

PREPAREDNESS AND RESPONSE TO PUBLIC HEALTH THREATS: HOW READY ARE WE?

HEARING

BEFORE THE

COMMITTEE ON
HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE
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PREPAREDNESS AND RESPONSE TO PUBLIC HEALTH THREATS: HOW READY ARE WE?

WEDNESDAY, NOVEMBER 19, 2014

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 10:08 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Thomas R. Carper, Chairman of the Committee, presiding.

Present: Senators Carper, McCaskill, Baldwin, Coburn, Johnson, Portman, and Ayotte.

OPENING STATEMENT OF CHAIRMAN CARPER

Chairman CARPER. Our hearing will come to order.

To all of our witnesses, thank you very much for being here. I just want to say to our staffs, both on the majority and minority side, a big thank you for pulling together a terrific line-up here on a subject that is real important to our country, I think to our world, and for all of you for making time to prepare for it today and to present today and to respond to our questions.

Normally, when Gil is here, we would put everybody under oath, but—no, we do not do that, only one time, when he was here for his confirmation. We are very pleased with the work that you are doing, pleased with the work that you are all doing.

Today, we will examine, as you know, our Nation's response to the ongoing Ebola epidemic and our overall preparedness for other public health threats. We are very fortunate to have a great panel of witnesses with us today, and I want to thank each of you again for, not just for your presence, but for your public service at a very challenging time in our Nation's history and certainly in the history of the countries in West Africa.

Since February, the public has watched an epidemic of Ebola virus grip the countries of Sierra Leone, Liberia, and Guinea, and now Mali. To date, roughly 5,200 people in West Africa, we are told, are believed to have died from the Ebola virus. The actual number of deaths may be significantly higher. The severity and the scale of this outbreak has challenged the worldwide public health community.

And, when I think about the tragedy that is playing out in West Africa and what role we should play, I am reminded of the New Testament, and I am reminded in particular of an answer that Jesus once gave when the Pharisees asked Him, "What are the two most important commandments?" And He told them what the first

one was, and then He said, "The second one is to love thy neighbor as thyself." And the Pharisees then asked Him, "Who is my neighbor?" And, famously, he told them the one about the good Samaritan, and if you do not remember the story of the good Samaritan, it is a good one to read, be refreshed on, because the question that we need to ask ourselves from time to time, especially those of us who are privileged to serve in these positions, is who is our neighbor? And, in this case, the folks, I think, in West Africa are our neighbors, as well, and we are responding, I think, in a way that is reflective of our belief, our embrace of the Golden Rule.

If we do not take care of our neighbors in West Africa, then we may see this deadly disease spread even faster across the world. And, that is why I believe it is vital that we, along with our international partners, continue to battle Ebola at its epicenter.

Ebola, like all infectious diseases, knows no borders. It has even reached our shores. And, over the weekend, the United States began treating its tenth patient for Ebola, who, sadly, passed away on Monday. His death marks the second Ebola-related death here at home.

In light of the Ebola virus epidemic, many Americans have asked this important question: How prepared is our Nation to handle a major public health threat? And, that is what we hope to help answer here at our hearing today.

Our goal for this hearing is not to create needless confusion. Doing that would be counterproductive, potentially putting more people at risk and exacerbating the public's understandable fear of this disease. Instead, I hope, I think Dr. Coburn hopes, we are able to find some lessons learned from our Ebola response and use them to inform our future responses to this disease and to others that could threaten our Nation and its people.

And, while I know the disease is far from being defeated and has even, as I mentioned earlier, it began to spread at least in Mali, it is my understanding that the number of cases in Liberia has substantially declined, and that is welcome news, although I know we could see a spike in cases with little notice there. We have seen in Nigeria the reporting of no new outbreaks, no new cases, I think since the end of August, and that is very welcome news. But, we must continue to pay close attention to the changing dynamics in Africa, and we must continually reassess the scales of the response needed overseas and here in the United States to end this epidemic.

Whether it is Ebola, whether it is influenza, or a disease we have yet to hear about, the bottom line is the same. We need to be better prepared. We need to be ready to respond.

To be most effective, of course, we must have a well-coordinated response at the Federal, State, and local level, and I might add, this is not all on America. We are a wealthy nation. We have a responsibility as a world leader to respond in situations like this, but it is not all on us. There are other nations out there that have some responsibilities, and I think in a number of these countries, and my staff are good, they are standing up and meeting their responsibilities and that is very reassuring.

We must also have clear guidance and protocols from the Centers for Disease Control (CDC) and Prevention and other public health

officials so that everyone knows exactly what to do and what not to do. We must also ensure that our State and local health and emergency response professionals have the training and tools they need to succeed. Finally, we must have a strong screening process in place at our ports of entry (POE) so we can better identify and monitor high-risk travelers.

I also believe that a critical part of addressing any public health threat is the availability of antivirals, therapeutics, and other medical countermeasures (MCM). In the case of Ebola, I have been encouraged by the significant progress that we have made in the last few months on a vaccine for the virus as well as therapeutics to treat the disease, and I appreciated the opportunity to talk with Dr. Frieden about that just yesterday. We look forward to hearing about the status of these countermeasures and the plan for getting them quickly to people in need.

To help meet the immediate and long-term needs of the Ebola epidemic, President Obama recently submitted an emergency funding request of nearly \$6.2 billion, and we look forward to hearing more about that request, particularly in light of the changing situation on the ground in Africa. As we discuss this funding request, I believe we should keep in mind our moral obligation to help the least of these in our society. We believe that in this Committee. We also believe in trying to do that in a cost effective way.

In closing, I just want to acknowledge the work of our witnesses and countless first responders and health professionals who are literally willing to risk their lives in order to help save people they do not even know. We are grateful for their courage and for their willingness to serve.

And, I also want to recognize and thank the non-governmental organizations who are so critical in this worldwide effort to stem the epidemic of Ebola.

And, with that in mind, I am going to turn it over to my compadre, Dr. Coburn, for any comments that he might have, and then we will come back to introduce the panel. Thank you. Dr. Coburn.

OPENING STATEMENT OF SENATOR COBURN

Senator COBURN. Mr. Chairman, thank you, and I apologize for being late.

I do not have a prepared statement other than to say I want to thank those presenting here today. I think we are very fortunate where we find ourselves today, whether that is because of our lack of knowledge or because of our knowledge. But, I think, overall, we have done a fairly effective job at each level. Even though we remain vigilant and worried, we appreciate the efforts on everybody's part.

And, I really want to hear from our witnesses more than I want to hear us make statements that the public might want to hear. I want to hear the knowledge, the recommendations. I am somewhat concerned that the request may be a little bit high, but other than that, there are things we need to do and things that we need to be prepared for.

So, personally, let me thank each of you for your efforts and your commitment and your service and I look forward to your testimonies.

Chairman CARPER. I want to take just a moment and introduce each of our witnesses.

Our first witness is Dr. Nicole Lurie. She is the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), a position she has held since 2009. Dr. Lurie is also a Rear Admiral, out of uniform here today, in the U.S. Public Health Service (USPHS). I love it when you all wear those uniforms. I am an old Navy guy, so I like to salute our admirals.

Previously, Dr. Lurie served as a Professor of Health Policy at the RAND Corporation and the University of Minnesota. She has also served in State Government as Medical Advisor to the Commissioner at the Minnesota Department of Health. Who was the Governor then?

Dr. LURIE. It was Jesse Ventura.

Chairman CARPER. Jesse Ventura?

Dr. LURIE. Jesse Ventura. I knew Jesse Ventura well and worked with him a lot.

Chairman CARPER. The only Governor I ever served with who wore snakeskin pants to work. [Laughter.]

Dr. LURIE. With his pink boa, yes.

Chairman CARPER. There you go. [Laughter.]

Next on our panel, we have Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention within the Department of Health and Human Services. Dr. Frieden has held this position since 2009. Previously, he served as Commissioner of the New York City Department of Health and Mental Hygiene from 2002 to 2009. He began his career at CDC in 1990 as an Epidemic Intelligence Service Officer. Nice to see you. Welcome.

Next, and no stranger to this Committee, is Gil Kerlikowske, who heads up the Customs and Border Protection (CBP) operation in the Department of Homeland Security (DHS). I was kidding him earlier, Tom, about how many places he has been police chief, and I think they include Buffalo, I want to say Seattle, and a couple places in Florida. Which ones?

Mr. KERLIKOWSKE. Fort Pierce and Port St. Lucie.

Chairman CARPER. There you go. That is it, just four? That is a pretty good run. And also, as I recall, a couple of times, were you not the leader of the National Police Chiefs Organization a couple of times?

Mr. KERLIKOWSKE. I was.

Chairman CARPER. That is pretty good credentials. You are accompanied today by Kathryn Brinsfield, who serves as the Chief Medical Officer for the Department of Homeland Security. Kathryn, would you raise your hand, please? Thank you. Nice to see you. Dr. Brinsfield is available for questions during the hearing. In case Gil slips up, she will just jump in and correct him.

Our fourth witness is Nancy Lindborg, nice to see you—Assistant Administrator for the Bureau for Democracy, Conflicts, and Humanitarian Assistance at the U.S. Agency for International Development (USAID). And, in this role, she leads the efforts of more

than 500 team members in the nine offices focused on crisis prevention, on the response, recovery, and transition. Before joining USAID, Ms. Lindborg was President of the Mercy Corps, where she spent 14 years with this organization.

And our final witness, last but not least, Dr. David Lakey, who served as Commissioner of the Texas Department of State Health Services (DSHS) since 2007. Dr. Lakey has served in a number of positions at the University of Texas Health Center, including Associate Professor of Medicine and Medical Director of the Centers for Infectious Disease Control.

Again, we thank you all for your service and for your testimony here.

I do not want to chair this hearing today. I want Tom Coburn to chair it. So, I am going to pass this gavel over to him and put him in charge and I will try to be a good wingman. All right, Thomas, it is all yours.

Senator COBURN. You want me to get the practice? [Laughter.]

Chairman CARPER. You might make a comeback. [Laughter.]

Senator COBURN [presiding]. Well, we thank you. It is very doubtful. [Laughter.]

Thank you all for being here. Dr. Lurie.

TESTIMONY OF NICOLE LURIE, M.D.,¹ REAR ADMIRAL, U.S. PUBLIC HEALTH SERVICE, AND ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. LURIE. Sure. Good morning, Chairman Carper, Ranking Member Coburn, and distinguished Members of the Committee. I am Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response at HHS. I very much appreciate the opportunity to talk to you today about the actions that ASPR has taken to enhance our national preparedness and strengthen our resilience to public health threats.

While it is absolutely essential that we continue to focus on controlling the Ebola outbreak in West Africa, we also have a critical responsibility to protect our country from this disease. Today, I will highlight three areas in which ASPR's work is critical to our domestic as well as international response.

First, the Biomedical Advance Research and Development Authority (BARDA), building on its previous success in medical countermeasure development, is speeding the development, testing, and manufacture of Ebola vaccines and treatments.

Second, the Hospital Preparedness Program (HPP), as I will call it, has since the beginning of this outbreak been preparing hospitals and first responders to recognize and treat patients suspected with Ebola.

And, third, our Federal resources and responders, whether the National Disaster Medical System (NDMS), the Medical Reserve Corps (MRC), or the U.S. Public Health Service, stand ready to support a comprehensive response, should it be needed in the coming months.

¹The prepared statement of Ms. Lurie appears in the Appendix on page 51.

BARDA, in coordination with other medical countermeasures partners, has a great track record in expanding the medical countermeasures pipeline and building needed infrastructure to do so. In addition to developing and procuring 12 products since Project BioShield's inception over a decade ago, BARDA Centers for Innovation and Advance Development and Manufacturing (CIADM) and its Fill-Finish Manufacturing Network are being used to produce, formulate, and fill vaccines and treatments for Ebola.

Complementing our successes in medical countermeasure development, ASPR has made great strides in U.S. health care system preparedness, as well. HPP investments have fostered an increased level of preparedness throughout communities and decreased reliance on Federal aid following many disasters. In the last several years, HPP awardees have demonstrated their ability to respond to and quickly recover from disasters, including tornadoes, floods, hurricanes, and the fungal meningitis from contaminated steroids.

Through HPP, ASPR has actively engaged in Ebola preparedness by developing and disseminating information, guidance and checklists, and serving as a clearinghouse for lessons learned. Together with CDC, we have launched an aggressive outreach and education campaign nationally that has now reached well over 360,000 people through webinars and national calls, including with public health officials, hospital executives, front line health care workers all over the country, and others across the United States.

My office, along with CDC, continues to recruit hospitals willing and able to provide definitive care to patients with Ebola in the United States. Concurrently, we are working with Personal Protective Equipment (PPE) manufacturers to coordinate supply and distribution and are working with HPP-funded health care coalitions to collaboratively assess and share supplies across communities.

The likelihood of an Ebola outbreak in the United States is quite small, but ASPR, HHS, and our interagency partners are, as you know, part of a coordinated whole-of-government response, a response that extends on the one hand to West Africa and on the other to State and local governments, to hospitals and communities throughout the United States.

As is typical for other emergencies and disasters, ASPR is responsible for public health and medical services and coordinates Federal assistance to supplement State, local, Territorial, and Tribal resources and response to public health and medical care needs during emergencies.

I would like to close with an overview of the recent emergency funding request from the Administration that includes \$2.43 billion for HHS. ASPR's request supports two major components, BARDA's product development efforts and HPP's preparedness initiatives. Specifically, funding will support development of Ebola vaccine and therapeutic candidates, clinical trials, and commercial scale manufacturing. Funding will ensure that communities will be able to purchase additional Personal Protective Equipment, that health care workers will receive additional training on patient detection, isolation, and infection control, and that we further build our preparedness for the future by ensuring that all States have facilities that can handle a serious infectious disease like Ebola.

Mr. Chairman and Members of the Committee, the top priority of my office is protecting the health of Americans. I can assure you that my team, the Department, and our partners have been working and continue to work to ensure our Nation is prepared to respond to threats like Ebola.

I thank you again for this opportunity to address these issues and welcome your questions.

Senator COBURN. Thank you for your testimony. We will come back to you for questions after we have had everybody testify. Dr. Frieden.

TESTIMONY OF THOMAS FRIEDEN, M.D.,¹ DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. FRIEDEN. Thank you very much, Chairman Carper, Ranking Member Dr. Coburn, Members of the Committee. We really appreciate the opportunity to share with you what is going on with Ebola here in the United States and in West Africa.

At CDC, we work 24/7 to protect Americans from threats, whether those threats are naturally occurring, like Ebola, or manmade, like anthrax, whether they are infectious, like Ebola and other infectious diseases, or non-infectious, whether they come from this country or anywhere in the world. CDC's work includes supporting States for preparedness and response. Also, we manage the Strategic National Stockpile and we support laboratory and epidemiologic capacity throughout the United States to detect and respond to threats.

The bottom line with preparedness, as far as our experience has shown, is that everyday systems are critical to protect us. If we have a great system that is shrinkwrapped in a closet and we try to bring it out when there is an emergency, we are likely not to be able to respond as effectively as if we have an everyday system that can be scaled up for use on the front lines for a flexible response to a situation.

Ebola is a real and present threat. It needs to be addressed not only in the United States, but most importantly, at its source. We cannot get the risk to Americans to zero until we control it at the source in Africa.

The basics of Ebola are relatively well known, though we will always continue to learn more. Everything we have seen in four decades of fighting Ebola in Africa suggests that patients are only infectious when they are ill, and they become more and more infectious the more ill they become, and that they only infect others by direct contact with body fluids of someone who is ill or someone who has died. That means the two main ways that Ebola spreads are through caring, health care or in communities and families, or burial practices in Africa, where there may be contact with body fluids.

The emergency funding request is really critical to protect Americans and to stop Ebola at the source. It is focused on speed, flexibility, and keeping the front lines first. Those, I believe, are the three most important principles in confronting Ebola.

¹ The prepared statement of Mr. Frieden appears in the Appendix on page 65.

In the three epicenter countries, Guinea, Liberia, and Sierra Leone, we are seeing changes in the nature of the epidemic. In Liberia, we have seen now proof of principle, that it is possible to stop the exponential increase that we were seeing before. But, we are still seeing hundreds of new cases per week and we need to step back and remember that a year ago, even a dozen cases would be appropriately considered to be a major emergency. So, we are nowhere near out of the woods. We have much further to go. But, we do have proof of principle that our approach can work.

In Sierra Leone, we are still seeing significant numbers of cases and possibly significant increases continuing.

In Guinea, where the outbreak probably started, the forest region remains very challenging, difficult to access, difficult to get to each of the communities that is at risk.

The emergency funding request for affected countries focuses on prevention through areas like screening and infection control, detection through laboratory and surveillance work and others, and response through core public health activities, such as contract tracing, rapid response teams, and support to ministries of health that will be able to respond flexibly and effectively. It is quite like a forest fire in the way that we have to both stop it at the source and protect the surrounding countries from sparks emerging and creating new fires.

In Mali, our team is on the ground today helping the government to trace more than 400 contacts of a cluster there.

In Cote d'Ivoire, we have been in place because we know that there is significant contact between two of the countries in Cote d'Ivoire.

In addition, the emergency funding request addresses prevention through biosafety and biosecurity issues that are quite familiar to this Committee, more broadly; detection, which is about three-quarters of the CDC request for the global health security area, so we have an alerting system, an alarm system, and know when problems are emerging; and response, through emergency operation centers that can stop problems before they expand broadly.

Within the United States component of the CDC ask in the emergency funding request, we would not only stop it at the source and deal with border protections, which we have worked very closely with CBP on, but strengthen State and local health departments, strengthen hospitals so that they will be better able to identify possible cases of Ebola, better able to prevent the spread of Ebola and other infectious diseases in health care facilities, and better able to respond, so that we can stop it at the source.

In conclusion, we are able to stop Ebola, we were able by surging rapidly to Nigeria to work with Nigerians to end a cluster there. But, we cannot let our guard down. We have much further to go than we have already come and we will not be able to fully protect Americans until we control the threat at the source. We have to be there until the last spark is extinguished. We have to strengthen our systems here to protect health care workers and the public. And, we have to build the basic warning and preparedness systems in other countries so that we do not face this type of problem again, because the vulnerability of any other country is potentially our own vulnerability, as well.

Thank you very much.

Senator COBURN. Thank you. Mr. Kerlikowske.

TESTIMONY OF R. GIL KERLIKOWSKE,¹ COMMISSIONER, U.S. CUSTOMS AND BORDER PROTECTION, U.S. DEPARTMENT OF HOMELAND SECURITY; ACCOMPANIED BY KATHRYN BRINSFIELD, M.D., CHIEF MEDICAL OFFICER, U.S. DEPARTMENT OF HOMELAND SECURITY

Mr. KERLIKOWSKE. Chairman Carper, Ranking Member Dr. Coburn, distinguished Members of the Committee, thanks for the opportunity to discuss the efforts of U.S. Customs and Border Protection as part of the whole of government response to the Ebola virus outbreak in West Africa. CBP, in carrying out our mission to secure and facilitate international travel to the United States, has an important role in minimizing the introduction and spread of communicable diseases such as Ebola.

As you know, CBP and the Centers for Disease Control and Prevention are conducting enhanced Ebola screening at five U.S. airports, Kennedy, O'Hare, Dulles, Atlanta, and Newark, which have been designated for the arrival of all passengers who have recently traveled through or from Liberia, Sierra Leone, Guinea, and as of Monday, Mali. CBP utilizes advance passenger information to identify the travelers, and we work with the airlines to reroute them, when necessary, to one of those five designated airports. I have visited each of the airports. I have met with our front-line personnel who are conducting that enhanced Ebola screening.

CBP and CDC have worked closely on communicable disease outbreaks in the past—H1N1, the Severe Acute Respiratory Syndrome (SARS), the Middle East Respiratory Syndrome (MERS). We have developed policies, procedures, protocols to identify and respond to travelers who may present a threat to public health. For example, CDC or other appropriate medical authority provides a “Do Not Board” order to CBP for individuals who are considered to be infected with a highly contagious disease and should be prevented from traveling to the United States on commercial aircraft.

Upon arrival at an airport designated for enhanced Ebola screening, identified travelers complete a health questionnaire. They provide contact information. They have their temperature checked. And, if there is a reason to believe that a traveler has been exposed to Ebola because of overt symptoms, a positive response to the targeted questions, or an elevated temperature, we refer that person to CDC immediately for evaluation on scene at that airport. All travelers who undergo enhanced Ebola screening are provided with information and instructions, and should he or she develop symptoms or have a possible concern of infection.

While the vast majority of travelers who have traveled from or through an affected country will arrive at one of the designated airports, all U.S. ports of entry, land, air, and sea, are prepared to conduct enhanced screening. In addition to the standard procedure of visually screening all passengers for overt signs of illness, CBP officers continue to inspect visas, entry-exit stamps of all passports, and they ask travelers about their recent travel history. CBP offi-

¹ The prepared statement of Mr. Kerlikowske appears in the Appendix on page 77.

cers at all the ports of entry are asking passport holders from Liberia, Sierra Leone, Guinea, and Mali, regardless of where they traveled from, if they had been in any of those countries in the last 21 days, and if they have, they are also referred for secondary screening.

Ensuring the health and safety of our employees is an absolute priority in responding to this outbreak, and all the CBP officers receive public health training to learn how to identify the symptoms of ill travelers, how to apply universal precaution procedures for infection control, and when encountering potentially ill individuals or when examining potentially contaminated luggage.

CBP also provides officers operational training and guidance on how to respond to travelers with potential illness, including referring individuals who display signs of illness to CDC officials and assisting CDC with implementation of its isolation and quarantine procedures. The Department of Homeland Security and CBP are deploying additional Personal Protective Equipment to ensure the safety of those front-line personnel.

And, the DHS Office of Health Affairs and the Centers for Disease Control and Prevention have provided guidance on the proper use of protective equipment. All CBP officers are required to complete a web-based video training. CBP and CDC are also providing onsite training at the five designated airports for our officers who are performing that enhanced screening.

We will continue to monitor the Ebola outbreak, and in coordination with DHS and our partners in the Federal Government, provide the necessary equipment, the guidance to front-line personnel to prevent the spread of Ebola in the United States.

Thank you for this opportunity and I look forward to your questions.

Senator COBURN. Thank you. Ms. Lindborg.

TESTIMONY OF NANCY E. LINDBORG,¹ ASSISTANT ADMINISTRATOR, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Ms. LINDBORG. Thank you, Chairman Carper, Ranking Member Coburn, and Members of the Committee. I very much appreciate your holding this hearing today.

And, as we have heard, the world faces the largest and most protracted Ebola epidemic in history, and it is a very sobering reminder of what happens when disease encounters weak health, economic, and governance systems, and reminds us that this rapid spread is happening in a region that is very affected by conflict, two of the countries emerging from decades of very bloody civil wars. And, it just underscores that we live in an ever more interconnected world, that we are all neighbors, that we must stop Ebola at its source in West Africa, and that we urgently need to build stronger and more resilient global health security systems so that we can prevent, detect, and rapidly respond to future outbreaks before they become epidemics.

This is a national security priority for the United States. It is a security priority for the world. We have to have a safety net without these kinds of holes.

¹ The prepared statement of Ms. Lindborg appears in the Appendix on page 82.

So, today, I really want to underscore three key points. The first is that when Ebola jumped borders and migrated to the urban centers this summer, the United States mounted an aggressive whole of government effort that was governed by four key pillars. The first is controlling the epidemic.

The second is mitigating second order impacts. We need to also blunt the very significant food security, economic, and social tolls that we are already seeing in these very weak States. These are countries where 58 percent already lived in extreme poverty, clean water was a luxury, and so today, on top of the epidemic, we also have a food and health crisis. We have countries where vaccination rates of measles have dropped precipitously. Women no longer have help at childbirth.

The third pillar was coordinating the United States and the global response. This requires not just a whole of government response, it requires a whole of the world response, and we have, with aggressive U.S. leadership, been able to galvanize a response that now includes significant resources of both funds and personnel from around the world.

The fourth is to fortify the global health security infrastructure.

And, just a few comments on controlling the epidemic. We have surged both civil and military personnel into the region to isolate and treat Ebola patients, provide safe and dignified burials, conduct extensive community outreach so that people have the information they need to keep their families and loved ones safe, and to help stand up command and control centers at both the national and county levels of the affected countries.

At USAID, we have deployed our Disaster Assistance Response Teams through the region and now into Mali, and with that team, we are coordinating with the State Department, CDC, the Department of Defense (DOD), HHS, the U.S. Forest Service, the United Nations, and our many Non-governmental organization (NGO) partners to ensure that we are all working against a coordinated strategy.

I was in Liberia in early October and, it really underscored—this is a country that is in the grip of a crippling rainy season, very poor infrastructure, what roads are there are usually impassable during the rainy season, and an absolutely destroyed health system. So, the response has been extraordinary. However, the U.S. Government moved in critical supplies. Personal Protective Equipment, all the suits, the plastic sheeting, thermometer guns, chlorine, these have all surged into the region along with labs to provide critical diagnostics, engineering, logistics, and transport capabilities. All of these have made a substantial difference. And, as the crisis evolves and the virus moves, we are adapting our strategy to have a highly mobile, very scalable strategy that allows us to go where the virus is.

In Sierra Leone, we have worked with the United Kingdom to adapt the Liberia strategy to Sierra Leone and learn the lessons. We saw in Liberia that we are having a decrease in average reported cases and we believe that some of the rapid scale-up of particularly the burial teams and the health outreach has been critical.

However, with the Mali cases, we are also seeing it is absolutely critical to invest in a stronger global health and preparedness system, and the USAID Emerging Pandemics Program has particularly focused in those areas where increased population pressures are increasing the chances of a jump from animal to human disease transition.

We have worked with CDC and the World Health Organization (WHO) to develop the Public Health Emergency Framework that is making a difference, and we are already seeing a decrease in the number of countries that are affected by H5N1, for example.

And, now that the Ebola virus has emerged, it is going to reoccur periodically, and that is why President Obama launched the Global Health Security Agenda (GHSA) in February 2014, acknowledging that we need a global effort to advance a world safe and secure from infectious diseases.

The request from President Obama for \$6.18 billion in emergency funding includes \$1.98 billion of urgently needed resources for USAID to continue to scale up the activities to control the outbreak, to support a critical recovery in West Africa, and to strengthen the capacity to address these threats immediately. It includes \$278 million in support of the Global Health Security Agenda and to expand our Emerging Pandemics Threat Program. This is essential. We cannot accelerate our efforts without this. And, without these funds, we will also be ill equipped to address crises around the world, as we have an unprecedented number of global crises.

I want to close just with a very special salute to the many good samaritans who have responded, to the health care workers and humanitarian workers who are on the front lines with great courage and great dedication helping us to address this pandemic, and I look forward to your questions.

Senator COBURN. Thank you. Dr. Lakey.

**TESTIMONY OF DAVID L. LAKEY, M.D.,¹ COMMISSIONER, TEXAS
DEPARTMENT OF STATE HEALTH SERVICES**

Dr. LAKEY. Thank you, sir. Good morning, Chairman Carper, Ranking Member Coburn, and Members. Thank you for the opportunity to be here today.

I have been the Commissioner of the Department of State Health Services for about 8 years. October of this year has been one of my most challenging months as Commissioner of the Department of State Health Services.

On September 30, 2014, the Texas State Public Health Laboratory, a laboratory that is part of the Laboratory Response Network (LRN) family of laboratories, diagnosed the first case of Ebola in the United States. The diagnosis of Mr. Duncan with Ebola set in motion a process that we in public health have refined through continued use, tried and true public health principles and protocols, which include identification of those who have had contact with an individual that is infected with a disease, monitoring those individuals, isolating and providing compassionate care to those individuals, and using quarantine when needed.

¹The prepared statement of Mr. Lakey appears in the Appendix on page 89.

The magnitude of the situation really was unprecedented. We at the Department of State Health Services, along with our colleagues in Dallas and at the Centers for Disease Control and Prevention, took the responsibility to contain the spread of this disease extremely seriously.

We organized a local incident command structure (ICS) to handle the event, and at the State level, we activated our Emergency Response Management Centers. While the core mission was simple in concept, to protect the public's health by limiting the number of individuals exposed to the virus, the challenges associated with carrying out that mission were enormous.

The care of Mr. Duncan presented its own challenges: The identification of the first person with a novel disease in the United States; infection control; the management of waste and its transportation; the availability of experimental treatments and vaccines; the training of health care workers in how to care for this novel disease; the availability and guidance on how to use Personal Protective Equipment.

And, when Mr. Duncan regrettably passed away, we handled issues such as how do you take care of the remains of this individual, which the remains have highly infectious Ebola, and it can be in that body for many, many months. And, unfortunately, during the care of Mr. Duncan, two nurses became infected.

Concerns related to the handling of the three Ebola patients include questions about how do you decontaminate the home and how do you take care of their automobiles, decisions about how to handle personal effects, the monitoring of pets, patient transportation issues, and addressing the public's concerns.

Additionally, identifying and locating potential contacts and monitoring those individuals who have had some risk of exposure also involved many challenges: Decisions about who to quarantine and at what level, balancing the public's health and the individual's rights; providing accommodations for those confined in one location for the 21-day monitoring period; quickly processing these control orders, and coordinating two symptom checks a day for each person under monitoring; and managing and transportation and testing of the laboratory specimens.

Throughout all these specific challenges, our experience in Dallas exemplified common requirements for successfully responding to any emergency situation, to have clear roles and responsibilities among all levels of government and all the entities that are involved, to have strong lines of communication, to use an incident command structure staffed by trained emergency management and public health professionals, and to do this in partnership.

The outcomes in Dallas prove up the strengths of the public health processes. Hundreds of individuals were monitored in the State. Two cases of Ebola resulted from direct care of the index case, and they were detected early in the disease onset and they recovered. No cases resulted from community exposure.

At this time, like other States, Texas is providing active monitoring for individuals who arrive in the United States from one of the outbreak countries. Texas has monitored approximately 80 individuals under this airport screening process. Texas is also, like other States, working to ensure that the capacity exists inside the

State of Texas to care for patients with high consequence infectious diseases like Ebola. Two centers currently are able to stand up on short notice to receive a patient, and Texas is working to identify additional capacity.

As Ebola screening and monitoring transitions into our routine processes, our focus in Texas is shifting to include complete evaluation of the response in Dallas and a discussion of how to improve the public health response system in Texas as a whole and sharing these experiences and lessons learned.

Governor Perry has put together a Task Force for Infectious Disease Preparedness and Response to evaluate Texas's system and to make recommendations for improvement, and I believe the discussion among governmental and non-governmental individuals, among varied stakeholders, and including experts that are pertinent fields will result in a Texas that is better prepared and a Nation that is better prepared.

We do not know what the next form or the next event will take. We do know that there will be another event. I tell my colleagues that it is my expectation to have at least one major disaster, one unthinkable event per year in the State of Texas, working with our national partners. That is why the funding that you provide to States through the CDC is so critically important, and that is why the need for strong partnerships between the local health departments, the CDC, and our many other Federal partners.

Finally, I want to thank our colleagues at both the Dallas County Health Department and our Federal partners for their support throughout this event, and I thank you for the opportunity to be here today. Thank you, sir.

Senator COBURN. Well, thank you for your testimony.

A couple of questions. Just so I get this straight, our inbound screening right now, Mr. Kerlikowske, covers 95 percent of the inbound from these countries, is that correct?

Mr. KERLIKOWSKE. It is 100 percent of the screening for everyone passing through those four countries at only those five airports.

Senator COBURN. I know, but those five airports account for only 95 percent.

Mr. KERLIKOWSKE. Everyone has to go through those five airports. We rerouted, working with the airlines authority.

Senator COBURN. So, nobody goes into Houston and nobody goes into DFW anymore?

Mr. KERLIKOWSKE. Correct, Doctor.

Senator COBURN. OK. Thank you.

Can you all explain your interaction with the President's Czar on Ebola and what the coordination is and what the communication is so we can get an understanding? I had asked that he testify today. They refused to have him testify. So, I would just like to know, this is the person that is working under the President that is coordinating what he knows, and information is going up to him and coming back down to you. Can you all please explain to me what your interactions are with this individual, Mr. Klain?

Dr. FRIEDEN. Well, I would say that Mr. Klain plays the policy coordination role. The response to Ebola requires many parts of the government to work together, both on the domestic aspect and on the global aspect. I can say that I have very frequent communica-

tions with him on a daily basis, multiple times, and that he has been very supportive and very focused on problem solving and identifying what we can do to make the response quicker, more effective, and more unified.

Senator COBURN. OK.

Dr. LURIE. Sure. I think I would reiterate Dr. Frieden's comments. I think most of us had the opportunity to meet with Mr. Klain the day or the day after he took office. We have had within the Department a very tight coordination structure within HHS, and that coordination structure, even before his arrival, really reached parts of the whole of government, because there were many other departments, as you know, involved in this that we had frequent communication with all the time.

Since his arrival, there has been a tremendous amount of coordination, collaboration, discussion, problem solving. I think we all talk with him frequently in small and large groups and we very much appreciated and see the benefits of his being there.

Senator COBURN. OK.

Ms. LINDBORG. I would just add that a number of us are going from here to our weekly strategy session with Mr. Klain.

Senator COBURN. All right.

Mr. KERLIKOWSKE. Many people within the Department of Homeland Security, and certainly Dr. Brinsfield and others and myself, have had interaction with him. Most of mine has been by e-mail or attending a particular meeting, because as you know, Doctor, we have a little bit narrower role in CBP.

Senator COBURN. OK.

Dr. LAKEY. I have had two interactions with Mr. Klain. A week ago, we had a meeting of the folks that do my job across the Southern part of the United States and with some of our Federal partners, and in that meeting, we had a 30-minute conversation by phone with Mr. Klain. And then last night, I had the opportunity to spend about 30 minutes with him to express some of our challenges in the State of Texas.

Senator COBURN. OK. All right. Thank you.

On ASPR, the request for your portion of this is \$2.43 billion, is that correct?

Dr. LURIE. For HHS.

Senator COBURN. For HHS.

Dr. LURIE. For HHS, yes.

Senator COBURN. And, what percentage of that is for BARDA?

Dr. LURIE. For BARDA, it is \$157 million to continue the development of vaccines and other therapeutics.

Senator COBURN. So, what is the other \$1.9 billion for?

Dr. LURIE. So, within ASPR, there is \$166 million for other aspects of domestic response, including within the Hospital Preparedness Program to provide additional training, in particular, Personal Protective Equipment, through health care coalitions, and other drills and exercises, and there is funding to establish the capability to treat Ebola patients diffused throughout the United States.

Senator COBURN. Just a question. Should the Federal Government be providing the protective equipment for the hospitals rather than the hospitals provide that, the insurance companies paying for that?

Dr. LURIE. So, what we are finding is that for both hospitals and other health care institutions to be prepared, they do not always have either the kind of the amount of Personal Protective Equipment that is required to safely care for an Ebola patient. And, as I think you know, there has been a pretty big hue and cry for people who are seeking that equipment.

One of the things that we have done with the Hospital Preparedness Program is really focus on preparedness at a community level instead of an individual hospital level, to be more efficient at sharing resources that are scarce.

Senator COBURN. Right.

Dr. LURIE. And, so, the funding would actually provide for purchasing of Personal Protective Equipment at a community level, in fact, to be efficient, so that not every hospital or doctor's office or anything else needs to stash a large amount of it but you have enough in the community.

Senator COBURN. And we have coordinated with DuPont on the increased manufacture of this?

Dr. LURIE. I have personally had the opportunity to speak with the leadership at each of the manufacturers of different kinds of Personal Protective Equipment. They are all now gone to 24/7 manufacturing. Some of them have made a decision to start with greenfields and stand up additional capacity for manufacture of other scarce PPE.

Also, we are coordinating with the manufacturers and distributors, to be sure that hospitals that need it, hospitals that are ready, EMS agencies that need it can get it on a priority basis. We have coordinated a lot with the Strategic National Stockpile that has purchased additional PPE to be sure that if an institution receives an Ebola patient, that we can get them sufficient PPE within a matter of hours. That is in addition to the Rapid Team from CDC that would be on the ground. And, then, we have been coordinating with USAID and others because the PPE needs are not only domestic, but international, and we want to be sure that we do not compromise the response in West Africa.

Senator COBURN. Why such a small amount at BARDA? They seem to have done such great work in the past.

Dr. LURIE. Thank you. They have done great work and we have appreciated the advance of that, of \$58 million in the CR so that they could get moving with the scale-up and manufacturing of, both of vaccines and the therapeutics. We think that this additional funding will help us both get to the point where the current vaccines that are in testing can be tested in clinical trials and then procured, I imagine by others, for use in West Africa if, in fact, the vaccine proves effective. And, because we never put all of our eggs in one basket, we have invested in the development of a couple of other vaccines—

Senator COBURN. Right.

Dr. LURIE [continuing]. As well as therapeutics to get those moving.

Senator COBURN. I have one question and then I will pass it on. Tom or Gil, answer this for me. When I go home to Oklahoma, people ask me these common sense questions. Somebody comes into this country and lies about whether or not they have been in one

of these three countries and is taking antipyretics. So, therefore, they have no fever, they have been dishonest about where they have been, and they come into our country. Why should we not worry about that?

Mr. KERLIKOWSKE. So, I think there are a couple things that are very helpful. One is that Customs and Border Protection officers go through a lot of training. They are in uniform. They have a badge. They are armed. They know how to ask questions. They know how to look for signs of deception.

We have a huge amount of passenger information in that manifest, which we get quite early. We look for things, particularly if there is broken travel, and that was the case with Dr. Spencer. So, the fallback positions are when you go to that Customs authority and that person is sitting there in the booth, plus we have the roving patrols, that person is asking questions. He or she is looking at that passport to see where they are from. They are looking for the stamps from any of those now four countries and they are looking at the visa applications.

So, could someone lie and essentially be deceptive? But, I think it is much more difficult when you are faced with that kind of onslaught of questioning and scrutiny that people need to go through in order to enter our country safely.

Dr. FRIEDEN. And, if I can add, in terms of taking an antipyretic or something else, if someone is tracked through the system, and we have now tracked more than 2,000 people through the system, we are then in close collaboration with CBP and DHS, providing the information to State health departments like Dr. Lakey's within just a few hours of their arrival. We also provide to the individual information about Ebola so that they will understand that if they do not get prompt care, not only may they die, but they may spread it to their family.

Senator COBURN. Yes.

Dr. FRIEDEN. We are providing them with a low-cost thermometer and with a wallet card to call the health department so that if they develop a fever, they can be safely and securely moved to a facility where they can be safely treated. That system is already in operation. We have already had multiple individuals who have had fevers, none of them from Ebola, call and be safely transported and cared for.

Senator COBURN. Tom, what do we know about the infectivity? We know in terms of body fluids. What do we know about temperature and infectivity? What is actually known? What is our science right now?

Dr. FRIEDEN. What we know is that as you get sicker and sicker with Ebola, the quantity of virus in your body increases dramatically, so that, generally, fever will be one of the first, if not the first, signs of illness. And, what we have seen in this country is people with very low-grade fevers—Dr. Spencer's was 100.3—and perhaps with the more intensive monitoring here, we are finding people with lower temperature levels. But, what we are finding in Africans consistently is over the course of the illness, infectivity kind of increases exponentially.

And, just as an indication of that, when we do the initial real time polymerase chain reaction (PCR) test to see if someone has

Ebola, it cannot infrequently be negative initially, not because there is a problem with the test, but because there is virtually no virus in the blood. Within 72 hours, it will become positive both in the test and the individual will get sicker.

Senator COBURN. OK. Thank you. Senator McCaskill.

OPENING STATEMENT OF SENATOR MCCASKILL

Senator MCCASKILL. Dr. Lurie, I would like to talk about BioShield. BioShield was passed in 2004 to protect the United States against chemical, biological, radiological, and nuclear (CBRN) threats to national security. We have spent \$3.3 billion, and I am really worried about how it has been spent, especially in light of what we have seen with the Ebola crisis.

Eight of the 13 BioShield contracts were signed in September 2013, the last month that the funds were available to spend. Five of those were related to anthrax. Obviously, BioShield is an organization that combines both DHS and HHS, as you are well aware, but I want to make sure the record is clear. I am asking you this because the Office of Science and Technology (S&T) is not here from DHS. So, you are going to get all of my attention this morning, but I want to make sure everyone understands that this is not just HHS that I think has made mistakes in this area. I think it is also the DHS Office of Science and Technology.

You have produced material threat determinations for 21 different chemical, biological, radiological, or nuclear agents. However, as of December 2013, you have contracts to procure countermeasures for only six of the 21 threats identified as high priorities. And, by the way, Ebola was identified as a material threat in 2006.

So, since 2006, there have only been two material threat determinations issued. So, we have gone now years and years and years without any significant additional material threats. Does this mean that these decisions are being made on an almost decade-old analysis?

Dr. LURIE. No, I appreciate very much your questions, and let me start by explaining a couple of things. First of all, I think when BARDA and BioShield were created, these were brand new systems and brand new programs, and I do not think that there is any question but that some of this got off to a rocky start. As I think you know, in 2010, after our experience with H1N1, the Secretary requested and we did an end-to-end review of the medical countermeasure enterprise and did a significant amount of retooling. We did this in concert with our colleagues at DHS and DOD and USDA, as well as all of the HHS components.

And, I will say, we now have procured 12 medical countermeasures. They are in the stockpile. When BARDA and BioShield started, there was almost nothing in the pipeline. There are now about 90 chemical, biological, radiological, and nuclear products in the pipeline and another huge host for pandemic flu. So, I think from those perspectives, they have been tremendously effective.

Two other things to keep in mind. One of the things that I did as Chair of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), was to ask that we go back over looking at the set of processes that we use to make material threat determinations and to set requirements, and we have been working very

closely with DHS to do that. It has borne a lot of fruit and we are continuing on that path.

I think the other thing to keep in mind with regard to Project BioShield is Project BioShield itself cannot spend money on procurement until a product is far enough along in development to be within a certain amount of time—8 years—of being able to be licensed by the Food and Drug Administration (FDA).

Senator McCASKILL. Well, what about Abthrax?

Dr. LURIE. What about what?

Senator McCASKILL. When you bought Abthrax, one of the multiple anthrax countermeasures you have bought, and when it was first looked at, it was a boutique product that the exact use of which was unclear. But, you spent \$722 million on it. It was also an additional product beyond the vaccine and three antibiotics that we already had to treat anthrax.

And, by the way, 44 percent of the money that has been spent in this program has been on anthrax. I mean, almost half. We have got 21 threats and almost half of the money has been spent on just one of them. How can that be justified?

Dr. LURIE. So, let me, again, take a step back and make a couple of comments. First of all, DHS has continued to assess that the No. 1 threat in terms of biothreats to our country, other than those produced by Mother Nature, which are significant, is anthrax.

Second, the anthrax products have been much further along in the stages of development and so those are the ones that have been first been ready for procurement.

This past year or two, we have taken a look at all of our requirements again. We have also taken a really careful look at what is in the Strategic National Stockpile and we have done some adjustment, both based on the threat, based on what we know about the disease, based on what those countermeasures are.

There is now a strategy, an implementation plan, that lays out for the next 5 years what it is that the PHEMCE will invest in and spend money on, and as we took a look at that, we, again, did some readjusting so that we were able to cover threat areas that were not covered well at the beginning of this program, including, by the way, viral hemorrhagic fevers.

Senator McCASKILL. Well, I understand that anthrax is a threat, although I am worried about the fact that a dose was \$2.26 in 1999 and we issued a contract to procure doses for \$24.50 6 years later. That worries me, that we are spending more than we need to on some of this and that we have done overkill on anthrax. But, anthrax does not spread. I mean, anthrax is not something that is highly contagious.

I look at the way you develop what the threats are. I look at the way the money has been spent. All of us get suspicious around here when a bunch of contracts are signed the month before the money expires. It always makes us believe that someone is rushing to spend the money, because if they do not, they are not going to have it anymore, as opposed to judiciously looking as to whether or not they are just buying what is available and easy as opposed to doing the hard work of figuring out whether we have put too many eggs in the basket of anthrax and not enough in the basket of highly contagious diseases like the pandemic flu or others that have been

identified as material threats for years and years and years, including Ebola.

Dr. LURIE. I appreciate your concerns, and that is, in fact, why we have been making so many adjustments in the program. In addition, we have been very much trying to move away from this idea of “one bug, one drug,” and moving much more toward the development of platform technologies that are nimble and flexible and, in fact, when confronted with a new disease like Ebola, can make either vaccines or other countermeasures much more quickly. And, in fact, it is those flexible platforms that you are seeing now in the development of the Ebola therapeutics.

So, we have shifted considerably in this program since 1999. We have certainly shifted considerably since 2006. And, since the review in 2010, I think we have been on a really terrific path targeting—

Senator McCASKILL. Well, the 2013 contracts do not indicate that. It still indicates a huge proclivity toward anthrax and anthrax domination in terms of this. The frustrating part from here is that this program was supposed to be identifying things like Ebola so that we are not rushing to fund after a crisis, but, rather, prepared when the crisis occurs. It looks like there was a rush to spend before the funds expired, but not a rush to truly identify additional threats that had developed and the severity of some of the threats that have not been addressed.

So, I am going to continue to follow up on this. As I say, S&T deserves a lot of these questions, and, hopefully, we will have other hearings in the next Congress that we can get to this. The fact that this happened in 2013 kind of swims upstream against your argument that everything has been retooled.

Dr. LURIE. We look forward to coming and briefing you and updating you about the program and where it has been.

Senator McCASKILL. Thank you.

Senator COBURN. Perhaps it would be great to have a Subcommittee hearing just on this.

Senator McCASKILL. As do I—

Senator COBURN. Yes. Also, could we have a direct answer on the differences in the cost of ciprofloxacin, which originally was purchased and why the differential in the price? I would like to know why we are paying such an exorbitant amount for the same drug to treat the same thing. So, can we have an answer, a written answer from you back on that contract and why we are paying those kind of prices?

Dr. LURIE. Absolutely.

