request for emergency funding to ensure that resources are available for both the immediate and longer-term to meet the evolving nature of the epidemic.

We believe that we have the right strategy in place, both at home and abroad, to respond to Ebola. Our strategy is designed around four core principles. First, to further strengthen our domestic preparedness. While we may see additional cases in the United States, we are confident that we will limit the number of cases here in the country. Second, to stop the epidemic at its source in West Africa, which is also how we best protect our homeland. Third, to accelerate research and development of vaccines, rapid diagnostics, and therapeutics to combat the disease and prevent future outbreaks. Fourth, to urgently establish what is needed to prevent spread of Ebola and to more broadly prevent, detect and rapidly respond to outbreaks before they become epidemics, through the Global Health Security Agenda.

I want to take a moment to recognize the health care and public health workers who are on the front lines of this response – ensuring that our hospitals and communities here at home are prepared and providing care and assistance for those at the source of the outbreak in West Africa. Unfortunately, Thomas Duncan, a visitor from Liberia, died of Ebola in Dallas on October 8th. Thankfully, the two Dallas nurses who provided care for Mr. Duncan and became infected have now been declared Ebola-free, including one who was treated at our own NIH Special Clinical Studies Center. Our thoughts and prayers are with Dr. Craig Spencer, who contracted this disease in West Africa while selflessly providing care for others, and with the hundreds of health care workers who are preparing our hospitals here in the United States and continuing the fight abroad, as well as with the people of Liberia, Sierra Leone, and Guinea who are facing this disease in their homes and communities.

HHS Response

The Department is requesting \$2.43 billion in emergency funding to execute our ongoing Ebola response strategy and see it through effectively. With the funding provided under the Fiscal Year 2015 continuing resolution, the Department has scaled up efforts to prepare public health and health care systems in the United States, accelerate research and development of vaccines and therapeutics, and combat and contain the spread of the virus in West Africa. Actions we have taken to date to further strengthen our readiness and recent developments demonstrate why we must continue to invest in our strategy.

Domestic preparedness is a top priority for this Administration, and we have taken a number of active steps as an Administration and at HHS to further strengthen our readiness. These steps include training and support to enable screening of travelers as they leave countries

with widespread transmission of Ebola on their way to the United States; funneling those travelers through one of five airports in the United States with enhanced screening mechanisms; and active post-arrival monitoring of those travelers for the full 21-day incubation period.

A central part of our preparedness here at home is ensuring that hospitals are in a position to manage the early recognition and isolation of a patient with Ebola symptoms and engage public health authorities appropriately. While hospitals throughout the country must be able to recognize and safely isolate a potential Ebola patient, we have worked with a targeted subset of hospitals to further strengthen their readiness to treat patients. As we speak, teams of experts are visiting hospitals that have volunteered to take Ebola patients and are assessing and helping to improve their readiness. At the same time, we are working to ensure that transportation from a screening to a treatment hospital is safe and effective. Patients will be transported in an ambulance or, if needed, a plane – in both cases the measures and protocol put in place are designed to protect the patient and the health care workers. CDC is also working with public health laboratories across the United States to build their capacity to test specimens as quickly as possible. If a case is confirmed, CDC has created dedicated response teams to provide immediate on-site assistance to hospitals, as well as state and local public health officials.

As a Department, we have ramped up outreach to hospitals and front-line health care workers. To date, more than a quarter of a million health care personnel have participated in HHS-sponsored information events. That includes calls with 10,000 nurses, 20,000 physicians and dentists, and targeted outreach to emergency responders, laboratory workers, waste management workers, hospital executives, and others involved at all levels of the response. CDC has also updated infection-prevention protocols for hospitals and health care workers, aircraft

crew and airport personnel, and laboratories handling specimens from suspected cases to ensure that personnel take all available and scientifically-based precautions to keep themselves safe.

