

EXAMINING THE U.S. PUBLIC HEALTH RESPONSE TO THE EBOLA OUTBREAK

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED THIRTEENTH CONGRESS

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¹The report has been retained in committee files and also is available at <http://docs.house.gov/meetings/IF/IF02/20141016/102718/HHRG-113-IF02-20141016-SD010.pdf>.

EXAMINING THE U.S. PUBLIC HEALTH RESPONSE TO THE EBOLA OUTBREAK

THURSDAY, OCTOBER 16, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 12:02 p.m., in room 2123 of the Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, Burgess, Blackburn, Gingrey, Scalise, Gardner, Griffith, Johnson, Long, Ellmers, Upton (ex officio), DeGette, Braley, Schakowsky, Castor, Welch, Yarmuth, Green, and Waxman (ex officio).

Also present: Representatives Matheson, Sarbanes, Harris, and Meadows.

Staff present: Gary Andres, Staff Director; Charlotte Baker, Deputy Communications Director; Sean Bonyun, Communications Director; Leighton Brown, Press Assistant; Rebecca Card, Staff Assistant; Karen Christian, General Counsel; Noelle Clemente, Press Secretary; Marty Dannenfelser, Senior Advisor, Health Policy and Coalitions; Brenda Destro, Professional Staff Member, Health; Andy Duberstein, Deputy Press Secretary; Brad Grantz, Policy Coordinator, Oversight and Investigations; Sydne Harwick, Legislative Clerk; Brittany Havens, Legislative Clerk; Sean Hayes, Deputy Chief Counsel, Oversight and Investigations; Kirby Howard, Legislative Clerk; Charles Ingebretson, Chief Counsel, Oversight and Investigations; Emily Newman, Counsel, Oversight and Investigations; Krista Rosenthal, Counsel to Chairman Emeritus; Macey Sevcik, Press Assistant; Alan Slobodin, Deputy Chief Counsel, Oversight and Investigations; Sam Spector, Counsel, Oversight and Investigations; Jean Woodrow, Director of Information Technology; Ziky Ababiya, Democratic Staff Assistant; Peter Bodner, Democratic Counsel; Brian Cohen, Democratic Staff Director, Oversight and Investigations, and Senior Policy Advisor; Lisa Goldman, Democratic Counsel; Elizabeth Letter, Democratic Professional Staff Member; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor, and Nick Richter, Democratic Staff Assistant.

Mr. MURPHY. Good afternoon. I convene this hearing of the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce.

Ms. DEGETTE. Mr. Chairman, I can't see the witnesses.

Mr. MURPHY. We will need to make sure that the media is—when the witnesses speak that we are clear of the center section.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Today, the world is fighting the worst Ebola epidemic in history. CDC and our public health system are in the middle of a fire. Job one is to put it out completely, and we will not stop until we do. We must be clear-eyed and singular in purpose to protect public health, and to ensure not one additional case is contracted here in the United States. We in Congress stand ready to serve as a strong and solid partner in solving this crisis because there is no greater responsibility for the U.S. Government than to protect and defend the safety of the American people.

The stakes of this battle couldn't be any higher. The number of Ebola cases in western Africa is doubling about every 3 weeks. The math still favors the virus, even with the recent surge in global response.

With no vaccine or cure, we are facing down a disease for which there is no room for error. We cannot afford to look back at this point in history and say we should have done more.

Errors in judgment have been made, to be sure, and it is our immediate responsibility today to learn from those errors, correct them rapidly, and move forward effectively as one team, one fight.

Let us candidly review where we stand. When the latest Ebola outbreak in West Africa was confirmed months ago, authorities thought it would be similar to the 1976 outbreaks and quickly contained. That turned out to be wrong. By underestimating both the severity of the danger and overstating the ability of our healthcare system to handle Ebola cases, mistakes have been made. What was adequate practice for the past has proven to fall short for the present.

The trust and credibility of the administration and Government are waning as the American public loses confidence each day with demonstrated failures of the current strategy, but that trust must be restored, but will only be restored with honest and thorough action.

We have been told: "virtually any hospital in the country that can do isolation can do isolation for Ebola." The events in Dallas have proven otherwise. Current policies and protocols for surveillance, containment, and response were not sufficient. False assumptions create real mistakes, sometimes deadly mistakes.

We must understand what went wrong so we can get a firm handle on this crisis: Why was the CDC slow to deploy a rapid response team at Texas Health Presbyterian Hospital? Why weren't protocols to protect healthcare and hospital workers rapidly communicated? What training have healthcare workers received?

And there are things about Ebola we don't know. How long does the virus live on surfaces or on certain substances? How do healthcare workers wearing full protective gear still get infected? Can it be transmitted from a person who does not yet have a high fever? Both CDC and NIH tell us that Ebola patients are only contagious when having a fever. However, the largest study of the cur-

rent Ebola outbreak found that nearly 13 percent of confirmed cases in West Africa did not have associated fever.

Now, I respect the CDC as the gold standard for public health, but the need for strong congressional oversight and partnership remains paramount. I want to understand why CDC and the White House changed course in 2010 on proposals first introduced in 2005 that would have strengthened the Federal quarantine authority. We are here to work through and fix these problems.

I restate my ongoing concern that administration officials still refuse to consider any travel restrictions for the more than 1,000 travelers entering the United States each week from Ebola hot zones.

A month ago, the President told us someone with Ebola reaching our shores was unlikely and that “we have taken the necessary precautions” to “increase screening at airports so that someone with the virus does not get on a plane for the United States.”

Screening and self-reporting at airports have been a demonstrated failure, yet the administration continues to advance a contradictory position for this failed policy that frankly doesn’t make sense to me, especially if priority one is to contain the spread of Ebola and protect public health.

It troubles me even more when public health policies are based upon a stated concern over cutting commercial ties with fledgling democracies rather than protecting public health in the United States. This should not be presented as an all-or-none choice. We can and will create the means to transport whatever supplies and goods are needed in Africa to win this deadly battle. We do not have to leave the door open to all travel to and from hot zones in western Africa while Ebola is an unwelcome and dangerous stow-away on these flights. I am confident we can develop a reasoned and successful strategy to meet these needs.

The current airline passenger screening at five U.S. airports through temperature taking and self-reporting is troubling. Both CDC and NIH tell us that Ebola patients are only contagious when having a fever, but we know this may not be totally accurate.

A determined, infected traveler can evade the screening by masking the fever with ibuprofen or avoiding the five airports. Further, it is nearly impossible to perform contact tracing of all people on multiple international flights across the globe.

So let me be clear to all the Federal agencies responding to the outbreak. If resources or authorization is needed to stop Ebola in its tracks, tell us in Congress. I pledge, and I believe this committee joins me in pledging, that we will do everything in our power to work with you to keep the American people safe from the Ebola outbreak in West Africa.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

Today, the world is fighting the worst Ebola epidemic in history. CDC and our public health system are in the middle of a fire. Job One is to put it out completely. We will not stop until we do.

We must be clear-eyed and singular in purpose to protect public health, and ensure not one additional case is contracted here in the U.S. We in Congress stand ready to serve as a strong and solid partner in solving this crisis. There is no great-

er responsibility for the U.S. Government than to protect and defend the safety of the American people.

The stakes in this battle couldn't be any higher. The number of Ebola cases in West Africa is doubling about every three weeks. The math still favors the virus, even with the recent surge in global response.

With no vaccine or cure, we are facing down a disease for which there is no room for error. We cannot afford to look back at this point in history and say we could have done more.

Errors in judgment have been made, and it is our immediate responsibility today to learn from those errors, correct them rapidly and move forward effectively as one team—one fight.

Let us candidly review where we stand.

When the latest Ebola outbreak in West Africa was confirmed months ago, authorities thought it would be similar to the 1976 outbreaks and quickly contained. That turned out to be wrong.

By underestimating both the severity of the danger and overstating the ability of our healthcare system to handle Ebola cases, mistakes have been made. What was adequate practice for the past has proved to fall short for the present.

The trust and credibility of the administration and Government are waning as the American public loses confidence each day with demonstrated failures of the current strategy. That trust must be restored, but will only be restored with honest and thorough action.

We have been told: “virtually any hospital in the country that can do isolation can do isolation for Ebola.” The events in Dallas have proven otherwise.

Current policies and protocols for surveillance, containment and response were not sufficient. We've learned frontline hospital workers were not fully trained in these procedures, do not have proper equipment, do not know how to properly put on and remove safety gear, so we still have a lot more work to do because educating, training and assisting our public health workforce on the frontlines across the country must be a priority.

We cannot be lulled into a false sense of security. We know we have the best healthcare system in the world, but this committee well knows from our previous hearings with other Federal agencies and notably General Motors, what happens when assumptions are made that foster complacency. False assumptions create true mistakes. Sometimes, deadly mistakes.

At the same time we must understand what went wrong so we can get a firm handle on this crisis: Why was the CDC slow to deploy a rapid response team at Texas Health Presbyterian Hospital? Why weren't protocols to protect healthcare and hospital workers rapidly communicated? What training have healthcare workers received?

There are things about Ebola we don't know. How long does the virus live on surfaces or on certain substances? How do healthcare workers wearing full protective gear get infected? Can it be transmitted from a person who does not yet have a high fever?

Both CDC and NIH tell us that Ebola patients are only contagious when having a fever. However, the largest study of the current Ebola outbreak found that nearly 13% of confirmed cases in West Africa did not have associated fever. With many lives at risk, we should investigate the findings, and take proper action.

I respect the CDC as a gold standard for public health, but the need for strong congressional oversight and partnership remains paramount given the CDC hasn't had a stellar year. There have been high profile mishaps such as transfers of live anthrax, some anthrax held in Ziploc bags, and mistaken shipments of a deadly strain of Avian flu unknown to CDC leadership for weeks. I also want to understand why CDC and the White House changed course on in 2010 on proposals first introduced in 2005 that would have strengthened Federal quarantine authority. We are here to work through and fix these problems. I restate my ongoing concern that administration officials still refuse to consider any travel restrictions for the more than 1,000 travelers a week entering the U.S. from Ebola hot zones.

A month ago, the President told us someone with Ebola reaching our shores was “unlikely” and that “we've been taking the necessary precautions” to “increase screening at airports so that someone with the virus doesn't get on a plane for the United States.”