Senator COBURN. Thank you.

The Senator from Wisconsin.

OPENING STATEMENT OF SENATOR JOHNSON

Senator JOHNSON. Dr. Lakey, have you in Texas put any kind of cost estimate on what it did cost your public health system to treat those three patients?

Dr. LAKEY. I can partially answer that question. If I look at the cost that we incurred as a State agency, including time of my staff, the cost to do the decontamination, waste, the control, transportation, et cetera, that is about a million dollars. The monitoring of

the individuals that have come back from overseas, that cost right now is a little shy of \$20,000 right now. The costs that Presbyterian incurred, I cannot tell you what that number is.

Senator JOHNSON. OK. But, the cost has been over a million dollars for a couple patients.

Dr. LAKEY. Yes.

Senator JOHNSON. Dr. Frieden, do you have any cost estimate of what it cost to cure some of these heroes? I mean, what does it cost?

Dr. FRIEDEN. The care of patients with Ebola can be quite expensive because it requires intensive care. It needs to be done in a place where you may have to actually not admit other patients—

Senator JOHNSON. Do you have a number, though? I have limited time.

Dr. FRIEDEN. No, nothing other than what I have read in the media.

Senator JOHNSON. Hundreds of thousands or millions of dollars per case, correct? In terms of the incubation period, at what point—how many days does it take to exhibit a fever?

Dr. FRIEDEN. The incubation period is between 2 and 21 days after exposure until illness, usually around 8 to 10, or 12 days.

Senator JOHNSON. So, in general, somebody could be infected and then really not exhibit any signs of illness or fever for about 8 days?

Dr. FRIEDEN. That is correct.

Senator JOHNSON. That is a real possibility. What are the current projections in terms of this outbreak as it progresses? Right now, I have about 14,000 cases in my briefing packet here. I do not know how many there were when we first admitted Mr. Duncan. What are we looking at 2, 3, 4 months down the road, because we have some pretty scary numbers.

Dr. FRIEDEN. That will depend entirely on our response and how rapidly we intervene. Currently, we think there may be between 1,000 and 2,000 new cases per week in West Africa, but we have seen areas of West Africa achieve very rapid reductions when they implement the comprehensive strategy such as that that we would be able to support through the emergency funding request.

Senator JOHNSON. So, we had heard estimates of this thing growing exponentially to over a million people by 2015. Are we past that point? Are we getting a handle on this that we are not looking at that kind of exponential growth?

Dr. FRIEDEN. In Liberia, we are no longer seeing exponential growth. I think that is a reflection of the proof of principle of the strategy. However, we are still seeing growth in Sierra Leone, and Guinea is a cautionary note because we have seen it come and go in waves whenever we have relaxed our efforts.

Senator JOHNSON. So, it still is possible to have tens of thousands, hundreds of thousands of cases with this current situation?

Dr. FRIEDEN. We do not think the projections from over the summer will come to pass. Those were projections of what would have happened if prior trends continued with no intervention. There has been very effective intervention with USAID, ourselves, the global community, and most importantly, the countries and the communities most affected.

Senator JOHNSON. OK. Well, that is good news. My point being, if this really does grow either exponentially or geometrically, we are going to have a whole lot more cases throughout the world, in West Africa. When we had about 10,000 or 12,000 cases, one individual got into this country, and we are seeing the cost of just treating one or two cases in the millions of dollars. I do not know how many cases of Ebola would utterly overwhelm our health care system.

So, from my standpoint, I think the goal we should really have would be to keep Ebola out of the United States. Now, we obviously have to treat these heroes, these health care workers that are going down there, and nobody is talking about isolating West African nations, but we really ought to set as an achievable goal, let us not let it spread out of there. Let us keep it in West Africa.

So, Mr. Kerlikowske, through our Customs and Border Protection process here, through the airlines, we cannot identify 100 percent of people that had been in West Africa in the last 21 days, correct?

Mr. KERLIKOWSKE. Probably not identify 100 percent, but we have come very close. We look for all the things—

Senator JOHNSON. Well, why would it not be 100 percent, because you have to fly here, right, I mean, and people have to have passports and those things are stamped. Why can it not be 100 percent?

Mr. KERLIKOWSKE. Well, there are people that can use broken travel, and that is why we have those secondary layered approach of looking for stamps, looking at their passport, asking them questions, what other countries they have traveled in.

Senator JOHNSON. But, again, people will lie, so we have to rely on documents and thorough evaluation of those documents to try and protect people from coming here, correct?

Mr. KERLIKOWSKE. Yes.

Senator JOHNSON. So, I was a little surprised at your answer to Senator Coburn. You said that we are funneling 100 percent of people into those five—because it did not sound like that from your testimony.

Mr. KERLIKOWSKE. Well, he was specific about the people coming into the airports that we have that information on, and that is why in my opening statement I also mentioned that all of our ports, including sea and land ports, also have the information and also have the ability to do any screening.

Senator JOHNSON. So, my point being is if we can screen, using passports, using stamps, understanding that people, when they were in West Africa, at a pretty high percentage, 95 to 100 percent, in light of the fact that treating just one case of Ebola could be more than a million dollars, why would we not set the achievable goal of saying, let us not let people into America other than the health care workers? Why not control that and let the world know that you are not going to come into America until you have been out of West Africa for at least 21 days? I mean, would that not be a reasonable restriction so that we do not overwhelm our health care system? Why would we not do that?

Mr. KERLIKOWSKE. So, Senator Johnson, I do not think I am probably the best person to answer that from that medical viewpoint, but I do know a couple things that have been expressed, and

one is that when we do a level of restriction and isolate those three particular countries, other countries may follow.

Senator JOHNSON. They already are doing that, are they not?

Mr. KERLIKOWSKIE. Other countries could follow our lead.

Senator JOHNSON. Let me just interrupt. Would that not be a good thing? Why would we want it to spread out of those three countries into any other country? Why do we not have a world effort to keep the disease in those three countries, flood resources, flood heroes to treat them, but why are we not really taking a look at let us keep it isolated in those three countries? It makes no sense to me. I do not think it makes sense to the American public that we do not really double our efforts to keep it contained in those countries and get it stamped out in those countries, do not let it spread.

Mr. KERLIKOWSKIE. Well, restricting or isolating those countries, I do not think, and has been explained to me, would be the best answer. The other is that I think it could drive people underground. You could easily leave any of those three countries without getting on an airplane and easily go somewhere else and surreptitiously or through deceit attempt then to enter the United States.

Senator JOHNSON. But why make it easier? I am out of time. Thank you.

Senator COBURN. Senator Ayotte.

OPENING STATEMENT OF SENATOR AYOTTE

Senator AYOTTE. I want to thank the Chair.

I want to thank all of you for what you are doing. This is very important to the country.

I want to also thank two of my constituents, Brigadier General Peter Corey, who is Deputy Commander of U.S. Army in Africa, who was deployed to Liberia in September and is helping to lead the U.S. military effort to halt the spread of Ebola in Africa. I know General Corey personally and I really appreciate his leadership. Also, our State Deputy Epidemiologist, Dr. Elizabeth Talbot, who is helping train humanitarian workers in Africa. I want to thank everyone who is trying and working very hard to combat Ebola and the spread of this deadly disease.

I wanted to follow up on the issue—Dartmouth Hitchcock in New Hampshire has been designated as a location where, if we were to receive an Ebola patient in New Hampshire, it would be our designated health facility. They have raised issues with me about the Personal Protective Equipment that Senator Coburn had asked about including concerns about not having access to that protective equipment if they were to receive a patient now. They also want to ensure that they train properly and prepare, should they receive a patient.

So, I know that we have discussed some of the manufacturing challenges, to some extent, of the availability of this equipment, but I wanted to delve into that a little bit further to understand if there are hospitals like the one in my State that are not able to have this protective equipment. What are they supposed to do in the interim?

Dr. LURIE. I appreciate your question. I think it is a very good one and it is one that we have heard about from other places. So, let me line a couple of things.

First of all, as I think you know, when a hospital determines that it might want to be in a position to treat Ebola patients and the State health officer agrees, one of the first things that happens is that they receive a checklist of things to start getting ready for, and when they feel that they are ready for a visit, the CDC will send out a Rapid Ebola Preparedness Team to do an assessment with them.

Senator AYOTTE. Mm-hmm.

Dr. LURIE. One of the things, ultimately, on that list that is required for them to be ready is to have a 7-day supply of Personal Protective Equipment on hand. We have been working, obviously, with CDC, with the States, with the hospitals, and if a hospital would like us to, we are in a position to give the name of that institution to the manufacturers and distributors of PPE so, in fact, they can be on a priority list to get what it is that they need, both to get ready and in the event that they have a patient.

As I indicated in my previous answer, the Strategic National Stockpile at the CDC has also bought Personal Protective Equipment, and in the event that a hospital were to receive a patient, they would, if needed, send additional PPE to that hospital.

One of the things that the manufacturers and distributors have told us—and we have been working quite a bit with them—is that for hospitals that want to train on equipment, that they will actually come out to a hospital with training equipment, not the stuff that is in short supply. The front-line health workers who would be in a position to need to use that equipment can practice and can drill and can be ready for that.

They have also told us, interestingly, that it is their perspective that many hospitals, because they are frightened, have been double and triple ordering equipment from various distributors and manufacturers. And, so, one of the things that we have been doing is working with front-line health workers all over the country to be clear about two points, No. 1, there are options on what you can buy, and that is in the CDC guidance, and No. 2, get a little clearer about, really, who needs what and how much you need so that we can cut down on the fear and the panic and be sure equipment gets to those who need it.

Senator AYOTTE. I appreciate that, and I think there needs to be, perhaps, better communication, because this is an issue where, Dartmouth Hitchcock, which is a great hospital in New Hampshire, and part of a research facility connected with Dartmouth College—probably needs increased communication on this issue so that there is a better understanding from the hospitals' perspective. So, I hope that will follow from this.

I wanted to followup, Mr. Kerlikowske, in terms of what Senator Johnson had asked you about. As I understand it, there have been other countries that have restricted travel in terms of the West African nations. Do you have a sense of what some of our partners have done in that regard and what their thinking is?

Mr. KERLIKOWSKE. Senator, the only country I know that has restricted travel has been Canada, and I am actually a little bit un-

sure as to what they actually have decided. As you know, from any of those four countries, there are no direct flights into the United States, so everybody leaving those four countries goes to Morocco, to France, to Belgium, et cetera, and they all fly into those countries.

Senator AYOTTE. So, Canada is the only country? So, I would think we would want to followup and understand, since they are such an important ally and, our neighbor—what their thinking was versus our difference in policy on that issue. I hope we will do that.

Mr. KERLIKOWSKE. We will.

Senator AYOTTE. I appreciate that.

I also wanted to ask about some of the agreements that are in place, regarding the intake at the airports where the enhanced screening is taking place. Are there already established areas of quarantine, if that is necessary, in those airports?

Mr. KERLIKOWSKE. All of those airports already have CDC personnel that have been there for many years, and at first—and I have to give a shout out to the United States Coast Guard, who actually stepped up with medical corpsmen before our contracts went into place, with Emergency Medical Technicians (EMT) and other local health care people to do the temperature screening. So, it has been a really good effort. And, of course, the key has been the relationships that our port directors have with those airports, with the CDC and others, who have all worked together.

Senator AYOTTE. So, my time is expiring but I had a specific question as to whether there are actual agreements between the five airports and the area hospitals. In other words, do we have direct memorandum of understanding (MOU) so there is clarity if we do have to act?

Dr. FRIEDEN. We have a detailed planning process so that for each of the five entry airports we have hospitals on the ready that we have visited with our Rapid Ebola Preparedness Teams that we have ensured are ready, and we have a mechanism to transport patients safely. So, for all of those, we have procedures in place that would allow us to do that. We have had a handful of people with fever or other symptoms coming in. They have been safely transported. None of them have turned out to have Ebola on the way in, but that is something that we have made sure is in place to the greatest extent possible.

Senator AYOTTE. Thank you.

Senator COBURN. Senator Portman.

OPENING STATEMENT OF SENATOR PORTMAN

Senator PORTMAN. Thank you, and I thank you all for not just being here today with us, but for the work you are doing every day to try to address this problem.

As some of you know, I have been critical of the response, mostly the timeliness of it, and I think it took us way too long to get a coordinator and I think it took us way too long to respond to the World Health Organization's very clear message to the world that this was going to be a crisis, and so we are behind. And, particularly in these countries and in West Africa, it is now much more difficult to address the issue.

I do continue to have concerns, as I expressed to Mr. Kerlikowske, as you know, early on about more screenings. I viewed active screenings as being necessary. You now have them, I think, at five of the airports, and I am glad we have that now. I think it could have avoided some of the problems that we have had in this country.

I will say in response to your question to Senator Ayotte, there are a lot of countries that have suspended visas. We have not. I think there are 40. So, short of a travel ban, doing some things to, as many African countries have done, to discourage people from leaving these countries at this point. A temporary suspension until we get our act together, I think, makes sense.

But, if I could switch to the hospital side for a moment, and again thanking you for the actions that have been taken more recently and some of the work, including the President's funding request, you have \$166 million in there for public health and social service emergency fund to immediately respond to patients with high infectious diseases. That \$166 million, I would like to ask you about for a second, and I am not sure who to direct this to, probably you, Dr. Frieden, from the CDC perspective.

But, as you know, in our State of Ohio, we were one of those States that was affected. We have over 100 individuals who were possibly exposed to Ebola, and because of this, hospitals around the State of Ohio rapidly prepared for the possibility of an individual coming through their doors. Fortunately, that has not been the problem that many had feared. But, my question for you is, will any of this \$166 million for emergency funding be allocated to those hospitals to help offset the costs of the preparedness efforts, particularly those in Northeast Ohio, in our case, but also in Texas and elsewhere who had to quickly respond to the concerns of those who had been affected?

Dr. FRIEDEN. So, I will start, and Dr. Lurie may want to comment further because hospital preparedness is a joint effort between CDC and ASPR.

Also, on timeliness, I would comment that CDC was on the ground in West Africa sending staff in March of this year, and again, we activated our emergency operations center in early July of this year. So, we are surging as quickly as we can and working throughout the U.S. Government and in the global community to respond. The emergency funding request is critical to our ability to continue to do that and extend that.

For hospitals, we see this as critically important, both to support State and local health departments so that they can have a community-wide approach of improving infection control and addressing Ebola and other severe infectious disease threats and hospital preparedness, ensuring that they are ready and improving their infection control program. CDC has had highly effective programs through State health departments to improve infection control in hospitals, and one of the things that we would do with the emergency funding request is extend that and expand the support available to hospitals and to public health to improve infection control.

Senator PORTMAN. Just quickly, would any of these funds be available for the hospitals that I talked about that had to quickly prepare?

Dr. FRIEDEN. In terms of the reimbursement for past expenditures up until now, that is something which the Administration has indicated it is quite willing to work out wording with Congress on.

Senator PORTMAN. Let me switch to, if I could, these hospitals, following on what, again, Senator Ayotte talked about, in her case with Dartmouth Hitchcock. As you probably know, I am introducing legislation today with Mr. Markey, and Senator Markey and I have been working on this for the last several weeks about ensuring that some hospitals on a regional basis have this expertise. We call it Centers of Excellence. We base it on the 10 Medicare regions around the country.

The legislation, which we worked with some of your folks on to ensure that it met the criteria that you might be looking for, would ensure that you have certain hospitals that do have not just the medical expertise, but the equipment to be able to respond, and not just to Ebola, but to other infectious diseases. It seems to me that is a much more efficient way to do it than to have every hospital in America be expected to have that expertise, and even to have the isolation rooms and the other necessary equipment. So, have you all thought about that issue further, and what would your response be to that kind of legislation?

Dr. FRIEDEN. Let me start, and then Dr. Lurie has important information to add. One of the components of our domestic ask within the \$621 million for the immediate part of the emergency response would be to expand programs like Prevention Epicenters, which we have had around the country, so that we can advance the science and preparedness in different regions of the country. It is, however, the case that every hospital needs to consider that someone might come in and have that thought through and that each State needs to work. We have worked very closely with public health and hospitals in Ohio. We have had visits to the hospitals to help them through our Rapid Ebola Preparedness teams, and Dr. Lurie can address the other hospital-based issues.

Dr. LURIE. Sure, and maybe I will just, to amplify on Dr. Frieden's comments here, our strategy for getting hospitals ready has been to build from the three biocontainment units that now exist at the National Institutes of Health (NIH), Nebraska, and Emory to be sure, first of all, that hospitals in those airport funneling cities are the first group that are prepared with training, with identified staff, with Personal Protective Equipment, with the physical infrastructure in place.

Building out from there, we are now working in States that receive large numbers of travelers back from West Africa or have large diaspora populations, and those are the States that we are now actively working to identify hospitals in, again, so that they can be prepared should an Ebola patient present in their State and need end-to-end care.

One of the things about this, though, is we are not entirely sure, No. 1, whether and where one of these patients would show up, and No. 2, I think one of the things that Ebola has shown us very clearly is Mother Nature always has the upper hand and that there will be diseases after this for which we need to be prepared with high containment facilities and training and equipment. We do not

know where that is going to strike, but it is clear to us that an additional component of our preparedness has to be to build out that capability. No, not every hospital in America needs to or could take care of patients that are this sick or are this contagious, but we do need to have capability across the Nation to be able to do that.

Chairman CARPER [presiding]. Dr. Lurie, I am going to ask you to hold it right there, before Dr. Coburn leaves. I do not know if it was my last year in the U.S. House of Representatives, but I had served in the U.S. House for a number of years. Maybe you remember Bob Michel. He had been the Republican Leader in the House for many years. Tip O'Neill was then the Speaker of the House. And, Bob Michel had never had a chance to—all those years in the House, he never had a chance to preside over the House, and he had served there for, like, several decades.

Tom Coburn has presided many times over Subcommittee hearings, but in the 2-years that we have been privileged to lead this Committee together, I do not believe, and although we have taken a couple of times when I run off to take a call or something and he is good enough to take over and run the show. But, I just want to say, as he prepares to weigh anchor, as we say in the Navy, weigh anchor and sail off into the sunrise, how much I appreciate the partnership that we have known for these 10 years and to say we have a lot to be proud of in this Committee this year. We have a lot more that we are working on and trying to get across the finish line. I want us to finish strong, and we are. Thank you, Tom.

Senator COBURN. Thank you.

Senator PORTMAN. My time was already expired, so he is indulging me, and I will be very brief, but just to say, first of all, thank you for the way you conducted this Subcommittee, my Subcommittees and the full Committee, Mr. Chairman, and the same with our Ranking Member. You are nice to give him the proper farewell.

In 2013, we passed this Preparedness Reauthorization Act and we spent \$255 million in grants in fiscal year 2014 and yet we found significant gaps, obviously, in our ability to respond. And, so, I am not disagreeing with what you said. As a matter of fact, I think what you said is consistent with what Senator Markey and I are trying to get at, which is the fact, of course, as Dr. Frieden says, every hospital has to be prepared for people to come through their doors. Every clinic does. You have done a good job, I think, in making them more aware, because in my home State of Ohio, as I have talked to people, they now ask the questions, have you been to West Africa and so on, that they never would have thought about before.

But, to have that expertise, as you say, is impractical at every hospital and every clinic, and that level of commitment of resources for the containment and isolation and so on. So, I hope you will look at this legislation and be willing to work with us to try to figure out the most effective and efficient way to deal with potential problems in the future.

Thank you, Mr. Chairman.

Dr. LURIE. That is one of the things that I think we have always appreciated, is the bipartisan spirit around preparedness. It has been really important, and I think everybody really understands that that is something important to our country and that we all

take really seriously. And, we all understand a chain is as strong as its weakest link.

Chairman CARPER. Senator Baldwin, good morning.

OPENING STATEMENT OF SENATOR BALDWIN

Senator BALDWIN. Good morning. Thank you for holding this vital hearing and I will tell Senator Coburn later that I appreciate it. Thank you to all our witnesses.

I want to inquire and get an update on maintaining a resolute response in West Africa on Ebola. I think there is growing consensus that in order to safeguard the United States, we have to take the fight there. And, I am interested in hearing an update from you, Dr. Frieden, but also from Ms. Lindborg on secondary impacts, economic impacts that we are seeing in the region that could also lead to chaos or additional economic crisis.

We had a time for which we could receive information 24/7 on Ebola. It has subsided a bit, and with that media spotlight only slightly diminished, I would like to hear directly from you, starting with you, Dr. Frieden.

Dr. FRIEDEN. Thank you. I will address the epidemic and Nancy Lindborg the secondary effects.

We continue to be in the midst of an epidemic of Ebola in West Africa. The three countries are hard hit. The most cases are still in Sierra Leone and Liberia. We are seeing it through many parts of each of those countries. In Liberia, it is in at least 13 out of the 15 counties. We continue to have diagnosed roughly a thousand—and reported—roughly a thousand cases per week. We think there may be as many as twice that many in the region overall per week.

We have, however, seen proof of principle that it can be controlled in individual communities, but we have also seen from Guinea that it comes back any time we let up our guard. We are also now surging to assist the Malian government in responding to the cluster there. There are already multiple cases from both household transmission and health care transmission.

So, what we are going to have to do over the next period is be ready for a long, hard fight against Ebola. We are going to have to trace every single chain of transmission, identify the contacts, rapidly isolate them, and do what we know works in Ebola very well in very many different places. That way, we can stop it from spreading. But, there is the risk that if we fail to do that, if we do not have the resources through the emergency funding request, if we cannot accelerate our control efforts, it could spread to other countries in the region and it could become a threat for years to come.

Senator BALDWIN. Ms. Lindborg, in the last hearing that I attended on this issue in, I think it was late September, one of our witnesses who was visiting from Sierra Leone talked about the economic impacts, hotels with nobody traveling for tourism, even business reasons, laying off their entire work force, schools being closed for public health reasons, so teachers are not drawing salaries. That has to have an incredible ripple effect. I am wondering how it is impacting issues like hunger and food security, and please tell us what our efforts are in that regard.

Ms. LINDBORG. Sure, and thank you very much for the question. Even as we maintain a very high tempo and rapid response to controlling the outbreak, which has to be an ongoing priority, as Dr. Frieden has said, and we have a very aggressive all of government effort working through the region to do that, at the same time, these were weak economies to begin with and we are seeing that the disease has further devastated food security systems, health systems. And, so, on top of the virus, we have health and food crises.

We are working rapidly to look at food security solutions and we want to do so in a way that both meets immediate needs, but is sensitive to rebuilding the markets. What we are finding is that many communities are affected not by the disease at all, but by the secondary effects of closed markets, missed planting, inability to travel about. And, so, you have communities that are in a very precarious situation without livelihoods, particularly women farmers throughout the region as they are unable to access seeds, they are unable to do the planting, they are unable to get to markets.

So, that is a significant effort, and in the emergency funding request, we do have critical funding not just to continue and accelerate the response, but also to meet food security needs as well as strengthening and restarting, essentially, the health system for non-Ebola health threats. We are seeing that the vaccination rates for measles in these countries is dropping to precipitously low rates. Women are no longer having access to assistance at childbirth. A whole host of diseases that were starting to get under control in these fragile States are slipping back. So, we have a significant effort to go in alongside the response to this virus and rebuild those systems and underscore those issues.

I want to also add that we are seeing in other parts of the world the importance and the positive impact of the preparedness agenda, and as we look at DR Congo and Uganda, they have both had Ebola and Marburg outbreaks in the last few months. Because of the important work that USAID, CDC, WHO has done in the past several years, those outbreaks were contained. They did not spread. They did not have this devastating impact. So, just to underscore the preparedness, it is critical around the world as we look at the need for strengthened global health security.

Senator BALDWIN. If I have time to put in one more question, I want to observe that during the time that this really was 24/7 in the media, there was misinformation as well as accurate information that was dispensed at that time. And, we have seen in prior epidemics the potential for the real medical epidemic and the epidemic of fear circulating amongst people. Tell me the components that you are looking at to make sure that there is constant accurate public information available for people who are anxious, have questions, need real information, both in the public health and medical community, but at the general public level, too.

Dr. FRIEDEN. We are committed to providing the most up-to-date and accurate information that is available as promptly and effectively and in as plain language as possible, and we do that through multiple means. We do that through communication with the health professionals, through our Health Alert Network (HAN), through our website and other measures, through a series of

webinars that we have had with other parts of HHS, in-person meetings and briefings, and we do that through a partnership with the media to convey the information on how Ebola spreads from everything that we know and how it does not spread and what really is most important to stop the outbreak and protect Americans, and getting back to the, I think, sometimes challenging but fundamental truth that we cannot make the risk zero in this country until we stop it in West Africa.

Chairman CARPER. From one side of Wisconsin to another. Senator Johnson, please.

Senator JOHNSON. Thank you Mr. Chairman. Dr. Lurie, you are with HHS. You are looking for about \$3 billion of funding. How detailed is that request? I have a sheet here. We have about five different areas. I mean, how have you drilled down and just really detailed out that budget request? And, if you have it in much greater detail, can you provide that just for my staff? I mean, is this pages and pages of detail, or is this a couple categories and we were kind of estimating we were going to throw a half-million here, half-billion there?

Dr. LURIE. Well, I have a couple pages even here of top-line issues, and we would be more than happy to provide it to your staff. I think we have really gone through it really very carefully, largely because we all appreciate the need to both respond to this epidemic with urgency and speed, but also really be responsible stewards of our society's resources.

Senator JOHNSON. Great. So, being an accountant, I would like that detail. And, Ms. Lindborg, the same from USAID and the State Department. It looks like it is about \$2 billion.

A question I do have is I know we are sending, what, about 4,000 of our military personnel there. I see very little in terms of funding from the military. Who can really speak to the military's role in West Africa?

Ms. LINDBORG. I can do that. They have funding that they reprogrammed from last year that they notified and got approval to spend about \$750 million. That is separate from this. President Obama mobilized the military to be a part of the response in mid-September when it became clear that the scale and size and the complexity really needed the unique capabilities of the U.S. military.

Senator JOHNSON. So, do you know how much the military will spend on their efforts? Any estimate?

Ms. LINDBORG. I do not know that we have that final, but they expect to be within that envelope.

Senator JOHNSON. I believe in your testimony, you were talking about what the role of the military would be. Can you describe that—

Ms. LINDBORG. Yes.

Senator JOHNSON [continuing]. In greater detail?

Ms. LINDBORG. Yes. So, they have played a critical role of, first of all, providing engineering and logistics capabilities. They built a 25-bed medical unit in Monrovia that is specifically for health care workers.

Senator JOHNSON. OK.

Ms. LINDBORG. They have provided engineering capabilities and have built or, will build a total of 10 Ebola treatment units (ETUs).

Senator JOHNSON. And, how many beds in each one of those treatment units?

Ms. LINDBORG. So, each of these are built initially—the plan is that they are built for about 10 to 20 initially with the possibility to scale up to 100. This is part of the need to be very modular.

Senator JOHNSON. Are they on the ground now? Do we have 4,000 members of the military in West Africa?

Ms. LINDBORG. No. They do not currently anticipate that they will need all 4,000—

Senator JOHNSON. How many are on the ground right now, and in which countries?

Ms. LINDBORG. They are in Senegal and Liberia, and the exact figure changes because they flow capabilities in and out, and we can get you that—

Senator JOHNSON. So, nobody in Guinea? Nobody in Sierra Leone?

Ms. LINDBORG. Correct.

Senator JOHNSON. Are they going to be coming in contact, because I thought you said—

Ms. LINDBORG. No.

Senator JOHNSON. I thought you said something about treatment of patients. I misheard that?

Ms. LINDBORG. We are supporting the treatment—USAID is funding the partners who are providing the management and the treatment inside the Ebola treatment units. Army personnel, or military personnel will not come into any contact with what we call hot zones.

Senator JOHNSON. Who is planning the foreign medical worker plan, the logistics of that? How many medical professionals need to be surged into there, and is it on a rotating basis, 30 days—I mean, can anybody speak to that plan?

Ms. LINDBORG. Yes. So, you are exactly right. There is an enormous need for a pipeline of trained and equipped health care workers. This has been one of the logistical challenges. In addition to the medical unit that provides the confidence for health care workers, that if they come in, they will get that American standard treatment, and that is for both Liberian and international health care workers, the military, U.S. military, has also stood up a training facility so that it can train up to 500 health care workers a week so they have that special training—

Senator JOHNSON. In those countries?

Ms. LINDBORG. In those countries.

Senator JOHNSON. OK.

Ms. LINDBORG. It is in Monrovia and outside of Monrovia. We work very closely with WHO, who runs a foreign medical team coordinating center, and those teams get deployed against the needs within these Ebola treatment units. Very importantly, the U.S. military is also helping with some of the critical transport of commodities and personnel. There is a base in Senegal that enables them to move from Senegal through the region with transport.

Senator JOHNSON. OK. Dr. Frieden, just for my last couple minutes here, I really want to ask some of those common sense ques-

tions that people just have on their minds. If we can get the answers to them, maybe we can alleviate some of the fears.

I know protocol was not, apparently, followed, but just specifically, how did those two nurses catch Ebola? Did they simply not have proper clothing? I mean, was their skin exposed? I mean, were they in just at the very height of Mr. Duncan's illness and all kinds of medical waste and fluids and stuff? Can you tell us what happened there?

Dr. FRIEDEN. We do not know definitively how the infections occurred. We believe from the investigation and the evidence that it is likely that they were infected actually prior to Mr. Duncan's diagnosis, from the 28th to the 30th of September, when he was very ill. He had a lot of body fluids, a lot of diarrhea, a lot of vomiting, and they were caring for him with protective equipment that they were trying to beef up so that they would be safer. But, in doing that, they may have inadvertently increased their risk. And that is why, immediately, we strengthened the level of safety and went to a new set of Personal Protective Equipment guidelines. Two of the essential components of those guidelines are that health care workers practice and practice and practice——

Senator JOHNSON. OK.

Dr. FRIEDEN [continuing]. So they are comfortable with doing, and that they are observed to put on and take off the equipment.

Senator JOHNSON. Can we talk a little bit about the survivability of the virus. We are talking about this, really, because of the burial practices in Africa, the virus is obviously present in those bodies and it, obviously, survives. If, it remains moist. Is that really all it takes, is just the virus to be in a moist environment and it will continue to survive?

Dr. FRIEDEN. The virus cannot live indefinitely outside of the body, as far as we know, but it will depend on the environmental conditions. We know that it is produced more by people as they are sicker.

Senator JOHNSON. Mm-hmm.

Dr. FRIEDEN. But, all of what we have seen in Africa has suggested that it takes direct contact with someone who is ill. Even one study we did showed that even family members who shared meals, lived in the same household with patients, if they did not have direct contact, they did not——

Senator JOHNSON. What is the theory of how it jumps from animals to humans? Is that through diet?

Dr. FRIEDEN. We do not know in particular. It has not been proven in Ebola. Our work has shown that in Marburg, a similar virus, bats are an important reservoir, and then contact, hunting and cleaning bush meat can bring people into contact with infected animals and their body fluids.

Senator JOHNSON. A quick question for Texas. We know Mr. Duncan got ill in a parking lot. What happened to the result of that illness?

Dr. LAKEY. What happened——

Senator JOHNSON. We heard it sat around for a couple days and then was just washed down a drain.

Dr. LAKEY. For the cleaning of the environment? Is that your question, sir?

Senator JOHNSON. Yes. Apparently, he vomited in a parking lot.

Dr. LAKEY. We brought in a crew to do cleaning, cleaning of the apartment. They went to several lengths to clean the apartment, clean all the environment around—there was a contractor that came in to do all that cleaning.

Senator JOHNSON. OK. Well, thank you, Mr. Chairman.

Dr. FRIEDEN. If I may, just the Ebola virus itself is relatively easy to decontaminate. It has an envelope, so soap and water, an alcohol-based wipe, bleach readily decontaminates it, but we want to make sure that is done thoroughly and completely any time there may be exposure.

Ms. LINDBORG. And, if I may, Senator Johnson, just to add, the funding request that is before you includes as a part of the two—the \$1.89 billion—funds that will enable the military to transition out so that there will be civilian capabilities coming in behind the military, which is why they do not anticipate exceeding their current funding envelope.

Senator JOHNSON. Thank you.

Chairman CARPER. Yes. I want to thank Senator Johnson for calling me during the, I guess it was at the time of the run-up to the election when we were not in session actually encouraging us to hold a hearing. He actually encouraged Dr. Coburn and I to hold a hearing a couple of weeks before the election, and we talked it over and decided that this might be a better time to do it. I thank him for raising the idea and certainly for being here again today to be with all of you and ask these questions, including the ones that are common sense questions.

Senator Rob Portman from Cincinnati, Ohio.

Senator PORTMAN. Thank you, Mr. Chairman.

So, we talked earlier about timeliness, and Dr. Frieden and I can probably have a debate over that. CDC was on the ground with a relatively small number of people relatively early, but it also got out of control, and I hope no one on the panel would disagree with that. Look at it as compared to, for instance, the severe acute respiratory syndrome (SARS) epidemic in China and how we reacted. And, I say “we.” I mean the global community. And, we are now paying the price. So, there have been over 14,000 people infected. That is probably a low number. Over 5,000 people have died. It sounds like we are beginning to get it under control in Liberia, but not necessarily in Sierra Leone and Guinea. I think it just speaks to the need to respond more quickly because of the way it spreads, as Dr. Frieden was talking about.

So, two questions. One, World Health Organization. I mentioned SARS because I think they responded appropriately and quickly there. I do not think they responded quickly here. Yes, they sent out a report saying this was a problem, but they did not send those treatment teams that you talked about as quickly as they could have, nor in the numbers that were needed, and I think the World Health Organization did not mobilize the donor community, meaning countries, as quickly as they could have, and have in other instances. So, what is happening? And, I do not know who wants to answer this question, who has the expertise on World Health Organization, but it seems to me we have to learn a lesson here, which is that the global response needs to be both more rapid and more

concerted, but also there needs to be more effort in funding early on.

Ms. LINDBORG. So, if I could just start, and then I will pass it to Dr. Frieden.

Senator PORTMAN. You guys are fighting for the microphone here.

Ms. LINDBORG. It speaks, really, to two things. One is the response and how quickly and how thoroughly we need to be able to respond. But, even more importantly, it speaks to the preparedness agenda and being able to understand how we help countries detect and respond effectively to these kinds of diseases much more quickly.

And, I will just say once again that even this year, these last few months, because of work that USAID, CDC, and WHO have done with the Democratic Republic of Congo and Uganda, they have both experienced outbreaks of Ebola and Marburg this year that were successfully contained. And, it is because of the under-investment in West Africa that we saw the Ebola virus just take fire the way we have seen. So, it is very important about the preparedness agenda.

Senator PORTMAN. OK.

Dr. FRIEDEN. That was actually one of the two points I wanted to make, and it is critically important and it is part of the emerging funding request, both for the countries around these three heavily affected countries so that they can have the detection, response, and prevention capacity so that it does not get out of hand there, and more broadly, so we have an alarm system globally so that we do not have something that festers for weeks or months and then spreads widely before we can respond.

Senator PORTMAN. Dr. Frieden, here is my question to both of you. What happened? I mean, why did we not have that in effect? I mean, are you defending the World Health Organization today? Do you think they did the right thing? Do you think they were ready? I mean, why was West Africa left off the map? Why did they not have the preparedness and why did they not respond more quickly? And, I do not mean just WHO, because there are a lot of great NGO's involved, also, and others. But, why was the response so slow and what role should the WHO have played and what has been learned?

Dr. FRIEDEN. First, the countries themselves have very weak public health systems, so they did not have in place the basic laboratory, surveillance and tracking, response capacity, and emergency response and prevention capacity that are not very expensive to get in place, but would potentially have prevented this from becoming epidemic there. And, in fact, if you look at what the World Bank has estimated, more than \$30 billion of costs in those countries, it would be a tiny fraction—less than a half a percent—to put in that kind of simple early warning and response system.

In terms of the World Health Organization, I think they themselves would say that the response has not been optimal, that both within the countries, the WHO offices and the Regional Office of Africa did not respond effectively. They have terrific people in the WHO and they have a critically important role to play, and one of the aspects of the emergency funding request is to provide re-

sources with accountability to WHO, because they need to have both a framework of providing guidelines globally, but also the ability to support response within capacity more than they have done so far.

Senator PORTMAN. Some experts I have talked to on this use the word “bureaucracy,” that there was a bureaucratic issue here in responding, and more money will not solve that problem. Maybe more accountability will.

Dr. FRIEDEN. I think we need to ensure that WHO has the resources to do the job that it needs to do and it also has the accountability to be held accountable for actually doing it.

Senator PORTMAN. Could we switch to the NGO’s for a second. One thing that I have been asking about, and I have talked to—you mentioned the World Bank, so I will mention Dr. Jim Kim, who is not only the President of the World Bank, but happens to be an expert on infectious diseases and had a lot of successes through Partners in Health over the years with Dr. Farmer and others, but I have also talked to Dr. Bill Frist, who, as you know, was a former colleague of ours, and others about why we are not putting together an effective private sector response to channel the generosity and the support of the American people through something like we did after Katrina, or after the earthquake in Haiti, which had an enormous impact on Haiti’s ability to get on its feet, and people were happy to help, or after the tsunami, where, you know, at a Presidential level, we put together an opportunity for people to give.

In some cases, the Red Cross has provided some of the infrastructure for that. I know the U.N. has its own fund, and I know that there are other NGO’s that are fundraising directly. I personally have contributed to Partners in Health, because I think they do a great job. The research I did showed that they probably put 96 percent of their money straight into service, which I was very impressed with.

But, my question is, should there not be a national response here, and I think a lot of people would be willing to help, but there has not been that kind of an organized effort as we have seen in these other either health care or natural disasters, and I wonder why and what could be done now.

Ms. LINDBORG. So, that is an important question and there are new efforts to galvanize some of the fundraising that you mentioned through using social media and working very closely with the NGO’s, and there are more campaigns that are coming online in the next few weeks to do exactly that. We have also worked very closely with the communications companies, that we are involved with them right now in using some of their technologies and expertise to improve data collection, data transmission, data analysis, and they have been very important partners with us on that.

Just yesterday, I followed Ron Klain to speak at a meeting of foundation and private sector individuals who are very interested in increasing their response in a very strategic way to how they can provide assistance. So, there is a lot of effort out there, both in terms of tapping into technologies, into products, and into fundraising possibilities, and you will see that continue over the weeks ahead.

Dr. FRIEDEN. And, if I may, two additional points. CDC has a foundation created by Congress in 1993. That foundation has raised more than \$45 million for the response, and that has been immediately deployed to accelerate the response in West Africa.

And, second, I have to give a lot of credit to Doctors Without Borders (MSF). They have been there on the front lines, on the ground at all times, and they have been right about their concerns and the alarms that they have raised.

Senator PORTMAN. Yes. And the CDC fund has attracted some major donors, and that is terrific. I guess my question is, and to Ms. Lindborg talking about all the efforts that are going on, people who are watching today—thank you if anybody on C-SPAN is actually watching—they do not know about any of this.

In the past, as I say, recent past, even, with regard to the earthquake in Haiti, the Presidential involvement in that, and also former Presidential involvement with regard to the tsunami, people knew about it and all of these media companies you are talking about were able to focus on one effort, one fund. It seems to me that makes sense. I just wonder if you are moving toward that.

In addition to the CDC work, which is very important, this could be a broader fund that deals with not just Liberia, but all the countries of West Africa and trying to do what Dr. Frieden said earlier, which is he said, and I quote, “You cannot remove the risk to the United States until we stop Ebola in West Africa,” and I think people get that, want to help. They have compassion, and I do not think they know where to channel their generosity.

Ms. LINDBORG. We could not agree with you more. Watch this space and we will be happy to keep you briefed as efforts evolve. And, I would add that about \$850 million has been raised from the private sector thus far, so they have already been significantly engaged, including some very strategic contributions from organizations like the Paul Allen Family Foundation, who provided transport and have been engaged with us on the medevac solutions. But, there is a need for more campaigns and we look forward to talking to you more about that in the coming weeks.

Senator PORTMAN. Well, I think, not speaking for all my colleagues, but a lot of us would be happy to be involved in that to help spread the word, but I think there needs to be an effort that is concerted, one effort that people understand and has accountability so that those generous Americans who want to help know their dollars are being well spent.

Thank you, Mr. Chairman.

Chairman CARPER. You bet. Thank you. Senator Portman, I know you spend a lot of time, have a lot of personal interest in these matters, and I applaud you for that. It shows.

Normally, the Chairman of the Committee leads off in the questioning here, as Gil knows and some others may recall, and I wanted others to go first today and I wanted to go last, and for about the next hour or two—it will not be that long. It may seem that long, but it will not be that long. [Laughter.]

I have a couple questions, if I could. I am reminded of something that Lincoln once said. He used to say, “The role of government is to do for the people what they cannot do for themselves.” That is what he would say.

Just a short question, and I invite a short answer. What is the role of government here, particularly our government? I am going to ask, is it Dr. Brinsfield, is that your name? Would you come to the table, please. You can be thinking about this. We will let you answer that one last. But, you are nice enough to come. I want to make sure we get our money's worth out of your appearance. [Laughter.]

But, what is the role of government, Dr. Lakey, very briefly?

Dr. LAKEY. I think government had a very important role in the response. I cannot speak to fighting on the front lines in Africa, obviously, a very important role, to make sure that we prevent it from coming to the United States. But, an individual person cannot do the things that the government, local, State, Federal Government did together. You cannot test for an individual, to have that system in place to test that somebody has this disease or not. It cannot do the epidemiology to figure out, who have you been in contact with? That is a role of government. It cannot decide that somebody has had enough of an exposure that you might have to do a quarantine, et cetera. That is a role of government. To plan ahead, to make sure you know what facilities are ready, to train those individuals, I think there is a very important role of government providing for that common defense—

Chairman CARPER. OK. Hold it right there. That is good. I want to give these others a chance to respond. That is very good. Thank you. Ms. Lindborg.

Ms. LINDBORG. A very critical role for the U.S. Government has been to provide the global leadership that helped galvanize a kind of response that was commensurate with the level of the threat. And, in addition, as we see with the Global Health Security Agenda that was launched actually in February, create the global conversation about the policies and the actions that are critical for all of us to have greater safety from emerging threats.

Chairman CARPER. Thank you. Gil.

Mr. KERLIKOWSKIE. Mr. Chairman, it is, I do not think, any different than when I was a police chief. It is to protect people, not only by the actions of government, but by equipping them with information and the steps that they can take themselves to be safer.

Chairman CARPER. All right. Thank you.

Dr. FRIEDEN. I would reiterate that. It is about getting information to people on what is happening with the disease and what they can do. It is about working to protect people from threats that they cannot protect themselves from because of the outbreak. And, it is working as a community to stop an outbreak in order to protect people in a way that we, as individuals, cannot do that. We cannot have the detection systems, response systems, and prevention systems that will be so effective.

Chairman CARPER. Good. Thanks. Dr. Lurie.

Dr. LURIE. Great. The perils of going last on this one here, but—

Chairman CARPER. No, next to last. We are saving the best for last. [Laughter.]

Dr. LURIE. Oh, OK. There you go. But, certainly to protect the public and to give people the information that they need to protect themselves. It is to lead. It is to educate. It is to be sure that an

infrastructure is in place so that people can be protected and educated. It is to support funding when funding is not available. And, it is ultimately to hold together with the public all the components accountable for outcomes. So, in some sense, it is to be sure that there is a system in place that knits all of the moving parts of this together so that it can work seamlessly and accountable to drive to outcome.

Chairman CARPER. Good. Thanks. Dr. Brinsfield.

Dr. BRINSFIELD. Thank you, sir, and thank you for inviting me. I think, in particular, it is our role to protect the homeland, and specifically our role to give the best advice possible to Mr. Kerlikowske, to our Secretary, to make sure that they are able to make the decisions necessary to protect both our workforce and the country. And, it is also our role in some sense to make sure the information is out there and available and that the response is equitable.

Chairman CARPER. All right. Thank you. Is he a pretty good listener?

Dr. BRINSFIELD. Very much, sir.

Chairman CARPER. All right. Good.

Each of you are going to be given about a minute to give just a brief closing statement—not yet, but just be thinking about that. We always ask our witnesses to give an opening statement, 5 minutes or so, and you will all be given a chance to offer just a brief closing statement, as well, so you might want to think about what you would say there.

I am a recovering Governor, as my colleagues know, and as Governor, I did hundreds of customer calls to businesses across Delaware, outside of Delaware, maybe outside the country, a lot of whom would have operations in Delaware. So, we are always interested in job creation, job preservation in those roles, and in this role, too. But, when I would do customer calls on businesses—I still do them—I ask, how are you doing, “you” being your business. How are we doing, “we” being the State of Delaware, Senate, Congress, Federal Government, and what can we do to help.

So, I am going to just—this is not a customer call as such, but we will just use those questions anyway. How are we doing? We have been pretty much asking that question all morning, and I am encouraged by how we are doing. I am encouraged by the sense of team and I am encouraged by the sense of not just the Federal Government, not just the State Government, not just public health, not just non-governmental entities, it is not just other countries, but it is all this writ large, a lot of volunteers, very good people.

But, in my sense, we are doing better, and in this country, I think we have done remarkably well when you actually look at the numbers. I am told that more people die of malaria in a week in this world than have died of Ebola maybe since we had our first fatality. It has been pretty remarkable, and yet we do not focus as much on malaria, nearly as much as we do, and yet the loss of life every day is so substantial.

OK. How are we doing? We have talked about that. How are you doing? For those you represent, how are we doing? And, most importantly, how can we help? I would just like to ask each of you, and I am going to start with you, Dr. Lurie, how can we help?

What are we doing right now that is really helpful? And, maybe one example of what do we need to do more of, or maybe even less of? Please, and just real briefly.