In addition to the successes at Emory University Hospital, the University of Nebraska Medical Center, and the NIH Special Clinical Studies Center, we are hearing encouraging news from the hospitals that have treated and are preparing to treat Ebola patients here in the United States—from Bellevue in New York, which treated Dr. Spencer to Duke University in North Carolina, which screened a potential patient just last week. Of the nine patients treated in the U.S., eight have survived. We have also seen positive signs about our screening and monitoring system. There have been examples in Oklahoma, North Carolina, Oregon, and Maryland where individuals reported symptoms to local authorities based on the screening and monitoring process. The Maryland case is a good example. When the traveler arrived at JFK from Liberia, she was given a CDC issued “CARE kit” with a thermometer and instructions for whom to contact if she started having symptoms. She took her temperature using the CDC thermometer as directed. When it read high she called the Maryland Health Department as instructed in the CARE kit and the health department facilitated her arrival at the hospital the state referred her to for evaluation. Fortunately, she tested negative. In this case and each of the others, the response followed protocol, minimizing exposure to the public, and in each of these cases the test results turned out to be negative.

The fact is, the best way to protect Americans here at home is to stop Ebola at the source. We have teams from across the Department on the ground in West Africa working alongside the U.S. embassies, the U.S. Agency for International Development (USAID), the U.S. military, local authorities, and non-governmental organizations. Since the start of the outbreak, CDC has deployed more than 600 people to the region to assist with outbreak control, support laboratory

and surveillance capacity, and conduct contact tracing. HHS has also deployed a total of 73 specialized Public Health Service Commissioned Corps officers to Liberia to manage and staff a hospital that was constructed by the Department of Defense (DoD) for health care workers who become ill. We are proud of these brave and dedicated men and women from across the Department, and grateful for their service and sacrifice.

Across HHS our employees are working with partners in the private-sector and around the world to develop vaccines and therapeutics to combat this disease. This work is crucial to our efforts government-wide to prevent future outbreaks, and may be needed to help halt the current epidemic. NIH has accelerated research and early development of Ebola vaccine and therapeutic candidates, which are then transitioned to ASPR's Biomedical Advanced Research and Development Authority (BARDA) for advanced development and manufacturing. BARDA is using funds provided under the continuing resolution to begin manufacturing Ebola vaccine candidates and potential therapeutics that will be used for clinical trials. While efforts to date have been critical, additional resources are necessary to bring safe and effective products to FDA approval.

On a parallel track, FDA is actively working to help expedite the development and availability of medical products – including treatments, vaccines, diagnostic tests, and personal protective equipment – with the potential to help bring the epidemic under control as quickly as possible. In addition, FDA has exercised its Emergency Use Authorization (EUA) authority five separate times to allow the use of Ebola diagnostics tests developed by U.S. Government agencies and private industry for the treatment of patients. I want to thank the Congress for providing that authority, and I believe this is an important example of FDA delivering on an authority provided by the Congress to serve the American people.

Emergency Appropriations Request

Although the U.S. Government's response to the Ebola outbreak to date has resulted in progress, additional funding is needed to plan and execute most effectively. The \$2.43 billion emergency request for the Department is designed around three core principles: first, \$1.22 billion to further strengthen the Department's ongoing strategy to prepare our public health and health care systems here at home, and to invest in the vaccines and treatments that may be used in responding to the current outbreak and in preventing future outbreaks; second, \$603 million to stop the outbreak in West Africa; and third, \$606 million to strengthen global health security, which reduces risks to Americans by enhancing capacity for high-priority countries to prevent disease outbreaks, detect them early, and swiftly respond before they become epidemics that threaten our national security. These are the same activities that are necessary to combat the spread of Ebola and reduce the potential for future outbreaks of infectious diseases that could follow a similarly devastating, costly, and destabilizing trajectory.