Screening and self-reporting at airports have been a demonstrated failure, yet the administration continues to advance a contradictory reason for this failed policy that frankly doesn't make sense, especially if “priority one” is to contain the spread of Ebola and protect public health.

It troubles me even more when public health policies are based upon a stated concern over “cutting commercial ties with fledgling democracies” rather than pro-

tecting public health in the United States. This should not be presented as an all-or-none choice. We can and will create the means to transport whatever supplies, and goods are needed in Africa to win this deadly battle. We do not have to leave the door open to all travel to and from hot zones in western Africa while Ebola is an unwelcome and dangerous stowaway on these flights. I am confident we can develop a reasoned and successful strategy to meet these needs.

We will have a rational, informed discussion about using commercial travel restrictions—the same ones being employed by British Airways, Air France, and more than a dozen nations—to protect Americans while at the same time ensuring aid and eradication efforts continue in West Africa.

The current airline passenger screening at five U.S. airports through temperature taking and self-reporting is troubling. Both CDC and NIH tell us that Ebola patients are only contagious when having a fever. The largest study of the current Ebola outbreak found that nearly 13% of confirmed cases in West Africa did not have associated fever. With many lives at risk, we should investigate the findings, and take proper action.

A determined, infected traveler can evade the screening by masking the fever with ibuprofen or avoiding the five airports.

Further, it is nearly impossible to perform contact tracing of all people on multiple international flights across the globe, when contact tracing and treatment just within the United States will strain public health resources.

The only way we can dispel the fear and hysteria surrounding Ebola is with clear, honest answers teamed with swift, effective action. This situation demands leadership from the top and by that I mean the White House. The 'lead from behind' strategy is recipe for disaster when trying to stop the transmission of Ebola. The legislative and executive branches of this Government are one team, and we will fight this together. We stand ready to meet with the administration at anytime and anywhere in this cause to help everyone.

So let me be clear. To all the Federal agencies responding to the outbreak: If resources or authorization is needed to stop Ebola in its tracks, speak up—tell Congress. I pledge to will do everything in my power to work with you to keep the American people safe from the Ebola outbreak in West Africa.

Mr. MURPHY. I now recognize the ranking member of the subcommittee, Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, Mr. Chairman.

On Monday, the Director General of the World Health Organization called the Ebola outbreak “the most severe, acute health emergency seen in modern times.” She warned that the epidemic “threatens the very survival of societies and governments in West Africa.”

This WHO assessment is no exaggeration. CDC predicts that up to 1.4 million West Africans could be infected with Ebola. Many more will die from treatable illnesses due to the collapse of these countries' public health infrastructures. This is a humanitarian crisis, and we have a moral imperative to help in West Africa. But ending the West Africa outbreak is also a U.S. national security imperative because doing so is the best way to keep Ebola out of the United States.

I was alarmed like all of us were when Thomas Duncan flew to the United States while harboring Ebola, and even more disturbed to learn of his discharge from the Texas Presbyterian ER with a fever after reporting that he had traveled from Liberia. Even worse, we learned this week that two nurses treating Mr. Duncan, Nina Pham and Amber Vinson, have contracted Ebola. I know, Mr. Chairman, we all join in sending these women and their families our prayers.

These new cases raise serious questions. The Washington Post wrote yesterday that Texas Presbyterian “had to learn on the fly how to control the deadly virus” and that the hospital was “not fully prepared for Ebola.” We need to find out why this hospital was unprepared and if others are too, and we need to make sure that the CDC is filling these readiness gaps. We should be concerned about the appearance of Ebola in the United States and the transmission to two health care workers, but we should not panic. We know how to stop Ebola outbreaks by isolating patients and tracing and monitoring contacts. The U.S. health care system can prevent isolated cases from becoming broader outbreaks, and that is why I am glad Dr. Frieden is here with us and Dr. Varga will be with us by video, because it would be an understatement to say that the response to the first U.S.-based patient with Ebola has been mismanaged, causing risk to scores of additional people. I know both of these gentlemen will be transparent and forthright in helping me to understand how we can improve our response when yet another person, and it will inevitably happen, shows up at the emergency room with these kind of symptoms.

I appreciate the steps taken by CDC and Customs to begin airport screenings. These steps are appropriate, and as some call for cutting off all travel, as the chairman said, this won’t be reasonable to be able to stop anybody with Ebola from coming into the United States, and we don’t want to take steps that would endanger Americans by interfering with efforts to halt the outbreak in Africa.

You know, there is no such thing as fortress America when it comes to infectious diseases, and the best way to stop Ebola is going to be to stop this virus in Africa. Experts from Doctors Without Borders have told us that a quarantine on travel would have “catastrophic impacts on West Africa.” Also, earlier this week the Director of NIH, Dr. Francis Collins, said had we adequately funded his agency for over a decade, we would already have an Ebola vaccine. His words are a reminder that key public health agencies have faced stagnant funding for several years, hampering our ability to respond to this crisis.

Mr. Chairman, 6 weeks ago when I first sent you a letter to ask for this hearing, the scope of the problem in West Africa was beginning to come into focus. Now the situation is dire. Let us work together to make sure that we stop it as quickly as we can.

With that, I yield the balance of my time to the gentleman from Iowa, Mr. Braley.

**OPENING STATEMENT OF HON. BRUCE L. BRALEY, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA**

Mr. BRALEY. Thank you.

Our duty today is to make sure the administration is doing everything possible to prevent the spread of Ebola within the United States. Our number one priority in combating this disease must be the protection of Americans, and we have to figure out the best way to do that.

My heart goes out to all those suffering from this horrible epidemic, and I am very proud of the hard work done by American troops, doctors, nurses, and other volunteers to combat this disease.

Congress must come together, put aside partisan differences and help stop this outbreak.

Today I hope to hear what steps the administration is taking to prevent the spread of Ebola and respond to the outbreak. I am greatly concerned, as Congresswoman DeGette has expressed, that the administration did not act fast enough in responding in Texas. We need to look at all the options available to keep our families safe and move quickly and responsibly to make any necessary changes at airports.

[The prepared statement of Mr. Braley follows:]

PREPARED STATEMENT OF HON. BRUCE L. BRALEY

Thank you. Today, we must make sure the administration is doing everything possible to prevent the spread of Ebola within the United States. Our number one priority in combating this disease must be the protection of Americans.

My heart goes out to those suffering from this epidemic, and I'm very proud of the hard work done by American troops, doctors, nurses, and volunteers to combat the disease. Congress must come together, put aside partisan differences, and help stop this outbreak.

Today, I hope to hear what steps the administration is taking to prevent the spread of Ebola and respond to the outbreak. I'm greatly concerned that the administration did not act fast enough. The administration needs to look at all options available to keep our families safe, and they need to move quickly and responsibly to make any necessary changes at our airports and hospitals that would prevent this disease from spreading further. And I'm going to ask specific questions on their plans for that.

One of the most important allies we have is a company in Ames, Iowa, called NewLink Genetics, with 120 employees working around the clock. NewLink has an Ebola vaccine that could help stop this disease, and they are currently trying to secure a contract with HHS to expand their manufacturing, so I hope to hear how HHS is moving forward as quickly as possible.

Thank you to the witnesses for being here today, and I look forward to a thoughtful and productive conversation.

Mr. MURPHY. The gentleman's time is expired. I now recognize the chairman of the full committee, Mr. Upton, for 5 minutes.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you.

Let me first begin by thanking our witnesses and all of the Members, Republicans and Democrats, for being here today.

You know, it is unusual to convene a hearing in DC during a district work period, but on this issue, there is no time to wait. I was likewise glad to see the President get off the campaign trail yesterday to finally focus on the crisis.

People are scared. We need all hands on deck. We need a strategy, and we need to protect the American people, first and foremost. It is not a drill. People's lives are at stake, and the response so far has been unacceptable.

As chairman of this committee, I want to assure the witnesses that we stand ready to support you in any way to keep Americans safe, but we are going to hold your feet to the fire on getting the job done, and getting it done right.

Both the United States and the global health community have so far failed to put in place an effective strategy fast enough to combat the current outbreak. The CDC admitted more could have been done in Texas. Two health care workers have become infected with

Ebola even as nurses and other medical personnel suggest that protocols are being developed on the fly. And none of us can understand how a nurse who treated an Ebola-infected patient, and who herself had developed a fever, was permitted to board a commercial airline and fly across the country.

It is no wonder the public's confidence is shaken. Over a month ago, before Ebola reached our shores, we wrote to Health and Human Services Secretary Burwell seeking details for the preparedness and response plan here at home and abroad, and it is clear whatever plan was in place was insufficient, but I believe that we can and must do better now.

We need a plan to treat those who are sick, to train health care workers to safely provide care, and to stop the spread of this disease here at home and at its source in Africa. This includes travel restrictions or bans from that region beginning today. Surely we can find other ways to get the aid workers and supplies in to these countries. From terrorist watch lists to quarantines, there are tools used to manage air travel to assure public safety. Why not here? We can no longer be reacting to each day's crisis. We need to be aggressive and finally get ahead of this terrible outbreak.

The American people also want to know about our troops and medical personnel who are courageously headed to Africa to treat the sick. How will they be protected? We want to know that health care workers here in America have the training and resources necessary to safely combat that threat as well.

So it is not just the responsibility of the United States. The global health community bears the charge to finally get ahead of the threat, develop a clear strategy, train all those who are involved in combating this disease, and eradicate this threat.

We have all heard the grave warnings that this will get worse before it gets better. People are scared. It is our responsibility to ensure that the Government is doing whatever it can to keep the public safe.

Diana DeGette and I have partnered together on the 21st Century Cures initiative to help improve the research and speed the approval of life-saving medicines and treatments, and while much attention has been paid to how this effort can help with diseases like cancer and diabetes, these same reforms can also help in the development of treatments for deadly infections like Ebola. We are all partners in this effort to save lives.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Let me begin by thanking our witnesses and all of the Members, Republicans and Democrats, for being here today. It's unusual to convene a hearing in Washington during a district work period, but on this issue, there's no time to wait. I was likewise glad to see President Obama get off the campaign trail to finally focus on this crisis.