Dr. LURIE. Great. Well, I would say one of the things that I think we have done very well is the preparedness has been built on the back of strong day-to-day systems. And, in fact, in this country, we have strong day-to-day systems that have let us detect, that have let us respond. We cannot take our foot off the gas here and we have to continue to build that, maintain it, and be sure it is in place, and I think we have to continue to look toward the future. We need to look at, as we do with any event, what are the lessons learned, what are the things that went well, and where do we need to build toward our future preparedness both in this country and globally. Obviously, there are lessons in that for both.

Chairman CARPER. We are going to come back and ask about lessons learned, but thank you for that.

Dr. Frieden, what can we do to help, maybe that we are already doing or not doing enough of, or too much of?

Dr. FRIEDEN. I think the basic principles of moving fast and flexibly and keeping the front lines first are the critical components here. And right now, we are very focused on the emergency funding request, because that is going to be in a critical pathway for our being able to stop it in West Africa, being able to protect the homeland by strengthening systems here, and being able to anticipate and set the alarm earlier if Ebola or another deadly threat spreads elsewhere through the global health security work.

Chairman CARPER. All right. Thank you. Gil.

Mr. KERLIKOWSKIE. Mr. Chairman, I think what is interesting to me is during the 6-years in the Administration, I have had two wonderful interactions with Senator Portman. So, as Drug Policy Advisor, it was all about enforcement. United States Customs and Border Protection is all about enforcement. My two interactions with Senator Portman, and, frankly, a number of other Members of Congress, have been about disease, have been about public health, and my work with Dr. Frieden on overdoses and prescription drugs and now on Ebola. And, what I think it clearly shows is that there is not a division. There is a true intersection of where public safety and public health come together.

Chairman CARPER. Thank you. Ms. Lindborg.

Ms. LINDBORG. So, even before the Ebola outbreak, we—

Chairman CARPER. Again, what I am really drilling down is what can we do to help, but please.

Ms. LINDBORG. Yes. Even before the Ebola outbreak, we had a record level of global crises around the world. Because of the fast-moving nature of Ebola, we had to push out hard and fast with all of our emergency responses, all of our resources. What you can most do to help is help us ensure that those mortgaged responses are still able to go forward. The emergency funding request is critical, both for maintaining our continual accelerated rapid response in West Africa, but also to ensuring that we are able to replenish some of our contingency accounts that were so critical for getting out fast.

Chairman CARPER. All right. Thanks.

Ms. LINDBORG. And then the second thing I would just say is the attention and the interest and the support from both the House and the Senate have been, I think, indispensable, both in terms of getting information out to the American public, but also just ensuring that there is this important ongoing dialogue. So, thank you for that.

Chairman CARPER. Thomas Jefferson used to say, "If the people know the truth, they will not make a mistake," and part of the reason for this hearing today for Dr. Coburn and myself and, I think, others, is to get to the truth, make sure that people in this country know the truth.

For me, a big piece of that was when the gentleman who died in Dallas, and we learned that the woman with whom he shared a bed, same sheets, same bedroom, the kids that were there, the adults who were there, none of them came down with the disease, that was just an eye-opener for me in what we were facing. And, it does not minimize the threat of what we were facing, but it was something that was, for me, really helped me understand the truth.

Dr. LAKEY, just very briefly. What can we do, what more or less of?

Dr. LAKEY. Well, first, thank you for allowing me to be here today. I think it is important to have a State voice in these conversations, and as policies are put into place, that there are individuals from the State and local level that can have input into how those policies are going to be played out on a local level.

Chairman CARPER. As a former Governor, I know how important those States are.

Dr. LAKEY. Well, thank you. I think what we are incumbent to learn from this experience and make sure that we are quicker, faster, and smarter in our ability to respond, things like permitting and cutting some of those bureaucracies so that we can move quicker the next time. And, I would ask you to remember that that public health—we do not like the word "infrastructure," but there is a capacity that needs to be in place to be able to do the detection, respond quickly, and that is a very important ability for us to respond to these events. Thank you, sir.

Chairman CARPER. Thank you. Dr. Brinsfield.

Dr. BRINSFIELD. Thank you, sir. So, to echo Mr. Kerlikowske, we clearly every day see the intersection of public health and security, and this is something that we felt very supported by this Committee and look forward to working with you further to codify some of those areas.

Chairman CARPER. OK. Thanks.

Dr. Lurie, you mentioned best practices. Let me just ask you each to name one, just something you have seen and you say, oh, that is a best practice. I always like to say, find out what works, do more of that. Find out what does not work, do less of that. And, maybe give us a good example of what works that we ought to do a lot more of. A best practice, please. Just one.

Dr. LURIE. Certainly, one best practice is having day-to-day systems that have people drill and exercise for emergencies that might happen.

Chairman CARPER. Thank you.

Dr. LURIE. So, I will just take a moment to respond to your other question, because it is all a best practice. I know that you are all going home for the holidays.

Chairman CARPER. Maybe.

Dr. LURIE. You are going to have opportunities to meet with your constituents, and I want to be sure before you leave that you have all the information you need to help your constituents understand what is going on with Ebola in West Africa and here, and to help them stay educated and help them stay calm.

Chairman CARPER. That is a great point. Yes. Thanks so much.

Dr. FRIEDEN. Lagos, Nigeria, experienced a traveler arrive, caused a cluster of Ebola. CDC and the Nigerian government and the Lagos government were able to respond to that very intensively. It required 19,000 home visits, creating an Ebola treatment unit, and moving out very rapidly, and with that intensive effort, they have made Nigeria Ebola-free. That kind of intensive effort is what we need to devote to every single case of Ebola that occurs anywhere in the world so we can push it back and get it out of these countries where it is spreading so widely.

Chairman CARPER. Thank you. I mentioned the incident in Dallas, the death of the gentleman, and the fact that those right around him, even in the same bed with him, never contracted it. For me, that was a moment of truth. And the other moment of truth was what you just pointed out in Nigeria, a country that successfully addressed this and basically stopped it in its tracks. Thanks.

Mr. Kerlikowski I almost called you "Doctor," so, Chief, go ahead.

Mr. KERLIKOWSKIE. I am with quite a few. After the laws, after the MOUs, after the agreements, after the policies, it really all comes down to those individual relationships. And, if you look at the complexity of an airport and to suddenly very quickly and very adaptively put in the type of screening that required the cooperation of the airlines, the airport authorities, the Chicago Public Health, or the State of New York Public Health, the relationships with CDC, all of these things to be—the United States Coast Guard—all of these things to be done very quickly so we can have great policies and MOUs, those relationships at the State and local level, as Dr. Lakey said, are critical.

Chairman CARPER. All right. Thank you, sir. Ms. Lindborg.

Ms. LINDBORG. Two things. One is having early on a joint strategy that was very clear and governed not just our response, but was closely aligned with the United Nations and with the affected countries made a difference. We were all able to move forward in the same direction.

And then, second, is applying a lot of hard lessons learned of how to be very organized in the heat of a crisis response and having the systems and the authorities so that when we send in our Disaster Assistance Response Team, we can call forward, whether it is from DOD or the U.S. Forest Service, the capabilities from across the U.S. Government that are most appropriate, and it is a much more seamless relationship now than it was in the past.

Chairman CARPER. All right. Thank you. Dr. Lakey.

Dr. LAKEY. I think one of the things that was helpful to us was to have an outside entity, an advisory board, to be able to hand off,

ask hard questions to, a board of prominent scientists from the State of Texas, individuals that run major agencies, have meetings that were public and so that we could have that outside entity advise us and be able to get the best scientific information as we devised our critical policies. Thank you.

Chairman CARPER. Thank you. Dr. Brinsfield.

Dr. BRINSFIELD. So, I also believe that the interagency dialogue, the coordination that has gone, we have improved greatly, and I think it is one of the real strengths of this response.

Chairman CARPER. OK. Thank you.

We have touched on the funding. You have, in some cases, responded in terms of what we can do to help, is to make sure that we are responsive to the Presidential request for supplemental funding. I am going to ask you to answer this question on the record, but before I ask the question, I will just try to draw a parallel here.

Earlier this summer, we had tens of thousands of people, mostly young people, sometimes, as Gil knows, very young people who were coming up from Honduras, Guatemala, El Salvador, trying to get into our country and to escape the wretched lives that they are living down in those three countries in particular. We spent a fair amount of time trying to figure out what we could do to strengthen the borders, stop people at the borders, and we spent about a quarter-of-a-trillion dollars in the last 10 years to do that. We really were trying to address the symptoms of a problem, the underlying problem and underlying cause is lack of economic hope, lack of opportunity, lack of safety in those countries, and that is why these people are getting out of there.

One of the questions I am going to ask you for the record is for some thoughts on underlying root causes. I always like to focus on root causes. We are so good at thinking about symptoms, how do we address the symptoms of problems, and for me, what I always like, what is the root cause of this particular problem? Let us make sure that we are dealing with that at the same time that we deal with the symptoms. So, I am going to be asking one question about the root cause.

The second question I will ask you is a somewhat different kind of question. It goes back to the Administration's funding request, but it relates to the border. The Administration came in, as Gil will recall, with a very substantial supplemental appropriations request back in mid-summer, remember, and I think it was about, I want to say, \$3.7 billion. It was then knocked down to \$2.7 billion. And, the flow of particularly young people to our borders slowed dramatically. We did a bunch of things. The Mexicans did a number of things. We launched this truth campaign down in those three countries in Central America to try to make sure the people there knew what they are actually facing, trying to get through Mexico, trying to get into this country, and I think that helped, as well. The weather slowed some people down.

But, we want to make sure that we are addressing root causes. We also want to make sure that the President's request, which 3.7—we never funded the 3.7. He knocked it down to 2.7. We did not fund 2.7. And, in the end, we asked the Administration to figure out and, like, literally take it out of their own hide, about \$400

million to try to address the challenges at the border and everything that flows from that.

You are going to get a lot of questions about a \$6.5 billion supplemental request, and I thought we had a good discussion about that today, but my question for the record will be, if we do not get it, if you do not get that kind of money, what does it mean? What does it mean if we do not respond in the way that the Administration is asking?

Ron, do you have any more questions? No?

I did say I was going to ask each of you to give one last parting comment, and no more than a minute, but, Dr. Brinsfield, again, thanks so much for joining us, and you get the last word.

Dr. BRINSFIELD. Thank you, sir, and thank you for inviting me. I have nothing further to add except to say that we have appreciated greatly the ability to work with our colleagues. We have certainly learned a lot of lessons about how we can better move and transfer data, how we can work together in a more efficient manner, and particularly want to thank our colleagues from Texas and State and local public health because it really is where the rubber meets the road and we have great support and faith in their ability to do the job that we have been asking them to do.

Chairman CARPER. All right. Thank you. Dr. Lakey.

Dr. LAKEY. Again, I want to thank you for the privilege of being here today to be able to share our experiences. I think it is incumbent on us to make sure we learn from those experiences so that we can protect our health care workers, we are able to be able to respond quickly. The infrastructure at States and the local level really is critical in that ability to respond quickly, and so, again, I want to emphasize that infrastructure is very important. It is also very important that we know each other. We have worked together on many events before and it really is a team effort in order to respond to a novel event like this. Thank you, sir.

Chairman CARPER. No, "I" in the word "team." It is a team and a good one. Ms. Lindborg.

Ms. LINDBORG. OK. So, this is the closing—

Chairman CARPER. This is your last minute—

Ms. LINDBORG. OK.

Chairman CARPER. Closing thoughts.

Ms. LINDBORG. So, Ebola preys on weak systems. We have seen what happens when it goes into countries that are ill prepared, especially countries that are recovering from conflict and just do not have the means. More than anything, this underscores that if we get upstream, if we pay attention to fragile States, if we work on strengthening the global health system, we are in the best position to keep this country safe and to avoid having to mount these very, very expensive, difficult responses. So, it is the root causes and the root causes are often fragility, poverty, repressive countries.

Chairman CARPER. All right. Thank you. Gil.

Mr. KERLIKOWSKE. As a police chief, it was important to arrest criminals. It was important to solve crimes. But, it was just as important to give people in Seattle the sense of confidence that their police department knew what the problems were, that they were action oriented, and that their first and primary task was to protect them. And, I think the opportunity to have this hearing and

let people know that government actually is very much involved, and even though, as Tom said, we will never reduce the risk to absolutely zero, we are much better ahead of the game because of the cooperation and the support that we all have.

Chairman CARPER. Thank you. Dr. Frieden.

Dr. FRIEDEN. Ebola is a serious threat. It is one of several serious threats, and unless we move out quickly, get the resources needed, the risk is that it will spread throughout other countries in Africa and be a threat for a long time to come.

The emergency response request for CDC, the funding is largely fixed, not dependent on the number of cases. It is to protect our systems here in the U.S. It is to prevent similar outbreaks of Ebola and other deadly diseases elsewhere and it is to surge into the three countries and the 11 countries around them to create the systems that will help them be safer and help us be safer by addressing some of those root causes of weak systems, weak public health systems, and establish the rapid response capacity that can end this epidemic and prevent the next one.

Chairman CARPER. All right. Thank you. Dr. Lurie.

Dr. LURIE. We have been hearing a lot about root causes, and preparedness, as I said, is really built on the back of strong day-to-day systems. We have seen weak systems in West Africa. Those are some of the root causes of what happened there. We need to keep our systems here strong. We cannot let them degrade.

We also have seen, with every investment in preparedness, there has been a peacetime return on investment. Our systems have gotten stronger. We have gotten better about preventing or detecting the next episode. And, we have been able to shorten the period between an event and, in some sense, recovery. One of the things that we really need to do with this emergency funding request is to deal with the acute situation in West Africa. I also anticipate that we will want to see the returns on investment, both in West Africa and around the ring countries, as Tom said, and around the globe, as well as the returns here from a strengthened public health and health care system that can deal with really deadly infectious diseases in the future.

Chairman CARPER. OK. Thank you.

I will give a short, maybe, closing statement of my own now, and I, too, again thank you all for coming today. Thanks for working together, and thanks for doing important work.

I often tell the story about listening to the National Public Radio (NPR) going to catch the train last year, one day last year—I go back and forth to my home State of Delaware almost every night from here and like to listen to NPR driving into the train station after I have worked out at the Y, catch that 7:15 train and come on down. And, one of my favorite recollections of listening to the news at the top of the hour, seven o'clock, is a question was asked about a year ago in an international survey, what do you like about your work, and it was a question asked of thousands of people all over the world. What do you like about your work?

And, the people had different answers. Some said they liked getting paid. Some said they liked health care as a benefit. Some said they liked to have a pension. Some people said they liked having their vacations. Some people said they liked the folks they work

with. Some people said they liked the environment in which they worked.

But, the thing that most people liked most, that gave them real satisfaction in their work, is that they knew the work they were doing was important and they knew they were making progress. Think about that. The work they were doing was important and they knew they were making progress.

There are few things more important than saving the lives of other people, whether in this country or other countries. Who is my neighbor? And, so I say to you, you are doing important work, and I am encouraged that we are making real progress here and starting to see some in Africa, as well.

I love to ask people who have been married a long time, 50, 60, 70 years, I love to ask them, what is the secret for being married 50 or 60 or 70 years. I get some hilarious answers. One of those is last month or so, I talked to a couple. They had been married 54 years. I asked the wife, what is the secret for being married to this guy for 54 years and she said of her husband, she said, "He can be right or he can be happy", "but he cannot be both." [Laughter.]

I get answers like this all the time. One of my favorite answers, and I have gotten this one a number of times, is the two Cs. The two Cs. The first time somebody said the two Cs, I said, what are those? The answer is, communicate and compromise. And, I have concluded over the years that that is not only the secret for a vibrant marriage between two people, but also the secret for a vibrant democracy, to communicate and compromise. And, I have added a third C, and the third C is collaborate. To communicate, compromise, to collaborate. Again, that third C stands up large as we explore this issue before us here today.

I have had the privilege of leading this Committee for the last 2 years with Dr. Coburn, and I said earlier he and I have worked very closely together. We took turns being Chair and Ranking Member of the Financial Services Subcommittee within this Committee, so we had a great time working together then and we have had, I think, just a lot of challenges this Congress, but some real satisfying moments, as well, and we are not done yet.

But, when he and I took over our leadership roles 2 years ago after Senators Lieberman and Collins had fled, at least this Committee, Lieberman into retirement and Susan to take on other responsibilities, but 2 years ago when Tom and I were talking about what lay ahead for the Committee and this Congress, the word "Ebola" never came up. The word Islamic State of Iraq and Syria (ISIS) never came up. The word "Sandy" was not something that we related to the kind of disaster that came to visit us on the East Coast. And, as it turns out, the nature of the challenges that we face to our homeland, to our people, evolves, continues to evolve.

One of the best ways we can deal with the threats, whatever they might be, is to communicate, maybe some compromise, and a whole lot of collaboration, and that is what we have an obligation to do on our side, so, clearly, you have that obligation, as well, and my hope is that we are meeting our obligation and we will in the future, as well, as you have met your obligation to do those, to be faithful to those three Cs.

And, in closing, I would say to the members of our staff, Committee staff, who are here how much I appreciate the great work that they have done, not for me, not for Dr. Coburn, but really for our country. As they know, it is very important work. What Tom and I have tried to do is just to work together, to demonstrate by not do as I say but actually do as I do, and hope that it will trickle down, and I really think that it has and I hope we have set an example for other Committees, as well.

And, I think, with that having been said, I think it is a wrap. We want to again thank you all for joining us, and I am supposed to say these last words. The hearing record will remain open for 15 days—that is until December 4, 5 p.m., for the submission of statements and questions for the record.

And, with that, this hearing is adjourned. Thank you all.

[Whereupon, at 12:32 p.m., the Committee was adjourned.]

A P P E N D I X

**Opening Statement of Chairman Thomas R. Carper
“Preparedness and Response to Public Health Threats: How Ready Are We?”
November 19, 2014**

As prepared for delivery:

Today, we will examine our nation’s response to the ongoing Ebola epidemic and our overall preparedness for other public health threats. We are very fortunate to have a great panel of witnesses with us today and I would like to thank all of them for their public service.

Since February, the public has watched an epidemic of the Ebola virus grip the countries of Sierra Leone, Liberia, Guinea and now Mali. To date, roughly 5,200 people in west Africa are believed to have died from the Ebola virus. The actual number of deaths may be significantly higher.

The severity and scale of this outbreak has challenged the world-wide public health community. When I think about the tragedy that is playing out in west Africa and what role we should play, I am reminded of the Parable of the Good Samaritan, where we learn that we should ‘Love our neighbors as ourselves.’

If we don’t take care of our neighbors in Africa, then we may see this deadly disease spread even faster across the world. That is why I believe it is vital that we – along with our international partners – continue to battle Ebola at its epicenter.

Ebola, however – like all infectious diseases – knows no borders. It has even reached our shores. Over the weekend, the United States began treating its tenth patient for Ebola, who sadly passed away on Monday. His death marks the second Ebola-related death here at home.

In light of the Ebola virus epidemic, many Americans have asked the important question: how prepared is our nation to handle a major public health threat? That’s what we hope to answer at today’s hearing.

Our goal for this hearing is not to create needless confusion. Doing that would be counterproductive, potentially putting more people at risk and exacerbating the public’s understandable fear of the disease. Instead, I hope we are able to find lessons learned from our Ebola response, and use them to inform our future response to this disease and others that could threaten our country.

While I know the disease is far from being defeated and has even, as I mentioned earlier, spread to Mali, it’s my understanding the number of cases in Liberia has substantially declined. This is welcome news. However, I know we could see a spike in cases with little notice. As a result, we must continue to pay close attention to the changing dynamics in Africa. And we must continually reassess the scale of the response needed overseas and here in the United States to end this epidemic.

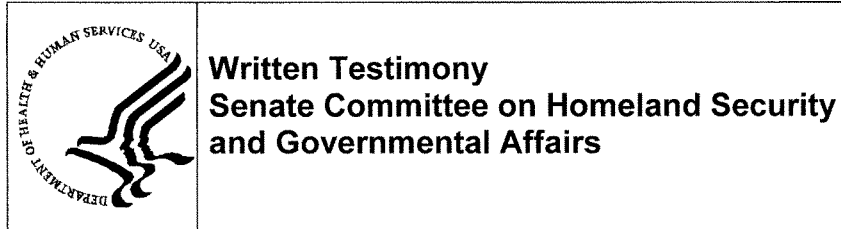
Whether it's the Ebola virus, influenza, or a disease we have yet to hear about, the bottom line is the same: we need to be better prepared and ready to respond. To be most effective, we of course must have a well-coordinated response at the Federal, State and local levels.

We must also have clear guidance and protocols from the Centers for Disease Control and other public health officials so that everyone knows exactly what to do and what not to do. We must also ensure that our state and local health and emergency response professionals have the training and tools they need to succeed. Finally, we must have a strong screening process in place at our ports of entry so we can better identify and monitor high-risk travelers.

I also believe that a critical part of addressing any public health threat is the availability of antivirals, therapeutics and other medical countermeasures. In the case of Ebola, I have been encouraged by the significant progress we have made in the last few months on a vaccine for the virus, as well as therapeutics to treat the disease. I look forward to hearing about the status of these countermeasures and the plan for quickly getting them to people in need.

To help meet the immediate and long term needs of the Ebola epidemic, President Obama recently submitted an emergency funding request of nearly \$6.2 billion dollars. I look forward to hearing more about the request, particularly in light of the changing situation on the ground in Africa.

As we discuss the funding request, I believe we should keep in mind our moral obligation to help "the least of these" in society, and doing so in an effective and fiscally responsible way. In closing, I would just like to acknowledge the work of our witnesses and the countless first responder and health professionals who have stepped up to fight this most recent challenge, and all public health threats. I also want to recognize and thank the non-governmental organizations who are so critical in this world-wide effort to stem the epidemic of Ebola.



**Preparedness and Response to
Public Health Threats: How Ready
Are We?**

Statement of

Nicole Lurie, MD, MSPH

Assistant Secretary For Preparedness and Response



For Release on Delivery
Expected at 10:00 a.m.
Wednesday, November 19, 2014

Good morning Chairman Carper, Ranking Member Coburn, and other distinguished Members of the Committee. I am Dr. Nicole Lurie and I serve as the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services (HHS).

I appreciate the opportunity to talk to you today about the actions ASPR has taken to lead the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters by supporting our communities' ability to withstand adversity, strengthening our health and response systems, and enhancing national health security. ASPR works within HHS and with its Federal, state, tribal, and local partners to advance the public health preparedness of our Nation, by helping to build communities that are more resilient when faced with events that have an adverse effect on the public's health, whether they are naturally occurring disasters, infectious disease outbreaks, or acts of terrorism. ASPR has led the public health response and recovery from natural disasters, such as Hurricane Sandy, the devastating earthquake in Haiti, and the Deepwater Horizon oil spill. We have responded to disease outbreaks including the H1N1 pandemic influenza and the current Ebola outbreak. In addition, ASPR provides public health and medical response capabilities for National Special Security Events, including Presidential inaugurations, the State of the Union Address, and other national events requiring high security. Over the past six years, we have improved our preparedness network with new and stronger partnerships with state, tribal, and local governments, health care systems and workers, industry, international entities, and many more. Across our mission space, I have placed a priority on working in partnership with industry and the private sector; building resilient communities; addressing the needs of the at-risk community; and instilling an enterprise

approach among our Federal partners. Collectively, we are moving aggressively forward to prepare for any contingency, ranging from natural to manmade threats.

ASPR has been uniquely successful in advancing the nation's preparedness through its coordination and collaboration with a broad array of partners. These day-to-day activities, and the infrastructure we have put in place, are key to responding to Ebola. In my testimony, I would like to highlight three areas of ASPR's work: the Biomedical Advance Research and Development Authority (BARDA), the Hospital Preparedness Program (HPP), and our emergency operations function. I will also review how ASPR's authorities provided through the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) and reauthorized by the Pandemic All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) have been critical to our response efforts. BARDA, a core component of ASPR, is dedicated to building our domestic capability to develop effective medical countermeasures (MCM).

In 2010, HHS established a plan to modernize the medical countermeasure enterprise with the release of the Public Health Emergency Medical Countermeasure Review. Key to the success of this effort was the establishment of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which oversees the entire MCM lifecycle to ensure that Federal Departments and Agencies are working well together to ensure the coordination and decision-making at all stages of the MCM research and development pathway, from identification of requirements for particular types and quantities of drugs, through product development, and ultimately to distribution, stockpiling, and use. ASPR leads the PHEMCE, working in close partnership with other HHS agencies – including the National Institutes of Health (NIH), the

Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) – and our interagency partners, the Departments of Defense (DoD), Homeland Security (DHS), Veterans Affairs, and Agriculture. This well-functioning, day-to-day system, is serving us well to help develop MCMs for public health threats, including Ebola, and to ensure that our health care system is prepared, and to make decisions with the best available science. In fact, not long after the outbreak began last spring, I convened a meeting of the PHEMCE partners to review whether there might be candidate products in the pipeline whose development could be accelerated. This led us to prioritize the development and testing of both vaccine and therapeutics candidates for Ebola. ASPR uses modeling projections to enhance preparedness and response capabilities for a broad range of threats. Its support for and coordination of mathematical and computational modeling studies across the Government and academia help to assess the current and future progression of the Ebola outbreak and assist in response planning. CDC, NIH, DOD, DHS, National Laboratories, international health partners including the U.S. Agency for International Development (USAID) and the World Health Organization (WHO), and academic organizations are all working together to ensure that biosurveillance and other data sources are being used to coordinate response decisions and to base them on the best available data and science.

Recognizing that substantial resources are essential to advance the development of new and improved MCMs, the Congress has provided critical authorities and has appropriated billions of dollars for the development and procurement of MCMS for use against chemical, biological, radiological, and nuclear (CBRN) threats. These investments, and the collective efforts of BARDA, NIH, FDA, CDC, and our private industry partners, have resulted in products that

protect the American public, and will ensure that we have the MCMs to protect and ensure the national health security of the United States in emergencies. BARDA has procured 12 products since the inception of Project BioShield a decade ago and has built a national stockpile of pandemic influenza vaccines. The FDA has approved seven products supported by BARDA, including antitoxin treatments for botulinum toxin and anthrax, which have moved through all phases of the medical countermeasure pipeline, from discovery to procurement.

These investments have also strengthened our MCM enterprise to respond to CBRN threats in the future. We have gone from having very few products in the MCM pipeline to funding over 80 candidate products. If products in this group are successfully transitioned from development to procurement contracts, we anticipate having the following new MCMs available in the Strategic National Stockpile over the next five years: (1) an entirely new class of antibiotics; (2) anthrax vaccine and antitoxins; (3) smallpox vaccine and antivirals; (4) radiological and nuclear countermeasures, including candidates to address the hematopoietic, pulmonary, cutaneous, and gastrointestinal effects of acute radiation syndrome; (5) pandemic influenza MCMs; and (6) the first set of antidotes to chemical threats, as well as diagnostics to speed the identification of patients with conditions specific to this threat.

With each experience, HHS examines lessons learned and opportunities for improvement. Following the H1N1 epidemic, we identified the need for more flexibility to develop and produce innovative, safe and effective MCMs. In 2012, HHS established the Centers for Innovation in Advanced Development and Manufacturing (CIADM), public-private partnerships that provide a significant domestic infrastructure in the United States to produce MCMs to

protect Americans. Last year, as part of its pandemic preparedness efforts, BARDA established the Fill Finish Manufacturing Network, which is now being used to formulate and fill multiple Ebola antibody and vaccine candidates into vials for potential clinical efficacy studies in West Africa. Last year, in response to the H7N9 influenza outbreaks in China, ASPR mobilized these partnerships to design, develop, manufacture, clinically evaluate, and stockpile several vaccine candidates in record time.

HHS is using this infrastructure right now to develop MCMs against the Ebola virus. The CIADMs are positioned to expand the production of Ebola monoclonal antibodies into tobacco plants and mammalian cells. In addition, the Fill Finish Manufacturing Network will be used to formulate and fill Ebola antibody and vaccine products into vials for studies and other uses. With respect to vaccines, HHS is working to scale-up to commercial scale the manufacturing of promising investigational Ebola vaccine candidates using funds provided by the Congress in the FY 2015 Continuing Resolution.

Moving to issues of response to domestic emergencies, under the National Response Framework, my office is responsible for coordinating the Emergency Support Function #8 response – Public Health and Medical Services – and coordinating Federal assistance to supplement state, local, territorial and tribal resources in response to public health and medical care needs during emergencies. My office manages the National Disaster Medical System (NDMS), and other critical medical and public health resources that can be activated during catastrophic events when requested by states and localities. ASPR supports state, tribal, and local preparedness, response and recovery efforts through coordination of the Medical Reserve Corps (MRC), the Emergency

System for Advance Registration of Volunteer Health Professionals and the Hospital Preparedness Program (HPP). HPP defines the capabilities required for effective health care system response, and focuses on strengthening the day-to-day activities required to effectively respond to emergencies.

Since 2002, as a result of funding from HPP, we have made great strides in the ability of the predominantly private-sector health care system to provide medical care during an emergency surge of a large number of patients. In order to prepare the U.S. health care system to respond to events in a coordinated and collaborative manner, rather than facility-by-facility, ASPR provides resources to 62 state, territorial, and local awardees through the HPP. HPP investments have fostered an increased level of preparedness throughout communities and contributed to a decrease in state, tribal, and local governments' reliance on Federal aid following disasters. In the last several years, HPP awardees have transitioned from providing most of their HPP funding to individual hospitals within their jurisdictions to supporting coalitions of health care facilities. This transition to supporting and building regional health care coalitions has provided dramatic examples of a community's ability to recover after a disaster. For example, in the aftermath of tornados in Joplin, Missouri; Tuscaloosa, Alabama; and Moore, Oklahoma, HPP members immediately responded, administered care to the injured, and evacuated patients to other regional facilities that were part of the health care coalitions in those jurisdictions.

The cornerstone of this regional health system preparedness is the Health Care Coalition (HCC) – a formal collaborative network of hospitals, health care organizations, public health providers, emergency management, emergency medical services, and other public and private sector health

care partners within a defined region. By fostering preparedness and collaboration at the regional level to strengthen the overall health care system, HCCs allow for the sharing of resources, leveraging of expertise, and increased capacity to respond during an emergency. Through the efforts of HPP and its state, territorial, and local awardees, there are over 16,000 members in HPP supported coalitions throughout the Nation to include 4,778 hospitals. As a result, hospitals can now communicate with other responders through interoperable communication systems; track bed and resource availability using electronic systems; protect health care workers with proper equipment; train health care workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises.

To prepare for and respond domestically to Ebola, HPP is actively engaged in a number of activities, including: providing key information, guidance, helpful checklist documents and lessons learned to state, tribal, and local public health officials, hospital executives, health care workers, and others across the United States through webinars and national calls; actively recruiting (along with CDC) hospitals willing to provide definitive care to patients with Ebola in the United States; working with personal protective equipment (PPE) manufacturers to identify and coordinate supply distribution; and serving as the clearinghouse for Ebola-related tabletop exercises for hospitals and jurisdictions, as well as hospital infectious disease plans, so facilities and jurisdictions can quickly access them and adapt them for use in their own facilities. Recognizing that state, tribal, and local response needs to be nimble to support their health care systems, the ASPR office informed HPP awardees that funds may be used to prepare for suspected or known Ebola patients, including the development of action plans, purchase of

supplies for health care facilities, and training for all personnel. In emergency circumstances, HPP awardees may request approval to use grant funds for activities outside the originally approved scope of work. Some awardees have already initiated these requests for Ebola.

ASPR supports a coordinated medical response capability to assist states, tribes, and localities in responding to disasters. NDMS and MRC bring health care and other personnel together to support preparedness and response missions. The NDMS is a unique program which deploys federalized responders to support communities with medical, veterinary, and mass fatality assistance after a disaster or public health emergency. Most of the 5,000 NDMS employees are active locally in a civilian job, but support the Federal Government through service as intermittent employees on one of the many NDMS teams located across the Nation. By comparison, MRC is a volunteer program, with over 1,000 MRC units and 200,000 volunteers, and is primarily managed and organized at the local level to support public health and response missions through local health department initiatives. Both programs are poised to backfill staff caring for Ebola patients in the Nation's hospitals, in the unlikely event that such support would be needed.

ASPR is deploying medical response capabilities where they are needed most to keep America safe. HHS has developed focused teams of U.S. Public Health Service (USPHS) Commissioned Corps officers who have deployed and will continue to deploy to West Africa to provide care for health care providers who require Ebola treatment. ASPR is supporting this mission through the development of recommended safety guidelines and by providing operational, logistical, personnel accountability, and pre-deployment training of USPHS officers at DHS's Federal

Emergency Management Agency's Center for Domestic Preparedness in Anniston, Alabama. USPHS officers are trained on PPE, medical screening, and safety and clinical treatment recommendations. MRC is also supporting domestic readiness; some jurisdictions are using local MRC units to support call centers, assist health departments with epidemiology and surveillance activities, disseminate guidance and information to their community partners (*e.g.*, health care coalitions, emergency management, health care workers, etc.), conduct volunteer training and community educational activities, and provide partner level updates to enhance situational awareness. ASPR is leading the effort to ensure that deployed personnel have access to and receive training in the use of PPE. This training is critical to domestic preparedness and readiness. Training personnel on the use of current PPE is an absolute requirement to ensure the safety of personnel engaged in the medical care of Ebola patients. Any deployment activities for the purpose of patient screening or care will include the necessary PPE training that meets the CDC standard. Additionally, ASPR is working with other Federal Departments and Agencies to help coordinate the U.S. Government's response to the high demand for PPE nationwide. It is actively engaged with PPE manufacturers and distributors to assess the availability of products and to develop strategies to address supply chain challenges so that there are no shortages of PPE either domestically or abroad.

Recognizing the global impact of public health emergencies, HHS has strengthened international partnerships that make America safer at home. Whether it is an H1N1 pandemic, a natural disaster, or an Ebola outbreak, public health emergencies know no borders – the health of the American people is inseparable from the health of people around the world. Moreover, the same

global capacity that is needed to combat the spread of Ebola will reduce the deadly impact of future infectious disease outbreaks.

ASPR has forged trusted networks and relationships with key international partners and continues to receive and share information with the WHO and countries around the world about Ebola. In its coordination role for the medical portion of the U.S. response effort, HHS interacts regularly with physicians in developed countries who treat patients with Ebola to facilitate information-sharing and best practices. In addition, ASPR maintains regular communications and coordination with G7 countries, Mexico, and the European Commission on public health measures, development and deployment of MCMs, and support for African countries. These collaborations range from discussing countries' domestic preparedness activities and policies including board protocols, mutual notifications of imported cases, support for medical evacuation and coordination of activities to develop and manufacture medical countermeasures. The USAID Disaster Assistance Response Team incorporates specialists from DoD and HHS (including CDC) and draws upon the resources and innovation of many different departments, agencies, and ministries of health to support Ebola treatment units that help isolate and treat those affected by the disease.

In order to ensure that appropriate Federal resources are brought to bear in our international and domestic fight against Ebola, on November 5, the Administration proposed emergency funding totaling \$6.18 billion, including \$2.43 billion for the Department of Health and Human Services. I want to highlight how this request is central to some of our key response activities. First, \$157 million of the emergency will be critical to supporting Ebola vaccine and therapeutic candidates, clinical trials, and commercial scale manufacturing. Funding through HPP will both

improve our ongoing Ebola preparedness, and also strengthen our nation's general preparedness by providing for at least one infectious disease containment center in every state, and supporting the PPE purchases, training, renovation, construction, and retrofitting facilities to create isolation units and separate laboratories. Because every hospital needs to be able to recognize and isolate a potential Ebola patient, additional money would be provided through health care coalitions to efficiently support the purchase of PPE and training for the broader network of hospitals, emergency medical services providers, and ambulatory care facilities that need to be ready to recognize, isolate, and care for a suspected Ebola patient until they can be transferred to a treatment facility.

PAHPA authorities have been critical in responding to Ebola, whether related to BARDA or HPP. In addition, flexibilities provided by PAHPRA to FDA's existing Emergency Use Authorization authority have helped to facilitate the issuance of critical Emergency Use Authorizations for multiple uncleared Ebola diagnostic tests that are in use now in the United States and West Africa. PAHPA also established the office of the ASPR, which is playing a vital role in this response. As part of the HHS leadership team responding to Ebola, I lead coordination activities supporting the HHS policy team including international engagement; establishing technical assistance for state, tribal, and local health departments and private-sector health care providers; the advanced development of vaccines and therapeutic MCM for Ebola, as well as testing and manufacturing; and preparation of Federal personnel for deployments to assist the U.S. response. I engage regularly and on an ongoing basis with the Secretary, other key HHS leadership, and Departments across the Federal Government, including the Ebola Response Coordinator, Mr. Ron Klain.

Together, we are mounting an aggressive whole-of-government response strategy to the Ebola crisis. We are focusing on controlling the epidemic; mitigating the secondary impact, including economic, social, and political tensions; coordinating the U.S. and broader global response; and reinforcing global health security infrastructure in the region and beyond.

These measures demonstrate our country's commitment to building the public health resilience needed to better prepare for disasters before they occur. Moreover, these investments require our continuing attention and commitment over the long-term and should not depend solely on the occurrence of a public health emergency. Building resilience makes us more secure from a range of public health emergencies – from an H1N1 pandemic, Ebola or other emerging infectious disease outbreak, to CBRN threats, and natural disasters.

Mr. Chairman and Members of the Committee, my team, our HHS colleagues, and our interagency partners have worked long hours to prepare our Nation for public health threats and ASPR is focusing all efforts on protecting America's health security. The best way to protect America from Ebola is to support the response to the epidemic in West Africa and to get infection and spread under control as quickly as possible. We are making efficient use of investments and leveraging the infrastructure and tools we have developed, and we are far better off than we were ten years ago following the anthrax attacks and the Hurricane Katrina response.

With that in mind, our continued success in containing the current Ebola outbreak and being prepared here at home depends on receiving the emergency resources recently requested by the President. These resources are vital for ASPR to continue supporting the advanced development

and manufacturing of promising therapeutics and vaccines. In addition, the request provides funding for health care coalitions around the Nation to purchase PPE and train staff on how to use it properly and safely and for states to establish Infectious Disease Treatment Facilities. I urge you to pass the President's request.

HHS stands ready to provide health and medical support to help our states and communities to respond and recover from public health emergencies. I thank you again for this opportunity to address these issues and welcome your questions.

Senate Committee on Homeland Security and Governmental Affairs

Preparedness and Response to Public Health Threats: How Ready Are We?

Statement of Tom Frieden, MD, MPH, Director, Centers for Disease Control and Prevention

Thank you, Mr. Chairman and Members of the Committee. I am Dr. Tom Frieden, Director of the Centers for Disease Control and Prevention (CDC). I appreciate the opportunity to appear before you to discuss public health preparedness in the United States. I first will discuss CDC's support of public health preparedness and response on the front lines and outline CDC programs and infrastructure critical to public health preparedness. The current Ebola epidemic in West Africa – and the consequences here in the United States – reinforce the importance of a robust preparedness program globally and in the United States. Ebola illustrates how CDC protects the homeland here at home by addressing disease outbreaks at their source, working closely with global, state, and local public health partners to prepare for and respond to health threats.

Public Health Preparedness and Response

CDC advances the health security of the Nation by helping communities prepare for, respond to, and recover from all hazards, including: chemical, biological, radiological, and nuclear threats; natural disasters; outbreaks; and epidemics. Whether the hazard is naturally occurring (Ebola and Middle East Respiratory Syndrome), accidental (the West Virginia chemical spill) or intentional (the Boston Marathon bombings, anthrax attacks), effective public health emergency response depends on building, maintaining and constantly improving on the capability of state and local health departments to prepare for and respond to public health emergencies. The all-hazards approach to public health preparedness and response fosters development of emergency-ready public health departments that are flexible and adaptable to the needs of a particular event.

There is one essential concept that we believe is key to keeping us safe. Emergency systems are most effective when they rely on everyday systems that are robust and can be scaled up in a crisis. Systems that are only intended for use during emergencies are less likely to be protective. For example, during the H1N1 flu epidemic, infrastructure that was available for the Vaccines For Children program was able to provide more than 300,000 vaccine deliveries without a problem because it drew on an existing, robust, and scalable program.

CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement program provides technical assistance and resources that support state, local, and territorial public health departments in demonstrating measurable and sustainable progress toward achieving public health preparedness capabilities. CDC's *Public Health Preparedness Capabilities: National Standards for State and Local Planning* assists state and local planners in identifying gaps in preparedness, determining specific jurisdictional priorities, and developing plans for building and sustaining public health capabilities. PHEP awardees use their cooperative agreement funding to build and sustain these 15 public health preparedness capabilities for all hazards. Awardees conduct jurisdictional threat and risk assessments and direct Federal preparedness funds to priority areas. The capabilities are divided into two tiers, with the first tier consisting of capabilities CDC considers central to building a strong basic foundation for public health preparedness. Tier 1 capabilities include a number that are essential to the domestic Ebola response, such as public health surveillance and epidemiological investigation, information sharing, public health laboratory testing, medical materiel management and distribution, and emergency operations coordination. Awardees are required to conduct annual preparedness exercises and submit after-action reports and improvement plans, and to demonstrate capabilities and identify areas that need to be strengthened.

PHEP funding in FY 2014 totaled more than \$600 million, awarded to 62 awardees – 50 states, four localities, and eight territories – according to a base-plus population formula, which ensures at least a certain minimum amount to each awardee. In addition, CDC personnel help PHEP awardees improve their performance by sharing knowledge, useful practices and lessons learned – along with the tools and resources needed to identify and address preparedness capability gaps. CDC guidance encourages states to allocate a portion of their PHEP awards to their local jurisdictions to assure they have adequate funding to prepare for public health threats.

Preparing for and responding to Ebola falls within the scope of the PHEP award and, when needed during an emergency situation such as the current Ebola response, PHEP funds can be used to enhance surge capacity. Any state needing immediate assistance can redirect a portion of PHEP funds to Ebola preparedness activities without prior approval (up to 30 percent of their award or up to \$1 million, whichever is less). Funds in greater amounts can be redirected with prior approval. The greater the flexibility of emergency funds, the more effectively they can be deployed in the event of an emergency.

The PHEP program has contributed significantly to the development of a state and local all-hazards public health emergency response platform. Before the program was formed in 2002, state and local health departments lacked critical systems needed not only to mount an emergency response, but also to conduct effective, routine public health activities. These systems include laboratory networks, electronic disease surveillance systems, risk communication networks and emergency operation centers. According to states, support from CDC's PHEP program contributed significantly to emergency response staffing in health departments; building complex public health systems; developing all-hazards response plans; and purchasing medical countermeasures, warehouse space to store them, personal

protective equipment for responders, communications equipment, information technology equipment, and maintenance support. Trends in public health preparedness capabilities of PHEP awardees show that CDC investments have made a measurable impact. Over the past three years, PHEP awardees have improved capacity in nearly all of the Tier 1 public health preparedness capabilities.

CDC is working with our colleagues in other components of the Department of Health and Human Services to enhance coordination between the Nation's public health preparedness programs and hospitals. The Hospital Preparedness Program provides funding to prepare health care systems for disasters and improves response and recovery efforts to reduce injury and loss of life during public health emergencies. For the past few years, we have worked to more closely align these two programs to improve efficiency and effectiveness of the Federal Government and of the awardees. Coordination between the Nation's public health and healthcare preparedness systems strengthens preparedness of both systems.

CDC supports states and localities through other direct and indirect methods. CDC provides extensive training and guidance to public health agencies and medical practitioners, and is on constant standby to deploy CDC experts – including “disease detectives” – to provide surge capacity and technical support to state and local officials when needed. The Epidemiology and Laboratory Capacity (ELC) grants provide state, local, and territorial health department grantees with the financial and technical resources to strengthen essential epidemiologic, laboratory, and health information systems to detect, prevent, and control infectious diseases. This enhanced capacity leads to better (e.g., quicker, more targeted) disease outbreak detection and response, and improved development, implementation and evaluation of public health interventions that protect the public health and safety of the American people. Additionally, working closely with the Department of Homeland Security (DHS), CDC supports the protection of the

Nation through quarantine stations at major ports of entry to prevent the introduction, transmission, and interstate spread of communicable diseases into the United States.

CDC also provides support in the form of coordination, scientific expertise and guidance specific to the threat. This support is provided through a variety of structures, programs and mechanisms, including:

- CDC's Emergency Operations Center (EOC): The EOC serves as the command center for monitoring and coordinating CDC's response to public health emergencies. Since the Ebola activation, over 1000 CDC staff and contractors from across the Agency have provided expertise in the response, through the coordinated structure of the EOC.

- The Health Alert Network (HAN): The HAN is CDC's primary method of sharing information about urgent public health incidents with public information officers; Federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories. HAN notices are sent to over 80,000 recipients, and it has the ability to reach over 1 million recipients when state and local jurisdictions cascade the information to their partners. The HAN has been used to provide guidance and response updates during the Ebola outbreak, see:

<http://emergency.cdc.gov/han/>.

- CDC's Strategic National Stockpile (SNS): The Stockpile manages and delivers life-saving medical countermeasures during a public health emergency. It is the largest Federally-owned repository of pharmaceuticals, critical medical supplies, and medical equipment available for rapid delivery in health security threat situations. CDC's SNS is working to provide personal protective equipment as needed in case a hospital receives an Ebola patient.

- The Laboratory Response Network (LRN): CDC is the lead Federal Agency for the LRN, providing subject matter expertise, policy guidance, financial resources, standardized testing protocols and methods, and specially developed tests and quality controlled reagents to LRN member laboratories. The LRN is a coordinated network of public health, Federal, military, food testing, veterinary, environmental and international laboratories that can respond to biological, chemical, and other public health emergencies, including emerging infectious diseases like Ebola. Because of the infrastructure in place, CDC was able to quickly roll out Ebola testing methodologies and supplies to LRN laboratories.
- The joint CDC/USDA Select Agent Program: This program protects the Nation from accidental or intentional release of dangerous pathogens, through regulation of entities in the United States that handle select agents, and restrictions on their import into the United States. Since Ebola is designated as a select agent, laboratories and other entities that work with Ebola are subject to the Select Agent requirements, and the import of Ebola samples is subject to the Import Permit Program.