The emergency request also includes \$751 million through a Contingency Fund. Resources provided to HHS through the Contingency Fund would only be made available following a Presidential emergency declaration, consistent with the funding structure used by the Congress in 2009 for the emergency funding for the H1N1 pandemic influenza. Given the changing nature of the Ebola epidemic, the Contingency Fund is requested to ensure that there are resources available to respond to the evolving situation. These funds can be transferred among Federal agencies to help meet any critical needs that may arise rapidly. For example, funds could be provided to the Department of Homeland Security to increase Customs and Border Control operations. If necessary, the Contingency Fund also could support increased

domestic efforts, such as a limited vaccination clinical trial campaign that could target health care workers treating infected patients (if a vaccine is proven safe and effective); an expanded response in Guinea and Sierra Leone; and enhanced global health security. As the rapidly evolving and unpredictable outbreak progresses, it will be necessary to have maximum flexibility to respond quickly.

Domestic Preparedness and Response

The Department will use \$787 million of the funds provided through the emergency request to enhance ongoing preparedness and response efforts here in the United States, including by strengthening hospital and public health capacity to identify and respond to potential Ebola cases.

Of this funding, \$621 million will support CDC's ongoing efforts to ensure that states and localities across the United States have the resources they need to prevent, detect, and respond to Ebola. The funding will strengthen public health and health care systems by improving readiness in hospitals, laboratories and communities across the country. With this funding, CDC will also support state and local health departments in their efforts to improve safety practices of their clinical laboratories and accelerate infection control implementation throughout U.S. hospitals. This includes hiring additional Career Epidemiology Field Officers to conduct contact investigation and monitoring for suspected cases, among other functions. It will also allow CDC to accelerate the development of training courses, materials and videos; work with local hospitals and public health departments to conduct exercises and develop improvement plans; and purchase additional personal protective equipment to be used as needed. Lastly, CDC will continue to work with Federal, state, international, and private partners to

ensure proper protocols are followed to identify and quarantine any travelers with a suspected case of Ebola, including enhanced entrance screening, contact tracing and monitoring of suspected cases.

In coordination with CDC's efforts, \$166 million is for ASPR to work to strengthen domestic preparedness efforts through improved hospital infrastructure, resources, and training. To optimize efficiency and communication in these efforts, ASPR will utilize its existing Hospital Preparedness Program infrastructure, which provides leadership and funding to states, territories, and eligible municipalities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. The requested funding will support the renovation and alteration of treatment hospitals designated to provide definitive care for patients diagnosed with or suspected to have Ebola. ASPR will also provide funding to states to support the purchase of personal protective equipment and the training of thousands of other hospitals so that their staff can screen for, identify, and provide initial care for Ebola patients. This funding will support giving hospitals and health care workers the training and equipment they need to properly care for Ebola patients while maintaining their own safety.

International Response

In West Africa, we are optimistic that our strategy is starting to have an impact, with declines in the number of new cases in parts of Liberia. However, progress is fragile and fluid, the number of new cases in Sierra Leone is still growing, hot spots continue in rural, remote parts of Guinea and Liberia, and more work needs to be done, especially to scale up. From the emergency request, HHS will use \$603 million to continue to contribute to the whole-of-Government public health response on the international scale, with a focus on long-term system

transformation to identify and prevent the spread of future outbreaks. CDC will focus on enhancing infection control and contact tracing; training public health workers both before deployment and in Africa; strengthening laboratory systems and the establishment of national and regional networks; enhancing public health education and outreach for health care workers; procuring and managing in-country operations and supplies for CDC responders during deployment; and establishing Emergency Operations Centers to analyze, validate, and efficiently work with emergency response partners to make sure they have the information and resources they need to operate effectively on the ground. Collectively, this means that we will be better positioned to rapidly diagnose, report and track Ebola cases in the affected countries, that our health care workers on the frontline of this response will be most effectively prepared for their work on the ground, and that we will be able to limit the spread of infection within the health care and community setting.

The Department will continue to work with communities, governments and other partners on the ground in West Africa to ensure that people are promptly diagnosed, effectively treated and, if they die, safely buried. While progress is fluid due to the evolving nature of the epidemic, to date these tactics do appear to be having an impact.