People are scared. We need all hands on deck. We need a strategy. We need to protect the American people, first and foremost. This is not a drill—a fact that the doctors and nurses working on the front lines understand. People's lives are at stake, and the response so far has been unacceptable.

As chairman of this committee, I want to assure the witnesses that we stand ready to support you in any way to keep Americans safe, but we are going to hold your feet to the fire on getting the job done, and getting it done right. Both the

United States and the global health community have so far failed to put in place an effective strategy fast enough to combat the current outbreak.

Just the other day, the CDC admitted more could have been done in Texas. Two health care workers have become infected with Ebola even as nurses and other medical personnel suggest that protocols are being “developed on the fly.” And none of us can understand how a nurse who treated an Ebola-infected patient, and who herself had developed a fever, was permitted to board a commercial airline and fly across the country.

It’s no wonder the public’s confidence is shaken. Over a month ago, before Ebola reached our shores, we wrote to Health and Human Services Secretary Sylvia Burwell seeking details for the preparedness and response plan here at home and abroad. It’s clear whatever plan was in place was insufficient, but I believe we can and must do better now.

We need a plan to treat those who are sick, to train health workers to safely provide care, and to stop the spread of this disease here at home and at its source in Africa. This includes travel restrictions from that region beginning today. Surely we can find other ways to get the aid workers and supplies in to these countries. From terrorist watch lists to quarantines, there are tools used to manage air travel to assure public safety. Why not here? We can no longer be reacting to each day’s crisis. We need to be aggressive and finally get ahead of this outbreak.

The American people also want to know that our troops and medical personnel who are courageously headed to Africa to treat the sick will be protected. We want to know that health care workers here in America have the training and resources necessary to safely combat this threat.

This is not just the responsibility of the United States. The global health community bears the charge to finally get ahead of this threat, develop a clear strategy, train all those who are involved in combating this disease, and eradicate this threat.

We have all heard the grave warnings that this will get worse before it gets better, and folks are scared. It is our responsibility to ensure that the Government is doing whatever it takes to keep the public safe. Diana DeGette and I have partnered together on the 21st Century Cures initiative to help improve the research and speed the approval of life-saving medicines and treatments, and while much attention has been paid to how this effort can help with diseases like cancer and diabetes, these same reforms can also help in the development of treatments for deadly infections like Ebola. We are all partners in this effort to save lives.

Mr. UPTON. I yield the balance of my time to Dr. Burgess.

**OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BURGESS. Thank you, Mr. Chairman, and my thanks to the panel for being here today, and I think everyone here agrees, we must fix this.

America’s response to the Ebola Virus Disease outbreak is not a political issue, it is a public health crisis and a very dire one at that.

The frightening truth is that we cannot guarantee the safety of our health care workers on the front lines. It has been known for some time that health care workers have an outsized risk in western Africa. They have a 56 percent mortality rate of those health care workers who catch this disease. Two nurses have contracted Ebola in the United States, and indeed, we have to learn from the current situation in Texas and use any information we can gather to better help prepare hospitals and protect our health care workers on the front line. We are here today because we need answers to these questions.

This past August, the Inspector General of the Department of Homeland Security issued a report on personal protective equipment and antiviral countermeasures. They found that, and I am quoting here, “The Department of Homeland Security did not adequately conduct a needs assessment prior to purchasing pandemic

preparedness supplies and then did not effectively manage its stockpile of personal protective equipment and antiviral medical countermeasures.” This just illustrates how unprepared we are. We have to get this right.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

America’s response to the Ebola virus disease is not a political issue. This is a public health crisis and a dire one at that. The frightening truth is that we cannot guarantee the safety of our health care workers on the front lines of response.

In West Africa, there have been 416 healthcare workers who have contracted Ebola. 233 of them have died. That is a 56% mortality rate.

As of today, two health care workers contracted Ebola in the United States. According to the CDC, they were exposed to the virus before Mr. Duncan, Patient Zero, was diagnosed. In turn, the focus must now be on preparedness for hospitals around the country.

Indeed, we must learn from the current situation at Texas Presbyterian and use any information we can gather to help better prepare other hospitals around the country.

We are here today because we need answers to our questions about both the CDC’s and the administration’s flawed responses. While I believe the CDC had protocols in place, it seems to me there was a breakdown in the communication between the CDC and hospitals around the country.

This past August, the Inspector General at the Department of Homeland Security issued a report on personal protective equipment and antiviral medical countermeasures.

They found that, and I quote, “The Department of Homeland Security did not adequately conduct a needs assessment prior to purchasing pandemic preparedness supplies and then did not effectively manage its stockpile of pandemic PPE and antiviral medical countermeasures.” This illustrates just how unprepared we may still be.

Drugs companies are stating that they will have basic information on the efficacy of their drugs and vaccines by the end of the year. The end of the year is too late. We have been actively funding research on vaccinations and drug treatments for over a decade, but now the time to perform is now. When will these protocols be expedited?

Relevant agencies have the statutory authority to quarantine and isolate individuals who are infected with or carrying an infectious communicable disease.

Secretary Burwell has this authority which is enumerated in the Public Health Service Act. When will this authority be used?

Numerous laws have been passed in the past decade to better prepare us for an outbreak of infectious illness, to increase coordination, and to fast-track drug development. The Assistant Secretary for Preparedness and Response, Dr. Lurie, has been notably absent.

I have a long-standing relationship with Texas Presbyterian. This crisis is in my back yard. I want to make sure we are doing everything in our power to stop Ebola.

Mr. BURGESS I would like to yield the balance of my time to Ms. Blackburn from Tennessee.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Dr. Burgess, and yes, indeed, welcome to all of our witnesses.

Everyone has mentioned we are here to work with you to protect Americans, and that includes the caregivers, and by that I mean the men and women working on the front lines, the Screaming Eagles of the 101st from Fort Campbell.

I will yield back my time and have further questions later. Thank you.

Mr. MURPHY. The gentelady yields back and time is expired. I would now like to introduce the witnesses—I am sorry. No, first I go to Mr. Waxman. I apologize.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman. I am pleased to have this opportunity to make an opening statement before we hear from the witnesses.

I think we have to put all of this in perspective and not panic. Everybody said not to panic, and then they made statements like “We are going to get tough. We are going to do something about it.” Well, what do we need to do?

First of all, we have got a problem in Africa, and this is a serious outbreak that could spiral beyond our control. On Tuesday, the World Health Organization estimated that soon there could be up to 10,000 new Ebola cases each week in West Africa, and CDC has warned that the outbreak could infect as many as 1.4 million people by the end of January. So this is a humanitarian crisis in Africa, and we have a responsibility to help because if we don’t help there, that outbreak is going to continue to spiral out to other places, and sealing people off in Africa is not going to keep them from traveling. They will travel to Brussels, as one of the people did, and then into the United States.

We can stop the epidemic from spreading in Africa or in the United States if we isolate the patient and monitor the contacts of that patient, and if we do that, we can stop it there and we can stop it here.

So in Africa, we need to know: Are we moving fast enough, do responders have adequate resources, are we effectively coordinating our response with other countries in international organizations?

But here, people are scared, and we shouldn’t make them even more frightened. Put this in perspective. We have had three recent cases of Ebola in this country: Thomas Duncan, who entered the United States while harboring Ebola and who flew through Brussels to get here; Nina Pham and Amber Vinson, the nurses who became ill while caring for Mr. Duncan. We should be concerned about these cases, and we need to act urgently, but we need not to panic. What we have to do is learn what we need to do, what mistakes we have made and not repeat them. We want to find out what happened at Texas Health Presbyterian Hospital, how CDC, State and local health officials and hospitals can improve procedures moving forward.

We should also use this as a wakeup call to ensure the adequacy of our own public health and preparedness safety net. We need to be prepared before a crisis hits, not scrambling to respond after the crisis.

In the past decade, the ability to fund research and public health programs has declined here in the United States. Since 2006, CDC’s budget adjusted for inflation has dropped by 12 percent. Funding for the Public Health Emergency Preparedness Cooperative Agreement, which supports State and local health department preparedness activities, has been cut from \$1 billion in its first

year of funding in 2002 to \$612 million in 2014. All of these were also subject to the sequestration, and those who allowed that sequestration to happen by closing the Government have to answer to the American people as well.

We need to commit adequate funding to public health infrastructure. We need to hold public health systems accountable to standards of preparedness. Based on what we know, it appears that Texas Presbyterian would have not met those standards, though in fairness, I suspect that many hospitals all over the country would also have struggled to respond. This is a problem we have to solve.

Mr. Chairman, before I run out of time, I want to acknowledge the health care workers and volunteers, those treating Ebola victims in the United States and those who have traveled to West Africa to help during this outbreak. It is dangerous work that they are doing. They are putting themselves in danger to save lives. They deserve our thanks and our praise.

I also want to thank all of our witnesses. You have my confidence, and I appreciate you joining us today to provide answers about how to stop the current Ebola outbreak in Africa and how to improve our public health systems to avoid the next crisis.

I am ending my career at the end of this year, but I have been through so many hearings where, when there is a crisis, we have Congressmen sit and point fingers. Well, let us point fingers at all of those responsible. We have our share of responsibility by not funding the infrastructure. In Africa, they have no infrastructure. We have to help them develop it to deal with this crisis, but we shouldn't leave ourselves vulnerable by these irrational budget cuts.

Mr. MURPHY. The gentleman's time is expired. Thank you.

I would now like to introduce the witnesses on the panel for today's hearing. Dr. Thomas R. Frieden is the Director of the Centers for Disease Control and Prevention. Dr. Anthony Fauci is the Director of the National Institute of Allergy and Infectious Diseases within the National Institutes of Health. Dr. Robin Robinson is the Director of Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response at the United States Department of Health and Human Services. Dr. Luciana Borio is the Assistant Commissioner for Counterterrorism Policy at the U.S. Food and Drug Administration. Mr. John P. Wagner is the Acting Assistant Commissioner of the Office of Field Operations within U.S. Customs and Border Protection at the U.S. Department of Homeland Security. And joining us today on videoconference from Texas will be Dr. Daniel Varga, who is the Chief Clinical Officer and Senior Vice President at Texas Health Resources.