Ebola Preparedness - Protecting the United States

From the time the Ebola situation in West Africa escalated from an outbreak to an epidemic, we have anticipated that a traveler could arrive in the United States with the disease. We prepared for this possibility by working closely with our state and local partners, and with clinicians and health care facilities so that any imported case could be quickly contained. The occurrences in Dallas and New York underscore the need to carefully follow the protocols that are developed, to work closely across levels of government, and to continue our urgent effort to address the epidemic in West Africa. We will only get to zero risk here when we end the outbreak at its source.

The first imported case of Ebola in the United States, diagnosed on September 30 in Dallas in a traveler from Liberia, required CDC and the Nation's public health system to rapidly respond with control measures. As far as we have seen in Africa and the United States, Ebola only spreads from people who are ill or who have died, or from their body fluids. The two primary means by which Ebola spreads are unsafe care (prior to and after health care facility admission) and unsafe burials. Cultural norms that contribute to the spread of the disease in Africa – such as burial customs – are not a factor in the United States. Ebola can be stopped with appropriate triage, rapid diagnosis, and meticulous infection-control practices in American hospitals. CDC works to continue to apply the best science and lessons we are learning to inform our guidance and actions.

We have been constantly monitoring and improving our response in the United States, and will continue to do so. Our layered approach to protecting the United States begins with exit screening in the airports of the affected countries. This begins with intensive airport exit screening in the affected nations, including temperature scanning for outbound passengers, which CDC staff worked to implement. CDC and U.S. Customs and Border Protection (CBP) within DHS have implemented a rigorous program of entry screening for travelers. On October 11, entry screening began for passengers arriving at JFK airport, and at four additional airports on October 16. The four additional U.S. airports are Newark, Washington-Dulles, Chicago-O'Hare, and Atlanta-Hartsfield International. On October 21, 2014, DHS announced that all travelers coming to the United States by air from Ebola affected countries will be required to enter the United States at one of the five airports where enhanced screening measures are implemented. Also, CDC and DHS announced that, effective Monday, November 17th, entry screening would begin for travelers from Mali due to the evolving nature of outbreaks there. Screening includes an assessment for risk exposure and early signs of infection, and triage of passengers with clinical

symptoms. With this assessment, appropriate public health actions can be determined and implemented, including movement restrictions when warranted.

On October 27, CDC updated its interim guidance for monitoring people potentially exposed to Ebola and for evaluating their intended travel, including the application of movement restrictions when indicated, and, consistent with this guidance, partnered with all 50 states to begin a program of active monitoring for 21 days for any individual arriving from West Africa. This monitoring program begins at the airport – where CBP and CDC obtain detailed contact information and provide passengers with detailed information on monitoring along with thermometers, health information, a log for temperature and symptoms, contact information for state health departments, and a wallet card to refer to in case of illness. Travelers with fever (all of whom have tested negative for Ebola) have used this information to contact the 24/7 hotlines every state has established and have been transported safely, and cared for safely, while an Ebola diagnosis was being ruled out. State and local authorities are provided contact information and a detailed risk assessment for passengers, allowing them to take steps to appropriately actively monitor those with potential Ebola risks.

CDC is committed to providing immediate support to the state and local health care and public health officials. Within hours of confirming the cases of Ebola, CDC had a team of people on the ground in Dallas; in New York City, CDC had a team already on the ground assessing the hospital, and sent additional staff even before the patient's diagnosis was confirmed, in order to assist the capable teams from state health departments, local authorities, and hospital staff. We have worked side-by-side with state and local officials to do all we can to prevent transmission to others. CDC supported the state and local officials to monitor people who may have been exposed to Ebola in Texas, New York City, and Ohio. These individuals were tracked for 21 days for any signs of symptoms, and were quickly isolated

if symptoms developed. And, as of November 7, all contacts in both Texas and Ohio are out of the 21-day period of monitoring for onset of illness.

We were deeply concerned to have learned of transmission of the Ebola virus from the first, or “index” patient in the United States, to two health care workers in Dallas. While we may never know exactly how these transmissions occurred, they demonstrated the need to strengthen the procedures for infection-control protocols which allowed for exposure to the virus. The care of patients infected with the Ebola virus can be done safely, but it requires meticulous and scrupulous attention to infection control. Based on experience in Dallas, as well as at NIH and Emory University, we updated our guidance for the use of personal protective equipment in the assessment and treatment of Ebola in the United States. We recommended that facilities keep the number of workers who care for anyone with suspected Ebola to an absolute minimum. We recommended that the procedures that are undertaken to support the care of an infected individual be limited solely to essential procedures. We are recommending there be a full time individual who is responsible only for the oversight, supervision, and monitoring of effective infection control while an Ebola patient is cared for. We will continue to evaluate and improve infection control and preparedness as we learn more in the United States and elsewhere.

We have taken additional steps to increase the preparedness of hospitals. CDC is leading teams of public health infection control experts to assess the readiness of hospitals. This endeavor prioritized geographic locations around the hospitals where increased screening is occurring at airports and continues in a strategic manner. By November 17th, these teams had visited 41 hospitals in 12 states and the District of Columbia. Every hospital should have the ability to recognize the signs of a possible Ebola case and isolate that individual. Further, the Administration’s emergency funding request includes resources for the Department of Health and Human Services to strengthen infection control to prevent spread of Ebola and other infectious diseases in the United States. CDC is also increasing

training for health care providers, including web based seminars on donning and doffing of PPE, and in-person events, such as one held at the Jacob Javits Center in New York, which was broadcast live and attended in-person by more than 5,000 people.

Additionally, CDC continues to build capacity in our states through the Laboratory Response Network (LRN). In addition to CDC's own world class laboratories, 31 LRN labs now have capacity to test for Ebola, increasing access to timely diagnosis – and surge capacity in case it is needed. CDC is also extensively consulted to support evaluation and, when indicated, test people who may have Ebola. With heightened alert, we are receiving hundreds of inquiries for help ruling out Ebola in travelers– a sign of how seriously airlines, border agents, public health departments, and health care system workers are taking this situation.

On November 5, the Administration proposed an emergency funding request, including \$1.83 billion for CDC to enhance our efforts to address the situation. This request includes \$621 million designed to fortify domestic public health systems. This request allows us to fully implement the urgent strategies outlined above, and includes support for the following activities:

- Improve Ebola readiness within State and local public health departments and laboratories.
- Support state health departments to improve and accelerate infection control implementation throughout U.S. hospitals.
- Procure personal protective equipment (PPE) for the Strategic National Stockpile.
- Increase support for monitoring of travelers at U.S. airports and in states and communities.

Protecting the United States Through Stronger Global Health Security

Our top priority at CDC is to protect Americans from public health threats. We work 24/7 to do that and I have outlined the extensive work CDC does domestically to prepare for public health emergencies.

However, from our recent experience with Ebola and our historical experience with SARS and other threats, we cannot keep Americans safe without addressing threats at their source. We know, for example, that eliminating America's risk from Ebola requires us to bring the epidemic under control in West Africa. The current epidemic in Guinea, Liberia, and Sierra Leone is the first time an outbreak has been recognized in West Africa, the first-ever Ebola epidemic, and the biggest and most complex Ebola challenge the world has ever faced. We have seen cases imported into Nigeria, Senegal, and Mali from the initially-affected areas and we have also seen in Nigeria and Senegal that proven practices, such as contact tracing, monitoring, and isolation and care, can prevent a small number of cases from growing into a larger outbreak. We are working intensively in Mali to apply these control measures.

The Administration's proposed emergency funding request includes \$603 million for CDC efforts to control the epidemic in the hardest hit countries in Africa by funding activities including: infection control, contact tracing and laboratory surveillance and training; emergency operation centers and preparedness; and education and outreach.

To address broader global health security, the Emergency Funding Request before the Congress will allow us to help strengthen capacity for essential disease control in at-risk countries by strengthening lab networks that can rapidly diagnose Ebola and other threats, supporting emergency operations centers that can swing into action at a moment's notice, and training 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 that countries are prepared to deal with the consequences of outbreaks in other countries. The Administration's proposed emergency funding request includes \$606 million for CDC to strengthen global health security, reducing risks to Americans by addressing unanticipated threats and enabling the world to detect them early, respond swiftly before they become

epidemics, and prevent outbreaks wherever possible. 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. We cannot truly be prepared in the United States until there is a baseline level of preparedness internationally.

Thank you again for the opportunity to appear before you today to discuss CDC's domestic preparedness activities. I appreciate your continued interest in this issue and I look forward to answering your questions.

Testimony
of
R. Gil Kerlikowske
Commissioner
U.S. Customs and Border Protection
U.S. Department of Homeland Security
Before the
U.S. Senate
Committee on Homeland Security and Governmental Affairs
For a Hearing On
“Preparedness and Response to Public Health Threats: How Ready Are We?”
November 19, 2014

Chairman Carper, Ranking Member Coburn, and distinguished members of the Committee I appreciate the opportunity to discuss U.S. Customs and Border Protection’s (CBP) role in the Federal government’s Ebola response.

The 2014 Ebola epidemic in West Africa is the largest in history – mainly focused on Liberia, Sierra Leone, and Guinea. In the midst of this crisis in West Africa, it is important to remember that the Centers for Disease Control and Prevention (CDC) has stated that the risk of a widespread Ebola outbreak in the United States is very low. CBP, as part of the Department of Homeland Security’s (DHS) overall strategy, is engaged on a daily basis with DHS interagency partners to prepare for and respond to Ebola and other potential threats to public health.

As you know, DHS is responsible for securing our nation’s borders and assisting the Department of Health and Human Services (HHS) in safeguarding the American public from communicable diseases that threaten to traverse our borders. In doing so, DHS is committed to ensuring that our responses to the Ebola epidemic are conducted consistent with established civil rights and civil liberties protections. DHS’s Office of Health Affairs (OHA) is at the intersection of homeland security and public health, better known as health security. OHA provides medical and health expertise to DHS components and senior leadership, and is helping to coordinate with components and provide them with medical advice regarding the Department’s efforts in preparing for and responding to Ebola. In today’s remarks, I will provide an overview of the Department’s efforts to protect the American people from Ebola, and CBP’s specific efforts within ports of entry to identify and respond to travelers who may pose a threat to public health.

As the Nation’s unified border security agency, CBP is responsible for securing our Nation’s borders while facilitating the flow of legitimate international travel and trade that is so vital to

our Nation's economy. Within this broad responsibility, CBP's priority mission remains to prevent terrorists and terrorist weapons from entering the United States. CBP also plays an important role in limiting the introduction, transmission, and spread of serious communicable diseases from foreign countries.

Targeting, Screening and Observation Protocols

Although we have recently seen a very small number of Ebola virus cases in the United States, the CDC believes that the U.S. clinical and public health systems will work effectively to prevent the spread of the Ebola virus, and CDC has provided support to those systems to prevent the further introduction, transmission and spread of communicable diseases into the United States. DHS has executed a number of measures to minimize the risk of those sick with Ebola entering the United States, and we take a layered approach to ensure there are varying points at which an ill individual could be identified. To this end, DHS is also focused on protecting the air traveling public and taking steps to ensure that travelers with communicable diseases like Ebola are identified, isolated, and quickly and safely referred to medical personnel.

CBP developed targeting rules that analyze advance passenger travel to identify travelers whose travel originated in or transited through Ebola-affected countries. Additionally, CBP collaborates with our international partners, to identify individuals traveling through key international gateways whose travel matches predetermined risk factors. This international engagement provides valuable opportunities and mutual benefits to expand our knowledge of individuals whose travel originated in, or transited through, an Ebola-affected country.

It is important to note that the CDC has worked closely with affected countries, and CBP has provided support and assistance, to ensure that all outbound travelers from the areas affected by the West Africa Ebola outbreak are screened for Ebola symptoms before departure from those countries. CDC provides "Do Not Board" recommendations to CBP and the Transportation Security Administration (TSA) regarding individuals who may be infected with a highly contagious disease, present a threat to public health, and should be prevented from traveling to the United States via commercial aircraft. TSA is performing vetting of all airline passengers coming to, departing from or flying within the U.S. to identify matches to the "Do Not Board" list and flag matched individuals' records in the Secure Flight system to prevent the issuance of a boarding pass. TSA is also supporting CDC requirements to identify all passenger reservations on flights where it has been determined that one or more passengers present an Ebola risk, such as when passengers have traveled from the affected African areas and have exhibited Ebola symptoms.

CBP and the CDC have closely coordinated to develop policies, procedures, and protocols to identify travelers to the United States who may have a communicable disease, responding in a manner that minimizes risk to the public. These pre-existing procedures – applied in the land, sea, and air environments – have been utilized collaboratively by both agencies on a number of occasions with positive results.

As a standard part of every inspection, CBP officers observe all passengers as they arrive in the United States for overt signs of illness, and question travelers, as appropriate, at all U.S. ports of entry. Officers look for overt signs of illness and can obtain additional information from the travelers during the inspection interview. If a traveler is identified with overt signs of a communicable disease of public health significance, the traveler is isolated from the traveling public and referred to CDC's Border Health Public Health Officers or state public health authorities for medical evaluation.

On October 21, DHS announced travel restrictions in the form of additional screening and protective measures at our ports of entry for travelers from Ebola-affected countries in West Africa. As of October 22, all passengers arriving in the United States who are identified as having recently traveled to, from, or through Liberia, Sierra Leone, or Guinea are required to fly into one of five airports – New York John F. Kennedy; Washington Dulles; Newark; Chicago O'Hare; and Atlanta International Airport. On November 17, Mali was included in the list of countries for which recent travel is being identified. CBP utilizes advance passenger information to identify those individuals who may have traveled to, from, or through an Ebola-affected country and are attempting to travel to the United States through a non-designated airport. In the event that such an individual is identified, CBP works closely with the airlines to route the traveler to one of the five designated airports with as little travel disruption as possible.

At these five airports, all travelers from the affected countries undergo enhanced screening measures consisting of targeted questions and a temperature check, through the use of non-contact thermal thermometers, seeking to determine whether the passengers are experiencing symptoms or may have been exposed to Ebola. Detailed contact information is also collected in the event the CDC needs to contact them in the future. If there is reason to believe a passenger has been exposed to Ebola, either through the questionnaire, temperature check, or overt symptoms, CBP refers the passenger to CDC for further evaluation. The CDC has surged staff to these airports to support this mission requirement.

In addition to these measures, CBP officers are asking all passengers traveling on a passport from Liberia, Sierra Leone, Guinea, and Mali, regardless of where they traveled from, whether they have been in one of the Ebola-affected countries in the prior 21 days. If the traveler has been in one of these countries in the prior 21 days, he or she will be referred for additional screening and, if necessary, CDC or other medical personnel in the area will be contacted pursuant to existing protocols.

The U.S. Coast Guard is also monitoring vessels known to be inbound from Ebola-affected countries, and is providing information to the Captain of the Port, District, and CDC representatives.

The CDC maintains Federal jurisdiction to determine whether to isolate or quarantine potentially infected arrivals. DHS personnel may be called upon to support the enforcement of the CDC's determinations, and we stand ready to help.

Information Sharing and Training

DHS has prioritized sharing information and raising awareness as important elements in combating the spread of Ebola, and CBP has a unique opportunity to deliver critical information to targeted travelers from the affected countries in ports of entry. Secretary Johnson recently directed CBP to distribute health advisories to all travelers arriving in the U.S. from the Ebola-affected countries. These advisories provide the traveler with information on Ebola, health signs to look for, and information for their doctor should they need to seek medical attention in the future.

CBP and TSA have posted messages from the CDC at select airport locations that provide awareness on how to prevent the spread of infectious disease, typical symptoms of Ebola, and instructions to call a doctor if the traveler becomes ill in the future.

We also share information with our nongovernmental and state and local partners. TSA is engaging with industry partners and domestic and foreign air carriers to provide awareness on the current outbreak, and has issued an Information Circular to air carriers reinforcing the CDC's message on Ebola and providing guidance on identifying potential travelers with Ebola.

OHA, through the National Biosurveillance Integration Center, is continuing to monitor the outbreak to coordinate information in response to the event. These reports on biological events are disseminated to more than 15,000 Federal, State, and local users, many of whom work in the public health sector or support 78 fusion centers across the Nation, helping to ensure that the most up-to-date information is available.

DHS is committed to ensuring that our own employees have up-to-date and accurate information. We have provided our own personnel with background information on the current outbreak, information on the regions of importance; symptoms of the virus and mode of transmission; and operational procedures and precautions for processing travelers showing signs of illness. CBP field personnel will be kept up to date on national, regional and location-specific information on Ebola preparedness and response measures through regular field musters.

All CBP officers and agriculture specialists receive public health training, which teaches personnel to identify symptoms and characteristics of ill travelers. CBP also provides operational training and guidance to frontline personnel on how to respond to travelers with potential illness, including referring individuals who display signs of illness to CDC quarantine officers and assisting CDC with implementation of its isolation and quarantine protocols. CBP officers are trained to employ universal precautions, an infection control approach developed by the CDC, when they encounter individuals with overt symptoms of illness or potentially contaminated items in examinations of baggage and cargo. Universal precautions assume that every direct contact with body fluids is infectious and requires exposed employees to respond accordingly.

DHS and CBP are implementing additional precautions and deploying additional personal protective equipment (PPE) to protect personnel at ports of entry. OHA and CDC have provided guidance to field personnel on the requirements of PPE, including proper procedures for putting on, taking off, and wearing PPE (which is available for employees at these airports along with

instructions for use). CBP has provided guidance to the field on baggage inspection for international travelers from impacted countries, proper procedures for inspection and handling of prohibited meat products, and proper safeguarding and disposal of garbage from all inbound international flights.

Enhanced Ebola screening training, required of all CBP officers and agriculture specialists, includes a web-based video course on the proper use of personal protective equipment differences in PPE requirements when in proximity of symptomatic versus asymptomatic travelers. CBP senior medical advisors, U.S. Public Health Service Federal Occupational Health, and CDC officials are providing onsite training on inbound enhanced screening for Ebola at select ports of entry. TSA also ensures that its employees are adequately trained and, where appropriate, are provided personal protective equipment. CBP is continuously engaged with CDC and other agencies involved in Ebola prevention and stands ready to meet future training needs as they arise. The health and safety of CBP employees is also our priority as we carry out this critical mission.

Conclusion

The Department of Homeland Security has worked closely with its interagency partners to develop a layered approach to identifying ill travelers and protecting the air traveling public. DHS and CBP are always assessing the measures we have in place and continues to look at any additional actions that can be taken to ensure the safety of the American people. I look forward to working with you to address this problem collaboratively. I will continue to closely monitor the Ebola developments, and will evaluate additional measures as needed.

Thank you for your time and interest in this important issue. I look forward to answering your questions.

**Testimony of Nancy Lindborg
Assistant Administrator, Bureau of Democracy, Conflict and Humanitarian Assistance,
U.S. Agency for International Development**

**Senate Committee on Homeland Security and Governmental Affairs
“Preparedness and Response to Public Health Threats: How Ready Are We?”**

November 19, 2014

Thank you, Chairman Carper, Ranking Member Coburn, and Members of the Committee for the opportunity to discuss the U.S. response to the ongoing Ebola epidemic in West Africa and other emerging health security threats.

Today, as you know, the world faces the largest and most protracted Ebola epidemic in history. This devastating virus has infected more than 14,000 people and killed more than 5,000 people across West Africa. Previously Ebola has been contained in small, rural outbreaks, but today's epidemic is a sobering reminder of what happens when the disease encounters weak health, economic, and governance systems, as evidenced by its rapid spread in Liberia, Sierra Leone and Guinea—fragile, conflict affected states.

We have also seen isolated cases in Nigeria, Senegal, Spain and the United States, and a new outbreak now in Mali, reminding us that we live in an increasingly interconnected world. This underscores why we must stop Ebola at its source in West Africa, and build resilient health security systems so that we can prevent, detect, and rapidly respond to future outbreaks before they become epidemics. These efforts are a national security priority for the United States and many other nations in the world.

Before the Ebola outbreak, USAID had implemented programs monitoring, detecting, and controlling animal-borne diseases like Ebola that can spill over into humans. USAID efforts have helped decrease the number of countries affected by outbreaks of H5N1 Avian Influenza from 53 to 10 between 2006 and 2014. Just this year, we helped the Democratic Republic of Congo and Uganda identify and contain outbreaks of Ebola and Marburg hemorrhagic fever. We have seen the importance of investing in preparedness in the front lines of these diseases, yet nations around the world still lack basic capacity to address outbreaks before they become international security threats. This is why the Obama administration launched the Global Health Security Agenda (GHSA) this year.

If we are to beat the diseases of tomorrow, we must double-down on our commitment to tackle Ebola today, learn the lessons of our response, and help the most vulnerable nations on Earth prepare for Ebola and the next threat they will face. Thanks to leadership from President Obama and the United States Congress, the U.S. is leading the international coalition to tackle Ebola.

President Obama has requested \$6.18 billion in emergency funding urgently needed to address this crisis and meet longer-term recovery and prevention needs. It includes \$1.98 billion in urgently needed resources for USAID—out of the \$2.1 billion joint USAID and State request—to rapidly scale up activities to control the outbreak, support recovery in West Africa, and

strengthen capacity to address threats immediately, in support of the Global Health Security Agenda.

This unprecedented epidemic requires an extraordinary global effort, and we have seen the importance of U.S. leadership to galvanize a worldwide response. Sustained support to all three countries, the broader region, and other vulnerable nations is essential to lock in our momentum, defeat this epidemic, and guard against future outbreaks that threaten human life, our national security, and the global economy.

U.S. STRATEGY AND RESPONSE TO EBOLA

When Ebola began jumping borders and migrating to urban centers, the U.S. mounted an aggressive whole-of-government effort governed by four key pillars to stop this crisis: control the epidemic; mitigate second-order impacts, including blunting the economic, social, and political tolls; coordinate the U.S. and broader global response; and fortify the global health security infrastructure.

This is the largest U.S. response to a global health crisis in history. On August 6th, USAID deployed a Disaster Assistance Response Team—or DART—to the region to coordinate the U.S. response. The DART is working with departments and agencies across the U.S. government, including the Department of State, the Centers for Disease Control and Prevention (CDC) and other staff of the Department of Health and Human Services, the U.S. Forest Service, and the Department of Defense. There are currently more than 2,100 U.S. Government and military personnel on the ground in West Africa.

As I witnessed firsthand during my recent trip to Liberia, in a country with few roads and a crippling rainy season, the flow of people, supplies and sanitation is complicated yet crucial for an effective response. The DART, which President Obama aptly described as the “strategic and operational backbone of America’s response,” is coordinating this complex pipeline of resources. USAID is also collaborating closely with partner governments, international organizations, including the UN Mission for Ebola Emergency Response (UNMEER), the World Health Organization (WHO), the World Food Program, and UNICEF, and NGOs, such as International Medical Corps and Global Communities.

Our current efforts are intensely focused on controlling the spread of the disease, and we are making progress, but quite frankly we need resources to get this to the finish line. The President’s request includes \$1.3 billion for this pillar, which has five key components: 1) effective isolation of cases in Ebola treatment units (ETUs) and through community care; 2) burial teams to remove dead bodies safely and quickly to prevent further viral transmission; 3) awareness and behavior change at the individual and community level; 4) improved infection control at general health clinics; and 5) an effective command and control system in each country.

The U.S. government has taken the lead in Liberia, where we are now seeing encouraging progress in highly affected areas. U.S. support in Liberia allowed 8 ETUs to open and more than 65 burial teams to be scaled up across the country. More than 200 tons of personal protective

equipment, infrared thermometers, chlorine, and plastic sheeting have been airlifted for the response in Liberia and the region.

Overall, the average reported cases per week in Liberia have decreased by more than a third in the past month. We believe that the rapid scale-up of burial teams, combined with intensive community outreach across the country, has contributed to this reduction in transmission. However, we are also seeing new cases emerge in rural and harder-to-reach areas, so we are adapting our strategy to be highly mobile and scalable to track the evolution of the virus.

In Sierra Leone, the United Kingdom has surged their response in recent weeks by building on the U.S. model and the lessons learned in Liberia, including focusing on early gains through burial teams and social mobilizations.

In Guinea, which has roughly three times the population of Liberia, we have expanded our Disaster Assistance Response Team to meet increasing needs, especially in Guinea's Forest Region, the epicenter of the outbreak. We are scaling up efforts where we have seen the most returns, including contact tracing, community mobilization, and support for ETUs. These efforts will make a difference in Guinea, as we have seen demonstrated in Liberia.

The President's request is essential to accelerate and expand our efforts as this dynamic crisis continues. The base request for USAID and the Department of State totals \$2.1 billion and includes: \$1.8 billion to control the outbreak, address food insecurity and other secondary impacts, and to support coherent leadership and operations. It also includes \$278 million to provide urgent capacity needed to advance the Global Health Security Agenda, which will help prevent Ebola from spreading and stop emerging threats before they become epidemics that threaten Americans.

SUPPORTING HEALTHCARE WORKERS

The capacity to respond to a crisis of this scale simply would not exist without the heroic work of health care workers who serve on the frontline. In addition to the 5,000 local healthcare workers needed once the regional response is operating at scale in January, we estimate that at least 1,000 international health care workers will be needed each month in West Africa. Recruiting these humanitarian heroes—and removing disincentives for them to volunteer—is critical to winning the battle against Ebola.

In partnership with WHO, Médecins Sans Frontières (MSF), and the Department of Defense, we have established a training site in Liberia, at which DOD is training up to 500 healthcare providers per week, enabling the healthcare workers to provide safe and direct supportive medical care to Ebola patients. This cadre of trained health workers will have the skills and knowledge of infection control standards to contain Ebola today, and ensure preparedness for future outbreaks.

Earlier this month, a 25-bed critical care hospital, constructed by the U.S. military and staffed by a 69-person team from the U.S. Public Health Service Commissioned Corps, opened outside of

Monrovia. The facility is providing high level of care to health care workers—both local and international—who contract the virus while treating Ebola patients.

ADVANCING INNOVATION

Advancements in innovation will make us more responsive to today's battle against Ebola and tomorrow's future challenges. That is why President Obama announced *Fighting Ebola: A Grand Challenge for Development*, a grant competition designed to produce better tools to tackle this disease in a matter of weeks, not years. We are exploring advances in diagnostics that reduce the difficulty of rapidly transporting blood samples over terrible roads, improved designs for personal protective equipment (PPE), and real-time data to better predict spikes and valleys in active cases. The Grand Challenge has already received over 1,250 submissions, over a third of which are focused on improving PPE.

MITIGATING SECONDARY IMPACTS

Beyond its devastating human toll, Ebola has shut down health systems, threatened livelihoods, and rolled back development gains that took years to achieve. Since the outbreak began, the number of births in Liberia attended by a medical professional has fallen by 30%, and maternal mortality is rising fast. The World Bank reports that the losses to Guinea, Liberia, and Sierra Leone could reach \$359 million by the end of this year. To contain Ebola and other public health threats over the long-term, we must invest in resilient health and agricultural systems in West Africa.

USAID is actively working on mitigating the longer-term impact of the crisis. The President's request to Congress includes \$190 million to address urgent food insecurity and avoid the destructive consequences of the epidemic for regional prosperity and stability, which ultimately affects our own national security.

To counter food insecurity, USAID is providing food aid to households and communities cut off from markets, and supporting food assistance for ETUs, community care centers and orphanages. To support health systems in Liberia, USAID is scaling up infection control support to non-Ebola specific health facilities country-wide. We will train health care workers on infection control protocols, and provide supplies, such as PPE, to non-Ebola health facilities in Liberia.

We will also work with countries to restart routine services. With the countries' health systems paralyzed by the sheer volume of Ebola cases, communities face many other health threats. Many die from lack of access to safe delivery, treatment of childhood infections, and other diseases. Our assistance includes giving families access to health information and essential health commodities. To the extent available, we will help develop innovative approaches to providing life-saving services that do not detract from Ebola containment.

The efforts we are scaling up today—from improved hygiene behavior to stronger health care systems—have the potential to significantly improve child and maternal survival throughout the region. They will also strengthen the ability of local health systems to report threats in real-time and stop health emergencies before they become epidemics.

BOLSTERING PREPAREDNESS

The Ebola epidemic brings into stark relief the importance of investing in stronger global health and preparedness systems to prevent, detect, and rapidly respond to emerging health threats. Over the past decade, infectious disease outbreaks have sown fear, cost lives, and been a drain on the global economy. To contain threats like Ebola before they threaten global security, we must invest in shoring up capacity in states with weak health and preparedness systems. USAID is helping to prepare unaffected countries to rapidly detect and control any introduction of Ebola both during and after this epidemic.

Using a combination of regional planning meetings and direct country level technical assistance, USAID is partnering with the CDC to help countries develop and test national Ebola Preparedness and Response Plans. By mid-2015, all 14 neighboring West African countries will have detailed Ebola preparedness plans, at least one laboratory capable of detecting the Ebola virus, and trained personnel at border sites to identify and manage suspect cases. This approach can also be used to prepare countries for other public health threats. Nigeria's successful effort to contain the Ebola outbreak demonstrates the effectiveness of a highly engaged government and a rapid and coordinated local response.

Efforts are already underway to plan for rebuilding these health systems in coordination with the Centers for Disease Control and Prevention and the Department of Defense's Cooperative Biological Engagement Program. We will support rapid assessments in collaboration with other donors, and we will review lessons and also leverage previous capacity provided by the U.S. and other donors before the Ebola epidemic. With country officials and other donors, we will help plan for building back resilient systems that can withstand unexpected disease outbreaks and serve the health needs of the countries' populations.

The Public Health Emergency Framework developed by USAID, in cooperation with WHO and CDC, will also continue to assist countries in Africa to more rapidly identify the cause of public health events so that an effective response could be triggered, and to conduct after-action reviews to identify areas for improvement. Piloted in the Democratic Republic of Congo and Uganda where we were able to quickly identify and contain outbreaks of Ebola and Marburg this year, this Framework will be expanded to other countries between 2015 and 2019.

STRENGTHENING CAPACITY TO PREVENT OUTBREAKS FROM BECOMING EPIDEMICS

Investing in urgent needs now – before they become global epidemics that threaten Americans – is an emergency. Ebola has shown us that. The Global Health Security Agenda (GHSA), launched by the United States with international partners in February 2014, seeks to advance a world safe and secure from infectious disease threats like Ebola and to bring together nations from all over the world to prevent, detect and rapidly respond to outbreaks before they become epidemics that threaten Americans. The funding we are requesting is urgently needed, and includes activities that are necessary to stop the spread of Ebola to travel hubs in priority countries and also to reduce the potential for future outbreaks of infectious diseases that could follow a similarly devastating, costly, and destabilizing trajectory.

USAID is uniquely positioned to establish elements of needed capacity, in coordination with the CDC. This includes a focus on strategies that unite animal health specialists, medical professionals, and environmentalists to effectively monitor and rapidly respond to emerging infectious diseases, especially animal viruses that spill over into human populations, including Ebola, Avian influenza, and the Middle East Respiratory Syndrome (MERS) Coronavirus.

Since 2005, USAID has monitored these viruses in animals, and supported their rapid detection and control. USAID's Pandemic Threats program has identified 900 viruses and helped mitigate risks where these diseases are most likely to spread to humans, such as live animal markets and places where bush meat is hunted and sold. Moreover, surveillance and lab capacity was strengthened in countries around the world where new public health threats are likely to emerge, and USAID responded to more than 20 infectious disease outbreaks in animals and humans.

We have proven that we can do this before and we can do it again with Ebola and other disease threats. A primary focus to date of USAID's pandemic prevention efforts has been the threat posed by H5N1 Avian Influenza. With USAID support, efforts to enhance viral monitoring and contain outbreaks in poultry have resulted in a decrease in the number of countries affected by H5N1 from 53 in 2006 to 10 in 2014. These efforts have proven results, underscoring the need to build upon successful models and expand their application to Ebola and other viruses in West Africa and elsewhere.

Now that Ebola has emerged in West Africa, it is likely to reoccur periodically as the virus is now endemic in certain wild life animals in the region. This is why now, more than ever, we must do more to expand our ability to monitor infectious disease threats like Ebola and build up the ability of vulnerable countries to detect, trace, and control outbreaks before they reach epidemic proportions. Over a decade ago, the Severe Acute Respiratory Syndrome (SARS) cost the global economy an estimated \$40 billion. Some have estimated that SARS cost the U.S. alone approximately \$7 billion. This is in addition to the devastation in lives lost and global economic costs from the anthrax attacks, H1N1, and other disease threats that we are fighting every day on the ground – like MERS – even while we work to stamp out Ebola in West Africa.

The President's request would allow us to expand the Emerging Pandemic Threats program to get ahead of these threats. With this funding, we will urgently enhance viral monitoring, strengthen laboratory capacity; and link human and animal disease reporting systems so that cases can be reported in real-time. This program, which has proven effective in reducing emerging health threats such as H5N1 Avian Influenza, has until now targeted a limited number of hot spots. The President's base request of \$278 million for Global Health Security will expand these efforts into hot spots in Africa and Asia where the risk of a virus emerging is significant and there is a history of emerging threats such as MERS. These efforts will allow us to detect Ebola and other emerging threats in wild life reservoirs before it reaches human populations. We will track the movement of the virus within its wildlife hosts, increase lab capacity to process samples quickly, and monitor human behaviors that increase opportunities for Ebola spillover to mitigate the risks of outbreak.

These efforts will build the capacity of CDC and USAID to prevent, detect and rapidly respond to outbreaks before they become epidemics that threaten the United States. We will prioritize urgently needed investments in vulnerable nations, transport hubs, and states without the capacity to prevent global spread of Ebola or stem the tide of future threats. It is important to maintain the flexibility to make adjustments given the dynamic national and global health security environment.

CONCLUSION

This unprecedented crisis underscores the importance of tackling fragility and extreme poverty. Ebola preys on weak systems, wreaking havoc in communities least prepared to fend off the disease. That is why we must work not only to control the epidemic at its source in West Africa, but to bolster our global health systems. These investments are critical if we are to avoid having future outbreaks that follow a similarly devastating and costly path. This effort is core to USAID's mission to both end extreme poverty and promote resilient, democratic societies that advance our global security and prosperity.

This is a fight we cannot afford to lose, and we must keep our momentum. To beat Ebola and prepare for the future, we must double down our efforts in concert with our global partners. We can beat this disease, but we will need all-in ideas and a commitment to see it through to prevent lives lost and future threats to our national security and the global economy.

Most importantly, we must commend and honor the health care, military, and humanitarian workers who are helping to turn the tide in West Africa. Their sacrifice and commitment to fight against Ebola is helping to save lives in West Africa and keep us safe and healthy at home.

Thank you for your time today and for the vital Congressional support that makes these efforts possible.

Dr. David Lakey
 Commissioner
 Texas Department of State Health Services
 November 17, 2014
 U.S. Senate Committee on Homeland Security and Governmental Affairs
 Preparedness and Response to Public Health Threats: How Ready Are We?

Introduction

On September 30, 2014, the Department of State Health Services (DSHS) Laboratory and Centers for Disease Control and Prevention (CDC) tested a specimen for Ebola virus, and found it positive. Mr. Thomas Duncan was the first Ebola patient to be diagnosed in the country; he passed away on October 8, 2014. Two secondary cases of Ebola occurred in nurses who directly cared for Mr. Duncan, and both nurses are now recovered. From September 30, 2014, to November 7, 2014, Texas public health monitored 177 individuals who had varying risks of exposure to the virus, and additional individuals were monitored due to potential exposure on two airplane flights. No secondary cases resulted from community exposure. The strengths of the public health system allowed Texas to contain the spread of Ebola in Dallas – state, local and federal partners working collaboratively with a single purpose, to protect the health of Texans.

Conclusion of this event now allows a systematic review of response efforts to take place. In Texas, this will occur through an after action review process, which engages input from local, state, and federal responders who were part of the effort, and analyzes each part of the response. The assessment will determine what worked, what can be improved, and how those improvements can be made. The final result will be enhanced preparedness plans for future infectious disease events.

Although this assessment is ongoing, certain themes are emerging that speak to the need for a broader conversation about the nation's public health response capacity for infectious disease. The Ebola outbreak in West Africa continues to pose a risk worldwide. Other diseases with risk of importation to the United States require a stable, robust public health infrastructure: extremely drug resistant Tuberculosis; measles; dengue fever; SARS (severe acute respiratory syndrome); Middle East Respiratory Syndrome (MERS); Lassa fever; and highly pathogenic influenza.

To facilitate a broader assessment of the public health response system in Texas, Governor Rick Perry has created a task force composed of 17 members with infectious disease, crisis management, and other areas of expertise. The purpose of the Task Force on Infectious Disease Preparedness and Response is to assess and enhance the state's capability to respond to outbreak situations. Texas' work in this regard would be complemented by a similar effort on a national scale. As has been abundantly evident in the past months, infectious disease response requires intense coordination and preparedness throughout the national public health system. Cohesive response also requires integration across agencies, health care systems, sector types, and differing organizational missions. A national discussion among experts of varied backgrounds, responsibilities, and levels of government has the potential to better prepare the entire country to quickly and effectively stand up in response to the next infectious disease event.

Infectious Disease Surveillance in Texas

For purposes of public health, the State of Texas is divided into eight health service regions. In areas where a local health department exists, DSHS health service regional offices provide supplemental or supporting public health services. In areas where there is no local health department or local health authority, DSHS health service regional offices act as the local health authority and may provide core public health services.

Local health departments are of varying size, resources, and capacities. While some health departments support a full array of services, others have more limited functions. Approximately 60 health departments in Texas are “full service,” while 80 offer fewer services. DSHS’ role is to fill in, as needed, core public health services not offered at the local level.

For infectious disease, DSHS health service regions ensure that disease surveillance occurs in every Texas county through the continual and systematic collection, analysis, and interpretation of health data. This effort is dependent on disease reporting by providers, which is required by law. Currently, in Texas, over 60 conditions are subject to mandatory reporting, including: foodborne, vector-borne, respiratory, and sexually transmitted diseases. Viral Hemorrhagic Fever, including Ebola, is an immediately-reportable disease in Texas.

In order to allow real-time monitoring of disease surveillance data, the Centers for Disease Control and Prevention (CDC) provides and maintains the National Electronic Disease Surveillance Network (NEDSS) for use by local, regional and state health departments. NEDSS is used by nearly every local health department in the state, and allows DSHS to identify unusual increases or pattern shifts in disease numbers.

In concert with NEDSS, Electronic Laboratory Reporting (ELR) has improved the timeliness and comprehensiveness of diseases reporting. ELR electronically links laboratory test reports to NEDSS, allowing immediate access by DSHS or the local health department with legal jurisdiction.

Infectious Disease Investigation and Response in Texas

Timely disease reporting to the public health system is imperative for quick mobilization of public health investigation and response efforts. Since Texas is a home rule state, epidemiological investigations begin at the local level, unless there is no local health department. While local entities have the statutory responsibility to lead infectious disease investigations, state and CDC guidance is available and widely used.

More complicated or widespread events can increase the state and federal roles. If an outbreak involves multiple jurisdictions, the state role becomes more prominent. If, at any time, an investigation goes beyond local capabilities, the state may take the lead. In turn, if an investigation exceeds state resources, the state may ask the CDC for assistance. Additionally, the CDC leads multi-state investigations. No matter the level of outbreak, the expectation is for all three levels of government to work in cooperation, with varying levels of state and federal

involvement depending on the size and type of infectious disease event, and the resources and expertise of the local entity.

Support provided by the state and CDC can include a number of options, depending on the scope of an investigation and local needs. This support might consist of subject matter expertise and onsite assistance; state or CDC laboratory testing; provision of personal protection equipment; or mobilizing of DSHS Rapid Assessment Teams or CDC Epi-Aids. The state and CDC can also assist with administering questionnaires and interviews to cases and potential contacts, inspecting relevant hospital facilities or restaurants, and helping examine pertinent records.

In cases of large-scale outbreaks, an incident command structure may be activated at the local and state levels. DSHS maintains the State Medical Operations Center (SMOC), which is the medical arm of Texas' emergency operations command and control facility, the State Operations Center (SOC). The SMOC's function is to ease the flow of information among multiple jurisdictions, provide dependable tracking of events, and facilitate requests for resources and supplies from local jurisdictions.

Successful Infectious Disease Response in Texas

The public health response system in Texas, led by local entities and supported by state and federal government, has a long history of successful outbreak responses. Texas has effectively contained events involving disease like Tuberculosis, measles, hepatitis, and salmonella.

While the Ebola response was ongoing in Dallas, DSHS disease investigators were concurrently involved in an infectious disease outbreak of a much wider scale. In concert with the local health authority in El Paso, Texas, DSHS tracked a number of exposures to Tuberculosis (TB) that occurred through a health care worker in the labor and delivery unit of a local hospital. This situation is a prime example of how, under the current system, all levels of government successfully work together to respond to an infectious disease event.

Once the index case was identified, local and state health department investigators meticulously examined hospital records to determine infants, parents, coworkers, and volunteers who were at risk of exposure. This investigation identified an initial 3,227 potentially-exposed newborns, and 69 potentially-exposed health care workers. Together, public health workers evaluated the index case's history to determine where exposure may have actually occurred. Then, they prioritized potential contacts by level of risk, decided on a contact investigation protocol specific to this incident, and executed the contact investigation. The CDC provided on-site assistance, and home office CDC staff provided expertise and advice. International coordination took place due to the city's proximity to the U.S.-Mexico Border; interstate coordination with New Mexico was also necessary.

Public health investigators were able to narrow down the initial 3,227 number to 940 exposure contacts: 860 infants, 69 healthcare workers, and 11 community contacts. Of these exposures, four babies and four adults were positive for TB infection. Appropriate public health follow-up and treatment recommendations are underway for all eight.

Public Health Emergency Preparedness Funds and Hospital Preparedness in Texas

Texas experiences several challenges in public health and health care preparedness planning. The state's large size and population, diverse geography, weather patterns, coastal area, and border proximity necessitate coordinated preparedness planning. Historically, Texas has had more federal disaster declarations than any other state, with 88 major disaster declarations between 1953 and 2013. These declarations have included floods, hurricanes, tropical storms, tornadoes, droughts, wildfires, and explosions.

These challenges have necessitated a strong focus on preparedness planning for the state. Emergency planning in Texas takes an all-hazards approach to preparedness and response, which includes natural events, biological events, hazardous material spills, radiological accidents, terrorist acts, and others. Each type of incident requires development of response plans, periodic training, and continuous improvement.

Two key federal funding streams support Texas activities in this area: the U.S. Health and Human Services (HHS) Hospital Preparedness Program (HPP), which is administered by the Office of the Assistant Secretary for Preparedness and Response (ASPR), and the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) program. The HPP provides resources to help hospitals and healthcare stakeholders prepare for and respond to bioterrorism and medical emergencies with a primary focus on coalition building. PHEP funds are used to increase state, regional, and local public health capacity for a flexible, all-hazards approach to emergency preparedness.

HPP and PHEP funds have allowed Texas to successfully respond to a broad array of incidents over the years. Since 2008, Texas has carried out effective response efforts in natural events like Hurricane Ike and Dolly, as well as the Bastrop wildfires; disasters like the West, Texas Fertilizer explosion; disease outbreaks including West Nile Virus, the H1N1 pandemic, Tuberculosis, Salmonella, and cyclospora; and other events like the Yearning for Zion Ranch compound.

The trends in funding for these preparedness activities are aligned with the major events of the time. The attack on the World Trade Center on 9/11 infused the system with support. Avian influenza in 2007 and H1N1 in 2010 resulted in additional support. However, since that time, HPP awards to Texas has consistently decreased from \$33.3 million in fiscal year 2004 to an anticipated \$15.8 million in fiscal year 2015. PHEP awards to Texas have similarly declined since 2002, a situation that does not allow Texas to fully keep up with rising costs and the need to continually prepare. Consistency at sustainable levels would better allow states to prudently plan preparedness and response activities.

Lessons Learned: Ebola and Infectious Disease

As with every response, the events in Dallas have provided lessons that must inform future preparedness and response activities. The lessons are augmented by experiences in other states that have received patients, managed potential contacts, and are trying to plan for the possibility of an Ebola suspect or known case within their jurisdiction.

Certain lessons were immediately apparent in Dallas, and confirmed previous knowledge. The crux of infectious disease response is reporting. Providers must be aware of what diseases are reportable to their local health department, and promptly report contagious disease through the reporting system. Provider awareness of this responsibility allows for more effective disease surveillance, and more timely response to developing infectious disease events.

Secondly, the Ebola cases in Dallas highlighted the need for providers to vigilantly take travel histories, and streamline sharing of this information while a patient is being diagnosed. Providers must be aware of outbreaks worldwide, to inform their consideration of patient travel history. Until the Ebola outbreak in West Africa is over, Ebola must be a differential diagnosis for those who have recently traveled from one of the outbreak countries. At the same time, moving forward, providers must be aware of what other outbreaks are occurring internationally.

Other lessons were arrived at through the provision of care for a late-stage Ebola patient. Two months ago, the national strategy was that any community hospital should be able to care for an Ebola patient. Treating Mr. Duncan shows how labor intensive care for a patient with Ebola is, the meticulous detail required to avoid secondary infections, and the amount of resources needed to prevent the spread of virus. Now, it is apparent that a nationwide network of predefined infectious disease treatment centers is needed for the care of patients with high consequence infectious diseases like Ebola. These treatment facilities must have a care team identified and carefully trained; a comprehensive plan for care, laboratory testing, waste disposal, patient transport; and mortuary services; pre-stocked medicines and post exposure prophylaxis (PEP); and a sufficient supply of personal protective equipment (PPE). In Texas, two facilities are prepared to treat patients with Ebola under short notice, and additional capacity is being identified.

The care of Ebola patients also informed the need to modify PPE and other Ebola-related guidelines. The overall lesson is that guidelines must be consistently reviewed and updated to ensure the smooth and safe care of infectious disease suspect and known cases, from beginning to end. Additionally, access to experimental therapeutics and PEP must be expedited and more flexible, and there must be an intensified focus on testing and producing Ebola vaccine and treatment drugs.