Vaccines, Therapeutics, and Diagnostics

On a separate track, HHS's science agencies will use \$420 million of the funding requested to invest in research and development of vaccines, therapeutics, and diagnostics to combat the virus. Of this amount, \$238 million is for the NIH National Institute of Allergy and Infectious Diseases (NIAID), home to the doctors and other health care workers who provided care for one of the Dallas nurses who recovered from the virus, to support new and accelerated

research to diagnose, treat, and prevent Ebola. In addition to NIAID's treatment capabilities for Ebola patients, much of the requested funding will support clinical trials to evaluate the safety and efficacy of investigational vaccines and therapeutics. This request will also support pre-clinical testing and discovery of new vaccines, therapeutics, and diagnostics to accelerate initial identification and evaluation of their toxicity, immunogenicity, and efficacy. Candidates that show notable progress within this early development could be transitioned into a pipeline of products for advanced development and manufacturing at ASPR/BARDA. Many of these activities could yield initial results in less than a year.

Within ASPR/BARDA, \$157 million in additional funding will support the manufacture of vaccines and other therapeutics for use in clinical trials. The funding will also support advanced development for new antibody and therapeutic options, which are available due to successful early development at NIH. This request will support the continued and timely manufacturing and development of antibody products, therapeutics, and vaccine candidates into FY 2016. It also will allow the Federal Government to continue the acceleration of these products towards FDA approval.

The request also includes \$25 million for FDA to sustain its aggressive efforts to support the pipeline of possible investigational medical products for Ebola and other serious emerging infectious diseases, including accelerating product development and review, facilitating access to investigational products, and supporting product surveillance. The funding will allow FDA to bring on additional staff to support the Ebola response by providing regulatory and scientific guidance and conducting product review, among other functions, to help expedite the availability of medical products for Ebola. This funding will also enable FDA to conduct the regulatory

science research necessary to facilitate the development and regulatory review of such products with the speed required.

Global Health Security

With an eye towards detecting and preventing outbreaks of this magnitude in the future, the emergency request includes \$606 million to urgently strengthen global health security in high-priority countries around the world. The most effective way to prevent the spread of disease to the United States is to address it immediately at its source. This requires building and strengthening critical health infrastructures in countries that are particularly susceptible to Ebola virus disease importation and outbreaks of other high impact infectious disease – meaning strengthening safe and secure laboratory capability to find diseases when they occur, standing up emergency operations centers, providing equipment and training to test patients and report data in real-time, and training the disease detectives needed to track the response. These activities are necessary to combat the spread of Ebola but also to reduce the potential for future outbreaks of infectious diseases that could follow a similarly devastating, costly, and destabilizing trajectory. More specifically, we will make it a priority to focus on countries in the ring around Guinea, Liberia and Sierra Leone, others in the region that are high-priority due to poor infrastructure and countries serving as major air transport hubs with the three affected countries.

Expediting the capability required to prevent, detect and rapidly respond to outbreaks before they become epidemics that threaten the American people is a top priority for HHS and the Administration. The Ebola epidemic, as well as other outbreaks of continuing concern, such as the Middle East Respiratory Syndrome Coronavirus in the Middle East and Ebola in West Africa, underscore that, in a world as interconnected as ours, outbreaks anywhere in the world

are a threat to the United States and our global partners. Over the past decade, infectious disease outbreaks have sown fear, cost lives and been a drain on the global economy. For example, the Severe Acute Respiratory Syndrome cost the global economy an estimated \$40 billion. During the anthrax attacks of 2001, 22 people were infected, five people lost their lives here in the United States, and the cleanup cost was more than a billion dollars. The global H1N1 influenza pandemic of 2009 killed 284,000 people worldwide in its first year alone. To contain threats at the source, before they threaten global security, we must immediately invest in shoring up capability in the highest-priority nations.

Conclusion

The Congress is a key partner in the response to the Ebola epidemic, and I appreciate the attention that you and your colleagues have paid to this important issue. I look forward to working with you on our response and ensuring that HHS and our partners have the necessary resources not only to control and eliminate this epidemic, but also to make the investments necessary to protect us from similar outbreaks going forward. We are committed to protecting the health and safety of the American people and contributing to the worldwide response.

Thank you for the opportunity to testify. I would be happy to answer any questions you may have.