I will now swear in the witnesses. You are all aware that the committee is holding an investigative hearing, and when doing so has had the practice of taking testimony under oath. Do any of you object to taking testimony under oath? None of the witnesses say so, and Dr. Varga?

Mr. VARGA. No.

Mr. MURPHY. Thank you. The Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any you desire to be advised by

counsel during your testimony today? Thank you. Everyone answers no. In that case, would you all please rise and raise your right hand and I will swear you in.

[Witnesses sworn.]

Mr. MURPHY. You are now under oath and subject to the penalties set forth in Title XVIII, section 1001 of the United States Code. We will call upon you each to give a 5-minute opening summary of your written statement.

Dr. Frieden, you are recognized for 5 minutes.

STATEMENTS OF THOMAS R. FRIEDEN, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBIN A. ROBINSON, DEPUTY ASSISTANT SECRETARY AND DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES; LUCIANA BORIO, ASSISTANT COMMISSIONER FOR COUNTERTERRORISM POLICY AND DIRECTOR, OFFICE OF COUNTERTERRORISM AND EMERGING THREATS, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; JOHN P. WAGNER, ACTING ASSISTANT COMMISSIONER, OFFICE OF FIELD OPERATIONS, U.S. CUSTOMS AND BORDER PROTECTION, DEPARTMENT OF HOMELAND SECURITY; AND DANIEL VARGA, CHIEF CLINICAL OFFICER AND SENIOR EXECUTIVE VICE PRESIDENT, TEXAS HEALTH RESOURCES

STATEMENT OF THOMAS R. FRIEDEN

Mr. FRIEDEN. Thank you very much, Chairman Murphy, Ranking Member DeGette, Chairman Upton, and Ranking Member Waxman. I very much appreciate the opportunity to come before you to discuss the Ebola epidemic and our response to it to protect Americans.

My name is Dr. Tom Frieden. I am trained as a physician. I am trained in internal medicine, in infectious diseases. I completed the CDC Epidemic Intelligence Service training, and I have worked in the control of diseases, communicable diseases and others, since 1990.

Ebola spreads only by direct contact with a patient who is sick with the disease or has died from it, or with their body fluids. Ebola is not new, although it is new to the United States. We know how to control Ebola, even in this period. Even in Lagos, Nigeria, we have been able to contain the outbreak. We do that by tried-and-true measures of finding the patients promptly, isolating them effectively, identifying their contacts, ensuring that if any contact becomes ill, they are rapidly identified, isolated, and their contacts are identified.

But there are no shortcuts in the control of Ebola, and it is not easy to control it. To protect the United States, we have to stop it at the source.

There is a lot of fear of Ebola, and I will tell you as the Director of CDC, one of the things I fear about Ebola is that it could spread

more widely in Africa. If this were to happen, it could become a threat to our health system and the health care we give for a long time to come.

Our top priority, our focus is to work 24/7 to protect Americans. That is our mission. We protect Americans from threats, and in the case of Ebola, we do that by a system at multiple levels. In addition to our efforts to control the disease at the source, we have helped each of the affected countries establish exit screening so that every person leaving has their temperature taken. In a two-month period of August and September, we identified 74 people with fever. None of them entered the airport or boarded the plane. As far as we know, none of them were diagnosed with Ebola, but that was one level of safety.

Recently, we have added another level of screening people on arrival to the United States. That identifies anyone with fever here, and we have worked very closely with the Department of Homeland Security and Customs and Border Protection to implement that program, and I would be happy to provide further details of it later.

We have also increased awareness among physicians throughout the United States to think Ebola in anyone who has fever and/or other symptoms of infection and who has been to West Africa in the previous 21 days. We have established laboratory services throughout the country so that not all laboratory tests have to come to the specialized laboratory at CDC. In fact, one of those laboratories in Austin, Texas, identified the first case here.

We also have fielded calls from concerned doctors and public health officials throughout the country. We found more than 300 calls and only one patient, Mr. Duncan, had Ebola, but that is one too many, and we are open to ideas for what we can do to keep Americans as safe as possible as long as the outbreak is continuing.

We also have established emergency response teams from CDC that will go within hours to any hospital that has an Ebola case to help them provide effective care safety.

[Slide.]

There is a lot of understandable concern about the cases in Dallas. I have one slide, if we can show it, of the contact tracing activities there, and I think we provided copies for the members. The two core activities in Dallas are to ensure that there is effective infection control and to trace contacts. Here you see a timeline of exactly what has happened in the identification of contacts. We have followed each of the contacts. When any become ill or if any become ill, we immediately isolate them so that we can break the chain of transmission. That is how you stop Ebola. I can go through the details when you wish.

We also are working to ensure that there is effective infection control there, and I can go through the details of that.

In sum, CDC works 24/7 to protect Americans. There are no shortcuts. Everyone has to do their part. There are more than 5,000 hospitals in this country. There are more than 2,500 health departments at the local level. We are there to support. We are there with world-class expertise, and we are there to respond to threats so that we can help protect Americans, and we are always open to new ideas. We are always open to data because our bottom

line is using the most accurate data and information to inform our actions and protect health.

Thank you.

[The prepared statement of Mr. Frieden follows:]

House Energy and Commerce Committee
Subcommittee on Oversight and Investigations

Public Health Response to Ebola

October 16, 2014

Statement of Dr. Thomas R. Frieden, M.D., M.P.H.

Director, Centers for Disease Control and Prevention

Good afternoon Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. Thank you for the opportunity to testify before you today and for your ongoing support for the Centers for Disease Control and Prevention's (CDC) work in protecting Americans. I am Dr. Tom Frieden, Director of the CDC. I appreciate the opportunity to be here today to discuss the epidemic of Ebola, as well as the work the CDC is doing to manage the consequences of this epidemic – both here in the United States and overseas – in the wake of the first diagnosed case here in the United States two weeks ago, which ultimately and tragically has become the first death from Ebola in the United States. Additionally, I will address the work CDC and public health officials in Texas are undertaking in response to the transmission of Ebola to two health care workers here in the United States, which occurred this week.

From the time the 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 have been preparing 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. This occurrence underscores the need to carefully follow the protocols that have been developed, to work closely across levels of government,

and to continue our urgent effort to address the epidemic in West Africa, which remains the biggest risk to the United States.

As we learn from the recent importation case in Dallas and subsequent transmissions, and continue the public health response there, we remain confident that Ebola is not a significant public health threat to the United States. It is not transmitted easily, and it does not spread from people who are not ill, and cultural norms that contribute to the spread of the disease in Africa – such as burial customs and inadequate public-health measures – are not a factor in the United States. We know Ebola can be stopped with rapid diagnosis, appropriate triage, and meticulous infection-control practices in American hospitals. And the United States is leading the international effort to stop it at the source in Africa. CDC is committing significant resources both on the ground in West Africa and through our Emergency Operations Center here at home.

We have been constantly monitoring our response in the United States, and will continue to do so. CDC and U.S. Customs and Border Protection (CBP) in the Department of Homeland Security (DHS) have implemented new layers of entry screening at five U.S. airports that receive over 94 percent of travelers from the Ebola-affected nations of Guinea, Liberia, and Sierra Leone. On October 11, 2014, we began screening New York's JFK International Airport, since in the 12 months ending July 2014, JFK received nearly half of all travelers from those three West African nations. The enhanced entry screening has expanded this week at Washington-Dulles, Newark, Chicago-O'Hare, and Atlanta international airports.

This is a whole-of-Government response, with agencies across the United States Government committing human and financial resources. Across HHS, CDC is actively partnering with the Office of Global Affairs, the Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health, and the Food and Drug Administration to coordinate and respond to this epidemic.

Also, CDC has embedded technical staff as the leads for the health, medical, and public health aspects of the response in the USAID-led DART team in West Africa. Additionally, staff, logistical support, and resources from the Department of Defense (DoD) are already being deployed to rapidly scale up our efforts to include constructing Ebola Treatment Units (ETUs) and training health care workers. We are working closely with our international partners to scale up the response to the levels needed to stop this epidemic.

Ebola is a severe, often fatal, viral hemorrhagic fever. The first Ebola virus was detected in 1976 in what is now the Democratic Republic of Congo. Since then, outbreaks have appeared sporadically. The current epidemic in Guinea, Liberia, and Sierra Leone is the first 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 and Senegal from the initially-affected areas and we have also seen in Nigeria and Senegal that proven practices such as contact tracing, monitoring, and isolation practices can contribute to managing Ebola and preventing a small number of cases from growing into a larger outbreak.

Ebola has symptoms similar to many other illnesses, including fever, chills, weakness and body aches. Gastrointestinal symptoms such as vomiting and diarrhea are common and profound, with fluid losses on average of 5-7 liters in 24 hours over a five day period. These fluid losses can result in life-threatening electrolyte losses. In approximately half of cases there is hemorrhage -- serious internal and external bleeding. There are two things that are very important to understand about how Ebola spreads. First, the current evidence suggests human-to-human transmission of Ebola only happens from people who are symptomatic-- not from people who have been exposed to, but are not ill with the disease. Second, everything we have seen in our decades of experience with Ebola indicates that Ebola is not spread by casual contact; Ebola is spread through direct contact with bodily fluids of someone who is sick with, or has died from Ebola, or through exposure to objects such as needles that have been

contaminated. While the illness has an average 8-10 day incubation period (though it may be as short as two days and as long as 21 days), we recommend monitoring for fever and signs of symptoms for the full 21 days. Again, we do not believe people are contagious during that incubation period, when they have no symptoms. Evidence does not suggest Ebola is spread through the air.

The earliest recorded cases in the current epidemic were reported in March of this year. Following an initial response that seemed to slow the early outbreak for a time, cases flared again due to weak systems of health care and public health and because of challenges health workers faced in dealing with communities where critical disease-control measures were in conflict with regular practices. As of last week, the epidemic has reached 8,997 reported cases, including 4,493 documented deaths, though we believe these numbers may be substantially under-reported. The effort to control the epidemic in some places is complicated by fear of the disease and distrust of outsiders. Security is tenuous and unstable, especially in remote isolated rural areas. There have been instances where public health teams could not do their jobs because of security concerns, although community outreach has resulted in acceptance of services in specific areas.