The epidemiological process of identifying, isolating, and diagnosing individuals for Ebola revealed its own lessons. The Lab Response Network (LRN), which receives support through PHEP funds, has been critical. The Texas State Public Health Laboratory is part of the LRN and had fortunately become certified to test for Ebola just before Mr. Duncan was identified as a possible Ebola case. The LRN must be robust nationwide to ensure that testing capacity adequately covers the nation.

A number of lessons have arisen with regard to monitoring and potential quarantine of numerous individuals. The language surrounding this process and the correlation between risk and public health action must be clearly delineated. This precision will help provide the public assurance that decisions are based on science, and to provide public health and government officials clear information by which to make decisions about contact monitoring and quarantine.

Moreover, government action regarding voluntary compliance guidelines and mandatory quarantine orders must occur in a manner that respects individual freedoms, and ensures necessary supports are provided to individuals who are asked to refrain from entering public venues. Concerns over employment, education, transportation, housing, and simple household issues such as groceries impact the willingness of individuals to comply with voluntary and mandated quarantine orders. Challenges have also emerged as asymptomatic persons under monitoring seek medical treatment for issues unrelated to Ebola, as public health looked for housing for individuals of quarantine, and officials negotiated waste management issues requiring coordination among multiple agencies.

Finally, the efforts of Texas and other states to prepare for the potential of an Ebola suspect or known case inform potential improvements for infectious disease response. Hospital, local, and state ability to access PPE supplies has become problematic. There is a gap in knowledge about what hospitals should have on hand and how to proceed if they are unable to purchase appropriate PPE. For states, a challenge exists in stockpiling and warehousing adequate PPE to be able to respond to surge situations, while ensuring that caches are on a rotation basis to avoid PPE expiration without use. Furthermore, while guidelines regarding airport screening and travel have been an area of focus, there appears to be a need to further refine maritime guidelines.

Identified Issues: All Hazards Events

The Dallas response exhibited particular needs associated with a biological event like Ebola. A response to a natural disaster involves mobilizing resources, managing finite supplies, transporting equipment and personnel, and providing established medical and social care. On the other hand, biological events like the Ebola response have fundamentally different characteristics from other emergency events. In Dallas, a greater focus was on less tangible activities, including: patient screening and isolation; epidemiological surveillance; management and sharing of epidemiological data; expert medical and public health decision making; legal resources, and coordination of multiple jurisdictions and agencies.

Despite these differences, all types of emergency response events require a level of training, communication, and leadership that is universal. The incident command structure (ICS) is a tool that brings public health, law enforcement, emergency management, and other essential functions together into a coordinated response effort. The incident command structure also helps ensure that three levels of government work together seamlessly, provides overall direction for the response effort, and ensures clear and accurate communication with the public. The ICS is essential, and must be consistently practiced in order to ensure effective execution in the event of an emergency response.

The ICS should integrate each participant into its structure, so that there is a clearly-delineated chain of command, and no question about the role of each jurisdiction. Defined roles and responsibilities for each individual within the ICS ensure that multijurisdictional responses work with a shared vision and purpose, and help avoid potential cross-agency issues. These structural decisions, however, must be largely outlined before a response occurs. Tabletop and active

exercises allow emergency management and public health planners to simulate these crucial decisions, and be more effective when an emergency becomes a reality.

Throughout a response, quality improvement must be a priority. Within the ICS, at least one individual should be designated to record events and identify issues that should be looked at more deeply once the response comes to an end. Only by beginning the learning process during a response will jurisdictions be able to maximize after action processes that inform better response in the future.

Conclusion

The response to Ebola in Dallas, Texas, exhibited the strength of public health processes. No secondary cases of Ebola resulted from community exposure. The two secondary cases that occurred were associated with direct care by health care workers of an Ebola patient. Quick identification of these cases allowed more immediate care, fast isolation of the patients, and a better chance for successful health outcomes.

At the same time, the response brought issues to light that can be improved. In Texas, the Task Force on Infectious Disease Preparedness and Response is examining the state's entire public health response system for infectious disease. The Task Force's work will undoubtedly result in a more ready Texas, whether the next event be another Ebola case or another, more infectious, disease. However, Texas represents just one part of a nation that must work together to respond to diseases that cross county and state lines. Just as the Texas Task Force is looking at these issues within its jurisdiction, national consideration of the country's public health response system should take place to ensure a more ready United States.



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**Statement
of the
American Hospital Association
before the
United States Senate Committee on Homeland Security and Governmental Affairs**

**“Preparedness and Response to Public Health Threats: How Ready Are We?”
November 19, 2014**

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our more than 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to submit this statement for the record as part of the hearing on the government’s response to fighting Ebola.

America’s hospitals are dedicated to the health and safety of every patient and health care worker and have joined together with physicians and nurses to work to protect patients and caregivers. We, along with the American Medical Association and American Nurses Association, believe that a solution-oriented, collaborative approach to Ebola preparedness is essential to effectively manage the care of Ebola patients domestically. Our members are using the most recent guidance from the Centers for Disease Control and Prevention (CDC) and the resources available to them in order to continue to train nurses, doctors and other staff who would be involved in caring for these patients. Hospitals are repeatedly drilling and exercising on the entire course of care, from diagnosis to final waste disposal, using the same equipment on which they will rely in order to safeguard their staff, patients and communities. This includes proper procedures for putting on and taking off appropriate personal protective equipment (PPE) under the watchful eye of a trained observer and proper handling and disposal of waste.

Since this summer, when the CDC began to warn providers to be on the lookout for travelers from the Ebola-stricken region of West Africa, the AHA has shared information with the hospital field to help them prepare to detect, diagnose and safely treat potential Ebola patients. We continue to send numerous advisories and alerts to the field as new guidance and resources are released. We also have convened multiple forums with officials from CDC and other agencies, as well as hospital leaders, to answer questions and share lessons learned. All of this information has been consolidated on our website at www.aha.org/ebola. It also includes links to lessons

shared, video demonstrations and toolkits from hospitals with Ebola experience, such as Emory University Hospital and the University of Nebraska Medical Center, as well as state public health departments.

Below, we detail how hospitals are preparing and the standards they are meeting, as well as the resources hospitals need to assist them in these efforts. Ensuring safe care for patients and protecting health care workers and communities from infectious diseases like Ebola also demands the combined efforts of inter-professional, state and federal organizations.

HOW HOSPITALS ARE PREPARING

Hospitals take very seriously their responsibility to safeguard patients and the public's health. That includes the health of their staff. There is no more valuable resource than the selfless, caring women and men of America's hospitals. Assertions that hospitals would put financial considerations before the lives and health of their staff are outrageous and totally unfounded.

Using lessons learned from hospitals that have treated Ebola patients, and from caregivers working on the frontlines in West Africa, hospitals have increased their readiness to respond to the Ebola crisis. Below are just a few examples of how hospitals across the country are preparing their facilities, securing necessary supplies, training staff and repeatedly drilling to ensure everyone knows how to safely care for a patient with a suspected or confirmed case of Ebola. We can provide the Committee with additional examples upon request.

New York City Health and Hospitals Corporation (HHC). The largest municipal health system in the country with 11 acute care hospitals, HHC has been rigorously training staff and conducting drills on how to detect, diagnose, isolate and properly treat Ebola. Since mid-September, HHC has sent trained staff members pretending to be patients with potential symptoms of the disease – travel history, fever, headache and stomach pain – to all 11 of its emergency departments (EDs) to test their preparations. The drill takes staff through the detection and isolation stages, including the use of PPE. Once the “patient” is revealed to be an actor, staff review what occurred with trained observers to fine-tune their protocols. Hospitals throughout the New York City area are regularly conducting similar drills.

Florida Hospital. The health system has been preparing for the possibility of Ebola for months, stressing stringent PPE protocols and training. It has created an Ebola care team consisting of 100 health care worker volunteers from various departments, including the ED, respiratory care, critical care, obstetrics and pediatrics. The health care worker volunteers have received even more extensive hands-on training in the safe use of PPE. While any of the system's locations are prepared to identify and isolate a potential Ebola patient, two facilities have been designated to treat a confirmed Ebola patient. The rooms have their own ventilation systems, are separate from other patient units and have a separate entrance and exit. For more on their preparation efforts, see the [video](#) the system has created and shared.

Mount Sinai Health System. The system's seven New York-area hospitals and affiliated health providers, in conjunction with the New York City Department of Health and Mental Hygiene

and Greater New York Hospital Association, sprang into action after the CDC's July 28 health advisory. The incident management system was activated, notifying the Chief Medical Officers, ED leadership, faculty and staff, and Infectious Disease Division. Providers quickly initiated procedures for the screening for travel and symptoms, isolation of suspected cases to ensure rapid evaluation, and notification and coordination of diagnostic testing with the local health department. An Incident Action Plan was developed and distributed targeting key areas such as EDs and outpatient clinics. Strict isolation protocols were put in place out of an abundance of caution, and an inventory of PPE was conducted. A screening tool was added to the electronic health record, and the physical plant was assessed to identify best locations for patient care. The system was tested on Aug. 4 when a patient with potential symptoms presented. He tested negative for Ebola, but the experience allowed the system to fine-tune its response. Like other New York hospitals, it continues to conduct drills and secret patient exercises.

External Partners. Hospitals continue to actively plan with their local partners, as well as the state. One example is on the management of ambulance Ebola waste. Ambulance providers need assistance with proper disposal of waste following the transporting and hand-off of an Ebola patient. Ambulance personnel also need assistance with the removal and disposal of their PPE. Hospitals and their local emergency medical services (EMS) providers have been working together to develop specific policies and procedures to address this area of their planning. Among other policies and procedures, hospital personnel (in appropriate PPE) will come out and meet the ambulance in the bay and transfer the patient to a designated area inside the facility. Hospital personnel plan to monitor and assist in the EMS personnel removal process, if needed. Hospitals also have an adequate supply of drums to collect, store and prepare for the hauling of medical waste, not only for their facility, but also for their EMS partners.

A MISSION OF SAFETY

Some have called for additional regulation of hospitals. As you will see below, however, hospital safety is already highly regulated. At best, new regulations would create additional burden for providers without improving safety for patients and health care workers. At worst, they could result in hospitals trying to navigate their way through conflicting and out-of-date requirements and stymie innovation that could result in better outcomes for patients, as well as hospital staff.

The existing infection prevention and control standards, including their assessment and enforcement by regulatory, accrediting and certifying bodies, have proven to be effective, functional and appropriate, and substantial resources are dedicated to their continuous maintenance and improvement.

Safety is our Highest Priority. The health and safety of every patient – and the health care workers who care for them – is hospitals' paramount concern. As such, hospitals and health care systems have long had in place effective and comprehensive programs that protect patients and health care personnel.

Compliance is Not Voluntary. Continuous education and training of new and current employees is the cornerstone of hospital infection control and employee health programs. This includes ongoing practice and refresher training. These programs are not “voluntary,” as some have suggested. They are mandated by the Centers for Medicare & Medicaid Services (CMS) and all accrediting agencies with deemed status from CMS, such as The Joint Commission. To participate and receive reimbursement from Medicare and Medicaid, hospitals must comply with program conditions of participation, and the standards of the accreditation organizations and state agencies. The basis for CMS’s standards is evidence-based guidelines from the CDC.

Hospitals that do not comply with CMS standards risk loss of their Medicare and Medicaid certification, or even their operating license, if CMS determines the facility has unsafe conditions related to infection control standards or life safety codes.

Hospitals also must comply with the U.S. Occupational Health and Safety Administration’s (OSHA) Bloodborne Pathogen regulations, General Industry Respiratory Protection standard and the General Duty clause. OSHA actively enforces compliance.

Improving Care and Safety for All. Hospitals devote much time and effort to facility-wide performance measurement and improvement. Hospitals are committed to a safety culture, as demonstrated through many successful programs focused on sustained infection reduction. According to the Department of Health and Human Services, hospital-acquired conditions decreased nine percent during 2011 and 2012. National reductions in adverse drug events, falls, infections, and other forms of hospital-induced harm are estimated to have prevented nearly 15,000 deaths in hospitals, avoided 560,000 patient injuries, and saved approximately \$4 billion in health spending over the same period.¹

RESOURCES KEY TO PREPAREDNESS

Preparedness is not a one-time investment. Rather, it is a dynamic process that changes over time. Hospitals and health systems have learned from each emergency situation, and it is crucial that they have the appropriate funding to adopt best practices, incorporate new technology into their emergency readiness plans and have the ability to care for their communities when a pandemic, disaster or terrorist attack occurs.

The Hospital Preparedness Program (HPP), the primary federal funding program for hospital emergency preparedness, has provided resources since 2002 to improve health care surge capacity and hospital preparedness for a wide range of emergencies. The HPP has supported enhanced planning and response, facilitated the integration of public and private sector medical planning to increase the preparedness, response and surge capacity of hospitals, and has led to improvements in state and local infrastructures that help hospitals and health systems prepare for public health emergencies. These investments have contributed to saving lives during many events, such as the Joplin tornado and the Boston Marathon bombing.

However, authorized funding levels and annual appropriations for the HPP have significantly declined since the program began. Congressionally authorized funding and appropriations for the HPP was \$515 million per year in the early years of the program. The Pandemic and All-Hazards

Preparedness Reauthorization Act of 2013 reduced authorized funding for the HPP to \$374.7 million per year for fiscal years (FYs) 2014 through 2018. For FY 2014, Congress appropriated only \$255 million for the HPP, more than a 50 percent reduction from prior years. Similarly, the president's FY 2015 budget proposal recommended only \$255 million for the HPP.

While the HPP has been of assistance to hospitals, all too often, the dollars appropriated by Congress for hospitals have been siphoned off. In the current situation, as hospitals are on the frontline dealing with Ebola, there needs to be a dedicated fund that will provide assistance directly to them. At a minimum, if funds are to flow through the HPP, Congress should legislate that at least 90 percent of those funds be provided directly to hospitals.

State governments are working with their state hospital associations and hospitals to designate Ebola treatment facilities. While all hospitals are prepared to identify, isolate, protect patients and other health care workers, and contact their local health department and the CDC in the instance of a possible Ebola patient, hospitals are stepping up to be designated facilities in their individual states. Funding must be provided to all hospitals designated by a state, as they have assumed a greater responsibility. There should not be a limitation imposed at the federal level on funding for hospitals so designated by a state.

We appreciate the interest by the Congress in providing much-needed funds to combat Ebola both domestically and abroad. As stated above, however, we believe a dedicated funding stream needs to be provided to designated hospitals. In addition, we are working with a number of our designated hospital members to ascertain what level of funding they will need and look forward to working with the Committee. The examples below represent the needs of hospitals.

SUNY Upstate University Hospital in Syracuse is one of 10 New York hospitals designated by Gov. Andrew Cuomo to treat Ebola cases. The hospital estimates its cost of Ebola preparedness could be in the hundreds of thousands dollars. Most of the 555-bed hospital's costs are related to Ebola training, modifying physical plant and providing personal protective and diagnostic and other testing equipment for a four-bed Ebola unit.

The University of Nebraska Medical Center (UNMC) in Omaha, which has treated patients who contracted Ebola in West Africa, also says additional resources are needed. The resources should be aligned with those hospitals that are likely to receive patients and transfer them after they are initially identified and stabilized elsewhere.

The medical center required 40 to 60 staff members for each case. Five medical workers tended to a single patient during each 12-hour shift, plus laboratory and other staff. One room was taken up by the laboratory, which was moved closer to the patient to keep it separate from other samples, and two rooms were set aside for clean supplies and dirty supplies. Preparation is costly. UNMC estimates it cost about \$1.6 million to treat the first two patients directed to them by the federal government. In addition to the direct treatment costs, the hospital estimates it has incurred \$148,000 so far in costs to take beds near the Ebola treatment ward out of service. As additional patients are directed to UNMC, the hospital will incur additional costs for treatment.

CONCLUSION

Ebola is a new disease in the United States. As such, it is understandably frightening for many. But America's hospitals and health care providers have a long history of battling new diseases – and defeating them.

Our nation's hospitals, professional physician and nursing organizations remain in communication with one another and with our nation's public health institutions at the local, state and national levels. We are committed to maintaining a strong collaborative effort to address this public health threat.

Hospitals are working hard to improve readiness and reassure their communities. They have learned from the experiences of organizations that have treated these first few Ebola patients and are updating the strategies they had put in place based on the latest scientific evidence and guidelines. They are taking the real-life experience of a handful of hospitals, and using it to strengthen the readiness of all.

We stand ready to work with the committee to enhance the safety of every patient, health care worker and community in America.

ⁱ Department of Health and Human Services. May 7, 2014. Accessed at: <http://www.hhs.gov/news/press/2014pres/05/20140507a.html>.

**Post-Hearing Questions for the Record
Submitted to The Honorable Nicole Lurie, M.D.
From Senator Thomas R. Carper**

“Preparedness and Response to Public Health Threats: How Ready Are We?”

November 19, 2014

CONTENT ACCURATE AS OF DECEMBER 16, 2014

1. We must continue to pay close attention to the changing dynamics of the Ebola epidemic in Africa, and we must continually reassess the scale of the response needed overseas and here in the United States to end this epidemic. To help meet the immediate and long term needs of the Ebola epidemic, President Obama recently submitted an emergency funding request of nearly \$6.2 billion dollars. What will the impact be on the U.S. response if Congress doesn't appropriate the full \$6.2 billion requested?

Response: The Consolidated and Further Continuing Appropriations Act, 2015 (H.R. 83), provided \$2.7 billion in emergency funding to the Department of Health and Human Services (HHS) for Ebola preparedness and response activities. The Act allocated \$1.8 billion to the Centers for Disease Control and Prevention (CDC), \$733 million to the Public Health and Social Services Emergency Fund for the Assistant Secretary for Preparedness and Response (ASPR), \$238 million to the National Institutes of Health (NIH), and \$25 million to the Food and Drug Administration (FDA). ASPR anticipates this funding will result in a strong return on investment in the United States and around the globe, by making public health and health care systems stronger to protect from deadly infectious diseases in the future.

In the Consolidated and Further Continuing Appropriations Act, 2015, Congress appropriated supplemental funding for BARDA consistent with the President's request. This additional funding supports the development, manufacturing, and testing of the most promising Ebola vaccine and therapeutic candidates by NIH and the Biomedical Advanced Research and Development Authority (BARDA) in ASPR. In the absence of this additional funding, these activities might have come to a halt. Further, BARDA's support of vaccine manufacturers to move vaccine manufacturing to commercial scale by mid-2015 would not be able to occur. This would result in a global inability to mount effective mass vaccination campaigns in the Ebola-affected West African countries in 2015 should the vaccine be found safe and effective. The funding also supports the development of Ebola therapeutic candidates, including tobacco-based Ebola monoclonal antibody therapies that Medicago, Fraunhofer, and other companies have initiated. Without this funding, these products might not have been available for testing in clinical trials nor as a safe and effective treatment modality in West Africa or the U.S. Lastly, without this funding, a delay might have occurred in providing medical countermeasures for viral hemorrhagic fever, including Ebola, under Project BioShield.

HHS, in collaboration with states and hospitals, is establishing a tiered approach to Ebola assessment and treatment. Nationwide, all hospitals and other health care providers must be prepared to recognize, isolate, and initially care for potential Ebola patients until they can be

transported to an appropriate designated facility. In addition to the three biocontainment facilities, HHS is evaluating states and/or cities that have the potential to be at higher levels of risk for needing to care for Ebola patients. To prepare for Ebola, funding will be provided to all states, with anticipated adjustments based on population and risk. These funds not only support an enhanced level of preparedness, but also enhance preparedness by addressing gaps in the ongoing Ebola outbreak.

In addition to supporting overall health care system preparedness and response, the Hospital Preparedness Program (HPP) anticipates providing funding to all 62 HPP awardees (states, territories, freely associated states, and select municipalities). This funding will then flow to Ebola Treatment Centers in high-risk jurisdictions, of which Minnesota is one, as well as Assessment Hospitals and health care coalitions (HCCs) nationwide. HCCs are formal collaborations among health care organizations and public and private partners, including health departments, hospitals, emergency medical services providers, and ambulatory care facilities that are organized to prepare for, respond to, and recover from emergencies that impact the public's health. Supplemental resources provided through HCCs will allow for regional purchasing of personal protective equipment (PPE) and proper training and exercises, specifically infectious disease control training. This will help to ensure readiness at the regional level while efficiently and effectively using scarce resources and funding. Supplemental funding also will support Federal knowledge sharing and other technical resources assistance and information exchange to ensure that all facilities learn best practices and share experiences.

We also recognize that caring for Ebola-infected patients is expensive. Hospitals that have cared for these patients have found that reimbursement by insurers and workers compensation programs do not cover many of the direct costs of care. These costs include, but may not be limited to, costs of PPE, costs associated with the management and disposal of Ebola contaminated waste, and transportation of Ebola-infected patients. The Consolidated and Further Continuing Appropriations Act of 2015 has provided funding to reimburse hospitals for such excessive costs. To date, four non-Federal hospital facilities have cared for one or more patients with Ebola. A priority is to provide reimbursement to these facilities and to be prepared to provide similar reimbursement for care of any additional infected persons.

**Post-Hearing Questions for the Record
Submitted to The Honorable Nicole Lurie, M.D.
From Senator Tom Coburn, M.D.**

“Preparedness and Response to Public Health Threats: How Ready Are We?”

November 19, 2014

- 1. At the hearing, you agreed to provide additional information to the Committee regarding the cost of anthrax countermeasures procured for the Strategic National Stockpile. Please provide a list of all contracts awarded for procurement of anthrax vaccine and antibiotics since implementation of Project BioShield, including the total cost and number of doses procured under each contract.**

Response: Anthrax medical countermeasures (MCMs), including vaccines and antitoxins supported under Project BioShield, are shown in the table below. Antibiotics, doxycycline and ciprofloxacin, which may be used during an anthrax event, are Food and Drug Administration (FDA) approved drugs and are purchased directly by the Strategic National Stockpile (SNS).

The anthrax vaccine, BioThrax - Anthrax Vaccine Absorbed (AVA) is manufactured by Emergent BioSolutions, purchased since 2008 by the SNS, and licensed by FDA for general use prophylaxis (GUP). Under Project BioShield, BARDA purchased the initial doses of BioThrax for the SNS and has supported late stage development of BioThrax for post-exposure prophylaxis (PEP). This resulted in Emergent's submission of a supplemental biological license application (BLA) for a PEP indication in October 2014. BLA is a request for permission to introduce or deliver a biologic product into commerce.

The monoclonal anthrax antitoxin, Raxibacumab, was approved by FDA in December 2012 for the treatment and prophylaxis of individuals symptomatic with anthrax or suspected of exposure to anthrax spores. Raxibacumab labeling includes pediatric dosing recommendations. Anthrax Immunoglobulin (AIG) is a polyclonal anthrax antitoxin manufactured by Cangene/Emergent, which submitted a BLA to FDA in July 2014.

Countermeasure Area/Project	Date of Contract Award	Delivery to SNS*	Contract Recipient	Status	Total Funding MM
Anthrax Therapeutics					
Monoclonal Antibody - ABthrax (Raxibacumab)	9/2005	Complete	HGS	20,000 doses, deliveries complete	\$174
Monoclonal Antibody - ABthrax (Raxibacumab)	7/2009	Complete	HGS	45,000 doses, deliveries complete	\$160
Anthrax Immune Globulin - (AIG)	9/2005	Complete	Cangene	10,000 doses deliveries completed	\$160
Replenishment of Anthrax Antitoxins	9/2013	N/A	Elusys	Base only	\$0.10
	9/2013	N/A	Emergent	Base and Cell Bank	\$0.45
	9/2013	NA	PharmAthene	Base and Cell Bank	\$1
	9/2013	Ongoing	GlaxoSmithKline (Raxibacumab)	4141/60,000 doses plus cell bank	\$197
	9/2013	Ongoing	Cangene (Plasma for AIG)	10,381 liters of plasma, to be stored as plasma	\$63
	9/2014	TBD	GlaxoSmithKline (Raxibacumab)	0/32,734 doses	\$105
Anthrax Vaccines					
AVA (Anthrax Vaccine Adsorbed) BioThrax	05/2005	Complete	Emergent	Original contract for 5 million doses with option exercised for additional 5 million doses	\$243
AVA (Anthrax Vaccine Adsorbed) BioThrax	9/2007	Complete	Emergent	Original contract for 18.75 million doses	\$456
rPA (Recombinant Protective Antigen)	11/2004	n/a	VaxGen	Terminated 12/19/06	\$2
Total obligated					\$1,562

2. You previously stated your role as the Assistant Secretary for Preparedness and Response (ASPR) is to be the principal advisor to the Secretary of Health and Human Services (HHS) on matter of public health emergency response. At the same time, both statute and the National Response Framework state the ASPR is the key federal official to coordinate the federal public health emergency response. Please describe how you have prepared to exercise your statutory responsibilities and responsibilities under the National Response Framework in the event of a major emergency.

Response: Federal statute and interagency frameworks and policies have established the Office of the ASPR, within the HHS, as the lead coordinator for preparedness and response to public health and medical incidents. Specifically, the Pandemic and All-Hazards Preparedness Act (PAHPA) and its successor statute, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), established ASPR as the principal advisor to the Secretary of HHS on all matters related to Federal public health and medical preparedness and response for public health emergencies. In addition, PAHPRA authorized ASPR with the lead

responsibility within HHS for Federal emergency preparedness and response policy coordination and strategic direction, as well as leadership in public health and medical international programs, initiatives, and policies. Furthermore, Emergency Support Function 8 (ESF-8) "Public Health and Medical Services" of the National Response Framework established ASPR as the primary coordinator of preparedness and response functions across the U.S. Government.

Under these responsibilities and authorities, ASPR provides leadership and support for activities to prepare for, respond to, recover from, and mitigate the impacts of public health and medical incidents. Planning is one key component that supports ASPR's programs and initiatives. With respect to planning for a possible Ebola Virus Disease (EVD) outbreak in the continental United States, ASPR has been involved in numerous efforts to make sure the Federal Government is best positioned to respond should such an outbreak occur. Specific activities include:

- In coordination with partners at the Centers for Disease Control and Prevention (CDC), drafted the HHS Support Plan and Communication Plan for a first case of EVD diagnosed in the United States.
- In coordination with partners at CDC, continue to draft and finalize the U.S. Government Ebola Virus Disease Plan to provide a framework for an EVD outbreak in the United States.
- In coordination with partners at the Department of Defense (DoD) and CDC, support a Department-of-State-led initiative to develop standard operating procedures and notifications for EVD patient movement.
- In coordination with CDC and other Federal partners, the Federal Emergency Management Agency (FEMA) developed a scalable unified coordination structure to include Federal, state, and local authorities, to support a response to a single EVD event or multiple EVD events (in multiple states).
- In coordination with FEMA and other interagency partners, reviewed the support that would be provided to the lead Federal Agency and the resources available in the first 72 hours of multiple EVD cases.
- Leading up to the African Leaders Summit in August 2014, ASPR discussed contingency planning for the National Capital Region in case one of the delegates from an African nation developed symptoms resembling Ebola. The procedures provided for enhanced medical surveillance, hospital incident tracking, and epidemiologic investigation.
- In coordination with partners at the Department of Veterans Affairs (VA), advised on plans for VA facilities to screen suspected EVD patients, care for confirmed EVD patients, and on interaction between VA and non-VA facilities designated for EVD patient use.

In addition, ASPR has participated in a number of exercises and training events to test planning assumptions, identify existing gaps, and strengthen planning efforts as needed. Specific activities include:

- Participated in a SOUTHCOM table top exercise in Miami, Florida assessing roles and responsibilities of the interagency in the event of an EVD event.
- Participated in a Maryland table top exercise in Baltimore, Maryland assessing roles and responsibilities of the local and state agencies in the event of an EVD event.

- Participated in a Federal table top exercise for the Domestic Resilience Group at the White House assessing roles and responsibilities of the Federal Departments in the event of an EVD event.
 - Participating in an interagency Latin American/Caribbean EVD planning effort. Reviewing actions to inhibit mass migration, assisting the Department of Homeland Security's Customs and Border Protection to determine medical screening and processing support, and assisting U.S. Coast Guard in determining maritime medical screening and treatment guidance for para-professional medical providers.
- 3. In reviewing federal pandemic response capabilities, the Government Accountability Office has recommended that the HHS and the Department of Homeland Security (DHS) perform frequent exercises and simulations to clarify and test all coordination mechanism.**
- a. How many training exercises and simulations has your office performed in coordination with DHS in each of the last five years? Please describe the type of exercise (e.g. tabletop or real-life), the nature of the simulated threat (e.g. infectious disease outbreak), and the officials involved.**

Response: Since 2010, the ASPR has coordinated with the Department of Homeland Security on 23 exercises. These exercises are outlined below.

Year	Type of Exercise	Scenario	Audience
2010	Federal Interagency Anthrax Response Workshop	Aerosolized Anthrax	Federal Interagency
2010	Arizona Anthrax Response Exercise	Aerosolized Anthrax	State and Federal
2010	Chicago Anthrax Response Exercise	Aerosolized Anthrax	City, State, Federal
2010	Baltimore Anthrax Response Exercise	Aerosolized Anthrax	City, State, Federal
2010	Louisiana Anthrax Response Exercise	Aerosolized Anthrax	State and Federal
2010	Region X Anthrax Response Exercise	Aerosolized Anthrax	City, State, Federal
2011	LA Medical Countermeasures TTX	Aerosolized Anthrax	City, State, Federal
2011	Dark Zephyr San Francisco	Aerosolized Anthrax	City, State, Federal
2011	Dark Zephyr Federal Interagency TTX	Aerosolized Anthrax	Federal Interagency
2011	Dark Zephyr Senior Officials Exercise	Aerosolized Anthrax	Federal DRG
2011	Minnesota Postal Plan TTX	Aerosolized Anthrax	City, State, Federal
2012	CDC Pandemic Influenza Exercise	Pandemic Influenza	State and Federal

2012	Derby City Quick Strike TTX	Aerosolized Anthrax	City State and Federal
2012	Operation Medicine Delivery FSE	Aerosolized Anthrax	City, State, Federal
2012	Philadelphia Postal Plan TTX	Aerosolized Anthrax	City, State, Federal
2012	San Diego Postal Plan TTX	Aerosolized Anthrax	City, State, Federal
2012	Boston Postal Plan TTX	Aerosolized Anthrax	City, State, Federal
2013	Senior Officials Exercise 1-13	Pandemic Influenza	Federal Interagency
2013	Smallpox Vaccine Response Strategy TTX	Smallpox	State and Federal
2014	Philadelphia Plague FSE	Plague	City, State, Federal
2014	International Sharing of Medical Countermeasures TTX	Smallpox	Federal, International
2014	HHS Anthrax Plan Validation TTX	Aerosolized Anthrax	Federal
2014	Principal's Level Exercise 1-14	Pandemic Influenza	Federal Interagency

b. What criteria were used to study performance and lessons learned in each exercise?

Response: HHS prioritizes the implementation of corrective actions in order to learn from past responses and continue to refine procedures and capabilities in order to improve response and mitigate lasting effects of public health and medical emergencies. For each of the above listed exercises, all design concepts and objectives were agreed upon by specific planners from various participating departments/agencies. The core theme throughout all the exercises included evaluating participant responses and actions during the exercises against expected responses and actions outlined in plans, policies, procedures, and capabilities. When participant responses or actions differed from those expected, exercise evaluators captured the input to determine why the actions were not as expected. The difference indicated a gap or omission in planning, policy, procedure or lack of capability. Confirmed gaps were included in the exercise after-action reports as recommended improvements or lessons learned.

4. Your office wrote several “playbooks” to plan for scenarios like aerosolized anthrax. These playbooks go into extensive detail about actions required, responsibilities, etc. Has your office produced a playbook for an escalating infectious disease outbreak (other than influenza)? If such a playbook has not been developed, why not?

Response: “Playbooks” for scenarios like aerosolized anthrax were produced in response to the National Preparedness Guidelines as required by the previous administration. At this time, such “playbooks” are no longer required within the Federal government.

Under the leadership of the current Administration, the Secretary of Homeland Security conducted a strategic national risk assessment to help identify the types of incidents that pose the greatest threat to the Nation's homeland security. Representatives from Federal interagency offices have supported this effort and released the Strategic National Risk Assessment (SNRA) in December 2011. The SNRA describes a wide range of threats and hazards that warrant national attention – threats include animal disease outbreaks, earthquakes, floods, pandemic outbreaks, chemical spills, dam failures, aircraft as a weapon, biological terrorists attacks, and explosive terrorist attacks to name a few. HHS is currently in the process of developing an All Hazards Plan to address these and other threats, and is collaborating with the Federal Interagency in developing annexes to the Federal Interagency Operations Plans for Response and Recovery.

- 5. The 2009 National Health Security Strategy included an implementation plan with a number of tasks for your office. The strategy required the ASPR, CDC, and DHS to develop measures to assess a health care organization's capability to respond to a health incident. One was for the ASPR, CDC, and others to work with partners to "develop and align surge [capacity] goals." Please list, in detail, the surge capacity goals developed by the ASPR in conjunction with other agencies.**

Response: Our Nation's preparedness is built on the back of strong day-to-day healthcare systems, which ASPR continues to help build and maintain to respond to future emergencies. ASPR's HPP program builds Healthcare Preparedness Capabilities in eight areas, including medical surge. HPP's approach facilitates preparedness funding according to HPP awardees who are required to submit annual applications, work plans, and budgets consistent with eight health care preparedness capabilities: consistent with (1) health care system preparedness, (2) health care system recovery, (3) emergency operations coordination, (4) fatality management, (5) information sharing, (6) medical surge, (7) responder safety and health, and (8) volunteer management.

Within this overarching framework, awardees conduct regular risk assessment surveys to identify areas of greater need and determine funding distributions among each capability. To ensure the ability to surge when needed, HPP awardees can use funds for health care coalitions to assist with the coordination of the health care organization response during incidents that require medical surge, coordinate integrated health care surge operations with pre-hospital Emergency Medical Services (EMS) operations, assist health care organizations with surge capacity and capability, and develop crisis standards of care guidance.

At the end of each funding year, HPP awardees report progress on health care preparedness capabilities through two program measures, one of which is medical surge. The medical surge program measure informs preparedness and response capabilities and the surge capacity of hospitals and health care organizations to respond to mass casualties and public health emergencies. There are a number of required indicators for the medical surge measure, which addresses the essential aspects along the continuum of care. Awardees must post their Crisis Standards of Care plans to an internal ASPR website, encourage their health care coalitions to adopt mass fatality management plans, and develop a recovery plan that addresses post-disaster behavioral and mental health care needs. Awardees must also work with their health care coalitions to develop a strategic plan, create a mechanism to help resolve health care coalition

member conflicts, and demonstrate the ability to: deliver appropriate levels of care to all patients, make at least 20 percent of staffed members' available within four hours of a disaster, monitor patient acuity and staffed bed availability in real-time, off-load and on-load patients, and track and document patient movement.

In July 2011, ASPR, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the National Highway Traffic Safety Administration, and the Federal Emergency Management Agency signed a memorandum of understanding for emergency preparedness grant coordination. The vision of a coordinated Federal emergency preparedness grant program is to promote and improve national resilience. One of the goals of grant coordination is to support emergency management, homeland security, public health preparedness, and medical and emergency medical systems coordination.

Specifically, HPP's medical surge efforts are supported by those of the Centers for Disease Control and Prevention's Public Health Emergency Preparedness (PHEP) program. The PHEP program provides funding to public health departments across the nation to help them better respond to a variety of public health threats. Since 2012, the HPP and PHEP programs have worked together, including through aligning their capabilities, to advance all-hazards preparedness and a national health security strategy. Like HPP, one of PHEP's Public Health Preparedness Capabilities is medical surge. To meet this capability, PHEP awardees must be able to: assess the nature and scope of an incident, support activation of medical surge, support jurisdictional medical surge operations, and support demobilization of medical surge operations. These efforts, conducted through public health departments, support HPP awardees' efforts which focus on regional health care systems.

**Post-Hearing Questions for the Record
Submitted to the Honorable Nicole Lurie, M.D.
From Senator Claire McCaskill**

“Preparedness and Response to Public Health Threats: How Ready Are We?”

November 19, 2014

DHS has produced material threat determinations for 21 different chemical, biological, radiological or nuclear agents. However, as of December 2013, HHS has contracts to procure countermeasures against just 6 of the 21 threats identified as high priorities by DHS.

1) If DHS has determined that these agents are material threats, why hasn't HHS used its authority to procure any countermeasures for most of these?

Response: The Department of Health and Human Services (HHS) has used its authority to procure medical countermeasures (MCMs) against the vast majority of the threats identified in the Material Threat Determination (MTD) and continues to add new products, as evidenced by the accelerated development and purchase of new products for Ebola virus disease. The Department of Homeland Security (DHS) has issued 13 MTDs that are currently active at this time, some covering multiple threat agents. Among those high priority chemical, biological, radiological and nuclear (CBRN) threats, HHS holds MCMs in the Strategic National Stockpile (SNS) against 11 (including anthrax, multi-drug resistant anthrax, botulism, cyanide, tularemia, plague, typhus, nerve agents, radiological and nuclear agents, and smallpox). Acquisitions are currently planned for MCMs to address glanders and melioidosis, and research and development are ongoing to develop MCMs to address the viral hemorrhagic fevers (Ebola and Marburg).

The HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Development Authority (BARDA) has made medical countermeasures (MCMs) available through Project BioShield for all but one threat, viral hemorrhagic fever. Today, BARDA is developing MCMs for Ebola that will address this last threat. The following Material Threat Determinations (MTDs) and Material Threat Assessments (MTAs) have been issued by the Department of Homeland Security (DHS): 6 Chemical threats; 2 Radiological/Nuclear threats; and 12 Biological threats. This information is detailed in the table below:

Agents	MTD Issued	MTA Published
Chemical		
Volatile Nerve Agents	September 2011 (Nerve Agents)	November 2005
Low Volatility Nerve Agents	September 2011 (Nerve Agents)	January 2007
Cyanide Initial Evaluation	N/A	January 2007
Pulmonary Agents	N/A	March 2007
Vesicants	N/A	May 2007
Blood Agents	September 2011 (Cyanide)	July 2007
Radiological / Nuclear		
Radiological Materials	September 2004	July 2005
Nuclear Detonation	September 2004	December 2005
Biological		
Botulinum Toxin	June 2004	August 2004
Plague	September 2006	August 2004
Anthrax	January 2004	April 2005
MDR Anthrax	September 2006	April 2005*
Smallpox	September 2004	February 2012
Tularemia	September 2006	December 2006
Typhus	September 2006	December 2006
Q-fever	N/A	December 2006
Rocky Mountain Spotted Fever	N/A	December 2006
Glanders	September 2006	February 2007
Melioidosis	September 2006	February 2007
Viral Hemorrhagic Fevers - Filovirus	September 2006	December 2006
Ebola Marburg	September 2006	December 2006
Viral Hemorrhagic Fevers - Junin, Arenavirus, Flavivirus, Bunyavirus	September 2006 (Junin) -- Rescinded September 2011	February 2007

*Extrapolated from Anthrax MTA

When Project BioShield was enacted, the CDC and others identified some critical countermeasure gaps against the CDC's own top priority Category A potential biological agents, including plague, tularemia, and viral hemorrhagic fevers like Ebola. Yet no BioShield funding been spent on research and development contracts for countermeasures against tularemia or the plague, and funding for Ebola vaccines began only after the most recent outbreak. Instead, a decision was made to prioritize additional anthrax countermeasures, including some that were quite speculative, even though a vaccine and 3 antibiotics already existed.

- 2) Please explain why additional countermeasures for anthrax were procured over countermeasures for material threats that have not received BioShield funding.

Response: In addition to vaccines, antitoxins, and antibiotics for anthrax, BARDA has procured under Project BioShield from 2005–2013, smallpox vaccines and antiviral drugs, a botulinum antitoxin, several different radionuclide decorporation agents, two different anti-neutropenia cytokines for Acute Radiation Syndrome, and an anti-convulsive drug for treatment of chemical agents (Fig. 1). The purchase of medical countermeasure products is predicated based on their availability, their development maturity for accession under Emergency Usage Authorization (EUA), threat status, manufacturing capacity, and the level of preparedness afforded by the PHEMCE and availability funding. Development and later purchase of anthrax vaccines and antitoxins under Project BioShield received attention in the earlier days of Project BioShield due primarily to the Amerithrax attacks and the availability of product candidates. Since readiness goals for anthrax have largely been met and product candidates emanating from BARDA investments in advanced development of product candidates have been successful, Project BioShield purchases moved to other medical countermeasures and will continue in FYs 2014-2018.

The current PHEMCE requirement for antibiotics for the treatment or post-exposure prophylaxis of tularemia and plague infection is 100 percent fulfilled within the SNS with commercially available generic antibiotics. The SNS has purchased these antibiotics since they are FDA-approved drugs. The fulfillment of this requirement places a Project BioShield acquisition for plague and tularemia as a lower priority relative to threats for which requirements have not yet been met. These antibiotics are recommended by CDC for the treatment of tularemia and plague infected patients. The stockpile contains a sufficient diversity of classes of antibiotics to treat these infections and minimize the impact of antimicrobial resistance.

BARDA's Broad Spectrum Antimicrobial program has invested more than \$260 million since 2010 with six companies for nine antibiotic candidates that may have antimicrobial activity against tularemia, plague, glanders, melioidosis, and other bacterial biothreats. Four of these drug candidates are in pivotal Phase 3 clinical studies to determine their utility against antimicrobial resistant bacteria. Four of the candidates have also demonstrated therapeutic efficacy in animal models of plague and tularemia infection. BARDA started consideration to support development of MCMs for viral hemorrhagic fever virus including Ebola earlier in 2014, when MCM candidates reached advanced development (i.e., completion of pre-clinical studies). BARDA accelerated the development of multiple Ebola vaccine and therapeutic candidates from early development supported previously by NIH and DoD into advanced development as part of the Ebola response.

BARDA has supported the development of better anthrax vaccines with greater and longer lasting immunity, requiring fewer doses to achieve protection in a shorter time span, to provide greater shelf-life for stockpiling, to address cold chain storage issues, and to manufacture more easily and more cost-effectively. BARDA has supported advanced development of both enhanced AVA (inactivated whole *B. anthracis* vaccines) and next generation recombinant protective antigen (rPA) vaccines. Since 2005, BARDA has also addressed the need for anthrax antitoxins to be used when antibiotics are not effective due to drug-resistance and when a life-saving measure is needed when antibiotics no longer work. BARDA has supported the development of six candidates with two acquired under Project BioShield and a third ready for procurement. One of these antitoxins has received FDA approval (2012).

To further provide clarification on BARDA funding, the percentage of both the ARD and Project BioShield budgets dedicated to anthrax MCMs has declined over the past several years in comparison to investment in MCM for other CBRN threats.

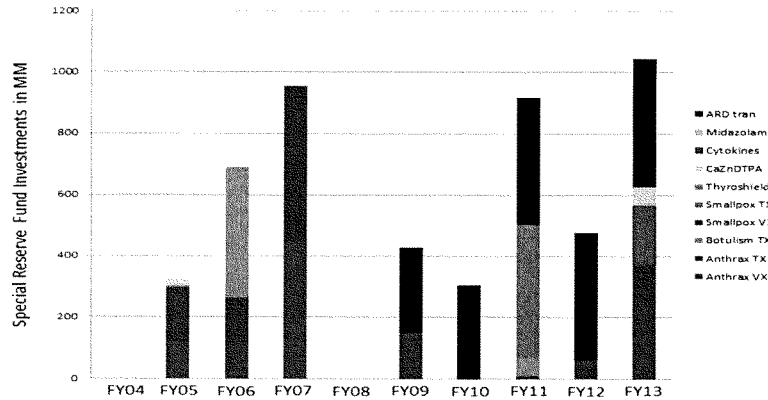


Figure 1. Project BioShield and BARDA Advanced Research and Development program spending from FY20105 – FY2013 on CBRN medical countermeasures.

The Department of Health and Human Services provided the Subcommittee on Financial and Contracting Oversight with documents that detailed the procurements that have been made with Project BioShield funds between 2004 and 2013. There were 18 procurements listed that totaled over \$3.3 billion. The documents provided show that 10 of the 18 were anthrax-related - for a total of over \$1.4 billion or over 43% of the funding spent.

3) Please explain why such a large portion of Project BioShield procurements involve countermeasures for anthrax.

Response: Of the 12 MCM procured under Project BioShield, only three were supporting anthrax preparedness – two anthrax antitoxins and one anthrax vaccine were delivered (Fig. 2) to address the continued threat of anthrax since Amerithrax in 2001. Additional risk-mitigation products, in the form of bulk plasma and cell lines are also included in these anthrax activities, though they are not delivered to the SNS.

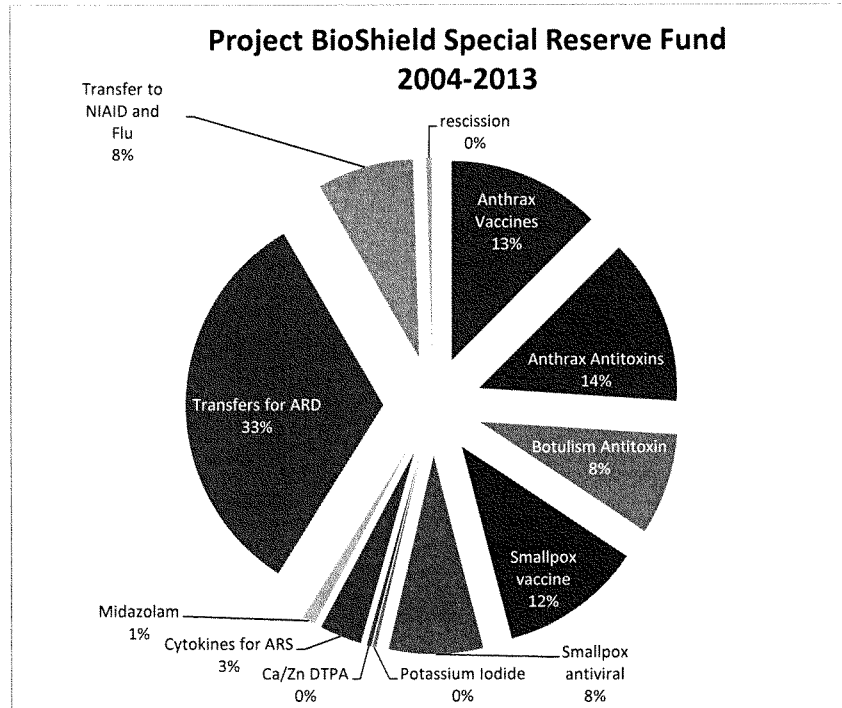


Figure 2. BARDA investments under Project BioShield and the Special Reserve Fund for purchase and development of CBRN MCMs from FY2004 – FY2013.