Many of the health systems in the affected countries in West Africa were weak prior to the Ebola outbreak, and do not reach into rural areas effectively. Health care workers are often too few in number and not reliably present at facilities, and those facilities have limited capacity. Poor infection control in routine health care in these three countries, along with traditions such as public funerals and preparing bodies of the deceased for burial, make efforts to contain the illness more difficult. Furthermore, the porous land borders among countries and remoteness of many villages have greatly complicated control efforts. The epidemic has further weakened these fragile healthcare systems – even to the point of collapse – and as a result local populations have lost access to treatment for other major health issues, such as malaria, diarrheal disease, or assistance with child delivery. The secondary effects of this outbreak also transcend the medical realm, as the economies of the affected countries have taken major

blows that could impact their growth and development for years to come. The region also faces greater international isolation, and the potential for political instability. These impacts are intensifying, and not only signal a growing humanitarian crisis, but also have direct impacts on our ability to respond to the Ebola epidemic itself.

Fortunately, we know what we must do. In order to stop an Ebola outbreak, we must find active cases, respond appropriately, and prevent future cases. The use of real-time diagnostics is extremely important to identify new cases. We must support the strengthening of health systems and assist in training healthcare providers. Once active cases have been identified, we must support quality patient care in treatment centers, prevent further transmission through proper infection control practices, and protect healthcare workers. Epidemiologists must identify contacts of infected patients and follow up with them every day for 21 days, initiating testing and isolation if symptoms emerge. And, we must intensify our use of health communication tools to disseminate messages about effective prevention and risk reduction. These messages include recommendations to report suspected cases, to avoid close contact with sick people or the deceased, and to promote safe burial practices. In Africa, another message is to avoid bush meat and contact with bats, since “spillover events,” or transmission from animals to people, in Africa have been documented through these sources.

Many challenges remain. While we do know how to stop Ebola through meticulous case finding, isolation, and contact tracing, there is currently no cure or vaccine shown to be safe or effective for Ebola. We are working to strengthen the global response, which requires close collaboration with the World Health Organization (WHO) and additional assistance from our international partners. At CDC, we activated our Emergency Operations Center to respond to the initial outbreak, and are surging our response. As of last week, CDC has over 139 staff in West Africa, and over 1,000 staff in total have provided logistics, staffing, communication, analytics, management, and other support functions. CDC

will continue to work with our partners across the United States Government and elsewhere to focus on key strategies of response:

- Effective incident management – CDC is supporting countries to establish national and sub-national Emergency Operations Centers (EOCs) by providing technical assistance and standard operating procedures and embedding staff with expertise in emergency operations. All three West African countries at the center of the epidemic have now named and empowered an Incident Manager to lead efforts.
- Isolation and treatment facilities – It is imperative that we ramp up our efforts to provide adequate space to treat the number of people afflicted with this virus.
- Safe burial practices – Addressing local norms on burial practices is one of the keys to stopping this epidemic. CDC is providing technical assistance for safe burials.
- Infection control throughout the health care system– Good infection control will greatly reduce the spread of Ebola and help control future outbreaks. CDC has a lead role in infection control training for health care workers and safe patient triage throughout the health care system.
- Communications – CDC will continue to effectively communicate facts about the disease and how to contain it, particularly targeting communities in these countries that have presented challenges to date.

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

The resources provided for the period of the Continuing Resolution will support our response for the 11 week period of the Continuing Resolution and allow us to ramp up efforts to contain the spread of this virus. More than half of the funds are expected to directly support staff, travel, security and related expenses. A portion of the funds will be provided to the affected area to assist with basic public health infrastructure, such as laboratory and surveillance capacity, and improvements in outbreak management and infection control. The remaining funds will be used for other aspects of strengthening the public health response such as laboratory supplies/equipment, and other urgent needs to enable a rapid and flexible response to an unprecedented global epidemic. CDC is working to identify our resource needs for the rest of the fiscal year, and possibly further, as we deal with this evolving situation. CDC will continue to coordinate activities directly with critical Federal partners—including the United States Agency for International Development (USAID), DoD, DHS, and the State Department—and non-governmental organizations. Over the past few weeks, we have seen progress, as the DoD has begun deploying assets to the area and laying the ground work to construct 17 ETUs, train local workers to staff these facilities, and move supplies into the area. In addition, USAID is working closely with non-governmental organizations to scale up efforts in all areas of the response. Currently, there are over 60 burial teams in all 15 counties of Liberia for the management of safe human remains. More than 70 organizations are providing Ebola education and awareness in Liberia, Guinea, and Sierra Leone. Organizations are also working to improve infection control practices in all health facilities to ensure functionality of the healthcare system. We continue to work with national governments, WHO, and USAID to provide for interim measures such as isolation in community settings with proper protections, and improvements to ensure the safe burial of those who have died from the virus.

Though the most effective step we can take to protect the United States is to stop the epidemic where it is occurring, we are also taking strong steps to protect Americans here at home. The imported case of

Ebola in Dallas, diagnosed on September 30th in a traveler from Liberia, required CDC and the Nation's public health system to implement rapid response protocols that have been developed in anticipation of such an event. Within hours of confirming that the patient had Ebola, CDC had a team of 10 people on the ground in Dallas to assist the capable teams from the Texas state health department and local authorities. We have worked side-by-side with state and local officials to do all we can to prevent transmission to others. Together, we assessed all 114 individuals who might possibly have had contact with the patient prior to his admission and isolation. We narrowed down the contacts to 10 who may have been around him when he was infectious and 38 others with whom exposure cannot be ruled out. These individuals will be tracked for 21 days for any signs of symptoms, and they will quickly be isolated if symptoms develop. We are also working to identify and learn lessons from the initial patient encounter and other events that complicated our response, and to apply them in any other responses.

We were deeply concerned to have learned last weekend that there had been transmission of the Ebola virus from the first, or "index" patient, to a health care worker. This health care worker had been monitoring her temperature and symptoms, in accordance with CDC guidelines, and upon finding an elevated temperature, immediately reported it to the hospital and was admitted and isolated. And just yesterday, we learned of a second transmission in another health care worker. While we do not yet know exactly how these transmissions occurred, they demonstrate the need to strengthen the procedures for infection-control protocols which allowed for exposure to the virus. We are working very hard to investigate the situation, but are not waiting for the completion of this investigation and have already helped the hospital implement new measures for safety.

In terms of safe and effective care of Ebola patients, we had already begun to increase education and training of health care workers at the facility which cared for the index patient. The care of Ebola can be done safely, but it requires meticulous and scrupulous attention to infection control, and even a single inadvertent slip can result in contamination. At this time, we are recommending to the facility that the

number of workers who care for anyone with suspected Ebola be kept to an absolute minimum. We recommend that the procedures that are undertaken to support the care of an infected individual be limited solely to essential procedures. We are examining the issue of personal protective equipment, understanding that there is a balance and putting more on isn't always safer as it may make it harder to provide effective care. And 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. Each day we work to evaluate and improve infection control, and these represent measures put into place so far. CDC has sent additional staff to Texas to assist with this response and we will continue to work closely with the State and local team. In particular, we are closely monitoring other health care workers who were part of the care team, because we now have reason to believe had an elevated risk of exposure.

Despite these latest incidents, we remain confident that our public health and health care systems can prevent an Ebola outbreak here, and that the authorities and investments provided by the Congress have put us in a strong position to protect Americans. To make sure the United States is prepared, as the epidemic in West Africa has intensified, CDC has done the following:

- Instituted layers of protection, starting in affected countries where our staff work intensively on airport exit screening, such as temperature scanning for outbound passengers.
- Provided guidance for airline personnel and for DHS U.S. Customs and Border Protection Officers on how to identify sick passengers and how to manage them. Though it was one of many false alarms, the recent incident with an inbound passenger to Newark, New Jersey shows how CDC's quarantine station at the airport worked with airline, DHS, airport, EMS, and hospital personnel to assess and manage a sick passenger, and to protect other passengers and the public.
- Developed guidance for monitoring and movement of people with possible exposures.

- Along with partners in DHS and state and local health agencies, continually assessed and improved approaches to inbound passenger screening and management, and as the President announced on October 6th, CDC is working with DHS to enhance screening measures at United States airports.
- Worked with American hospitals to reinforce and strengthen infection controls, and CDC has provided checklists and instructions to health care facilities to assess patients for travel history. We have also worked with state and local health departments to ensure that these practices are being followed.
- With state health departments, intensified training and outreach to build awareness since the Dallas case.
- Through the Laboratory Response Network (LRN), expanded lab capacity across the United States – in addition to CDC’s own world class laboratories, 14 LRN labs now have capacity for testing, ensuring that we have access to labs for timely assessment – and surge capacity in case it is needed.
- Developed response protocols for the evaluation, isolation, and investigation of any incoming individuals with relevant symptoms.
- Extensively consulted to support evaluation and, when indicated, tested suspect cases. With heightened alert, we are receiving hundreds of inquiries for help in ruling out Ebola in travelers – a sign of how seriously airlines, border agents, and health care system workers are taking this situation. So far just over a dozen of these hundreds of suspect cases have required testing, and only one (the Dallas patient) has been positive.

Our top priority at CDC is to protect Americans from threats. We work 24/7 to do that. In the case of Ebola, we are doing that in many different ways here at home, but we also need to retain our focus on stopping the outbreak at its source, in Africa.

Working with our partners, we have been able to stop every prior Ebola outbreak, and we will stop this one. It will take meticulous work and we cannot take short cuts. It's like fighting a forest fire: leave behind one burning ember, one case undetected, and the epidemic could re-ignite. For example, in response to the case in Nigeria, 10 CDC staff and 40 top CDC-trained Nigerian epidemiologists rapidly deployed, identified, and followed 1,000 contacts for 21 days. Even with these resources, one case was missed, which resulted in a new cluster of cases in Port Harcourt, Nigeria. However, due to the meticulous work done in Nigeria, no new cases have been identified, and the outbreak appears to have been extinguished there.

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

Investments in strengthening health systems in West Africa have been very challenging due to the low capacity of the systems. Strengthening the public health infrastructure in West Africa could detect such outbreaks earlier and contain them. This Ebola epidemic shows that any vulnerability could have widespread impact if not stopped at the source.