Response: The PHEMCE, which is comprised of agencies within HHS, DHS, DoD, VA, and USDA and led by HHS/ASPR, has worked with DHS to review processes to make material threat determinations in order for the PHEMCE to set CBRN MCM requirements. The PHEMCE is composed of both HHS agencies (ASPR, CDC, NIH/NIAID, FDA) and interagency partners (DHS, DoD, VA, USDA). DHS has continued to assess anthrax as a significant threat to our country since Amerithrax in 2001. Over the past two years, the PHEMCE has reviewed all CBRN MCM requirements and has carefully reviewed what MCMs are in the SNS; adjustments have been made based on the threat, what we know about the threat scenarios, and the development pipeline and availability of CBRN MCM candidates.

The portion of the funds that were used to develop the candidate products, in addition to procurement, was not captured in your question. Though the anthrax vaccine was commercially available it was not licensed for post-exposure prophylaxis and both anthrax antitoxins needed support for non-clinical, clinical and manufacturing to further develop the products toward

licensure/approval. In addition, both anthrax antitoxins required funding to support non-clinical, clinical, and manufacturing activities to support licensure and approval, funding that was included in the early Project BioShield awards. The large investments in anthrax countermeasures were made to address the most serious threat identified at the time with clear remembrance of Amerithrax in 2001. Even with the large investments, the PHEMCE has been unable to fulfill the requirements for both vaccines and antitoxins for anthrax for all threat scenarios. The only requirement that has been met is for antibiotics and those products did not require any funding for development; they were commercially available and also relatively inexpensive compared to vaccines and biological therapeutics.

Note: As clarification to question 3, the largest percentage of the Project BioShield appropriation actually went to support the ARD budget for BARDA, as Congress transferred funds from FY09-FY13 to directly support the CBRN candidate pipeline.

It is my understanding that when ABthrax was first looked at, it was considered a boutique product the exact use of which was unclear. It was also an additional product beyond the vaccine and 3 antibiotics that already existed to treat anthrax.

- 4) Please explain the decision making process that led to the inclusion of a drug like that in your spending priorities when the CDC has identified so many other capability gaps and we already had anthrax countermeasures?**

Response: As clarification to question 4, ABthrax is Raxibacumab anthrax antitoxin¹ and is the first biothreat antitoxin product approved by FDA under the Animal Rule. It is a therapeutic that potentially could be effective against an antibiotic resistant anthrax infection and when present antibiotic therapy is not working. Because it attacks the anthrax toxin, it has a different mechanism of action from antibiotics and addresses a significant, different aspect of an acute anthrax infection.

The decision making process used by HHS in determining which MCMs to acquire is detailed in answer to question #1 above. The PHEMCE conducted a review of the types of medical products that would be needed to respond to an anthrax attack as part of the medical consequence analysis which is based on the MTA process. The PHEMCE identified vaccines, antimicrobials and other treatments for symptomatic anthrax patients as critical to the overarching needs. The antibiotics that are stored in the SNS (oral ciprofloxacin and doxycycline) are designed to rapidly provide the requisite 60 day treatment course for large-scale post exposure prophylaxis (PEP) to the general population in an affected area. Vaccines have been procured to address those needs for longer-standing prophylaxis of individuals presumed to be at continued risk of exposure, either due to occupational risks, or potentially due to long-term residency in a presumed anthrax contaminated environment. Antitoxins are needed to treat the effects of toxemia induced by the bacillus, since the toxins themselves are not responsive to antibiotic therapy aimed at the whole organism. Intravenous antibiotics are stockpiled to treat severely ill patients after symptoms occur. Oral suspension of antibiotics are purchased for prophylaxis of very young (≤ 2 years) individuals. The diversity of antibiotics held for anthrax is designed to be responsive to the

¹ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm332341.htm>

potential for either engineered antibiotic resistance, or for any naturally-occurring resistance by the anthrax bacillus. It is important to recognize that we are continually looking to improve these products to reduce the overall cost of procurement, storage or use. Changes to the schedule, dose or formulation of the vaccine are all done with the intent to decrease costs through outcomes such as holding fewer doses, or to allow for much more rapid immune responses, or expanded product shelf life.

The PHEMCE anthrax MCM strategy is built on three pillars: antibiotics as the first line of post-exposure prophylaxis, vaccine as an adjunct to provide long term protection, and antitoxins to treat the toxemia in acute infections. As new products become available, and achieve approval or licensure, corresponding refinements to the concepts of use will be developed and implemented. The 2012 licensure of Raxibacumab (ABthrax) is a case in point, with patient care guidelines now reflecting the availability of this critical therapeutic.

The HHS PHEMCE anthrax programmatic priorities include:

- Achieving FDA approval for PEP use of the currently approved vaccine (sBLA submitted October 2014)
- Pursuing dose- and antigen-sparing approaches for the currently approved vaccine
- Reducing vaccine life cycle costs
- Developing next-generation anthrax vaccine candidates
- Providing and maintaining enough vaccine regimens for the SNS to meet the established PHEMCE goal
- Enhancing the sustainability of anthrax vaccines by lowering cost per dose
- Encouraging competition among product sponsors
- Building in redundancy to mitigate risk
- Investing in novel expression and manufacturing platform technologies that are readily transferrable before or after a public health emergency to increase production capacity for anthrax vaccine
- Achieving FDA approval for one or more additional anthrax antitoxins
- Conducting animal model testing to support approval under the Animal Rule for antimicrobials currently approved for other indications to use against inhalation anthrax
- Development of new antimicrobial drugs with activity against drug-resistant anthrax strains and other pathogens cited in the CARB National Action Plan

18 BioShield contracts were finalized in September 2013 totaling over \$517 million, the last month before the original funding authorized by Congress for BioShield was due to expire.

- 5) Please explain the reasons for the last minute procurement of these countermeasures, why five of the eight contracts signed were for anthrax-related, and whether any of the procurements are redundant to countermeasures already available in the strategic national stockpile.**

Response: The MCMs acquired under Project BioShield are completed based on readiness of industry, both to make a proposal to the U.S. Government and state of readiness of the specific product(s). Two of the products procured in September 2013 (filgrastim, or Neupogen® [Amgen], and sargramostim, or Leukine® [sanofi pasteur]) are cytokines that would be used to treat the neutropenia associated with Acute Radiation Syndrome (ARS). These commercially

available products are approved for the treatment of chemotherapy-induced neutropenia and have been viewed as potential candidates for inclusion in the SNS for many years. In fact, the SNS procured a small quantity of filgrastim as a preparedness measure in 2003, although the product was not licensed for the emergency indication. The U.S. Government subsequently tried to procure products for the treatment of neutropenia due to ARS under Project BioShield on two occasions, the first in FY 2006. On each occasion the solicitation that was issued had to be withdrawn because it failed to attract BioShield-eligible products. It was only with the most recent solicitation, and after both shifts within the marketplace and a highly favorable assessment by an FDA Advisory Committee about the use of the products for the emergency indication, that Amgen and sanofi pasteur became interested in partnering with the U.S. Government under the Project BioShield program.

Midazolam, the product procured in September 2013, for the emergency treatment of seizures following nerve agent exposure, had been under development by the National Institutes of Health (NIH) and the Department of Defense (DoD) for many years. However, it is a generic drug and did not have an obvious commercial champion until Meridian Medical Technologies, the maker of autoinjector devices, took an interest in partnering with the U.S. Government. This partnership led to an important clinical study on the pre-hospital treatment of status epilepticus, the Rapid Anticonvulsant Medication Prior to Arrival Trial (RAMPART). According to investigators, the RAMPART study showed comparable safety and efficacy of intramuscular midazolam to intravenous lorazepam, as reported in the article published in the New England Journal of Medicine in February 2012 and named the 2013 Trial of the Year by the Society for Clinical Trials. The RAMPART study cleared the way for the procurement of midazolam autoinjectors for the SNS under Project BioShield, a procurement that was not completed until September 2013. However, midazolam has not been FDA-approved for a seizure indication.

The final awards in FY 2013 replenished the existing quantities of anthrax antitoxins stored in CDC/SNS to maintain the current state of preparedness.

The strategic national stockpile has a limited amount of funding and storage capacity, and we have to replenish the stockpile with all of these countermeasures as their shelf life expires and pay for any new ones.

- 6) Please provide a projection of the funding and storage shortfalls for existing and new potential countermeasures in the stockpile over the next 10 years and what plans are in place to mitigate risk.**

Response: Each year, the PHEMCE goes through a review and prioritization of the SNS formulary and budget. Strategic decisions are made by PHEMCE partners on how the SNS budget should be invested for the out-years. The most recent SNS annual review, completed in 2013, impacts the formulary and prioritization for the FY2016 SNS budget. All PHEMCE partners participate in the review and it is based on the multiyear budget process for primarily BARDA and the SNS based on potential procurements. In addition, BARDA and CDC are looking for the potential of multiuse products such as cytokines for which there is a commercial market for these products. If the products already have a commercial market, they can be managed under vendor managed inventory (VMI). Under VMI, the products are maintained by the manufacturer and rotated through their commercial stocks. Thus, VMI allows the PHEMCE

access to unexpired, stockpiled product for immediate distribution in the event of an incident. The use of VMI reduces the substantial life-cycle management costs associated with storage and replenishment. This is not an option for all products but, when feasible, BARDA and CDC pursue this option. Examples held under this type of inventory management include products for sub-syndromes of acute radiation exposure, broad spectrum antimicrobials, and products to address burns.

The government's ongoing investment in the Strategic National Stockpile (SNS) generated a guaranteed supply of critical medical countermeasures (MCMs) held in a network of secure storage sites located strategically for rapid delivery throughout the United States. In addition to rare countermeasures for which there is no commercial demand, the SNS also holds many commercially available MCMs that are not available in the marketplace in sufficient quantities or are prepositioned throughout the country (e.g., products in Chempacks) because they cannot be delivered with the necessary speed for a large scale emergency. Because of the capacity provided by the SNS for certain products, CDC is currently engaging with commercial partners to explore ways the SNS can provide rapid, short-term support to the commercial market during shortages for certain products, such as the spot shortages associated with antiviral drugs for influenza or the specific personal protective equipment items required for care of patients with Ebola virus disease.

The MCM assets held in the SNS are currently valued at more than \$6.3 billion dollars, and the cost of sustaining this inventory from year to year fluctuates, based on a series of cost drivers. The primary costs each year include the types and quantities of MCMs expiring, the current pricing and availability of required MCMs, the ability to extend the shelf life of existing MCMs through FDA testing, and existing gaps and requirements for new MCMs to be purchased.

To account for these variables and create accurate projections of costs for current and future fiscal years, CDC maintains and updates sophisticated models of SNS costs based on all available data and current inventory information. These models generate detailed projections of SNS costs to support multiple discrete scenarios for the current fiscal year as well as the next five fiscal years. This modeling informs SNS procurement strategy at CDC, as well as supporting decision making through detailed analysis and long term cost projections for proposed changes to SNS holdings. Additionally, BARDA's annual portfolio review factors life cycle management costs into each product's overall worth as an asset and provides a long-term estimate (5-10 yrs.) of product candidates that will move from BARDA's Advanced Development CBRN MCM programs to Project BioShield. This is based on product maturity and accession under EUA. Transition from Project BioShield to CDC/SNS for purchase is based on FDA approval status.

To ensure SNS costs and requirements are incorporated into the government's MCM investment strategy, CDC participates in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). In addition to the scientific and subject matter expertise that CDC contributes to PHEMCE deliberations of MCM requirements and strategies, the agency also contributes detailed five-year SNS cost projections for incorporation into the PHEMCE Multi Year Budget. Where the ongoing work of the PHEMCE governance process establishes, evaluates, and validates the MCM requirements for future investment by NIH, BARDA, FDA,

and CDC, the Multi Year Budget is designed to clearly identify the costs for each participating agency to implement those requirements.

The PHEMCE governance process provides annual guidance to CDC on the prioritization of MCM procurement to ensure SNS capabilities are aligned to minimize risk to U.S. populations through the stockpiling of MCMs to protect individuals and communities from the most likely threats that they face. For fiscal years in which projected appropriations indicate a shortfall to sustain all existing SNS capabilities, PHEMCE provides specific guidance to reduce costs through calculated reductions in procurement of specific products. These recommendations are aligned to the fiscal year three years removed from the year of the review, and are reported in the SNS Annual Review Report. The most recent report completed was the 2013 SNS Annual Review Report, which provided guidance for SNS procurement in FY 2016 and was finalized and submitted in August 2014.

The Department of Health and Human Services is preparing a report on the PHEMCE Multi Year Budget Report to Congress and the current indications based on PHEMCE work on this activity. When it is finalized and submitted, this report will show the projected requirements and anticipated shortfalls for each participant in the PHEMCE governance process, including the SNS.

7) Have any plans been made to end certain procurements or prioritize others? If so, please list any countermeasures that will not be replenished once they expire.

Response: During the SNS Annual Review process, PHEMCE subject matter experts and leadership use the criteria described in the 2012 PHEMCE Strategy and Implementation Plan (PHEMCE SIP) to provide policy recommendations to CDC that will improve responsiveness and provide cost considerations for the SNS formulary. Some of those policy recommendations included reductions or replacements of holdings based upon updated information or policy. These include:

- Reduce holdings of the oral suspension formulations of antibiotics (ciprofloxacin and doxycycline) stockpiled for post-exposure prophylaxis of anthrax for pediatric populations to align with updated recommendations from the American Academy of Pediatrics and subject matter experts on the PHEMCE Pediatric/Obstetric Integrated Program Team regarding use of these suspension formulations in only the youngest children. Older children's needs would be covered through crushing and mixing oral solid dosage formulations of these antibiotics.
- Reduce holdings of intravenous formulations of levofloxacin to levels needed for treatment of anthrax patients and individuals with febrile neutropenia; this countermeasure is no longer stockpiled for other bacterial threats (plague or tularemia).
- Replace diazepam with midazolam as an improved anticonvulsant for treatment of patients following nerve agent exposure.

- Replace Mark 1 Kits with DuoDotes® for treatment of patients following nerve agent exposure; Mark 1 Kits are no longer being manufactured.
- Allow expiry of rimantadine tablets to be replaced with an improved influenza antiviral drug.
- Reduce holdings of inhalational zanamivir to match adjusted acquisition targets for influenza antiviral drugs.
- Reduce holdings of intravenous formulations of gentamicin for bacterial threats until an assessment of effectiveness can be completed.
- Allow expiry of amphotericin B for treatment of fungal infections in patients following a nuclear event; replacement products will be recommended in a future SNS Annual Review.
- Replace silvadene cream from the Burn & Blast kits with silver-impregnated dressings and tubular dressing retainers for improved patient care following a nuclear event.

PHEMCE leaders recommended reductions in the holdings for anthrax vaccine adsorbed (AVA) and oral solid dosage PEP formulations of antibiotics (ciprofloxacin and doxycycline) to meet the projected budget appropriations. These deliberations considered how to achieve the greatest level of all-hazard capability across our identified spectrum of threats. PHEMCE recommended the reductions that would make the most minimal impact possible. However, if similar budgetary constraints are applied in future years, MCM preparedness will be affected for a greater number of high-priority threats currently addressed by SNS holdings.

In 2011, the most recent data the CDC has available, there were over 1,500 deaths from the flu. CDC estimated that same year that there were 47.8 million illnesses from foodborne agents and over 3,000 deaths. We've had 1 anthrax attack in the U.S. 10,000 people were considered at risk of possible exposure. 22 people got sick. 5 of them died.

- 8) As a medical expert, how do you feel about our spending priorities on pandemic flu preparedness, food safety and bioterrorist threats? Do the levels of funding currently allocated for a terrorist biological attack to a natural biological threat accurately reflect the probabilities of each threat? Please also detail whether the current funding levels allocated to each type of threat is appropriate and where funding could be re-allocated based on risk.**

Response: It is certainly difficult to predict the type, frequency or probability of the multiple types of naturally-occurring and intentional threats to our national security, however there are certain basic elements that cut across the various challenges identified in the question. We have approached this uncertainty in two specific ways. First, we have pivoted our focus to those capabilities that are needed in response to any type of threat requiring medical-countermeasure response. This orientation begins to change how we organize and coordinate for key functions of developing, procuring and using MCMs. To the extent that specific products are already in the

commercial market, and appropriations are available for procurement of products for the SNS, or through a vendor-managed inventory structure, we have items at the ready across the slate of those types of threats. Pandemic flu preparedness and food safety fall to a large degree within that environment. For those conditions for which a MCM is not commercially available, building a network of connected capabilities to readily perform studies, quickly make a product in agile manufacturing, test and fill the product using clinical trials networks and dedicated fill and finish facilities, and work with commercial industries for scale up and distribution is the key to future, emerging threats. Secondly, developing a risk-based assessment method to deeply analyze the assumptions and current intelligence information as it applies to relative likelihood of certain scenarios or impacts is very useful for helping to adjust our current formularies. As information about the threats we face and the risks posed by them changes we update our acquisition strategies and priorities as needed.

In 2010, after our experience with H1N1, ASPR conducted an end-to-end review of the medical countermeasure enterprise with a vision that our Nation must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized, naturally occurring emerging infectious disease. ASPR accomplished this in concert with our colleagues at DHS, DoD, and the U.S. Department of Agriculture (USDA), as well as all of the HHS components, and has now procured 12 MCMs that are now in the SNS. When BioShield was enacted and BARDA formed, there were few MCMs in the pipeline. There are now about 90 chemical, biologic, radiologic, nuclear products in the MCM pipeline, and another huge host for pandemic flu.

As the chair of the PHEMCE, ASPR has worked with DHS to review processes to make material threat determinations and to set MCM requirements. There is now a strategy and implementation plan that identifies PHEMCE investments for the next five years. Upon reviewing these investments, the PHEMCE made readjusting so that we were able to more fully cover threat areas, including viral hemorrhagic fevers. In addition, the PHEMCE is moving away from *one bug, one drug*, toward the development of platform technologies that are nimble and flexible, so that when we are confronted with a new disease like Ebola, we can make either vaccines or other countermeasures much more quickly. There are flexible platforms in use now in the development of the Ebola therapeutic.

As recently as 1999, the Defense Department was buying an anthrax vaccine for \$2.26 per dose. In 2005, HHS awarded a contract to procure anthrax vaccines for \$24.50 per dose.

9) What accounts for the sharp price increase?

Response: The actual price that DoD paid per dose of anthrax vaccine in 1999 was \$10.36. The manufacturer could not deliver product at the lower price and DoD ultimately renegotiated the contract, agreeing to pay a higher amount per dose and reducing the total number of doses to be delivered. The renegotiated contract also required product with a two year expiry, up from the original one year expiry.

In 2005, CDC awarded a contract for procurement of vaccine at \$24 per dose that was transitioned to BARDA. In 2007, BARDA renegotiated the procurement and started procuring the anthrax vaccine for \$17.32 for 2 year expiry. This increase in costs from 1999 to 2005 (from

\$10.36 to \$17.32) is based on increased manufacturing costs due to inflation and research conducted by BARDA. Prior to initiation of any procurement solicitation, BARDA performs an Independent Government Cost Estimate (IGCE) that becomes part of the acquisition strategy and plan. The IGCE uses commercial information on the costs of similar products to determine what fair and reasonable costs would be. Anthrax immunoglobulin (AIG) is a human derived plasma anthrax polyclonal antitoxin. Human derived products are more expensive than monoclonal products derived from traditional manufacturing from cell lines. One example is the human derived product BabyBIG that is an antitoxin against botulism toxins A and B with a dose price in excess of \$45,000. Additionally, HHS undertook studies to discern whether the antigen- and/or dose-sparing of the existing BioThrax anthrax vaccine stockpile may be afforded in an emergency. Results from these animal challenge and human immunogenicity studies indicated that two doses rather than the current three doses of BioThrax vaccine or three doses at half the normal antigen dosage may provide sufficient immunoprotection. Thus, the available anthrax vaccine stockpile may be expanded and the cost per dose is reduced further without purchasing more anthrax vaccine.

Finally, BARDA's renegotiated contract also stipulated that up to \$23.33 would be paid per dose for product with a four year expiry. BARDA and the PHEMCE are willing to pay a premium for pharmaceuticals with a greater expiry to decrease the Federal government's overall life-cycle management costs associated with replenishment.

HHS also spent \$8,200 per dose on one anthrax treatment drug, and \$3,100 per dose on another.

10) How does HHS know whether it is getting a good price for these countermeasures?

Response: The contracts awarded for the procurement of MCMs are negotiated. BARDA provides, as required by the Federal Acquisition Regulation, the Acquisition Strategy and specifically part of the Acquisition Plan, the IGCE. The IGCE is developed using historical as well as current market costs for similar products such as commercial antibodies used for other diseases like cancer, respiratory syncytial viral diseases, and arthritis as well as antivirals used to treat influenza and herpes. The results of these comparisons showed that the U.S. Government received a fair market price for these types of antibody products. The U.S. Government negotiation position is determined by the pricing data contained in the IGCE.

11) How do you determine what is a reasonable cost of countermeasures since there is no mass market for these countermeasures?

Response: We determine reasonable costs by a cost realism analysis. The costs are determined to be realistic for the work to be performed and reflect the clear understanding of our requirements and are consistent with the elements of the offering party's technical proposal.

12) Has there been any discussion to encouraging the public to get vaccinated?

Response: CDC has communication messages ready if the decision is made to offer vaccine to the public during an anthrax emergency. CDC has developed and tested materials about

receiving anthrax vaccine during an event that provides detailed information about the vaccine. These communications are based on vaccine prioritization guidance and depend on how many areas are affected, how many people are potentially exposed, how many people in the first tier will need the vaccine, and how much vaccine is available.

CDC released updated clinical recommendations for anthrax in adults, pregnant and postpartum women, and children in 2014. These articles describe in detail recommendations for preventing anthrax, evaluating patients, and treating patients with anthrax:

- Centers for Disease Control and Prevention Expert Panel Meetings on Prevention and Treatment of Anthrax in Adults (http://wwwnc.cdc.gov/eid/article/20/2/13-0687_intro.htm)
- Special Considerations for Treatment of Anthrax in Pregnant and Postpartum Women (http://wwwnc.cdc.gov/eid/article/20/2/13-0611_intro.htm)
- Pediatric Anthrax Clinical Management: Executive Summary (<http://pediatrics.aappublications.org/content/early/2014/04/22/peds.2014-0564>)
- Clinical Report: Pediatric Anthrax Clinical Management (<http://pediatrics.aappublications.org/content/early/2014/04/22/peds.2014-0563>)

We don't have unlimited funds to procure medical countermeasures, so every dollar spent on one countermeasure is a dollar less you can spend on another priority.

13) At what points in the overall process, from risk assessments to procurement of countermeasures, are costs taken into consideration?

Response: Costs are best considered after development of the stockpiling goals, at the time of setting specific acquisition targets for procurement by either BARDA (using the SRF) or by CDC (using annual SNS appropriations). However, BARDA does factor product costs into investment decisions about advanced development of MCM candidates based on overall life cycle management costs. While it is always preferable to try to minimize costs of procurements, this must be balanced against the safety, efficacy (effectiveness) and "end-user" operational needs of the product(s) being acquired. Ideally, we would want to purchase products that are inexpensive, easy to use, and highly effective, but this optimum is not always available. The characteristics for individual products are laid out in documents called "Product Specific Requirements" and specific levels of performance are defined in Target Product Profile, which lay out an "acceptable" and a "preferred" level of performance. Cost is factored in to the extent that if we can identify a solution that achieves these performance characteristics, and is affordable based on estimated appropriations and portfolio management considerations.

The stockpiling goals are based on MCM need, as estimated through risk assessment and public health consequence modeling, and the amount of MCMs that can be effectively utilized in a public health emergency (i.e. the operational quantity). Costs and resource availability, as well as scientific opportunity, are then factored in during the prioritization processes that result in the ultimate acquisition targets.

14) Is any type of cost-benefit analysis conducted for each procurement? If so, what agency or subcomponent conducts that assessment and what are the costs and benefits that are weighed?

Response: The need to maximize preparedness within existing budgetary constraints has been recognized for many years and the PHEMCE has taken a number of steps to reduce costs. This is done by leveraging our investments in multiuse products, extending the shelf life of products that must be stockpiled, exploiting vendor managed inventory arrangements when feasible, and reassessing threat prioritization and legacy requirements.

PHEMCE partners conduct cost-benefit analyses of MCM procurements to maximize preparedness. Beginning with the PHEMCE Implementation Plan for CBRN Threats in 2007 and as reiterated in the 2012 PHEMCE SIP, the PHEMCE has emphasized the value of broad spectrum or multiuse products and platform approaches in managing overall costs. Objective 1.3 of the 2012 SIP charges the component agencies of the PHEMCE with “[ensuring] a robust and sustainable product pipeline for MCMs that emphasizes multi-functional capabilities rather than stand-alone outcomes (e.g., platform technologies, host-based innovations, broad-spectrum MCMs) and includes consideration of viable commercial markets and/or routine public health applicability.” The SNS Annual Review process has allowed for continual improvements and rebalancing of the SNS formulary. CDC and NIH have each taken steps, which they can address, to optimize our current investment portfolio with an eye towards life cycle cost management.

For its part, BARDA has taken a number of steps to improve its internal processes for evaluating the costs and benefits of specific programs and specific procurements within a larger strategic framework. In recent years, for programs supporting the development of Broad Spectrum Antimicrobials, Radiological and Nuclear MCMs, and Thermal Burn Treatments, BARDA has emphasized investing in products with potential commercial viability. The FY2013 procurement of filgrastim and sargramostim for the SNS was the first under Project BioShield to exploit Vendor Managed Inventory as a measure to control the life cycle costs of preparedness over the long term. In addition, BARDA undertakes an annual portfolio review to assess its current investments. Specifically, BARDA assesses the projected total life cycle costs of each project and includes multi-functionality as one of five value criteria. Cost management is also emphasized in periodic Integrated Project Reviews to the point where each funded countermeasure is subjected to critical milestone decision points.

These contractors have absolutely no downside risk at all. If the drug does not pan out, it is federal research and development money down the drain. If it does, the companies make the government pay for the countermeasures and pocket the profits.

15) If the federal government is paying for the research and development, and we are the only customer, why aren't we keeping the intellectual property?

Response: For patentable inventions that result from the development of MCMs supported by the U.S. Government, non-exclusive licensing rights paid up in perpetuity are granted to the Federal Government and are transferrable to third-parties. These rights have been used as needed. For example in 2009 and 2013, reverse genetics technology for vaccine development

and manufacturing was utilized for the production of H1N1 and H7N9 vaccines, respectively. NIH and BARDA supported projects where these patentable inventions developed and became available for the U.S. Government as needed in 2009 and 2013.

16) Have you done a cost-benefit analysis on whether we should bring this work in-house?

Response: Yes. The U.S. Government commissioned several analyses, conducted between 1998-2010, which recommended the establishment of facilities operated by the pharmaceutical industry rather than the government. The recommendations highlighted the pharmaceutical industry's rapid and nimble capabilities to develop and manufacture vaccines and biological products (e.g., monoclonal antibodies) in response to public health emergencies. This resulted in BARDA establishing three HHS Centers for Innovation for Advanced Development and Manufacturing (CIADM) as public-private partnerships with industry and academia (i.e., Novartis, Emergent, and Texas A&M University System). Additionally, DoD is establishing a smaller version of these Centers in coordination with HHS. The HHS CIADMs played a major role in the development, manufacturing, testing, and stockpiling of vaccine to address the potential pandemic threat with H7N9 virus outbreaks in China in 2013 and the Ebola epidemic this year.

DHS issued a material threat determination for Ebola, which allows HHS to spend BioShield funding on research, development and procurement of Ebola countermeasures, including a vaccine.

17) What was the rationale for not using BioShield money on a deadly virus that was known to exist and of which there had been previous outbreaks?

Response: In 2014, Ebola MCM candidates were not sufficiently mature to be considered for acquisition under Project BioShield or accessible under EUA at that time. By FY2016, BARDA expects several Ebola vaccine candidates to be developed sufficiently for acquisition under Project BioShield, provided that they meet all of the product specific requirements (i.e., multivalency for Ebola and Marburg viruses, long expiry dating, and storage at 2-8 degrees C).

The administration has requested \$6.18 billion in supplemental funding to implement a comprehensive strategy to contain and end the Ebola outbreak. The request includes resources for testing and development of new vaccines, therapeutics, and diagnostics.

18) Why is supplemental funding necessary for these efforts when BioShield funding has already been authorized for the same exact purpose?

Response: The Ebola outbreak in West Africa occurred quickly and with devastating effect. The portfolio of medical countermeasures (MCMs) against the Ebola virus was relatively immature (i.e., pre-clinical stage of early development) as compared to the pipelines for anthrax or smallpox. Due to the outbreak, the relative priority of MCMs for the Ebola virus was raised. This necessitated a shift of funding from other portfolios and additional funding from Congress via the Ebola Emergency Funding Request. Therefore, BARDA transitioned many Ebola vaccine and therapeutic candidates much earlier than normal and provided extensive technical,

regulatory, and clinical assistance using BARDA's core service assistance programs (i.e., BARDA's national MCM response infrastructure) to move them forward.

Project BioShield is authorized to provide funding for the procurement of MCMs that have reached a mature stage of development. In the fall of 2014, Ebola MCM candidates were not sufficiently mature for the consideration of being acquired under Project BioShield. In fact, none of the vaccines or therapeutics currently invested in by HHS has been tested in humans in clinical trials. Additional funding was needed to rapidly accelerate production of these promising MCMs, optimize manufacturing at commercial scale, and to conduct Phase I clinical trials—activities not funded by Project BioShield.

The funding provided by Congress to BARDA for action during FY 2015 will support Advanced Research and Development of promising Ebola vaccine and therapeutic candidates supported previously during early development by NIH's National Institute of Allergy and Infectious Diseases and DoD's Defense Threat Reduction Agency. By FY 2016, BARDA expects that several Ebola vaccine candidates will be developed sufficiently for acquisition under Project BioShield provided that they meet all of the established requirements (*i.e.*, efficacy against multiple strains of Ebola and Marburg viruses, sufficient shelf-life, and storage at 2-8°C).

19) How does the funding of Ebola research and countermeasure development by the National Institute of Allergy and Infectious Diseases and the Department of Defense factor into the plan for countermeasure development by BARDA and the use of Project BioShield funds?

Response: BARDA exists to address the medical consequences of these threats and to bridge the gap between early research and development to advanced development and eventual FDA approval and procurement of MCMs for novel threats by supporting the ARD of MCM candidates. ARD includes critical steps needed to transition a candidate into a product that is ready to use. These steps include optimizing and validating manufacturing processes such that products can be made at commercial scale; optimizing product formulation for optimum field usage, storage, and product longevity and effectiveness; 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 required for approval of products developed under the animal Rule. Since 2006, BARDA has funded and successfully managed the advanced development of more than 160 MCMs for CBRN threats and pandemic influenza. Eight of these products have received FDA approval in the last two years alone and twelve of these products have been made available for use under Project BioShield.

Over the last decade, the PHEMCE has supported basic research and early stage development of numerous Ebola and Marburg virus MCM candidates. BARDA is now coordinating, providing funding, and offering technical assistance for the development and scaled-up manufacturing of the ZMapp monoclonal antibody therapeutic and several Ebola vaccine candidates that NIH/NIAID and DoD/DTRA supported through early development. BARDA aims to ensure that these MCM candidates are available for clinical evaluation for safety and efficacy as soon as possible and that these products can be manufactured reproducibly and robustly at commercial scale in a controlled manner to produce large enough quantities for use in a meaningful public

health response. Ultimately, we strive with our partners to have these MCMs approved by FDA as soon as it is feasible, as warranted by the results of these clinical evaluations.

Specifically, BARDA, along with its PHEMCE partners, uses public-private partnerships with industry to ensure that we have the MCMs to protect the national health security of the United States in emergencies. 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 MCMs. For example, in 2013 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, BARDA is working with a wide array of partners that include other countries, specifically affected and at-risk African countries; the World Health Organization; the Bill and Melinda Gates Foundation; and others. These expanded partnerships are critical to our efforts to address the current Ebola epidemic.

The Department of Defense (DOD) sits on the Public Health Emergency Countermeasures Enterprise (PHEMCE).

20) How, if at all, does this affect coordination of research between DOD and HHS?

Response: Through the PHEMCE, DoD and HHS coordinate their research in multiple ways to promote synergy, minimize redundancy, and, to the extent feasible, harmonize MCM development efforts. Specific examples are provided below.

PHEMCE collaboration

HHS put in place the PHEMCE to serve as a framework to support coordination and collaborative decision-making, when appropriate, of MCM efforts across Federal departments. Under the auspices of the PHEMCE, DoD and HHS collaborate and share information on research, advanced research, development, procurement, stockpiling and management, and distribution of MCMs. DoD and HHS both have voting membership within the PHEMCE at multiple levels, including at the subject matter expert level (e.g., Integrated Product Teams (IPT), Requirements Working Group, and Project Coordination Teams); program manager level at the Enterprise Executive Committee (EEC); and senior leadership level on the Enterprise Senior Council (ESC). Additionally, DoD participates in all In-Process Reviews conducted for BARDA programs and in the PHEMCE-wide portfolio reviews led by ASPR. BARDA program managers participate in a number of DoD Integrated Product Teams, specifically including those associated with chemical and radiological/nuclear MCMs. Additional senior level individuals participate in DoD's Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) Joint Life Cycle Management Reviews, and in various In-Process Reviews (for all DoD MCM programs), as well as on the DoD Overarching Integrated Product Team.

BARDA Centers for Innovation in Advanced Development and Manufacturing (CIADMs) and DoD MCM Advanced Development and Manufacturing Capabilities (ADMC)

Each organization has visibility regarding the other's program in establishing their respective Centers and the ADCMC. These are high-value, public-private ventures established with pharmaceutical leaders to assist in advanced development and surge capacity for MCMs addressing both intentional CBRN threats, pandemic influenza (CIADMs only), and outbreaks

of naturally occurring emerging and genetically engineered infectious diseases. The HHS Centers and DoD ADMC each have unique capabilities that can potentially be used to accommodate the needs of the other program. Coordination has been established to maximize this potential.

Integration of resources between DoD and HHS

Beyond information sharing, DoD and HHS also coordinate on the research, development, and procurement of safe and effective MCMs of mutual interest. For example, DoD and HHS/CDC collaborate closely on the acquisition and management of MCMs for anthrax and smallpox. There are Interagency Agreements and a Memorandum of Agreement between CDC's SNS and DoD to purchase, store, and distribute anthrax and smallpox vaccines. Additionally, HHS (BARDA) and DoD collaborate on the acquisition and management of pre-pandemic influenza vaccines. Development of the smallpox antiviral drug ST-246, currently in the SNS, was also supported by both DoD and HHS (BARDA and NIH) and treatment courses of this drug have already been provided to DoD for use under an Investigational New Drug Application. HHS and DoD are jointly supporting development of MCMs against chemical threats and to address gastrointestinal injury associated with ARS. Finally, HHS and DoD have technology transfer agreements and an MOU on contingency for medical materiel requirements in place and are currently working on developing an MOU for co-development of antimicrobials to address shared MCM needs.

PHEMCE Integrated Portfolio for CBRN MCMs

This program was established within the PHEMCE in 2008 to provide a framework for collaboration among the MCM-related program components of HHS and DoD. The Portfolio Advisory Committee (PAC), co-chaired by DoD and HHS, comprises program representatives from the various organizations responsible for the CBRN MCM programs within each department. Through the PAC, the EEC, and the ESC, DoD and HHS coordinate their efforts to promote synergy, minimize redundancy, and, to the extent feasible, harmonize requirements for MCM development. A significant example of collaboration is the development of the Portfolio Tracking Tool, which was developed jointly by HHS and DoD to capture contract performance information for all CBRN MCM development efforts across HHS and DoD. Both organizations have currently populated the data set with all contracts related to work at or above Technology Readiness Level 4, and the full, web-based tool was rolled out in 2014.

21) Does DOD share specifics with HHS on their research and development plans?

Response: Yes, the PHEMCE is the mechanism for sharing information between HHS and DoD, among other partners. The PHEMCE coordinates Federal efforts to enhance chemical, biological, radiological and nuclear threats and emerging infectious diseases preparedness from a MCM perspective. The PHEMCE is led by ASPR and includes three primary HHS internal Agency partners: CDC, FDA and NIH, as well as several interagency partners: DoD, the U.S. Department of Veterans Affairs (VA), DHS, and the U.S. Department of Agriculture (USDA).

22) How certain are you that none of HHS's work on biodefense duplicates DOD's research?

Response: Quite confident, as both agencies participate in formal PHEMCE Portfolio reviews led by the ASPR, along with PAC reviews of HHS and DoD CBRN MCM portfolios. Additionally, select DoD staff members participate in PHEMCE IPTs and serve as reviewers on technical proposals for contracts and grants that support CBRN MCM R&D. HHS participates routinely on DoD MCM development technical evaluation panels and reviews. Senior leaders from each agency sit on each other's strategic and advisory boards.

I understand that there are several advisory committees that are involved in the Material Threat Assessment and Material Threat Determination process that include non-governmental experts.

- 23) What role do these advisory committees play?**
- 24) Is anyone on any of these committees associated with any of the companies that are conducting research and development for possible countermeasures against the threats DHS and HHS identify?**
- 25) If there are representatives from companies that are contracting with the federal government to do research and development of countermeasures, what controls are in place to identify conflicts of interest?**
- 26) Has the risk assessment process ever been audited by an outside group to see if DHS is identifying real risks and utilizing a sound methodology?**
- 27) Material threat determinations and BioShield procurements are based on "plausible, high consequence events." How do you define "plausible"?**
- 28) What does "high consequence" mean? Is there a specific number of possible deaths or illnesses that would trigger a procurement?**

Response to #s 23-28: We defer to DHS on matters pertaining to its Material Threat Assessment and Material Threat Determination processes.

- 29) What are the factors that determine the quantity of countermeasures to be purchased for the strategic national stockpile?**

Response: The overall process of determining which MCMs will be acquired by HHS is discussed in detail in previous responses above. HHS decisions regarding which MCMs to acquire for the SNS are based on: (1) MCM stockpiling goals vetted through the interagency PHEMCE; (2) the PHEMCE Prioritization Framework laid out in the 2012 PHEMCE SIP; (3) market factors; and (4) resource availability. Stockpiling goals are based on MCM need, as estimated through risk assessment and public health consequence modeling, and the amount of MCMs that can be effectively utilized in a public health emergency.

MTAs are the foundation for the DHS issuance of MTDs. In the past, when MTAs showed that population exposures to a CBRN agent reached a prescribed threshold, the Under Secretary of DHS Science and Technology Directorate (DHS S&T), in coordination with the Offices of Health Affairs, Infrastructure Protection, Intelligence & Analysis, and Policy, recommended that the DHS Secretary consider issuing a MTD, meaning that the agent was deemed a "material threat against the United States population sufficient to affect national security." Concurrently, HHS assessed public health and medical consequences to understand if a significant number of human casualties and fatalities would result from the MTA scenario(s).

As the chair of the PHEMCE, ASPR has worked with Federal partners to review processes to make material threat determinations and to set MCM requirements. A Strategic Implementation Plan (SIP) was formalized in 2012 as a robust collaborative relationship among DHS, HHS, and other Federal partners in the PHEMCE to conduct MTAs. The SIP outlines the roles, responsibilities, policies, and procedures for conducting MTAs, and documents the advancement of collaborative efforts between DHS, HHS, and other Federal partners in this effort. MTAs will inform the issuance of MTDs by DHS and the assessment of public health and medical consequences by HHS. MTAs also support activities of many other stakeholders across the national health security and civilian defense workforce of the Federal Government. This process will enable a detailed understanding of the effects of an attack with various CBRN agents and help enable risk-informed decision making. Future MTA development will result from better decisions by both DHS and HHS decision- and policy-makers by clarifying scientific gaps that warrant experimental resolution and with a sophisticated awareness about agents that present a sufficient material threat to national security. This includes improved PHEMCE MCM requirements and better informed threat-characterization and emergency response efforts. A combination of MTD issuance and the assessment of public health and medical consequences inform what MCMs are necessary and appropriate for acquisition by HHS with the Project BioShield Special Reserve Fund (SRF).

The MTAs are used as the basis for the PHEMCE requirement setting process, which includes Scenario Based Analysis and Product Specific Requirements documentation.

We had an anthrax attack in this country in which as many as 10,000 people were deemed to have been at risk for exposure, 31 tested positive for exposure, 22 had confirmed anthrax infections and 5 people died.

30) Did this real world event lead to any changes in HHS's consequence modeling?

Response: Yes. The HHS medical and public health consequence modeling program in BARDA did not exist prior to the 2001 anthrax attack. The Project BioShield Act created the requirement for DHS and HHS to work together to create MTAs and MCAs. Through continued coordination, HHS and DHS have developed a Strategic and Implementation Plan to conduct second generation MTAs and are currently updating and improving these assessments.

**Post-Hearing Questions for the Record
Submitted to the Honorable Nicole Lurie, M.D.
From Senator Heidi Heitkamp**

“Preparedness and Response to Public Health Threats”

November 19, 2014

As you point out in your testimony, the domestic Ebola cases brought our nationwide preparedness and response system to the forefront and I believe highlighted its strengths as well as some weaknesses.

- **What lessons from the ASPR and, specifically, the Hospital Preparedness Program’s response to the domestic Ebola outbreak will you incorporate into future decision making?**

Response: The Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program (HPP) focuses on regional level preparedness and response instead of at the individual hospital level so health care systems can be more efficient and effective during emergencies. Two clear lessons emerged from the United States’ response to the Ebola outbreak: the importance of health care coalitions (HCCs) and the importance of adequate and sustained preparedness funding. HCCs are formal collaborations among health care organizations and public and private partners that are organized to prepare for, respond to, and recover from emergencies that impact the public’s health. HCCs support a regional, rather than facility-by-facility, approach to link health care, public health, and other community partners, which allows for a comprehensive and coordinated preparedness and response effort. Nationwide, HCC membership is growing rapidly; between 2013 and 2014, there was a 47-percent increase in membership. However, not all health care facilities are currently members of HCCs. HPP and the states, territories, and municipalities it funds are continuously working to increase and diversify HCC membership.

As referenced in the HHS Office of the Inspector General’s recent report, *Hospital Emergency Preparedness and Response during Superstorm Sandy*, strong regional coordination through HCCs can mitigate challenges associated with scarce supplies and resources during an outbreak or other public health event. For example, if a regional health care system has extra PPE available in some of its facilities, this equipment can be dispersed to local health care providers who need it.

The second lesson learned from the Ebola outbreak is the importance of adequate and sustained funding to support health care system preparedness. HPP’s preparedness and response strategy revolves around ensuring that HPP awardees can meet eight national health care preparedness capabilities. These capabilities provide an all-hazards approach and include: health care system preparedness, health care system recovery, emergency operations coordination, fatality management, information sharing, medical surge, responder safety and health, and volunteer management. Health care system preparedness, emergency operations coordination, and health care system recovery address the planning and preparation that must be done at every stage of an

incident (preparedness, response, recovery, and mitigation). Fatality management and medical surge are focused on rapid health care coordination, the ability to scale up operations, and resource allocation during an emergency. Information sharing highlights the need for the health care system to share information during an emergency with both system members and the public. Responder safety and health identifies and procures resources needed to protect health care workers. Volunteer management is the ability to coordinate and utilize volunteers to augment incident operations.

Research and history show that if HPP awardees can strengthen their regional health care preparedness capabilities, they will be ready to respond to any given disaster or public health event. It is vital that health care systems maintain a baseline level of preparedness on all capabilities, so that whatever the event – be it Ebola, a terrorist attack, or natural disaster – the regional system can respond quickly and effectively to save lives.

HPP awardees originally targeted all eight health care preparedness capabilities. Because HPP's approach is flexible and allows awardees to tailor preparedness funding to their priorities, many awardees have since prioritized their efforts by focusing on five of the eight capabilities. These five capabilities are: (1) health care system preparedness; (2) health care system recovery; (3) emergency operations coordination; (4) information sharing; and (5) medical surge. Responder safety and health has been identified as an opportunity for improvement by many awardees, emphasized during the Ebola outbreak.

To re-emphasize responder safety and health, funding from both the emergency supplemental and annual cooperative agreement program will support activities that build this capability, such as exercises, health care worker trainings, and optimizing the planning for and management of protective equipment for health care workers. In addition to supporting overall health care system preparedness and response, the Hospital Preparedness Program (HPP) anticipates providing funding to all 62 HPP awardees (states, territories, freely associated states, and select municipalities).

These resources will then flow to the approximately 500 HCCs. The supplemental resources provided through the network of HCCs will allow for regional purchasing of PPE and training. Moving forward, the responder safety and health capability will be a focus of ongoing HPP funding priorities.

- **While the President's emergency funding request focuses specifically on critical needs to address and contain Ebola, how should resources be apportioned going forward to ensure a strong domestic preparedness and response system is in place to respond to the next crisis?**

Response: As mentioned above, robust HCCs will be critical for a strong domestic response to any hazard. The supplemental funding provided to HPP in the Consolidated and Further Continuing Appropriations Act, 2015, will allow HCCs to enhance preparedness and response systems through HCC-level training and PPE purchasing. It will also support hospitals throughout the U.S. to improve their capacity to treat infectious diseases. Although the system of treatment hospitals is being developed in response to the immediate need to address Ebola, the

national network of treatment hospitals will serve as a foundation for safe and effective expert care of patients with serious communicable diseases in the future. National health security depends on having a system in place to address emerging infectious diseases (for example, novel flu strains, Middle East Respiratory Syndrome, and Severe Acute Respiratory Syndrome) and the threat of bioweapons.

In addition to the supplemental funding in the Consolidated and Further Continuing Appropriations Act, 2015, the annual HPP appropriation will continue to support regional health care system preparedness and response efforts. The Public Health Service Act, the underlying authorization for HPP, specifies how funding must be distributed to awardees. The components in determining the awards include a base amount (which may not be greater than the minimum amount specified later in the authorization), an increase on the basis of population, and may include amounts to address significant unmet need and/or degree of risk. This minimum level ensures that awardees with small populations are protected in formula determinations. In FY 2014, the HPP cooperative agreement formula incorporated accepted terrorism risk scores and factored in risk for certain natural disasters. The formula distribution anticipated for FY 2015 will include risk factors similar to those used in FY 2014, but additional factors may be considered to ensure an appropriate balance of risk.

- **How are we preparing first responders and other health professionals for the next large-scale public health threat, whether through additional equipment, training, etc.?**

Response: Our Nation's preparedness is built on the back of strong day-to-day healthcare systems, which ASPR continues to help build and maintain to respond to future emergencies. Related to current preparedness efforts for the Ebola virus disease, ASPR is leveraging a number of opportunities to ensure first responders are properly trained on the use of Personal Protective Equipment (PPE). Specifically, ASPR is ensuring that members of the National Disaster Medical System (NDMS) deployable response teams have access to and are receiving training in the use of PPE. ASPR recognizes training NDMS personnel on the use of current PPE is an absolute requirement to ensure the safety of any personnel engaged in the medical care of Ebola patients. Any deployment activities for the purpose of patient screening or care would include the necessary PPE training that meets the Center for Disease Control and Prevention (CDC) standard. NDMS headquarters personnel including the Chief Medical Officer program, which includes an Occupational Safety professional, as well as the NDMS Program Support Branch, have developed training requirements that will be adhered to in the event NDMS is activated to support clinical care. Additionally, NDMS has the ability to train personnel in an online environment as a complement to hands-on training. Likewise, while Medical Reserve Corps (MRC) units are primarily guided by their local jurisdictional missions and training policies, headquarters staff have encouraged training in the current PPE recommendations from CDC, and have provided information and links to training resources for the units using listserv and social media platforms. Many MRC units have reported training health professionals in their units, as well as sharing and disseminating those materials further to community partners such as emergency management agencies, hospital coalitions, local emergency medical technician groups, and public health officials.

In addition, HPP awardees utilize funding to support exercises that bring regional partners together to practice and train for potential public health and medical incidents. Over time, a number of exercises demonstrated their value in real response scenarios. For example, during both the West, Texas fertilizer plant explosion and the response to the Boston Marathon bombing (both in April 2013), disaster preparedness exercises in the weeks and months prior to the incidents helped coalition and state partners enhance communication, identify gaps in preparedness, and implement corrective actions to close those gaps, boosting local resilience and reducing the need for Federal assistance. HPP awardees are continuing to support exercises to enhance preparedness and improve existing capabilities in communities across the nation. In fact, HPP has served as the nerve center for Ebola-related tabletop exercises for hospitals and awardee jurisdictions, as well as hospital infectious disease plans, so facilities and awardees can quickly access plans and adapt them for use in their own health care systems.

Emergency Medical Services (EMS), emergency management agencies, local health departments, health centers and clinics, hospitals, hospices, skilled nursing facilities, home health agencies, and psychiatric facilities are all members of HCCs. In the last year, overall HCC membership increased by 47 percent (from 16,262 members to 23,790). Nationwide, 4,943 EMS organizations are part of HCCs. The percentage of EMS organizations involved in HCCs has grown from 16 to 24 percent in the last year alone.

As HCC members, EMS organizations benefit from all the training, exercises, and coordination that take place at the HCC level. According to a recent impact assessment survey, support from HPP is the primary funding source for establishing, maintaining, and strengthening regional health care system preparedness. Approximately 86 percent of HCC funding comes from HPP. To ensure that first responders and all other health system partners are prepared for future public health threats, broad participation in HCCs is critical, and HPP will continue to work to increase HCC membership.

Throughout the domestic Ebola response, HPP has been actively engaged in activities that target both Ebola preparedness and general infection control. These include: providing key information, developing guidance and helpful checklist documents, and sharing lessons learned with state and local public health officials, hospital executives, health care workers, and others across the U.S. through webinars and national calls. Building on this Ebola related work, the annual HPP funding will continue to support HCCs so that preparedness will be a coordinated effort between all health system partners, not isolated actions by individual facilities.

Geographic barriers, a finite workforce, aging and facilities and equipment mean that states like North Dakota have limited capabilities and infrastructure in rural areas to address ongoing chronic public health challenges, let alone ensuring preparedness for unknown future threats.

- **How is the federal government partnering and coordinating with state and local public health departments to leverage funds and ensure efficiency in areas with limited resources?**

Response: The HPP is administered through ASPR and provides cooperative agreements to 62 state, territorial, and specific metropolitan health departments to develop an integrated Federal, state, and local disaster health care system that is prepared and ready to respond to any emergency. HPP funding is channeled through these 62 awardees to support roughly 500 health care coalitions (HCCs). An HCC is a formal collaboration among healthcare organizations and public and private sector partners and it is organized to prepare for and respond to an emergency, mass casualty or catastrophic health event. HCCs generally include hospitals, public health departments, emergency management, emergency medical services, and other types of health care organizations. As a multi-agency coordinating body, the HCC assists with mitigation, preparedness, response, and recovery activities related to disaster operations. These activities include planning, organizing, equipping and training HCC members and their organizations to respond to a disaster. To improve response, HCCs plan and conduct exercises and after-incident or after-exercise evaluations. During response, HCCs provide multi-agency coordination, advice on decisions made by incident management, information sharing for situational awareness, and resource coordination. An HCC can coordinate preparedness and response in ways that individual institutions cannot.

Through this regional approach to disaster preparedness and response (rather than a facility-by-facility approach), HPP links health care, public health, and other community partners, allowing for a comprehensive and coordinated preparedness and response effort. In rural areas, where health care resources may be limited, the HCC structure allows individual health care facilities with limited capacity to access the collective resources through a network of providers. In addition, HPP funds trainings to empower health care providers and existing institutions to cover rural gaps. For example, in regions with limited access to trauma centers, health care providers may attend trainings on stabilizing and preparing patients for transport to more specialized facilities in neighboring states.

- **What kind of flexibility do state and local health departments have in using federal funds to build and strengthen their preparedness and response systems?**

Response: HPP's approach is flexible and allows awardees to tailor preparedness funding to their priorities. HPP requires awardees to submit annual applications, work plans, and budgets aligned with eight health care preparedness capabilities: (1) health care system preparedness, (2) health care system recovery, (3) emergency operations coordination, (4) fatality management, (5) information sharing, (6) medical surge, (7) responder safety and health, and (8) volunteer management. Within this overarching framework, awardees conduct regular risk assessment surveys to identify areas of greater need and determine funding distributions among each capability.

Beyond offering flexibility in determining activity priorities, HPP allows awardees to determine the most ideal governance structure under which to organize their regional disaster preparedness and response plans. Currently, there are more than 23,000 organizations participating in nearly 500 HPP-supported HCCs across the nation. Among these, HPP has observed variations among HCCs including geographic size, leadership, and membership representation among different facilities, which can include acute care hospitals, emergency medical services, specialty and

primary care providers, long term care facilities, behavioral health providers, public agencies, and private organizations.

- **How does ASPR focus on the unique challenges in creating and maintaining a rural public health infrastructure?**

Response: To provide technical assistance and facilitate knowledge exchange among rural peers, ASPR has supported research and trainings to identify and mitigate common challenges in rural health care preparedness. HPP awardees identify topics for calls and trainings based on their needs, such as how to organize HCCs in rural settings, ways to evaluate preparedness, and how to modify risk and vulnerability assessment tools to support a rural community. HPP funding can be used to send rural HCC members and individuals to trainings to facilitate rural preparedness. These could include trainings such as advanced burn support and pre-hospital trauma, which helps improve local response and patient stabilization in rural areas that may require patient transport to higher levels of care.

In addition, in September 2014, ASPR published a report in conjunction with the National Association of County and City Health Officials (NACCHO) to identify promising practices that local health departments and HCCs are using to plan for medical surge needs. This report helps awardees recognize best practices their peers use within emergency preparedness planning in rural areas.

Funding for the HPP has shrunk the past five fiscal years, to well below the authorized level. Cuts to the overall program this year resulted in a 30% budget cut for North Dakota; this comes at a time when our public health officials have had to deal with challenges (e.g., fires, explosions, and derailments) associated with the Bakken oil boom and natural disasters including severe flooding.

- **Why has the Secretary consistently requested less funding for the program and what efforts are you undertaking to ensure that smaller states, like mine, receive sufficient support?**

Response: Since 2002, HPP has provided nearly \$4 billion in resources to assist states, territories, and certain metropolitan jurisdictions in preparing for and responding to public health emergencies. HPP funds support a regional presence, rather than facility-by-facility, to link health care, public health, and other community partners for a comprehensive and coordinated preparedness and response effort. The cornerstone of this regional preparedness approach is the HCC, formal collaborations among health care organizations and public and private partners that are organized to prepare for, respond to, and recover from an emergency, mass casualty event, or catastrophic health event.

HPP funding for fiscal year FY2014 was \$255 million. To adjust appropriately, ASPR reviewed its funding formula to help maximize the use of funds. ASPR encourages hospitals and health care partners to forge or participate in coalitions within their community and region. Fostering preparedness and collaboration amongst provider types at the community level strengthens the

overall health care system by allowing for the sharing of resources, leveraging of expertise, and increased capacity to respond during an emergency.

In addition, ASPR recognized awardees' needs to revise their program and reconsider their plans. ASPR provided awardees opportunities to share best practices in sustainable funding models, the option to implement a capability tier structure, as well as other guidance, while remaining cognizant of the fact that awardees best understand their jurisdictions and the risks and capabilities that they most want to prioritize. Thus, the current funding continues to support and build broader regional HCCs as well as link daily delivery of care systems to emergency preparedness.

The President's emergency request includes significant investment in the Biomedical Advanced Research and Development Agency (BARDA) to manufacture vaccines and synthetic therapeutics for use in clinical trials.

- **How will BARDA ensure a diverse vaccine development and treatment pipeline and invest in varied approaches to fighting Ebola and other infectious diseases?**

Response: BARDA has developed a strategic goal, implemented as a best practice, to maintain a robust and formidable medical countermeasure advanced development pipeline for chemical, biological, radiological, and nuclear threats, pandemic influenza, and now the emerging infectious diseases - Ebola. Since last summer, BARDA has been contacted by more than 150 companies with potential Ebola medical countermeasure candidates and met with more than 120 companies and academic institutions through our Tech Watch program to learn in depth about these candidates. BARDA supports development and large-scale production of medical countermeasures as a response measure for public health emergencies. Today, BARDA is transitioning Ebola medical countermeasure candidates from early development and support from the National Institute of Allergy and Infectious Diseases and the Department of Defense's Defense Threat Reduction Agency into advanced development. BARDA is working with industry as partners – both small companies and large, fully integrated, pharmaceutical companies across the U.S. and the world. This is done to develop and scale up production of Ebola vaccines and monoclonal antibodies to ensure commercial scale manufacturing will be possible when needed.

Specifically, we have implemented a three-pronged approach to maximize the production of promising Ebola monoclonal antibodies like ZMapp.

- First, we awarded a contract in September to Mapp Biopharmaceuticals for development and manufacturing of ZMappTM produced by Kentucky Bioprocessing (KBP) using tobacco plant-based technologies. This product candidate has been provided to nine (9) Ebola-infected persons under an Emergency Investigational New Drug Application. Efforts to optimize production have already seen a nearly two-fold increase in production yield. The clinical trials to demonstrate safety and efficacy for this product started in Liberia using the common master protocol in February 2015 and are slated to start in Sierra Leone in March 2015.

- The present manufacturing process at KBP is pilot scale; BARDA is expanding manufacturing capability of ZMapp by enlisting the help of other tobacco plant biopharmaceutical companies including Medicago and Fraunhofer.
- Lastly, we are increasing Ebola antibody production by partnering with Genentech and Regeneron, who routinely make monoclonal antibodies at commercial scale for other diseases and have developed innovative, state-of-the-art, monoclonal antibody technologies in specialized CHO mammalian cells. We are testing these new Ebola antibodies now in animal challenge studies, and, if successful, in human clinical trials shortly thereafter.

Additionally, we are negotiating a contract with the manufacturer of an Ebola antiviral drug candidate supported currently by NIH for further development, manufacturing assistance, and Phase 2 clinical trials in West Africa. With respect to vaccines, BARDA is currently supporting the development of three vaccine candidates; first from Profectus for manufacturing of clinical investigational lots for Phase 1 clinical trials in the Spring of 2015, the second from Newlink Genetics/Merck partnership, which is in Phase 2/3 clinical trials in Liberia, for product development and commercial scale-up manufacturing, and third candidate from GlaxoSmithKline, which is also in Phase 2/3 clinical trials in Liberia, for product development and commercial scale-up manufacturing. With additional funds, BARDA is considering support for commercial manufacturing scale-up and further clinical trials for other promising Ebola vaccine candidates from Johnson & Johnson/Bavarian Nordic partnership and Novavax to ensure that additional vaccines are available for clinical trials and vaccination campaigns.

BARDA is also in final contract negotiations for support of advanced development of a point-of-care Ebola diagnostic lateral flow rapid diagnostic device.

In support of medical countermeasure development, manufacturing, and testing activities for these threats, BARDA has established a national medical countermeasure response infrastructure that assists product developers on a daily basis and respond immediately in a public health emergency - today BARDA has engaged its core service assistance programs for response to the current Ebola epidemic as follows:

- Nonclinical Studies Network to conduct critical animal challenge studies to evaluate new Ebola monoclonal antibody and therapeutic candidates,
- Centers for Innovation in Advanced Development and Manufacturing to expand production of Ebola monoclonal antibodies,
- Fill Finish Manufacturing Network to fill Ebola antibody and vaccine products into vials,
- New Clinical Studies Network to help CDC plan and conduct vaccine clinical trials in Sierra Leone in March 2015, and
- Modeling unit to coordinate Federal and international modeling efforts for evolving Ebola epidemiology and interventions.

BARDA has made investments since 2010 to build this response infrastructure that is now playing a major role in the Nation's response to the current Ebola epidemic.

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**Post-Hearing Questions for the Record
Submitted to The Honorable Thomas Frieden, M.D.
“Preparedness and Response to Public Health Threats: How Ready Are We?”
U.S. Senate Committee on Homeland Security and Government Affairs
November 19, 2014**

From Senator Tom Coburn, M.D.

1. Disposal of medical waste from treating a patient with a highly infectious disease has been a major source of difficulty for several hospitals. One report notes, “A single Ebola patient treated in a U.S. hospital will generate eight 55-gallon barrels of medical waste each day.” Such waste can be the source of additional infections.
 - a. In a pandemic in which there may be extraordinary amounts of medical waste, how is the CDC prepared to help facilitate rapid and efficient disposal of waste?
 - b. The CDC recommended incinerating this waste, but some states prohibit it. Has the CDC worked with states to identify restrictions on disposal of medical waste that would be highly burdensome during a pandemic?

Answer: Medical waste generated in the care of patients with known or suspected EVD is subject to procedures set forth by local, state and Federal regulations. CDC, in collaboration with the Assistant Secretary for Preparedness and Response (ASPR), the U.S. Department of Transportation (DOT), and the Occupational Safety and Health Administration (OSHA), have issued guidance on the disposal of medical waste from patients with Ebola to help states and hospitals coordinate for safe management of waste. Ebola-associated waste disposal is subject to state and local regulations. There has been much work to address questions about the management and safe removal of medical waste resulting from the treatment of Ebola cases. ASPR took a leadership role in coordinating and addressing waste management challenges, working closely with CDC and DOT. Through this collaboration, ASPR, CDC, and DOT developed a mechanism that allowed for the safe removal and legal transportation of contaminated medical waste from civilian health care facilities treating confirmed cases of Ebola. One of the results was the Pipeline and Hazardous Materials Safety Administration issuing a non-site specific special permit (Special Permit DOT-SP 16279) to certain waste haulers, which authorizes the transportation and disposal of waste contaminated with or suspected of being contaminated with Ebola. Notably, Ebola-associated waste that has been appropriately inactivated or incinerated is no longer infectious.

2. The Strategic National Stockpile is a critical component to any major pandemic response, given that it holds equipment and countermeasures for both civilian and military personnel. A key aspect to pandemic planning would be to have a relationship established with the major manufacturers of personal protective equipment. For example, one key manufacturer of personal protective equipment (PPE) is DuPont.
 - a. On what date did the CDC first contact DuPont about stockpiling PPE or ramping up production in an emergency outbreak? On what date did the ASPR do so?

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Answer: CDC's Division of Strategic National Stockpile (DSNS) established direct relationships with many supply chain partners (distributors and manufacturers) since its inception in 1999. Relationships with PPE manufacturers and distributions strengthened during the 2009 H1N1 Pandemic Influenza response in efforts to coordinate government visibility of supply chain capacity and potential shortages, which may require government intervention, including the release of assets from the SNS.

In 2014, as U.S. hospitals began placing PPE orders to prepare their facilities in the event of the need to care for Ebola virus disease (EVD) patients, CDC, other HHS components, and other Federal Departments and Agencies started to receive reports of delays and long delivery lead times for certain PPE items in the commercial supply chain. HHS/ASPR convened a teleconference with CDC and FDA on October 16 to coordinate outreach to PPE manufacturers on this issue. HHS/ASPR communications with DuPont specifically started with a call on October 17. Direct DSNS communications with DuPont started on October 26th. Throughout the response, HHS components shared information from these private sector discussions to maintain Departmental and Interagency situational awareness. Discussions with private sector partners focused on understanding current market capacity and identifying possible solutions to support hospitals receiving an Ebola patient without sufficient PPE on hand to care for the patient based on CDC PPE guidance.

b. Did the CDC or the ASPR know what DuPont's maximum production capacity was before the outbreak?

Answer: CDC did not know the detailed production information, including maximum production capacity, for any PPE products manufactured by DuPont prior to the Ebola outbreak.

3. Most of the Strategic National Stockpile is maintained by manufacturers. Many of those assets, therefore, are not centrally located. During major pandemics, manufactures and shipping companies could be expected to experience significant employee absenteeism.

a. How does CDC assure that, during such a pandemic, it will be able to access these supplies and equipment, despite non-central storage and employee absenteeism?

Answer: More than 98 percent of the medical countermeasures held in SNS are maintained in secure SNS storage sites located strategically across the country for rapid deployment to any U.S. jurisdiction requesting support. These storage sites are operated by third party logistics providers with extensive experience in medical logistics management and are managed under strict service contracts and quality agreements with direct oversight by onsite CDC employees. The capability of these sites to ship SNS assets within the required timeframes is tested annually through drills and exercises.

The remainder of SNS assets is maintained by manufacturers or distributors in their storage space for deployment on order in accordance with the terms of their contractual agreement with CDC. These arrangements are termed "vendor managed inventory" contracts and are solicited and maintained by CDC for products that do not require immediate shipment to meet the delivery requirements of state and local partners to protect their populations. Vendor managed inventory contracts must also be cost effective for the government, where manufacturers have the capacity and commercial market to rotate the products with little additional holding costs and are able to offer the service for less than the government's costs to buy and maintain the product in SNS storage. For medical countermeasure requirements that meet this and other criteria for feasible vendor managed inventory arrangements, CDC implements contracts with specific requirements for the contractor, including shipment,

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maintenance and response time standards.

- b. What steps does CDC take to ensure manufacturers maintain the contracted amount of product for the Strategic National Stockpile?**

Answer: CDC conducts annual inventory audits of all manufacturers or distributors holding SNS medical countermeasures under vendor managed inventory arrangements, as described in the response above. These audits include the validation of the quantity and condition of the contracted product.

- 4. In the current Ebola outbreak both domestically and abroad, the federal response has relied heavily on an ability to perform contact tracing to identify and monitor vulnerable individuals.**

- a. In quantitative terms, what is the combined federal, state, and local capacity for contract tracing and what situations would overwhelm that capacity?**

Answer: Contact tracing is a critical public health activity routinely conducted by state and local health departments for multiple diseases (*e.g.*, syphilis, tuberculosis). If a large-scale response required contract tracing at levels beyond those that could be met by state and local health departments, resources can be redirected from these diseases in the short term. In addition, CDC can provide surge capacity staff to support these increased efforts. It is unlikely that the combined local, state, and Federal capacity would be overwhelmed.

- b. Has CDC assessed what the best course of action would be if our contact tracing ability was overwhelmed during a significant outbreak?**

Answer: Alternative methods are possible to make the most effective use of limited resources during a large-scale response requiring extensive contact tracing. For example, monitoring of well individuals can be achieved through remote means such as teleconferencing. Should capacity be overwhelmed, other options could be considered that use additional methods to reduce transmission and reach individuals remotely. Our current strategy is to monitor individuals returning to the United States from the heavily-affected West African countries to allow for early identification and to prevent subsequent transmission through early identification and isolation of Ebola patients.

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From Senator Kelly A. Ayotte

1. In your written testimony, you note that the Centers for Disease Control and Prevention (CDC) is leading teams to assess the readiness of certain hospitals across the country to combat Ebola. In your team's visits, what have they found?

Answer: CDC has formed Rapid Ebola Preparedness (REP) and Infection Control Assessment and Response (ICAR) teams that, upon invitation by state health officials, deploy to hospitals for the purpose of assessing their readiness for being an Ebola Treatment Center. Ebola Treatment Centers provide comprehensive care to persons diagnosed with Ebola virus disease (EVD) and are designated via a collaborative decision made between the state and local health authorities and the hospital administration. REP and ICAR teams are comprised of 4-10 CDC experts in infection control, occupational health, and laboratory issues; other HHS personnel including NHPP Field Project Officers and other regional staff; Federal and state Office of Safety and Health Administration (OSHA) staff; and external local experts. During the site visit, the team assesses a hospital's ability to meet minimum capabilities for treating patients with Ebola. These assessments also include an analysis of the hospital's inventory of personal protective equipment (PPE) recommended by CDC and OSHA to protect healthcare workers. These assessments are conducted by the CDC's Division of Strategic National Stockpile. Based on these assessments, CDC can assist hospitals in working with manufacturers and distributors to fill any shortages, or prepare to ship items from the SNS in the event the hospital receives a patient and PPE supplies are limited.

Representatives from ASPR's Hospital Preparedness Program (HPP) joined the REP visits to provide insight and expertise on hospital and healthcare system preparedness.

In most cases, the facilities visited showed an advanced level of preparedness. Where critical gaps were identified, CDC provided technical assistance to address the gaps and followed up regularly with the facilities. CDC also followed up routinely with state and local health department authorities to help ensure facilities were capable of safely treating EVD patients. As of December 16, 2014, there are 40 hospitals that are ready to care for patients with EVD, for a total of 60 beds nationally.

2. Have the CDC team visits found that most hospitals in the U.S. are prepared to handle Ebola or other serious threats to public health?

Answer: CDC is evaluating the capacity of that small subset of U.S. hospitals via a collaborative decision made between the state and local health authorities and each hospital's administration. In most cases, the facilities visited showed an advanced level of preparedness.

3. In cases where a hospital's preparations might be deemed inadequate, has there been any follow-up from CDC or any additional assistance offered by your agency so that hospitals can be better prepared to address serious public health challenges?

Answer: In addition to the technical assistance noted in, CDC and HHS are facilitating ongoing technical assistance and clinical consultation by facilities with recent experience caring for patients with EVD as needed. Additionally, gaps in PPE inventory are being addressed by CDC through DSNS engagement with PPE manufacturers and distributors to identify priority facilities and improve access to critical PPE assets in the event that a facility receives an EVD patient.

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4. Did similar visits to assess hospital readiness take place prior to the arrival of the first Ebola patient in the U.S.?

Answer: CDC developed the Rapid Ebola Response teams following the arrival of the first Ebola patient in the United States.

5. Do you anticipate the continuation of these team visits in the future so that the CDC can see up close whether hospitals are prepared to combat future public health threats?

Answer: Decisions regarding future REP and ICAR team visits will be made based on national needs for Ebola preparedness and pending availability of resources. Implementation and adherence to CDC recommendations lies with individual hospitals. However, a positive corollary of the intensive training and preparation at these facilities may be increased readiness for other disease outbreaks in the future.

6. In your written testimony, you discuss the CDC's Health Alert Network, which is designed to share urgent news related to public health. Is news from the Health Alert Network shared with hospitals across the U.S.?

Answer: CDC's Health Alert Network (HAN) is the Agency's primary method of sharing information about urgent public health incidents with: public information officers; Federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories. CDC's HAN collaborates with Federal, state, territorial, and city/county partners to develop protocols and stakeholder relationships that will ensure a robust interoperable platform for the rapid distribution of public health information.

7. Prior to the first case of Ebola being diagnosed in the U.S., was a Health Alert Network notice issued to hospitals warning them to keep a lookout for symptoms that could be associated with a potential Ebola case? Did such an alert include information related to the importance of asking patients about their recent travel history?

Answer: CDC issued a HAN on July 28, 2014, prior to the first case of Ebola in the U.S., that alerted public information officers; Federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories about the first case in Nigeria and of two U.S. citizens working in a hospital in Monrovia, Liberia, with confirmed Ebola virus infection. In this notice, CDC reiterated the recommendation that healthcare providers in the United States consider EVD in the differential diagnosis of febrile illness, with compatible symptoms, in any person with recent (within 21 days) travel history in the affected countries and consider isolation of those patients meeting these criteria, pending diagnostic testing. In addition, a HAN was released August 1, 2014, that provided updated guidance to healthcare providers and state and local health departments regarding who should be suspected of having EVD. Since August 1, six other HANs have been issued that addressed Ebola management issues.

8. Are there ways to more efficiently and effectively inform the entire health care system, as well as the general public, when a serious threat to public health, such as Ebola, arises?

Answer: CDC has a large reach across the entire health care system, directly to health care facilities and healthcare providers. Additionally, CDC and ASPR's message can be amplified through clinical professional organizations, public health organizations, on-line clinical partners (e.g., Medscape) and the media.

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CDC and HHS can utilize a variety of channels for distribution of information and messages to provide information about Ebola or other emerging public health threats. These notifications will go to the media, the public, public health partners, healthcare providers, and medical responders. Key information channels include, but are not limited to:

- Media briefings, including televised press conferences and telephonic briefings for reporters,
- Websites (www.cdc.gov, www.hhs.gov, www.phe.gov, etc.),
- Health Alert Network (HAN), which can alert state and local public health agencies, healthcare facilities, and healthcare providers directly when an issue arises.
- Clinical professional partners (e.g., hospital associations, EMS, emergency department staff, healthcare unions),
- Social media channels (e.g., Twitter, Facebook, YouTube, podcasts, text messaging, etc.)
- Morbidity and Mortality Weekly Report (MMWR),
- Conference calls and webinars, and
- Online partners (e.g., WebMD and Medscape).

9. What lessons can be learned from the initial response to the first Ebola patient in the U.S. so that there is greater awareness and preparedness among all hospital officials and health care professionals when the next public health threat arises?

Answer: CDC and ASPR are incorporating lessons learned as the response evolves and has adjusted guidance, recommendations, and procedures based on developing information and knowledge. CDC and ASPR's current guidance for domestic response reflects best practices in public health strategies as appropriate and feasible for the environment and settings in the U.S. Effective approaches in the fundamental public health activities are in use domestically and internationally. Some examples of changes that have already occurred based on evolving experience include:

- Issuing updated CDC and ASPR guidance for Emergency Medical Services (EMS) personnel and other first responders managing suspected Ebola cases based on lessons learned from the recent experience caring for Ebola patients in a U.S. health care setting.
- Offering additional support to hospitals nationwide, CDC has established dedicated CDC Ebola Response Teams (CERT) that within hours can be at any hospital that receives a confirmed Ebola patient. These teams provide expertise, support, and training for areas that include infection control, safety, medical treatment, contact tracing, waste management, and public education and help state and local public health practitioners and clinicians follow strict protocols to ensure patient and worker safety. CDC's most recent response to an Ebola case in the United States is an example of the assistance now being provided to states based on lessons learned.
- Updating guidance for U.S. health care settings, reflecting lessons learned from the recent experiences of U.S. hospitals caring for Ebola patients and emphasizes the importance of training, practice, competence, and observation of healthcare workers in correct donning (putting on) and doffing (removal) of PPE selected by the facility.

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- Revising guidance to include active Ebola monitoring of travelers based on lessons learned from the recent experience of Ebola patients in the United States. All travelers arriving to the United States whose travel originates from Sierra Leone, Liberia, or Guinea are being monitored—regardless of symptoms—by state and local health officials for 21 days from the date of their departure from West Africa.

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From Senator Heidi Heitkamp

The CDC equips states with tools to build a strong system for public health preparedness and response, including funding surveillance, communication, and training initiatives.

- **What kind of flexibility does current CDC funding provide state and local governments in developing and strengthening their response systems?**

Answer: CDC provides state and local Public Health Emergency Preparedness (PHEP) cooperative agreement awardees funding to build and sustain their public health preparedness capabilities according to the standards described in CDC's Public Health Preparedness Capabilities: National Standards for State and Local Planning document. CDC also provides state and local PHEP awardees with the flexibility to direct their PHEP funding to priority areas within their jurisdictions based on their jurisdictional needs. The PHEP cooperative agreement provides funding, technical assistance, and other resources to help state, local, and territorial public health departments build and sustain their public health preparedness capabilities and response systems.

Awardees review annually their current preparedness status to identify preparedness and response gaps. That information, along with other data sources such as their jurisdictional risk assessments, incident after-action reports and improvement plans, and site visit observations, and other jurisdictional priorities and strategies, is used to determine their strategic priorities and to identify preparedness and response gaps. Collectively, this information allows state and local awardees to prioritize their preparedness investments, ensuring that federal preparedness funds are invested to effectively strengthen their preparedness and response systems.

- **How does CDC communicate clear guidance to state and local health departments, first responders, and the health care community to ensure an appropriate and timely response to public health threats?**

Answer: CDC's Health Alert Network (HAN) is the agency's primary method of sharing information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories. CDC's HAN collaborates with federal, state, territorial, and city/county partners to develop protocols and stakeholder relationships that will ensure a robust interoperable platform for the rapid distribution of public health information.

Additionally, CDC provides guidance to state and local PHEP awardees in a number of other ways:

- Issuing annual PHEP guidance on the use of each year's PHEP funding. PHEP awardees are expected to use their cooperative-agreement funding to build and sustain public-health-preparedness capabilities, ensuring that Federal preparedness funds are directed to priority areas within their jurisdictions as identified through their strategic-planning efforts.
- Directing PHEP awardees to collaborate closely with other Federal preparedness programs, such as U.S. Department of Homeland Security's (DHS) Federal Emergency Management Agency (FEMA), local Metropolitan Medical Response Systems (MMRS), and local Medical Reserve Corps (MRC) in their jurisdictions to maximize resources, prevent duplicative efforts, and to coordinate appropriate and timely responses to public health threats.

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- To advance all-hazards preparedness and national health security, promote responsible stewardship of federal funds, and reduce awardee administrative burden, working together with the Office of the Assistant Secretary for Preparedness and Response (ASPR) to align administrative and programmatic aspects of the ASPR Hospital Preparedness Program (HPP) and the CDC PHEP cooperative agreements. Among other benefits, this alignment is advancing and public health and health care preparedness and response to public health threats through improved public health and health care systems coordination and better integration with the daily health care delivery system.
- As part of the alignment, working with ASPR to conduct joint activities, including: issuing annual funding guidance; holding at least monthly conference calls with awardees to discuss programmatic issues; conducting joint site visits and providing coordinated technical assistance to give awardees a common understanding of HHS guidance and cooperative agreement requirements; And running a coordinated training and exercise program to help awardees close operational gaps and sustain jurisdictionally-required preparedness competencies.

The President's emergency request focuses on both domestic and international approaches to address the Ebola epidemic.

- **What non-monetary resources has CDC contributed to the Ebola control efforts in both urban and remote areas in Western Africa?**

Answer: CDC is providing incalculable non-monetary support to halt the outbreak in West Africa. CDC's non-financial contributions include:

- Working closely with U.S. Agency for International Development (USAID), Office of Foreign Disaster Assistance (OFDA), to support the deployment to Liberia of a Disaster Assistance Response Team (DART), which is coordinating the U.S. Government's Ebola response in West Africa.
- Supporting countries with widespread Ebola transmission to establish their own national and sub-national EOCs. All three West African countries at the center of the epidemic each have an Incident Manager, reporting to the President of the country, to lead response efforts.
- Providing hundreds of CDC staff members for logistics, staffing, communication, analytics, management, and other support functions for the response. As of December 16, 2014 CDC has deployed more than 900 public health experts to the West Africa region. CDC staff are deployed to Guinea, Liberia, Nigeria, Senegal, Sierra Leone, and Mali to assist with response efforts, including surveillance, contact tracing, data management, laboratory testing, and health education. CDC experts have also been deployed to non-affected border countries in West Africa, including Cote d'Ivoire, to conduct assessments of Ebola preparedness in those countries. CDC teams also respond to newly recognized clusters of Ebola disease, supporting implementation of all aspects of control efforts.
- Assisting with setting up an emergency response structure, contact tracing, providing advice on exit screening and infection control at major airports, and providing training and education in

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countries with widespread Ebola virus transmission.

- Through our health promotion teams consisting of health communicators and public health advisors deployed to Guinea, Liberia, and Sierra Leone, working closely with country embassies, UNICEF, WHO, ministries of health, and nongovernment organizations to develop public health messages and implement social mobilization activities.
- Working with airlines to address crew and airline staff concerns while ensuring the ability of humanitarian and public health organizations to transport assistance into the affected countries.
- Working with airlines, airports, and ministries of health in West Africa to provide technical assistance for developing exit screening and travel restriction in countries with Ebola outbreaks. This includes assessing the capacity of countries and airports to conduct exit screening; assisting with development of exit screening protocols, and training staff on exit screening protocols and appropriate PPE use.
- **In addition to case numbers and death tolls, what other metrics is CDC using to monitor the effectiveness of our global response to contain the outbreak?**

Answer: CDC is consistently gathering information, working to improve surveillance systems, and actively monitor the outbreak situation and the effectiveness of response efforts. For example, CDC monitors measures that indicate effective epidemic management through incident management structure (IMS) and Emergency Operations Centers (EOCs); breaking chain of transmission through effective isolation, treatment, and through safe burials; supporting infection control in healthcare facilities; and community outreach. In addition to numbers of suspect, probable, and confirmed cases, and numbers of deaths, CDC supports collection of:

- Progress toward full implementation of a set of 25 indicators of Emergency Operations Center capacity,
- Percentage of targeted inpatient and large outpatient facilities with a trained infection control specialist & with uninterrupted supply of PPE, and
- Numbers of lab tests done and turnaround time for lab results,
- Number of (and estimated percentage of total) cases in Ebola Treatment Units,
- Number of (and estimated percentage of total) cases in health care facility, community or home isolation,
- Numbers of contacts identified and of contacts reached,
- Proportion of cases that are identified among known and monitored contacts,
- Proportion of safe burials, and
- Percentage of targeted households reached with Ebola information and basic hygiene information.

As the outbreak changes and the response evolves, the needed metrics may change.

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From Senator Thomas R. Carper

1. We must continue to pay close attention to the changing dynamics of the Ebola epidemic in Africa, and we must continually reassess the scale of the response needed overseas and here in the United States to end this epidemic. To help meet the immediate and long term needs of the Ebola epidemic, President Obama recently submitted an emergency funding request of nearly \$6.2 billion dollars. What will the impact be on the US response if Congress doesn't appropriate the full \$6.2 billion requested?

Answer: On December 9, 2014, the Continuing Appropriations Act of 2015 was released, which included an emergency appropriation for Ebola response activities totaling \$5.4 billion across the U.S. Government. The portion allocated for the Department of Health and Human Services is \$2.4 billion, and CDC received \$1.771 billion to support efforts to respond to Ebola both domestically and internationally, and to establish a global health security capacity to enable countries around the world to respond to public health incidents before they become epidemics.

CDC is actively prioritizing its work and resources to meet the most critical needs as effectively as possible. Even in the midst of a fluid situation, critical non-Ebola related public health issues require support. Efforts on non-critical activities have been shifted to provide greater support to essential operations.

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From Senator Rob Portman

1. The President's emergency funding request for Ebola includes \$166 million provided in funding through the Public Health and Social Services Emergency Fund to "immediately response to patients with highly-infectious diseases such as Ebola". Will any of the \$166 million requested in the emergency funding be allocated to hospitals to help offset the costs of Ebola preparedness efforts, particularly hospitals, such as those in NE Ohio and Texas, which had to quickly respond and prepare for the possibility of treating and diagnosing patients with Ebola?

Answer: In addition to supporting overall health care system preparedness and response, the Hospital Preparedness Program (HPP) anticipates providing funding to all 62 HPP awardees (states, territories, freely associated states, and select municipalities). This funding will then flow to Ebola Treatment Centers in high-risk jurisdictions, as well as Assessment Hospitals and health care coalitions (HCCs) nationwide. HCCs are formal collaborations among health care organizations and public and private partners, including health departments, hospitals, emergency medical services providers, and ambulatory care facilities that are organized to prepare for, respond to, and recover from emergencies that impact the public's health. Supplemental resources provided through HCCs will allow for regional purchasing of personal protective equipment (PPE) and proper training and exercises and infectious disease control training. This will help to ensure readiness at the regional level while efficiently and effectively using scarce resources and funding. Supplemental funding also will support federal knowledge sharing and other technical resources assistance and information exchange to ensure that all facilities learn best practices and share experiences.

We also recognize that caring for Ebola-infected patients is expensive, and hospitals that have cared for these patients have found that reimbursement by insurers and workers compensation programs does not cover many of the direct costs of care. These costs include, but may not be limited to, costs of PPE, costs associated with the management and disposal of Ebola contaminated waste, and transportation of Ebola-infected patients. FY 2015 supplemental appropriations provided funding to reimburse hospitals for some costs. As of December 16, 2014, four non-federal hospital facilities have cared for one or more patients with Ebola. It is an HHS priority to provide reimbursement to these hospital facilities, and to be prepared to provide similar reimbursement for care of any additional Ebola-infected persons. In the event a hospital takes care of a confirmed case of Ebola, HHS may provide reimbursement for uncompensated health care and transportation costs subject to the availability of funds.

2. As you know, U.S. hospitals are investing a significant amount of time and resources to prepare for the potential threat of an Ebola patient coming through their doors. I understand the CDC will be designating certain hospitals as "Ebola treatment centers". Does the CDC plan to provide any additional funding or resources to these hospitals to assist them in maintaining the adequate training and capabilities to be prepared to provide the complex treatment necessary to care for Ebola patient?

Answer: CDC is evaluating the capacity of that small subset of U.S. hospitals that have been designated as Ebola Treatment Centers via a collaborative decision made between the state and local health authorities and the hospital administration. Where critical gaps were identified, CDC provided technical assistance to address these gaps and is now providing regular follow-up to the facility and to state and local health department authorities to help ensure the facility is capable of safely treating a patient with EVD.

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CDC provides state and local Public Health Emergency Preparedness (PHEP) cooperative agreement awardees with the flexibility to direct their PHEP funding to priority areas within their jurisdictions based on their jurisdictional needs. The PHEP cooperative agreement provides funding, technical assistance, and other resources to help state, local, and territorial public health departments build and sustain their public health preparedness capabilities and response systems. CDC directs state and local PHEP awardees to use their PHEP cooperative agreement funding to build and sustain their public health preparedness capabilities according to the standards described in CDC's Public Health Preparedness Capabilities: National Standards for State and Local Planning document.

- 3. Is emergency transportation a factor that CDC has considered in its thinking about funding for emergency preparedness? Has CDC considered designating specific organizations to provide transportation of potential Ebola patients?**

Answer: The Office of the Assistant Secretary for Preparedness and Response (ASPR) has considered facilitating transportation. CDC defers to ASPR regarding this issue.

- 4. Currently, it is my understanding that physicians and treatment facilities are relying on word of mouth to discover what countermeasures are available to treat Ebola and similar infectious diseases. Has the CDC considered implementing an objective system by which the government shares information (risks/benefits) with hospitals and treatment centers in the U.S. on investigational agents where no approved ones exist to combat infectious diseases?**

Answer: The U.S. Food and Drug Administration regulates and coordinates investigational products; a mechanism for exploring these options exists through their website. CDC offers technical assistance to the attending clinicians to discuss treatment options for any confirmed patient with EVD who is admitted to a U.S. hospital.

Post-Hearing Questions for the Record
Submitted to the Honorable R. Gil Kerlikowske and Dr. Kathryn Brinsfield
From Senator Tom A. Coburn, M.D.

“Preparedness and Response to Public Health Threats: How Ready Are We?”
November 19, 2014

Question: During a major pandemic, federal agencies as well as private sector organizations are likely going to experience absenteeism at a significant level. The 2009 National Health Security Strategy included an action task for DHS to work with infrastructure partners on continuity plans during a major pandemic.

Has DHS developed the mandated continuity plans with infrastructure partners in case of a pandemic?

Response: DHS published guidance in 2006 for preparedness, response, and recovery to pandemic influenza threats for critical infrastructures and key resources (found at: <http://www.flu.gov/planning-preparedness/business/cikrpandemicinfluenzaguide.pdf>). During the 2009 H1N1 influenza outbreak, DHS worked with the Sector Coordinating Councils to craft specific guidance for pandemic preparedness for each critical infrastructure sector. Work on pandemic preparedness continues with these partners. For example, this past October, the Financial Services Sector Coordinating Council held the second part of a pandemic influenza webinar session with Federal Executive Boards in New York City and Northern New Jersey, FEMA and HHS regional officials, New York City Department of Health, and the Securities Industry and Financial Markets Association.

Although the Department of Health and Human Services is the lead for public health and medical response contingency planning to prevent the spread of infectious diseases, DHS participates in interagency contingency planning efforts and has published relevant guidance for critical infrastructure. FEMA co-led the development of a Pandemic Crisis Action Plan which guides a whole-of-government response. This plan was created to prepare for potential issues arising from either H7N9 (Avian Influenza) or MERS-Coronavirus but is adaptable to be used for a range of threats. The National Response Framework, which provides context for how the whole community works together on response efforts, includes a Biological Incident Annex that outlines the actions, roles, and responsibilities associated with response to a human disease outbreak of known or unknown origin. Work is currently ongoing to develop a more operationally focused Annex that is able to be implemented for a pandemic or biological attack. This is expected to be completed next year. The Biological Incident Annex and other National Response Framework materials can be found at: <http://www.fema.gov/national-preparedness-resource-library>.

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Primary:	The Honorable Tom A. Coburn
Committee:	HOMELAND SECURITY (SENATE)

DHS also has a Pandemic Workforce Protection Plan (PWPP) in place for its own workforce to ensure protection from many diseases, reduce absenteeism and ensure continuity of operations. This document provides a framework of authorities and responsibilities that can be applied to pandemic influenza and expands preparedness planning to other emerging infectious diseases throughout the Department. The PWPP supplements the DHS Component continuity of operations plans to address considerations and elements specific to pandemic events and emerging infectious diseases, including workforce absenteeism, and has the flexibility and scalability to guide the Department's preparedness for any outbreak.

Additionally, DHS has issued a guide for Program Managers and Contracting Officers entitled "Contractor Performance During an Emergency Event" to ensure critical DHS contractors are able to fulfill their responsibilities to keep mission essential DHS operations viable in the event of a health emergency such as a pandemic. The guide provides information on planning for contractor support during such an emergency and includes model clauses for incorporation in contracts that have been determined to be critical to successful continuation of DHS mission essential functions.

Question: Has DHS contacted healthcare suppliers and manufacturers to ensure adequate preparation, PPE, and ability to respond in the event of a pandemic? For example, has DHS contacted DuPont to determine whether its PPE production can meet demand during a pandemic?

Response: The Department of Health and Human Services is the Federal agency charged with ensuring general pandemic preparedness for the United States. DHS's responsibility with respect to pandemic preparedness is to ensure that DHS personnel have sufficient supplies and training to allow them to perform their critical missions in a pandemic scenario. DHS maintains emergency stockpiles of personal protective equipment (PPE) and medical countermeasures to ensure we have appropriate supplies for a pandemic. Further, our frontline operators, such as those with TSA and CBP, use PPE regularly in the course of their duties and their components maintain PPE supplies for regular use.

Using procurement tools, DHS purchases only the PPE needed and maintains an emergency stockpile, so that our purchases have the most limited impact to others who need to purchase this equipment.

Question: How is DHS working with public and private partners to ensure continued operation and protection of critical infrastructure during a pandemic? What trainings and exercises has DHS performed with those partners? Have any audits assessed our readiness in this area?