In February, the United States Government joined with partner governments, WHO and other multilateral organizations, and non-governmental actors to launch the Global Health Security Agenda (GHSa). Over the next five years, the United States has committed to working with over forty partner countries (with a combined population of at least four billion people) to improve their ability to prevent, detect, and effectively respond to infectious disease threats - whether naturally occurring or caused by accidental or intentional release of pathogens. As part of this Agenda, the President's FY 2015 Budget includes \$45 million for CDC to accelerate progress in detection, prevention, and response, and we appreciate your support for this investment. We are working to evaluate the needs to strengthen the Ebola-affected nations and neighboring ones most at risk, and are asking that GHSa partners make specific commitments to establish capacity in West African countries in two or three years to prevent, detect and rapidly respond to infectious disease threats. The economic cost of large public health emergencies can be tremendous – the 2003 Severe Acute Respiratory Syndrome epidemic, known as SARS, disrupted travel, trade, and the workplace and cost the Asia-Pacific region alone more than \$40 billion. Resources provided for the Global Health Security Agenda can improve detection, prevention, and response and can potentially reduce some of the direct and indirect costs of infectious diseases.

Improving these capabilities for each nation improves health security for all nations. Stopping outbreaks where they occur is the most effective and least expensive way to protect people's health. While this

tragic epidemic reminds us that there is still much to be done, we know that sustained commitment and the application of the best evidence and practices will lead us to a safer, healthier world. With a focused effort, and increased vigilance at home, we can stop this epidemic, protect Americans, and leave behind a strong system in West Africa and elsewhere to prevent Ebola and other health threats in the future.

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

Mr. MURPHY. Thank you, Dr. Frieden. I now recognize Dr. Fauci for a 5-minute summary of your statement.

STATEMENT OF ANTHONY S. FAUCI

Mr. FAUCI. Thank you, Chairman Murphy, Ranking Member DeGette, Chairman Upton, and Ranking Member Waxman. You have just heard about the public health aspects of Ebola Virus Disease from Dr. Frieden. I appreciate the opportunity to speak with you this morning for a few minutes on the role of the National Institute of Allergy and Infectious Diseases in research addressing Ebola Virus Disease.

Of note is that our activities actually started with the tragic events of 9/11/2001, which were followed closely by the anthrax attacks, which many of the members remember, against the Congress of the United States and the press. It was in that environment that a multifaceted approach towards bioterrorism was actually mounted by the Federal Government, one of which was the research endeavor to develop countermeasures. We soon became very aware that naturally occurring outbreaks of disease are just as much of a terror to the American and world public as a deliberate bioterror event.

[Slide.]

You see on this slide a number of what we call Category A pathogens from anthrax to botulism, plague, smallpox, and tularemia, but look at the last bullet, the viral hemorrhagic fevers including Ebola, Marburg, Lassa and others. The viral hemorrhagic fevers are particularly difficult because they have a high degree of lethality and a high infectivity upon contact with body fluids. Therapy is mainly supportive without specific interventions, and we do not have a vaccine.

And so what is the role of the National Institutes of Health—if we could advance the slide—in the research endeavor?

[Slide.]

As you can see on this slide, we do basic and clinical research, and importantly, we supply resources for researchers in industry and academia to advance product development. The end game of what we do are diagnostics, therapeutics, and vaccines. I am sorry. Could we get the slide back on, the last slide?

This is a multi-institutional endeavor. As you can see on this slide, the NIH is responsible for fundamental basic research and early concept development, something that we did relatively alone because of the lack of interest on the part of industrial partners in making interventions. We partnered with BARDA, who you will hear from shortly with Dr. Robin Robinson, and then we partnered with industry, as I will tell you in a moment, ultimately in collaboration with the FDA to get the approval of products. Next slide.

[Slide.]

You have heard a lot about therapeutic interventions. I would just like to spend a moment talking to you about a few of them. First, it is important to realize that they are all experimental. None of them has proven to be effective. So when you hear about giving a drug that has a positive effect, we do not know at this point, A, is it a positive effect, or B, is it causing harm? And that

is the reason why we need to study these carefully at the same time we rapidly make them available to the people who need them.

The first one on the list is ZMapp. You have heard of it. That was given to Dr. Brantley and Nancy Writebol. It looks very good in animal models. It still needs to be proven in humans. There are others such as the BioCryst product, which is a nucleoside analog. You have heard about the Tekmira drug, which was developed with support from the Department of Defense, which is also being used, and others that you will hear about such as Brincidofovir and Favapiravir. These are just a few of those that will be going into clinical trials and that are actually being used in an experimental way with compassionate use with approval from the FDA in certain individuals.

[Slide.]

Let me turn to this slide here, which is an important one, regarding a vaccine. We have been working on an Ebola vaccine for a number of years. We did the original studies shown in an animal model to be quite favorable. We are now right at the point where we are in Phase I trials that some of you may have heard of, started at the NIH on September 2nd. Testing of a second vaccine was started just a couple of days ago by the U.S. military in collaboration with the NIH. When we finish those Phase I trials, namely asking is it safe and does it induce a response that you would predict would be protective, it is important to make sure it is safe. If those parameters are met, we will advance to a much larger trial in larger numbers of individuals to determine if it is actually effective as well as not having a paradoxical negative deleterious effect. The reason we think this is important is that if we do not control the epidemic with pure public health measures, it is entirely conceivable that we may need a vaccine, and it is important to prove that it is safe and effective.

I would like to close by making an announcement to this committee because I am sure you will hear about it soon in the press. This evening, tonight, we will be admitting to the special clinical studies unit, at the National Institutes of Health, Nina Pham, otherwise known as Nurse Number One. She will be coming to the National Institutes of Health, where we will be supplying her with state-of-the-art care in our high-level containment facilities.

Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Fauci follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Examining the Public Health Response to the Ebola Outbreak

Testimony before the

House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

Anthony S. Fauci, M.D.

Director

National Institute of Allergy and Infectious Diseases

October 16, 2014

Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee:

Thank you for the opportunity to discuss the National Institutes of Health (NIH) response to the global health emergency of Ebola virus disease. I direct the National Institute of Allergy and Infectious Diseases (NIAID), the lead institute of the NIH for conducting and supporting research on infectious diseases, including viral hemorrhagic fevers such as those caused by Ebola virus infection.

For over six decades, NIAID has made important contributions to advancing the understanding of infectious, immunologic, and allergic diseases, from basic research on mechanisms of disease to applied research to develop diagnostics, therapeutics, and vaccines. NIAID has a dual mandate that balances research addressing current biomedical challenges with the capacity to respond quickly to newly emerging and re-emerging infectious diseases, including bioterror threats. Critical to these efforts are NIAID's partnerships with academia, pharmaceutical companies, international organizations such as the World Health Organization (WHO), and collaborations with other Federal entities, particularly the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA), the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DOD).

OVERVIEW OF EBOLA VIRUS DISEASE

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

discovery of Ebola virus in 1976, outbreaks of hemorrhagic fever caused by Ebola virus have had fatality rates ranging from 25 percent to 90 percent, depending on the species of virus and the availability of medical facilities and staff to care for infected patients. West Africa is currently experiencing the most severe Ebola outbreak ever recorded. As of October 12, 2014, there have been 8,997 reported cases, including 4,493 documented deaths according to the WHO. The ongoing Ebola epidemic in Guinea, Liberia, and Sierra Leone has generated more cases and deaths than the 24 previous Ebola outbreaks combined. The recent death of a patient diagnosed with Ebola in Dallas, Texas, after traveling from Liberia, and the cases transmitted outside of Africa (to two healthcare workers in Dallas and a nurse in Spain) intensify our concerns about this global health threat.

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

HISTORY OF NIAID EBOLA VIRUS RESEARCH: RELATIONSHIP TO BIODEFENSE RESEARCH

The ability to safely and effectively prevent and treat Ebola virus infection is a longstanding NIAID priority. Since the 2001 anthrax attacks, NIAID has vastly expanded its

research portfolio in biodefense and naturally emerging and re-emerging infectious diseases. This research targets pathogens that pose high risks to public health and national security. NIAID has designated pathogens with high mortality such as anthrax, plague, smallpox, and Ebola virus as NIAID Category A Priority Pathogens to highlight the need for medical countermeasures against these dangerous microbes.

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

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

DEVELOPMENT AND TESTING OF EBOLA MEDICAL COUNTERMEASURES

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

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

Diagnostics

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

Therapeutics

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

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

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

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

with Ebola virus and the related Marburg virus. BioCryst has announced that a Phase 1 clinical trial of this drug is expected to begin in late 2014 or early 2015. NIAID also is evaluating therapeutics licensed or in development for the treatment of other diseases for their potential activity against Ebola virus. One of these investigational agents is brincidofovir, an antiviral originally developed with NIAID support for use against other viruses.

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

Vaccines

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

The NIAID Vaccine Research Center (VRC) has a robust viral hemorrhagic fever vaccine development program. Since 2003, the VRC has evaluated three early-generation Ebola vaccine candidates and one Marburg vaccine candidate in Phase 1 clinical trials at the NIH campus. An additional Phase 1 clinical trial was conducted in Kampala, Uganda, in collaboration with DOD.

None of the early-generation candidates raised safety concerns in these small trials; however, they did not elicit the level of immune response thought to be needed to provide protection against the viruses. The data from those trials have contributed directly to the VRC's current Ebola vaccine collaboration with the pharmaceutical company GlaxoSmithKline (GSK). VRC and GSK have developed an experimental vaccine that uses a chimpanzee virus (similar to the common cold virus), Chimp Adenovirus 3 (CA3), as a carrier, or vector, to introduce Ebola virus genes into the body; these genes encode Ebola proteins that stimulate an immune response. The vaccine candidate has shown promising results in animal models against two Ebola virus species (bivalent vaccine), including the Zaire Ebola species responsible for the current epidemic in West Africa. A small Phase 1 study to examine the safety and ability of this candidate to induce an immune response in humans began on September 2, 2014, at the NIH Clinical Center in Bethesda, Maryland. All twenty of the study volunteers have been vaccinated. The trial is now moving forward to two other U.S. sites (University of Maryland and Emory University) to gather additional safety and immunogenicity data. Results from all sites are anticipated by the end of 2014 and will inform future development of the vaccine.

As part of Phase 1 studies, the NIH will also support testing of a related vaccine candidate, including just a single Ebola virus gene from the Zaire Ebola virus (monovalent vaccine). NIAID and GSK also have donated doses of this vaccine candidate to enable further testing by NIAID partners in the United Kingdom and the West African country of Mali; the U.K. study has already begun. Plans are underway with GSK and WHO partners for an additional, larger clinical study of the monovalent vaccine in Geneva/Lausanne, Switzerland.

Additionally, starting this month, NIH will collaborate with DOD and NewLink Genetics Corporation on Phase 1 safety studies of an investigational Ebola vaccine based on vesicular

stomatitis virus (VSV). The VSV will serve as a vector or carrier for an Ebola gene similar to how the Chimp adenovirus serves as a vector or carrier as described above for the NIAID/GSK vaccine. This vaccine candidate was developed by and licensed from the Public Health Agency of Canada.

In addition to these Ebola candidates entering Phase 1 trials in 2014, NIAID supports a broad portfolio of Ebola vaccine research. NIAID has supported the biopharmaceutical company Crucell to develop a recombinant adenovirus-vectored Ebola vaccine. In animal studies, this vaccine candidate protected against filovirus infection, including Ebola virus. NIAID has played an instrumental role in the recent announcements by Johnson & Johnson (parent company of Crucell) and Bavarian Nordic that they will collaborate on a two dose (prime-boost) vaccination regimen that will begin Phase 1 testing in 2015.

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

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

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

NIAID also advances vaccine product development by providing preclinical services such as animal testing to researchers in academia and industry. More than 30 different filovirus vaccine formulations have been evaluated through NIAID's preclinical services since 2011 using animal models and assays that NIAID has developed over many years.

Clinical Trials to Evaluate Efficacy

It is important to balance the urgency to deploy investigational medical countermeasures in an emergency such as the current Ebola outbreak with the need to ensure the maximal safety and to determine the efficacy of candidate drugs and vaccines for Ebola. We will do this with the strictest attention to safety considerations, established scientific principles, and ethical considerations, and compassion for and realization of the immediate needs of the affected

populations. The United States Government, working in partnership with industry, has an established mechanism for testing and reviewing the safety and efficacy of potential medical interventions. Randomized controlled clinical trials remain the “gold standard” for the evaluation of candidate drugs and vaccines because they represent the most efficient way to prove efficacy and lack of an unexpected harmful effect. This is particularly important for vaccines since they are administered to healthy individuals.

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

CONCLUSION

While NIAID is an active participant in the global effort to address the public health emergency occurring in West Africa, it is important to recognize that we are still in the early stages of understanding how infection with the Ebola virus can be treated and prevented. As we

continue to expedite research while enforcing high safety and efficacy standards, the implementation of the public health measures already known to contain prior Ebola virus outbreaks and the implementation of treatment strategies such as fluid and electrolyte replacement are essential to preventing additional infections, treating those already infected, protecting health care providers, and ultimately bringing this epidemic to an end. We will continue to work with biopharmaceutical companies and public health agencies throughout the world to develop and distribute medical countermeasures for Ebola virus disease as quickly as possible. NIAID remains committed to fulfilling its dual mandate to balance research on current biomedical challenges with the capability to mobilize a rapid response to newly emerging and re-emerging infectious diseases.

Mr. MURPHY. Thank you, Doctor. I now recognize Dr. Robinson for 5 minutes for a summary of your statement.

STATEMENT OF ROBIN A. ROBINSON

Mr. ROBINSON. Good afternoon, Chairman Murphy, Chairman Upton, Ranking Members DeGette and Waxman, and other distinguished members of the subcommittee. Thank you for the opportunity to speak with you today about our efforts by the Government on Ebola.

I am Dr. Robin Robinson, a former vaccine developer in industry, and for the last 10 years a public servant working on pandemic preparedness and many other biothreats.

BARDA was created by the Pandemic and All-Hazards Preparedness Act in 2006. It is the Government agency responsible for supporting advanced development and procurement of novel and innovative medical countermeasures such as vaccines, therapeutic drugs, diagnostics and medical devices for the entire Nation. BARDA exists to address the medical consequences of biothreats and emerging infectious diseases. BARDA has supported medical countermeasure development for manmade threats on a routine basis under Project BioShield in responding to emerging threats like the H1N1 pandemic in 2009 and the avian influenza H7N9 outbreak in China last year.

Today, we are immersed in responding to Ebola, which is simultaneously a biothreat with a material threat determination issued by the Department of Homeland Security and an emerging infectious disease.

As you have said and my colleagues have said, when it comes to Ebola as a biothreat and emerging infectious disease, the best way to protect our country is to address the current epidemic in Africa, the worst on record.

BARDA works with its Federal partners to transition the medical countermeasures from early development, as Dr. Fauci said, into advanced development, toward ultimate FDA approval.

Since 2006, we have built an advanced development pipeline of more than 150 medical countermeasures for chemical, biological, radiological and nuclear threats, and pandemic influenza. Seven of these products have been FDA approved in the last 2 years, and today we are transitioning several promising and maturing Ebola vaccines and therapeutic candidates from early development, under NIH and DoD support, into advanced development and ensuring that commercial-scale manufacturing capacity for these product candidates is available as soon as possible.

BARDA, in concert with our Federal partners, utilizes public-private partnerships with industry to ensure that we have countermeasures to protect our citizens. Over the past 5 years, BARDA with NIH, CDC, FDA and our industry partners have built a flexible and rapid response infrastructure to develop and manufacture medical countermeasures. As a result of the Pandemic and All Hazards Preparedness Reauthorization Act, improved framework for medical countermeasures development has been afforded to Federal and industry partners, and last year we made five new vaccine candidates in record time for the H7N9 outbreaks in China. Currently, we are working with a wider array of partners including both small

and large pharmaceutical companies, Canada, the U.K., western African countries, the World Health Organization, and others to make and evaluate the safety and efficacy of these Ebola product candidates.

BARDA has established a medical countermeasure infrastructure to assist product developers on a daily basis to respond immediately in a public health emergency. We are using a number of our core service assistance programs. There is the Nonclinical Studies Network, our Centers for Innovation and Advanced Development and Manufacturing, and our Fill Finish Manufacturing Network to make these products available as soon as possible. Additionally, our staff are onsite at the manufacturer, people in plant, to provide technical assistance and oversight to expedite product availability.

Additionally, we are working with CDC and others across the Federal Government and internationally with our modeling efforts to look at the Ebola outbreak as it becomes epidemic and also what possible impacts and interventions may occur.


BARDA supports large-scale production of medical countermeasures and response measure for public health emergencies like the H1N1 pandemic and H7N9 outbreaks. Today we are assisting Ebola vaccine and therapeutic manufacturers with scaled-up production. Specifically, we are supporting the development and manufacturing of ZMapp monoclonal antibody therapy for clinical studies at one manufacturer, expanding overall manufacturing capacity of ZMapp by enlisting the help of other tobacco plant-based manufacturers, and working on alternative Ebola monoclonal antibody candidates to expand production capacity. Pending the outcome of ongoing animal challenge studies, BARDA is prepared to support advanced development of additional promising therapeutic candidates that Dr. Fauci talked about to treat Ebola patients.

On the vaccine front, BARDA is working with industry partners to scale up manufacturing of three promising Ebola vaccine candidates, one of which we will make an announcement today, from pilot scale to commercial scale for clinical studies in Africa next year. In addition to BARDA's efforts in the Ebola response, ASPR is supporting a number of other response activities including supporting health care system preparedness, developing policies and guidance on patient movement, repatriation, standards of care and clinical guidance, supporting the logistical aspect of deploying U.S. public health service officers to West Africa, and ongoing coordination and communication with national and international communities responding to the threat.

Finally, we face significant challenges, as has been discussed, in the coming weeks and months with the Ebola epidemic continuing and as these medical countermeasures are manufactured and evaluated, but bottom line is that my colleagues here and our industry partners will use all of our collective capabilities here and abroad to address today's Ebola epidemic and to be better prepared for future Ebola outbreaks and bioterrorism events going forward.

I want to thank the committee and subcommittee for your generous and continued support over the past decade and the opportunity to testify. Thank you.

[The prepared statement of Mr. Robinson follows:]

	<p>Written Testimony Committee on Energy and Commerce Subcommittee on Oversight and Investigations United States House of Representatives</p>
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**“Examining the U.S. Public Health
Response to the Ebola Outbreak”**

Statement of

Robin A. Robinson, Ph.D.

*Deputy Assistant Secretary and BARDA Director
Office of the Assistant Secretary for Preparedness and
Response*

U.S. Department of Health and Human Services



**For Release on Delivery
Expected at 12:00 p.m.
Thursday, October 16, 2014**

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

Ebola is a potential biological threat agent as determined by the Department of Homeland Security through the issuance of a Material Threat Determination in 2006 , as well as an emerging infectious disease. The current Ebola epidemic is the worst on record. As the Centers for Disease Control and Prevention (CDC) has stated, we do not view Ebola as a significant public health threat in the United States; however, the best way to continue to protect our country from any domestic threat posed by Ebola is to take action to address the epidemic in West Africa.

ASPR is supporting the Federal Government's Ebola response effort through policy development, advancements in medical countermeasures, logistical support for deployed personnel, and broader community and healthcare preparedness and resilience through grant funding, dissemination of information to state and local partners, and communication with international partners concerning health security issues. Originally authorized by the Pandemic and

All-Hazards Preparedness Act (PAHPA) of 2006, ASPR leads the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters by supporting communities' ability to withstand adversity, strengthening our health and response systems, and enhancing national health security.

BARDA is the Government agency mandated to support advanced research and development and procurement of novel and innovative medical countermeasures such as vaccines, antimicrobial drugs, therapeutics, and medical devices, including diagnostics, to support the Nation in addressing the medical consequences of chemical, biological, radiological, and nuclear (CBRN) agents that might be used in terrorism-related activities. It also addresses naturally-occurring, emerging, and reemerging threats like the H1N1 influenza pandemic, last year's H7N9 influenza outbreak, and the current Ebola epidemic.

BARDA exists to address the medical consequences of these threats and to bridge the gap between early research and development and eventual Food and Drug Administration (FDA) clearance and procurement of medical countermeasures for novel threats by supporting advance development of medical countermeasures.