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Topic:	major pandemic
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Tom A. Coburn
Committee:	HOMELAND SECURITY (SENATE)

Response: The National Response Framework (NRF) is always in effect and outlines the concepts for intergovernmental coordination for all hazards, including the most complex and catastrophic events. The NRF provides a flexible approach to assigning a lead Federal agency and the use of a variety of statutory authorities based on the type of incident, including pandemics. While Ebola is not a pandemic, the U.S. Government response provides an example of how the NRF is leveraged for a variety of incidents. Under the NRF and Federal Interagency Operations Plan (FIOP), the Department of Health and Human Services (HHS) is the lead Federal agency for the current Ebola incident with DHS providing support for the overall response. As with any incident, HHS and DHS are coordinating with other Federal departments and agencies to adapt existing plans that have been developed previously for this incident. This collaboration includes HHS and CDC operational and departmental-level plans, lessons learned from past responses to pandemic threats such as the Federal Pandemic Plan from 2009 and the H1N9 Pandemic Crisis Action Plan from 2013, and the ongoing development of a draft Biological Incident Annex to the FIOP for Response.

As mentioned previously, DHS published guidance in 2006 for preparedness, response, and recovery to pandemic influenza threats for critical infrastructures and key resources (found at:

<http://www.flu.gov/planningpreparedness/business/cikrpandemicinfluenzaguide.pdf>). DHS supports Sector Coordinating Councils, which are self-organized, self-run, and self-governed sector-specific groups created or identified by critical infrastructure owners and operators that coordinate with the government on a wide range of critical infrastructure protection activities and issues. One of the primary purposes of these Councils is to facilitate inclusive organization and coordination of the sector's policy development regarding critical infrastructure protection planning and preparedness, exercises and training, public awareness, and associated plan implementation activities and requirements. During the 2009 H1N1 influenza outbreak, DHS worked with the Sector Coordinating Councils to craft specific guidance for pandemic preparedness for each critical infrastructure sector. Work on pandemic preparedness continues with these partners. For example, this past October, the Financial Services Sector Coordinating Council held the second part of a pandemic influenza webinar session with Federal Executive Boards in New York City and Northern New Jersey, FEMA and HHS regional officials, New York City Department of Health, and the Securities Industry and Financial Markets Association.

The DHS Office of the Inspector General (OIG) is currently auditing DHS pandemic preparedness and response. The OIG released the report on the first part of their audit in August 2014. This audit focused specifically on DHS management of personal protective

Question#:	1
Topic:	major pandemic
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Tom A. Coburn
Committee:	HOMELAND SECURITY (SENATE)

equipment and medical countermeasure stockpiles. DHS has been constantly seeking to improve our pandemic preparedness since these programs were established, and is committed to protecting its employees in order to ensure the effectiveness of our mission. These programs have enhanced their capabilities, and we are now ahead of most civilian Federal agencies in regards to medical countermeasures (MCM) protection for employees. The OIG began the second part of their audit, which will focus on the adequacy of pandemic preparedness plans, as well as Component coordination efforts regarding the response to the Ebola threat in 2014. Other past audits include: GAO-07-781, Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy; GAO-08-539, Influenza Pandemic: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning; and OIG-14-10242014T, DHS's Management of Pandemic Preparedness Supplies. Recommendations for these past audits are closed.

DHS does train its frontline employees for preventing the spread of disease and watching for overt signs of illness. For example, CBP administers mandatory, annual training on blood-borne pathogens for all of its officers and agriculture specialists. This training provides critical information on universal signs and symptoms of illness, as well as general precautions for infection control. Although Ebola is not a pandemic, it is worth noting that CBP officers in all airports selected for enhanced screening for Ebola receive additional on-site training that includes practical instruction for donning and doffing basic and enhanced personal protective equipment (PPE). CBP officers at all other POEs will receive video-based training on donning and doffing basic and enhanced PPE.

Question#:	2
Topic:	coordination mechanism
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Tom A. Coburn
Committee:	HOMELAND SECURITY (SENATE)

Question: In reviewing federal pandemic response capabilities, the Government Accountability Office recommended HHS and DHS perform frequent exercises and simulations to clarify and test all coordination mechanism. How many training exercises and simulations has DHS performed in coordination with HHS in each of the last five years? In your response, please describe the type of exercise (e.g. tabletop or real-life), the nature of the simulated threat (e.g. infectious disease outbreak), and the officials involved in each exercise.

Response: In the past five years, the Department of Homeland Security's (DHS) Federal Emergency Management Agency (FEMA) has offered courses relevant to pandemic preparedness and infectious disease control and trained approximately 537,457 participants representing Federal, State, local, and tribal governments, the private sector, and volunteer organizations. FEMA surveys participants 90 days following course completion to monitor the quality of the training. In fiscal year 2014, over 95 percent of participants reported that they were better prepared to deal with disasters and emergencies as a result of the training they had completed with FEMA. FEMA delivers training through several providers, to include the Center for Domestic Preparedness, the Emergency Management Institute, and the National Training and Education Division that funds training partners across the Nation.

DHS also coordinates an annual exercise through FEMA called Eagle Horizon to test the readiness and capabilities of Federal departments. Eagle Horizon, part of a series of congressionally-mandated preparedness exercises, plays an important role in ensuring we are prepared to respond during a wide range of threats or incidents, and to ensure continuity of government operations and services. HHS, among other Executive Branch agencies, participates in Eagle Horizon.

The DHS Office of Health Affairs provides occupational health advisories and guidance to the workforce on infectious disease control. OHA staff has deployed to select ports of entry to train CBP staff conducting enhanced screening on infection control protocol and proper use of personal protective equipment (PPE), in collaboration with the Centers for Disease Control.

Also during the past five years, FEMA supported development and delivery of 41 pandemic exercises. Of those 41, three were pandemic-focused tabletop senior officials' exercises that included participation by the Homeland Security Council Principals' Committee and its membership of Secretaries and Assistant Secretaries.

Question#:	2
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The pandemic preparedness and infectious disease exercises provided whole community partners, including but not limited to Federal, state, governmental and nongovernmental, public and private organizations, with the opportunity to examine the capabilities and the planning to deliver the requisite capabilities in response to a public health outbreak. DHS also sponsors training and exercises for biological threats for critical infrastructure partners.

Question#:	3
Topic:	detaining refugees
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Tom A. Coburn
Committee:	HOMELAND SECURITY (SENATE)

Question: In the face of a pandemic — especially one occurring in Central American — the Border Patrol would likely play a significant role in detaining refugees who may actually be infected.

Does DHS have a plan to maintain border security require in the event of increased cross-border migration due to an outbreak, particularly migration of infected individuals requiring quarantine?

Response: Each U.S. Customs and Border Protection (CBP), Office of Field Operations (OFO) Field Office has developed a mass migration plan to mitigate the risk to life from a hazardous event and to ensure that the borders are secured while ensuring that legitimate trade continues to cross our borders without significant delays. These incident management strategies are designed to facilitate CBP's ability to mitigate, prepare for, and respond to the impact of such incidents under extreme circumstances. These plans include trigger points that activate additional security and mitigation actions to ensure continued port security, safety of CBP personnel and travelers, as well as continue facilitation of legitimate trade and travel.

The OFO Field Offices have also developed a pandemic preparedness and response plan that provides guidance on pandemic preparedness activities; recognition of potentially ill travelers (watching for illness); processing potentially ill travelers; transportation of potentially ill travelers; workforce protection personal protective measures; public affairs communications; targeting potentially ill travelers; public health screening; coordination with public health officials; and procedures for isolation, quarantine, and detainment. Isolation and quarantine procedures are based on the Centers for Disease Control and Prevention (CDC) guidance referred to as RING: Recognize potentially ill travelers, Isolate potentially ill travelers, Notify CDC for additional guidance, and Give the appropriate support to the travelers.

CBP is part of a U.S. Government planning team developing an Americas Ebola Virus contingency plan. The planning and coordination workgroup includes representatives from the Department of State, Department of Defense, Department of Health and Human Services, and the Department of Homeland Security (DHS) to include CBP, Federal Emergency Management Agency (FEMA), U.S. Coast Guard (USCG), Office of Health Affairs (OHA), and U.S. Immigration and Customs Enforcement (ICE).

Question#:	3
Topic:	detaining refugees
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Tom A. Coburn
Committee:	HOMELAND SECURITY (SENATE)

Question: How would CBP maintain border security if an outbreak resulted in high levels of employee absenteeism?

Response: Each CBP OFO Field Office has developed a mass migration plan to mitigate the risk to life from a hazardous event and to ensure that the borders are secured while ensuring that legitimate trade, particularly National Priority Goods, continue to cross our borders without significant delays. These incident management strategies are designed to facilitate CBP's ability to mitigate, prepare for, and respond to the impact of such incidents under extreme circumstances. These plans include trigger points that activate additional security and mitigation actions to ensure continued port security, safety of CBP personnel and travelers, as well as continue facilitation of legitimate trade and travel.

OFO has developed Continuity of Operations Minimum Staffing Level Plans that identify triggers and estimate minimum staffing numbers required at each POE to maintain necessary mission critical operations. In the event of high levels of employee absenteeism, plans are in place to reassign personnel to help maintain, relocate or to cease operations, as directed. OFO is prepared to augment mission critical functions, utilizing Mobile Response Team personnel from alternate locations, if necessary. OFO Field Office management has also developed Staffing Recovery Plans to maintain operations during multiple or continuous extended periods of absenteeism that may last for several months each. Plans may include suspension of non-mission critical activities, shift adjustments, re-deployment of local and field office-wide assets, increased overtime, closures of low volume ports, and cancellations of annual leave, training and temporary details. These plans include communicating with other government agencies to assess alternative staffing plans during an escalating pandemic.

**Post-Hearing Questions for the Record
Submitted to the Honorable R. Gil Kerlikowske and Dr. Kathryn Brinsfield
From Senator Jon Tester**

**“Preparedness and Response to Public Health Threats: How Ready Are We?”
November 19, 2014**

Question: In states like Montana, Customs and Border Protection (CBP) Officers staff rural ports of entry that do not always have immediate access to 24-hour hospitals nearby. In particularly rural and inaccessible areas such as Goat Haunt in Glacier National Park, for example, Customs officials are even limited in their ability to transport individuals they apprehend without assistance from Canadian or National Parks Service officials. Without easy access to 24-hour hospitals at such rural border crossings, Customs officials can sometimes be limited in their ability to apprehend and submit for proper treatment individuals suspected of serious contagious illness.

At rural ports of entry, what responsibilities does a CBP officer have when they encounter an individual suspected to be infected with a serious and potentially contagious pathogen, such as Ebola?

Response: U.S. Customs and Border Protection (CBP) and the Centers for Disease Control and Prevention (CDC) have closely coordinated to develop policies, procedures, and protocols to identify travelers to the United States who may have a communicable disease of public health concern, responding in a manner that minimizes risk to our uniformed officers, agents, and the public. These pre-existing procedures – applied in the land, sea, and air environments – are standard protocol at all ports of entry and have been utilized collaboratively by both agencies on a number of occasions with positive results.

CBP is committed to ensuring that appropriate safety equipment, protocols and training are in place to protect our frontline personnel, especially during this period of heightened risk potential due to the Ebola virus. In support of the potential risk from an Ebola Virus Disease (Ebola) outbreak, CBP conducted a jobs hazard assessment (JHA) to determine exposure risk during operations and appropriate protective measures required and has purchased and deployed appropriate levels of Personal Protective Equipment (PPE) to all ports of entry (POE).

In the event that CDC or Public Health determine detention, isolation and/or quarantine of an ill traveler is warranted, CBP will work in coordination with CDC and local Emergency Medical Services (EMS) personnel during detention, isolation and/or quarantine process. Consistent with CBP guidelines, directives and applicable law, CBP Officers will assist quarantine officers with the enforcement of quarantine rules and regulations. In the event a symptomatic traveler is directed by the CDC to be transported to a medical facility for further testing and/or evaluation, local EMS will be contacted to transport the individual to the medical facility. In extenuating circumstances where EMS

Question#:	4
Topic:	ports 1
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Jon Tester
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is unable to transport, CBP will coordinate transportation with the appropriate CDC officials and federal, state or local law enforcement to identify transportation needs and transportation safety guidance for CBP officer that may be required to assist with the transport of a symptomatic traveler.

Question: Moreover, should a 24-hour hospital or medical facility that is not equipped to treat Ebola not be immediately available, what are the CBP Officer's options?

Response: CDC has informed us that more than 80 percent of returning travelers from Ebola-affected countries live within 200 miles of one of these Ebola treatment centers. Regardless of a facility's pre-designated role, CDC is ready to support any U.S. hospital or medical clinic that identifies a probable Ebola patient by sending a CDC Ebola Response Team (CERT) within a few hours of the diagnosis.

CBP will contact the servicing CDC Quarantine Station and appropriate Public Health Authority for coordination of the appropriate medical evaluation. In the event that CDC or Public Health determine detention, isolation and/or quarantine of an ill traveler is warranted, CBP will work in coordination with CDC and local Emergency Medical Services personnel during detention, isolation and/or quarantine process. Consistent with CBP guidelines, directives and applicable law, CBP Officers will assist quarantine officers with the enforcement of quarantine rules and regulations. In the event a symptomatic traveler is directed by the CDC to be transported to a medical facility for further testing and/or evaluation, local Emergency Medical Services (EMS) will be contacted to transport the individual to the medical facility by local EMS. In extenuating circumstances where EMS is unable to transport, CBP port managers will coordinate transportation with the appropriate CDC officials and federal, state or local law enforcement to identify transportation needs and transportation safety guidance for CBP officer that may be required to assist with the transport of a symptomatic traveler.

Question#:	5
Topic:	ports 2
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Jon Tester
Committee:	HOMELAND SECURITY (SENATE)

Question: While a majority of the President's funding request was for the Department of Health and Human Services, I wanted to discuss the training and preparedness of Customs and Border Protection officials to properly handle individuals suspected of having Ebola. We know that CBP Officers, Border Patrol Agents, and Air and Marine Interdiction Agents are trained in a variety of different scenarios. That said, CBP officers and agents stationed in rural ports of entry have to shoulder a large burden should they identify an individual infected with a serious disease—such as Ebola—trying to cross the border.

Are the CBP Officers at these ports provided all necessary personal protective equipment (PPE) to reduce their chance of infection?

Response: U.S. Customs and Border Protection (CBP) Office of Field Operations (OFO) is committed to ensuring that appropriate safety equipment is readily available, and that protocols training are in place to protect our frontline personnel, especially during this period of heightened risk potential due to the Ebola Virus Disease (Ebola). In coordination with the CBP Office of Human Resource Management (HRM), Occupational Health and Safety, CBP has purchased and deployed Personal Protective Equipment (PPE) to all ports of entry (POE).

Question: Are these officers trained how to put on and remove this equipment in order to reduce their risk of infection?

Response: U.S. Customs and Border Protection (CBP) Office of Field Operations (OFO) has implemented a comprehensive training plan in response to enhanced screening for Ebola. The training plan was developed by CBP Senior Medical Advisors, Office of Human Resources Management (HRM), Occupational Safety and Health (OSH), and Office of Training and Development (OTD) with input from the Department of Homeland Security, Office of Health Affairs, Occupational Safety and Health Administration (OSHA), and the Centers for Disease Control and Prevention (CDC).

Prior to the advent of heightened risk due to the recent Ebola outbreak, CBP administered mandatory, annual training on Blood-Borne Pathogens. This training provides critical information on universal signs and symptoms of illness, as well as general precautions for diseases with vectors of contagion similar to Ebola. This training is required for all CBP Officers and CBP Agriculture Specialists.

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Topic:	ports 2
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Jon Tester
Committee:	HOMELAND SECURITY (SENATE)

As a result of the enhanced medical screening for Ebola being conducted at the five international airports, CBP has implemented additional on-site training for CBP Officers and CBP Agriculture Specialists that includes practical instruction for donning and doffing Basic and Enhanced Personal Protective Equipment (PPE) and delivery of an Enhanced Screening instructional video. On-site training is delivered by CBP Senior Medical Advisors, Federal Occupational Health (FOH) physicians, and the CDC.

In addition an instructional course titled “Inbound Enhanced Screening for Ebola at Selected U.S. Ports of Entry” has been delivered by CBP Senior Medical Advisors and FOH medical personnel in coordination with HRM OSH Safety Officers at the five (5) international airports performing the enhanced medical screening. The content of this training course includes an overview of the Ebola virus, PPE, workforce safety and public health, enhanced screening process, cleaning, sanitizing and decontamination, and biohazard waste handling.

Question: Has all necessary personal protective equipment already been provided to every port of entry across the United States?

Response: U.S. Customs and Border Protection (CBP) is committed to ensuring the appropriate safety equipment, protocols, and training are in place to protect our frontline personnel, especially during this period of heightened risk potential due to the Ebola virus. In coordination with CBP HRM, OSH, CBP has purchased and deployed PPE to all POE.

CBP Office of Field Operations (OFO) distributed “DHS Ebola Entry Screening Guidance” and a CBP Ebola Job Hazard Analysis developed by CBP HRM OSH that outlines the PPE requirements necessary to protect frontline personnel from Ebola exposure risks that they may encounter on the job based on specific job tasks, types, and conditions of travelers.

While OFO employees are all familiar with the utilization of “Basic” PPE (gloves, masks, and hand sanitizer) during this period of additional screening due to Ebola, “Enhanced” PPE items over and above “Basic” PPE are required. The “Enhanced” PPE items are as follows:

- Face Shield or Non-Ventilated Goggles
- Disposable Impervious Suit or Gown
- Disposable Impervious Suit with Hood
- Disposable Shoe Covers

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All POEs have been instructed to maintain a 60-day supply of both “Basic” and “Enhanced” PPE. Currently, all POEs have met the required inventory for “Basic” PPE. The five international airports conducting the enhanced medical screening have also met the requirement for “Enhanced” PPE. All other POEs are in the process of acquiring their inventory of “Enhanced” PPE factoring in the availability of PPE from vendors and manufacturers. CBP is closely monitoring PPE inventories for all POEs to ensure full compliance.

Question: Do the facilities at all rural CBP ports of entry have isolation facilities necessary to house an individual infected with a serious illness such as Ebola?

Response: U.S. Customs and Border Protection (CBP) Office of Field Operations (OFO) operational protocols provide instruction for OFO Field Offices to coordinate with the Center for Disease Control (CDC), Port Authorities, and other key stakeholders to identify and designate sites for isolation and quarantine of potentially infectious travelers and detainees for all air, sea, and land border ports.

If CDC requires a dedicated space for assessing traveler health and applying rapid detection tools and temporary quarantine detentions, POEs will assist CDC and facility management in identifying a suitable space that will be available, as needed.

If a CBP Officer identifies a traveler at risk for being contagious, OFO will notify CDC, place a surgical mask on the traveler, and place the traveler in a designated isolation room that is well ventilated away from the traveling public. OFO will consult with the CDC to determine when an immediate health assessment is required.

**Post-Hearing Questions for the Record
Submitted to the Honorable R. Gil Kerlikowske and Dr. Kathryn Brinsfield
From Senator Rob Portman**

**“Preparedness and Response to Public Health Threats: How Ready Are We?”
November 19, 2014**

Question: In August 2014, the DHS OIG released a report finding numerous flaws in the Department’s management of its own stockpile of Personal Protective Equipment (PPE). The department did not determine its need for pandemic preparedness supplies prior to purchasing those supplies, had no clear methodology for its purchases, had no replenishment plan, and had no inventory controls to monitor the stockpiles. I echoed these concerns in my September 15, 2014 letter to Secretary Johnson. In his response, Deputy Secretary Mayorkas highlighted that DHS “Assigned an office responsible for the management and accountability of PPE, effective January 2014”.

Who specifically will lead that office, who will he or she report to, and what will their specific responsibilities be?

Response: Responsibility for the management and accountability of Personal Protective Equipment (PPE) is the Office of the Chief Readiness Support Officer within the Management Directorate and executed by respective Components within DHS. The Office of the Chief Readiness Support Officer will establish policy, guidance and oversight for the Department through a PPE Pandemic Logistics Support Plan, and through the application of a set of Department-wide PPE contracts with industry suppliers, oversee acquisition of PPE supplies. Further, through the use of the Department’s existing personal property inventory management system, the Office of the Chief Readiness Support Officer will establish management and inventory controls for pandemic PPE.

Question#:	7
Topic:	OIG report
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Rob Portman
Committee:	HOMELAND SECURITY (SENATE)

Question: Additionally, the Deputy Secretary noted “that DHS had previously identified many of the issues raised in the Office of Inspector General (OIG) report ...”

If that was the case, why was the agency delayed in correcting these problems, given DHS’s significant role in pandemic response?

Response: DHS is prepared for a pandemic, has been constantly seeking to improve our pandemic preparedness since these programs were established, and is committed to protecting its employees in order to ensure the effectiveness of our mission. DHS’s responsibility with respect to pandemic preparedness is to ensure that DHS personnel have sufficient supplies and training to allow them to perform their critical missions in a pandemic scenario. This goal is achieved through the purchase and management of personal protective equipment (PPE) and medical countermeasures (MCM). DHS is not purchasing or providing Personal Protective Equipment (PPE) or medical countermeasures (MCM) for anyone but its employees, critical contractors and those in its care and custody.

The Office of the Inspector General (OIG) report does not make distinctions between initial concerns in PPE and MCM management in years past and the ongoing management of these programs. For example, the Department was still a maturing agency during initial purchases of PPE and MCM, and procedures for documenting decision-making and retaining those records were still being developed. The management of MCM and PPE programs within DHS has been continuously improving since their creation. These programs have enhanced their capabilities, and we are now ahead of most civilian Federal agencies in regards to MCM protection for employees.

Prior to the OIG audit, the Department had formed a Pandemic Steering Committee, consisting of senior officials from across DHS Components, to coordinate pandemic preparedness activities, identify gaps and make improvements. Some of those gaps identified by DHS leadership and ongoing efforts to close them were captured in the OIG report. This committee also led the development of the Pandemic Workforce Protection Plan (PWPP), which improved and standardized pandemic procedures and planning for the Department. The PWPP was finalized in the fall of 2013 and built off earlier preparedness planning efforts for the 2005 H5N1 pandemic influenza threat and 2009 H1N1 pandemic, incorporating improvements and lessons learned from those events. As future incidents and exercises occur, DHS will continue this cycle of capturing lessons learned and improving its preparedness and response plans.

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Topic:	OIG report
Hearing:	Preparedness and Response to Public Health Threats: How Ready Are We?
Primary:	The Honorable Rob Portman
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The Department has also improved by identifying the requirements to determine the appropriate amount and type of personal protective equipment that may be needed in a pandemic based on functional risk assessments performed by the components, normal use of personal protective equipment and the surge needed for permissive use by DHS personnel. A “just-in-time” procurement strategy prevents incurring costs of the surge unless it is actually required.

In addition, DHS has planned for the life extension of the antivirals and antibiotics in its MCM stockpile. The antivirals within the stockpile are used to protect against pandemic Influenza, whereas the antibiotics are used in the event of an Anthrax attack. DHS works closely with the Food and Drug Administration, who administers the Federal Shelf Life Extension Program, to test MCM that have reached their expiration date and evaluate whether they can continue to maintain their effectiveness. OHA has already successfully extended the life of antibiotic MCM that have reached their expiration date and will submit its antiviral MCM for testing as they reach expiration. Based on DHS’s understanding on the success of antivirals generally tested through the Federal Shelf Life Extension Program and the storage conditions for the stockpiled antivirals, DHS expects that it will have appropriate antiviral MCM coverage for 2015. DHS has also updated existing standard operating protocols on the security and storage of MCM.

In an ever-evolving risk environment, DHS continually assesses the potential for exposure and impacts to the DHS workforce, and ensures that appropriate actions are taken in response to adapt to this risk.

**Post-Hearing Questions for the Record
Submitted to Kathryn Brinsfield, M.D.
From Senator Rob Portman**

“Preparedness and Response to Public Health Threats: How Ready Are We?”

November 19, 2014

3. The Deputy Secretary also stated that “OHA has worked closely with DHS operational Components and is satisfied that DHS employees have sufficient PPE available for the Ebola response, and that they have been trained on how to use this PPE to minimize their risk of exposure.”

- Has this claim been subsequently verified by the OIG?

[Answer from DHS OIG]:

This claim has not been verified by the OIG. We have incorporated this question into an ongoing audit that is focused on DHS’s plans to continue its operations during a pandemic and its response to Ebola. At the conclusion of this second audit, we will be able to address more clearly the accuracy of the Deputy Secretary’s statement and the status of the Departmental response to Ebola. Consistent with our responsibility under the *Inspector General Act*, we will provide copies of our report to this Committee once the audit is complete.

**Post-Hearing Questions for the Record
Submitted to The Honorable Nancy Lindborg
From Senator Tom Coburn, M.D.
“Preparedness and Response to Public Health Threats: How Ready Are We?”**

November 19, 2014

Question #1:

In the Administration’s emergency appropriations request, the administration asked for \$340 million for USAID’s global health security activities, and \$1.83 billion for CDC, in part to improve international disease detection.

How much have the CDC and USAID each spent on global health security and international disease detection in the past three years?

Answer:

During the last three fiscal years, USAID has programmed \$186 million and CDC has programmed \$191 million for international Global Health Security activities.

Question #2:

Are CDC and USAID agencies’ global health security and international disease detection programs duplicative? If not, how do you ensure that?

Answer:

The U.S. Government's Global Health Security Agenda provides the strategic direction for domestic and international activities and is coordinated within the interagency to ensure that we are maximizing the impact of each dollar, preventing duplication or gaps, and making investments sustainable.

USAID and CDC have a long history of working together for the past 50 years in Africa. Both agencies have extensive experience in working with host-country partners, international organizations, and academia on rapidly collecting, analyzing, and sharing data from disease outbreaks in animals and people. While CDC focuses on the human to human transmission of disease, USAID focuses on animal to human transmission.

In response to the Ebola epidemic in West Africa, USAID is the lead agency for the overall U.S. response, partnering with U.S. government agencies including CDC, which is leading on public health and medical response activities. USAID and CDC continue to work together to leverage our unique capabilities and ensure coordination and collaboration on technical and operational matters. We will continue to coordinate closely as investments in global health security are scaled up in the context of the response.

**Post-Hearing Questions for the Record
Submitted to the Honorable Nancy Lindborg
From Senator Heidi Heitkamp
“Preparedness and Response to Public Health Threats”**

November 19, 2014

The Ebola outbreak has only further exacerbated governmental stability, food security, limited health care, and economic issues in impacted regions.

Question #1:

I understand USAID is helping affected governments collaborate by providing logistical planning and other technical resources. How is this assistance being strategically employed to improve the preparedness and response infrastructure in the region to address future, long-term needs?

Answer:

To improve the preparedness and response infrastructure in the region that can address future, long term health crises like Ebola, USAID is implementing the Global Health Security Agenda (GHSa). In partnership with other nations, international organizations, and public and private stakeholders, USAID is working to prevent avoidable epidemics, detect threats early, and respond rapidly and effectively to disease outbreaks. While CDC will focus on human to human transmission of disease, USAID will focus on animal to human transmission by building capacity to routinely monitor for the presence of dangerous pathogens in the animal population, and capacity in areas of surveillance, laboratory capacity, and effective and timely infection control. We will focus on Ebola impacted West African countries, neighboring countries and transit hubs to ensure rapid and effective actions against the potential introduction of the Ebola virus in this area.

GHSa activities will strengthen Ebola preparedness in West Africa, including targeted disease surveillance at ports of entry, laboratory capacity, response capability, protocols for managing isolation and confirmation of suspected cases, risk characterization and mitigation, and communications in neighboring West African and other African countries to ensure rapid and effective actions against Ebola and other viruses. Using a “One Health Strategy,” professionals from public health, medicine, veterinary medicine, and wildlife conservation will also be engaged to strengthen country capacity to monitor and respond to animal viruses that become threats to public health.

Additionally, USAID will use funds to strengthen key parts of the broader digital infrastructure, including mobile telephone networks, the broadband backbone, digital financial payment systems, data and mapping systems, as well as e-governance platforms. The lack of adequate digital infrastructure significantly hindered the Ebola response because there was little to no communications infrastructure to disseminate factual, timely messaging and information about the disease. USAID will work with the public and private sectors to facilitate further expansion,

including partnering with the international and local private sector communities to introduce new innovative technology solutions that are capable of delivering sustainable, high capacity, low cost, connectivity solutions suitable for low-population density, lower income rural settings common in these countries.

Question #2:

How can we better encourage the rest of the global community to further partner and contribute to containing the Ebola outbreak?

Answer:

Many countries are already contributing to the effort through both financial and in-kind donations. As of March 12, 2015, the most significant contributors include: the United Kingdom with \$330.5 million, as well as military and civilian assets; the European Union with about \$128.3 million; Germany with \$175.2 million, air bridge support, and personnel; France with \$108.3 million, health responders, and treatment unit and training facility construction; and China with \$47 million and over 200 medical personnel. Other partners making major contributions include South Korea, Japan, Canada, Norway, Italy, Sweden, and Denmark.

The United States is working with dozens of countries to urge them to do more, while matching the assistance they can offer with needs on the ground. U.S. Government efforts have helped foster a growing understanding among world leaders that Ebola is a global threat requiring a robust, global response. Though there are still gaps, we believe that the momentum we have built will achieve our goals.

The international private sector has also made large contributions to the effort. As of March 13, 2015, the Paul Allen Family Foundation has pledged \$100 million; the Bill and Melinda Gates Foundation has pledged \$50 million; Facebook CEO Mark Zuckerberg, and his wife Priscilla Chan have donated \$25 million; Google has pledged \$15 million and Google's CEO, Larry Page, donated \$15 million through his family foundation; and the MTN Group has pledged \$10 million. According to the UN's Financial Tracking Service, overall the private sector (including companies, foundations, and individuals) has contributed and pledged \$412.9 million to the effort as of March 13, 2015.

Efforts to track the epidemic have been supported through important collaborations with private sector partners in information sharing. Facebook, for example, expanded short-term connectivity in remote areas through deployment of satellites, which improved our data capabilities in previously "dark" areas. United Parcel Service's (UPS) air transport as well as others in-country have supported road construction and last-mile logistics that have been highly valuable to our response efforts.

USAID and the State Department are actively engaging with the private sector and NGO community to help secure additional resources to support relief and recovery in the region. For example, the State Department facilitated the engagement of senior engineers from our nation's top tech companies who are now working on information and communications technology

infrastructure support at the UN's Mission for Ebola Emergency Response (UNMEER) in conjunction with USAID and Department of Defense.

USAID launched the Fighting Ebola Grand Challenge – announced by the President on September 29, 2014, that generated hundreds of proposals from the private sector to improve supplies such as the personal protective equipment needed by clinicians to safely treat Ebola patients and rapid, mobile diagnostics to speed up treatment. The U.S. Government plans to support as many as 15 innovations to improve health care workers' safety so they may provide better care to patients while facing less risk of heat stress, exhaustion, and infection, thus enhancing our ability to combat this epidemic.

Lastly, USAID will engage the private sector in economic recovery, as well as resilience and preparedness activities. To solicit collaboration from the private sector for partnerships focused on Ebola recovery and resilience, USAID will use mechanisms such as the Global Development Alliance (GDA) Annual Program Statement (APS) to in order capitalize on the distinctive capabilities and expertise, as well as financial co-investment that the private sector can bring to bear.

Question #3:

Many of these countries have experienced a significant primary impact that may already have or will create secondary effects in the country's economy and governmental stability. What does USAID see as the long-term impacts in the wake of Ebola for these countries? What steps are being taken by USAID to address these long-term impacts across societies?

Answer:

As we continue to focus on getting to zero cases in the region, USAID is also addressing long terms impacts – also known as second-order impacts – brought about by the Ebola crisis. We are working to restore health systems in the region, address food security concerns, address the weak capacity of government institutions, support education and crisis mitigation and improve information and communications technology. USAID will address these second-order impacts of Ebola programs in Liberia, Guinea, and Sierra Leone using the comparative strengths of our mission and our headquarters staff.

Health Systems Recovery in the Region:

USAID will provide funding to help address the longer-term recovery of health systems to improve the ability to manage future health crises, service delivery, strengthen the existing health system, and establish increased capacity. Funding will support core investments in rebuilding a better trained and skilled health workforce and strengthening core health systems functions. To rebuild, expand, and improve the skill-base of health workers in these countries, USAID will join other partners to strengthen curriculum, teaching, and infrastructure at pre-service training institutions, as well as recruit and train faculty to develop a generation of new and better-trained clinicians and health managers. USAID will also help address urgent priorities in the areas of health workforce systems, including hiring and compensation. Other activities will include strengthening health sector governance, pharmaceutical management and commodity logistics,

communications and routine information systems, quality improvement, laboratory systems, and health financing.

Restoring Emergency Non-Ebola Health Services in the Region:

The Ebola crisis caused a significant deterioration in the access to and use of essential health services due to the general collapse of public health care systems and services. USAID is focused on restoring essential non-Ebola health services by providing training and supervision as well as protective equipment for infection prevention and control. These activities are critical to ensuring that non-Ebola health facilities can re-open safely. Activities will focus on restoring and strengthening service delivery and providing the technical assistance needed to rebuild sustainable capacity, including activities to address adverse effects on maternal and child health

Food Security:

Fear, restrictions in movement, increased operating and market costs and lowered agricultural production and sales have caused household incomes and income generation opportunities to decrease in all three countries. As a result, food availability has decreased, particularly for poor households that are market- and income-dependent to meet their daily food consumption needs.

USAID's Famine Early Warning Systems Network (FEWSNET) estimates that over 40 percent of Liberians, Sierra Leoneans, and Guineans will experience acute food insecurity in 2015. This analysis indicates access to food - not availability - is the challenge facing households. USAID is, therefore, partnering with NGOs working in the region to provide vouchers and cash transfers to households that lost their livelihoods and resupply farmers who ate their seeds or sold their tools in order to make ends meet so that they can resume farming.

Governance and Economic Crisis Mitigation:

As a result of the Ebola outbreak, governments have closed schools and furloughed non-essential workers, many expatriates have departed, and citizens have reduced their engagement in production and trade due to fears of contagion. For these reasons, Ebola affected countries have an elevated risk of civil unrest and weakened political legitimacy, including potential intra- and inter-communal conflict and violent expression of dissatisfaction with the government performance.

USAID will support efforts to increase the effectiveness, transparency, accountability, and responsiveness of governance structures and maintain momentum on key governance reforms. We will capitalize on the community-level engagement developed on the Ebola response to further governance reform, increase civil society participation in provision of key services, and mitigate conflict.

USAID will also look to engage the private sector in economic recovery, resilience and preparedness activities. Our objective is to leverage and catalyze long-term, sustained investment from private sector entities currently operating in the affected countries, as well new entrants into these markets.

Education:

Schools were closed across the region as a result of the outbreak leading to a delay and possible decrease in education outcomes. USAID is continuing to support the re-opening of schools, including working with school authorities in the affected countries to test protocols and train teachers on how to manage suspected cases of Ebola, inform parents or guardians, and transport possibly infected children to facilities for further investigation. We are helping integrate Ebola awareness into the school curricula and install hygiene and hand-washing stations to keep children and teachers safe and reassure parents.

Information and Communications Technology:

Building on the success of the largely manual data collection system in Liberia, we are working with the U.S. Government and international community to lead an effort to streamline health informatics with technology. We are also engaging open source community and local governments in building more consistent approaches and capacity. Our hope is to foster a robust bio surveillance and early warning system that works in this operating environment.

To improve communications, USAID is tapping into broader array of possible implementation partners and the local carriers to mitigate major gaps in communications infrastructure and accompanying challenges, such as power and maintenance.

**Post-Hearing Questions for the Record
Submitted to The Honorable Nancy Lindborg
From Senator Rob Portman
“Preparedness and Response to Public Health Threats: How Ready Are We?”**

November 19, 2014

INFORMATION IS ACCURATE AS OF FEBRUARY 5, 2015

Question #1:

The United States has taken the lead combating the Ebola epidemic in Liberia. I'd like to get a better understanding of the response from our international partners.

- How are other international donors meeting the needs in Guinea and Sierra Leone?

Answer:

The response to date has been a truly international effort. Strong host government commitment combined with the United Kingdom's efforts in Sierra Leone and France's efforts in Guinea have allowed us to make significant strides in eradicating Ebola, although much work remains to be done. The United Kingdom has committed \$330 million of support which has gone toward supporting vital command and control platforms, the roll-out of 200 community care centers, and the construction of six Ebola Treatment Units totaling 700 treatment beds in Sierra Leone. France has pledged over \$108 million which includes \$95 million for the construction of five Ebola Treatment Units and more than 150 support personnel in Guinea. Additionally, France has coordinated Ebola preparedness in all of Francophone West Africa, including Mali, Côte d'Ivoire, Liberia and Cameroon.

Many other countries, including Germany, Sweden, Norway, Japan and members of the African Union and Economic Community of West African States (ECOWAS), have sent healthcare workers that have helped stem the tide of the Ebola crisis. Multilateral partners, such as the World Bank, are mobilizing nearly \$1 billion in financing for the countries in the region while the International Monetary Fund is providing debt relief.

As we move toward a broader focus to include second order impacts, transition, and recovery we will continue to work with the State Department to engage the host governments, donor governments, and multilateral institutions to leverage as many resources as possible and get these countries back on their feet. We are grateful for the contributions made by donors, bilateral and multilateral, thus far, but all donors must collectively remain focused on getting to zero.

- Do you have any concerns about the efforts in those countries and implications for jeopardizing any gains the United States will make in Liberia?

The three most-affected governments and key donors recognize that no country can be considered fully Ebola-free while the outbreak persists in neighboring areas. The Mano River Union recently committed to extinguishing the virus across the region. USAID is also stressing the need to remain focused on getting to zero in all three countries, even as planning begins for

transition and early recovery efforts in some areas. In addition to emphasizing the regional objective, USAID notes the potential and risk of complacency given the tremendous progress that has been achieved to date. Therefore, USAID will continue to work with international partners to maintain the sense of urgency that has brought us to where we are now while leveraging resources to lay foundations for the future.

Question #2:

I am interested in the role the United Nations is playing in combatting Ebola.

- How much has been donated to support the U.N. Ebola trust fund?

Answer:

The U.N. Ebola Trust Fund, also called the UN Ebola Response Multi-Partner Trust Fund (MPTF), presently has \$136,860,712 committed from over thirty partners. USAID directly funds partners engaged in Ebola response efforts and had been funding both UN and NGO partners prior to the creation of the UN Mission for Emergency Ebola Response (UNMEER) in September. Consequently, USAID has not funded the U.N. Ebola MPTF.

- What is the mission of the U.N. Mission for Ebola Emergency Response (UNMEER), and when will it be fully stood up?

The UN Mission for Emergency Ebola Response (UNMEER), established on September 18, 2014, is an unprecedented UN health mission, established to bring a unified UN response to the Ebola outbreak. UNMEER provides a platform to coalesce all the competencies of relevant UN actors, as well as other partners, for the delivery of assistance against the needs identified. Since its inception, UNMEER has focused on supporting the national governments in their efforts to plan, support, and fully implement effective and sustainable responses to the Ebola crisis. UNMEER has supported many Ebola response technical operations, including: providing emergency food supplies to case contact families under self-quarantine; rapidly transporting by UNMEER helicopters investigation and medical teams to remote sites, and urgent laboratory specimens to Ebola laboratories.

- How is UNMEER coordinating with the U.S. and other donor countries?

UNMEER has worked alongside the U.S. to build a regional platform capable of delivering rapid international assistance to address the urgent needs of the affected countries. The mission aims to coordinate the international Ebola emergency response at the operational level, provide direction across the U.N. system, and draw upon the capabilities and expertise of a broad range of agencies, including the World Health Organization, UNICEF, United Nations High Commission for Refugees, and UN World Food Program, as well as the U.N. Mission in Liberia and U.N. country teams. UNMEER's objectives are to stop the spread of the disease, treat those who are infected, and prevent the spread of Ebola to countries currently unaffected.

- How are all of these efforts being coordinated with the World Health Organization?

The UN's Ebola response is a multilateral one, coordinated by UNMEER, which takes a "whole of UN approach" to bring together the capabilities and competencies of all relevant UN actors, including the World Food Program, the World Health Organization and UNICEF.

Question #3:

Regional organizations within West Africa have also committed resources to combating Ebola.

- What role is the Economic Community of West African States, the West African regional body, playing?

Answer:

The overall objective of the response by the ECOWAS Commission and West Africa Health Organization (WAHO) is to reduce the mortality rate through early detection, adequate response, and building the capacity of Member States.

This is mainly provided through support to improve surveillance skills of healthcare providers, ensure adequate care for cases in the three countries, and strengthen the capacity of healthcare facilities through the provision of protective equipment, medicines, materials for hygiene and sanitation, as well as laboratory supplies.

In addition, the Commission and WAHO are working towards strengthening preventive and surveillance measures at borders; raising awareness, informing, and educating the communities on preventive measures; and strengthening collaboration among health ministries and other departments for a multi-sectoral response.

- What will be the mission of the 1,000 personnel pledged by the African Union?

On August 19, 2014, the African Union (AU) authorized the immediate deployment of an AU-led Military-Civil Humanitarian Mission, comprising medical and paramedical personnel and military. The AU Support to Ebola Outbreak in West Africa (ASEOWA) envisions up to 1,000 health workers in the field on a rotational basis as needed. As of February 5, 835 AU staff have been deployed.

Duties of the ASEOWA team are as follows:

LIBERIA:

- Managing the 100 bed MOD1 Ebola treatment unit (ETU) in Monrovia. (16 ASEOWA staff members and 168 local staff)

- Supporting the Chinese ETU in Monrovia
- Supporting the training of medical teams and 60 traditional and religious leaders, youths and women in Liberia
- Donating supplies to support Cape Mount St. Timothy Referral hospital
- Supporting Grand Cape Mount County on Ebola Awareness campaigns
- Supporting the re-opening of the Redemption Hospital in Monrovia
- Working with Ebola survivors in MOD 1 and Chinese ETU
- Supporting the survivors network in Monrovia through awareness campaigns
- Providing epidemiological support to 9 counties in Liberia

SIERRA LEONE:

- Managing a 100 bed ETU with 242 local staff in Bombali
- Managing a lab in Freetown
- Training the local medical teams
- Supporting the opening of a new lab in Koinadugu
- Providing epidemiological support in six districts

GUINEA:

- Supporting one ETU in Eastern Guinea
- Supporting a second ETU in Conakry
- Providing epidemiological support in 6 prefectures

- How will they coordinate with other bilateral and international efforts?

The ECOWAS and WAHO are working with WHO, other UN agencies, member states and others to more effectively coordinate a regional response to Ebola. ECOWAS has convened several meetings of regional health ministers and others to develop and agree on coordination, commitment and standard protocols for responding to and preparing for Ebola. This process is evolving and continues with strong USAID engagement.



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December 19, 2014

The Honorable Thomas Carper
Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, DC 20510-6250

Dear Senator Carper:

Thank you for the opportunity to respond to the questions from the members of the Committee on Homeland Security and Governmental Affairs subsequent to my November 19, 2014, testimony on the ebola outbreak in Dallas, Texas.

Attached you will find the questions and my responses in the format requested. Please let me know if you, or any of the other members have any additional questions. I may be reached at (512) 776-7363 or david.lakey@dshs.state.tx.us.

Sincerely,

A handwritten signature in black ink, appearing to read "DL Lakey MD".

David L. Lakey, M.D.
Commissioner

Dr. David Lakey
Commissioner
Texas Department of State Health Services
December 17, 2014
U.S. Senate Committee on Homeland Security and Governmental Affairs
Preparedness and Response to Public Health Threats: How Ready Are We?

The Honorable Tom Coburn, M.D.

When the first case of Ebola was identified in Texas in October 2014, you stated, “Prior to this event, the national strategy was that community hospitals would be able to care for individuals, and I think our experience with individuals here shows that that strategy needs to change.” What are your suggestions for how current federal preparedness programs could be improved to better prepare for infectious disease outbreaks?

Commissioner David L. Lakey, M.D. – response to the Honorable Tom Coburn, M.D.

The Center for Disease Control and Prevention’s (CDC’s) three-tier approach to creating a national network of facilities prepared to receive, assess, and/or provide treatment to a patient with Ebola is an appropriate strategy. The three-tier strategy ensures that finite resources may be appropriately managed, and that training efforts can be focused.

To facilitate a broader assessment of the public health response system in Texas, Governor Rick Perry has created a task force composed of 17 members with infectious disease, crisis management, and other areas of expertise. The purpose of the Task Force on Infectious Disease Preparedness and Response is to assess and enhance the state’s capability to respond to outbreak situations. Texas’ work in this regard would be complemented by a similar effort on a national scale. As has been abundantly evident in the past months, infectious disease response requires intense coordination and preparedness throughout the national public health system. Cohesive response also requires integration across agencies, health care systems, sector types, and differing organizational missions. A national discussion among experts of varied backgrounds, responsibilities, and levels of government has the potential to better prepare the entire country to quickly and effectively stand up in response to the next infectious disease event.

The Honorable Heidi Heitkamp

You highlighted the specific challenges encountered in Dallas to address the unprecedented public health threat of Ebola.

- How can the federal government better support state and local health departments to not only meet critical and immediate public health needs but ensure strong preparedness and response systems in the event of future threats?
- What forms of guidance and technical support did federal entities provide that were particularly critical to partner in containing and preventing the spread of Ebola?

Commissioner David L. Lakey, M.D. – response to the Honorable Heidi Heitkamp:

- The federal government can better support state and local health departments ensure strong preparedness and response by initiating a broader discussion of public health preparedness issues, similar to the Task Force in Texas. This should involve representation by state health officials, from multiple federal agencies, and from impacted stakeholders. This discussion would allow a thoughtful analysis of how the U.S. can improve, particularly in regards to communications among federal agencies, and in between federal and state agencies.
- Centers for Disease Control and Prevention (CDC) assistance can take a variety of forms in response efforts, depending on the nature of the event. In this instance, every guidance issued by CDC in relation to Ebola informed state and hospital action in the Ebola response in Dallas. Timely and accurate guidance and data from CDC is crucial to successful state response to infectious disease outbreaks. Areas that should be more comprehensively addressed are: issues related to Ebola and livestock and domestic animals; experimental drugs and therapies; medical waste transport and disposition; and pediatric Ebola care.