BARDA works with Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) partners to transition medical countermeasures from early

research and development into advanced development and ultimately to FDA for regulatory review and clearance. Advanced development includes critical steps needed to transform a candidate to a product that is ready for use in humans. These 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 often required for approval. Since 2006, BARDA has funded and successfully managed the advanced development of more than 150 medical countermeasures for CBRN threats and pandemic influenza. Seven of these products have received FDA approval in the last two years alone, and twelve of these products have been procured under Project BioShield for potential use in a public health emergency.

Over the last decade, the PHEMCE has supported funding basic research and early stage development of numerous Ebola and Marburg Viral Hemorrhagic Fever medical countermeasure candidates. Now, as a result of this work, several promising Ebola vaccine and therapeutic candidates have matured enough for BARDA to transition them rapidly from early development into advanced development. BARDA aims to develop medical countermeasures that can be clinically evaluated for safety and efficacy, and once safety and efficacy are established, to manufacture these products on a commercial scale in large

enough quantities for use in a meaningful public health response. Ultimately, we strive to have these medical countermeasures cleared by the FDA as soon as it is feasible. Specifically, BARDA is now providing funding and providing technical assistance for the development and scaled-up manufacturing of the ZMapp monoclonal antibody therapeutic and several Ebola vaccine candidates that the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) and the Department of Defense (DoD) Defense Threat Reduction Agency (DTRA) supported through early development. Given the manufacturing processes involved and the state of the development of the product, scaled-up manufacturing of the ZMapp monoclonal antibody therapeutic may produce sufficient doses for clinical safety and initial efficacy studies, but it cannot be produced on commercial scale in large quantities at this point.

BARDA, along with its PHEMCE partners, uses public-private partnerships with industry to ensure that we have the medical countermeasures 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 medical countermeasures. Last year, for example, 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. In the current Ebola response, the PHEMCE is working with a wide array of partners in addition to its Federal partners. They include other countries,

specifically the affected and at-risk African countries; the World Health Organization (WHO); the Bill and Melinda Gates Foundation; and others. These expanded partnerships are critical to our efforts to address the current Ebola epidemic.

BARDA has established a medical countermeasure infrastructure to assist product developers on a daily basis and enable rapid response in a public health emergency. BARDA is employing this infrastructure to respond to the current Ebola epidemic by helping the development and manufacturing of several investigational Ebola therapeutics and vaccines. BARDA's Nonclinical Development Network is conducting critical animal challenge studies for promising investigational Ebola therapeutic candidates. Established in 2012, BARDA's Centers for Innovation in Advanced Development and Manufacturing are positioned to expand the production of Ebola monoclonal antibodies like those in ZMapp, in tobacco plants and mammalian cells. Last year, as part of its pandemic preparedness efforts, BARDA established the Fill Finish Manufacturing Network, which will be used to formulate and fill Ebola antibody and vaccine products into vials for studies and other uses. The investments BARDA has made to create this infrastructure over the past four years are helping the Nation respond to the current epidemic.

BARDA also supports large-scale production of medical countermeasures as an essential part of the response to public health emergencies. BARDA led the

manufacturing of vaccine and antiviral drugs in response to the H1N1 influenza pandemic in 2009 and of vaccines as a preparedness measure for H7N9 influenza in 2013. In the current Ebola epidemic, BARDA is providing assistance to vaccine and therapeutic manufacturers to scale up production from pilot scale, in which a handful of doses can be made, to commercial scale. For ZMapp, BARDA is currently supporting the manufacture of sufficient doses for clinical safety and initial efficacy studies. Furthermore, with funds from the Fiscal Year (FY) 2015 Continuing Resolution (CR), BARDA is expanding production capacity to other domestic manufacturers who can produce monoclonal antibodies targeted against Ebola antibodies using tobacco plants. Additionally, BARDA is working on an alternative manufacturing process for these monoclonal antibodies using mammalian cells. These mammalian cells are commonly used in the production of other monoclonal antibodies for other diseases, and may serve as a means of further expanding production capacity for this product.

With respect to vaccines, BARDA is working with industry partners to scale up the manufacturing of one of several promising investigational Ebola vaccine candidates to commercial scale with funds provided by the FY2015 CR.

In the coming months, BARDA and our industry partners face challenges to manufacture these Ebola medical countermeasure candidates. The major challenge is being able to provide sufficient quantities quickly to support clinical studies. BARDA is prepared to meet those challenges and provide resources,

expertise, and technical assistance for these and other promising investigational Ebola vaccine and therapeutic candidates. BARDA is working with our Federal Government partners, new and existing industry partners, and international partners including the WHO, non-governmental organizations, West African countries, and other allied donor nations to meet these challenges.

In addition to supporting and facilitating the manufacturing of Ebola medical countermeasures, the BARDA Analytic Decision Support team leads the interagency discussion of models of the epidemiology of the West Africa Ebola epidemic, as well as forecasts of the impact of mitigation measures that are in the process of development and/or deployment. This interagency forum facilitates the exchange of the latest available information and discussion among subject matter experts to provide informational products to support decision making by senior leadership.

Related to support for the Ebola outbreak in West Africa and in addition to medical countermeasure development, ASPR is supporting a number of activities including: supporting healthcare system preparedness; developing a number of policies and guidance documents on patient-movement issues and repatriation issues, and standards of care and clinical guidance; supporting the logistical aspect of deploying U.S. Public Health Service (USPHS) officers to West Africa; and, ongoing critical coordination and communication within the national and international communities responding to the threat.

Through the Hospital Preparedness Program (HPP) staff in ASPR, both the Office of Emergency Management and the Office of Policy and Planning (OPP) are supporting domestic preparedness by producing and disseminating educational materials on awareness and response regarding potential Ebola patients. ASPR is working to ensure state and local partners have relevant information at their fingertips to understand the emerging situation and have the right protocols and procedures in place to mitigate the threat. Specifically, ASPR HPP staff, along with other ASPR and HHS partners including CDC, assisted with the development and dissemination of a suite of checklists to prepare healthcare providers, hospitals, emergency medical services, and community healthcare coalitions. The checklists provide practical and specific suggestions to ensure healthcare workers, facilities, and coalitions are able to detect possible Ebola cases, protect their employees, and respond appropriately.

In addition, the HPP staff have collected and disseminated various “promising practices” from healthcare facilities and jurisdictions to advance the healthcare system’s preparedness for Ebola. Specifically, HPP staff have disseminated various examples of Ebola-related tabletop exercises for hospitals and jurisdictions, as well as examples of hospital infectious control plans, so their facilities and jurisdictions can quickly adapt and use them. More broadly, ASPR, in coordination with CDC, the Federal Emergency Management Agency, the Association of State and Territorial Health Officers and the National Emergency Management Association coordinated conference calls with State Health

Officials, State Directors of Public Health Preparedness, State Emergency Management Officials, and State Homeland Security Advisors to share information regarding Ebola preparedness and response. This call offered an opportunity to provide up-to-date information as well as address and respond to questions real-time. HPP staff are assisting CDC with the recruitment of U.S. hospitals that are willing and able to volunteer to care for confirmed cases of Ebola among U.S. citizens that are medically evacuated to the United States from the affected countries in West Africa. Lastly, HPP awardees may use their current HPP funds 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 currently approved scope of work. Some awardees have already initiated these requests.

ASPR is also working closely with other HHS and Federal partners to support the development of policies to address a number of emerging issues related to Ebola response. Specifically, ASPR co-leads a group to identify and resolve clinical issues that arise, ranging from clinical guidelines for standards of care to the requirements for the 25-bed hospital that will be staffed by the Commissioned Corps officers in Liberia. ASPR is also addressing and collaborating with other Federal partners on protocols for contingency evacuation and repatriation, including issues related to patient movement when infected patients return to the continental United States.

Regarding the international response, OPP, through its international health security efforts, continues to receive and share information with the WHO and countries around the world about Ebola through the International Health Regulations National Focal Point. In addition, ASPR maintains regular communications and coordination with G7 countries, Mexico and the European Commission on public health measures, development and deployment of medical countermeasures, and support for African countries.

In conclusion, ASPR has established a solid track record in developing and manufacturing medical countermeasures and coordinating successful emergency responses. ASPR, in coordination with the rest of the PHEMCE partners, is using all of its capabilities to address the Ebola epidemic in West Africa, and has identified crucial additional steps that can be supported through the end of FY 2015. These investments in Ebola medical countermeasures and response will help to address the current epidemic and any future Ebola outbreaks, and will also help the United States to become better prepared for a potential bioterrorism event. Again, I would like to thank the Subcommittee for your continued support and for the opportunity to testify. I look forward to your questions.

Mr. MURPHY. Thank you, Dr. Robinson. Dr. Borio, you are recognized for 5 minutes.

STATEMENT OF LUCIANA BORIO

Ms. BORIO. Thank you. Good afternoon, Chairman Murphy, Ranking Member—

Mr. MURPHY. If you could just please pull the microphone as close to you as possible. Thank you.

Ms. BORIO. Good afternoon, Chairman Murphy, Ranking Member DeGette and members of the subcommittee. Thank you for the opportunity to appear before you today to discuss FDA's actions to respond to the Ebola epidemic, a tragic global event. My colleagues and I at the FDA are determined to do all we can to help end it as quickly as possible.

The desire and need for safe and effective vaccines and treatments is overwhelming. FDA is taking extraordinary steps to be proactive and flexible. We are leveraging our authorities and working diligently to expedite the development and manufacturing availability of safe and effective medical products for Ebola. We are providing FDA's unique scientific and regulatory advice to companies to guide their submissions. We are reviewing data as it is received. These actions help advance the development of investigation of products as quickly as possible, and for example, in the case of the two vaccines that Dr. Fauci mentioned, FDA took only a few days to review the applications and to allow the studies to proceed. As a result, the vaccine candidate being co-developed by the NIAID and GlaxoSmithKline began Phase I clinical testing on September 2nd and the vaccine candidate being developed by NewLink Genetics began similar clinical testing on October 13th. We are also partnering with the U.S. Government agencies that support medical product development including NIAID, BARDA, and the Department of Defense.

Because of FDA's longstanding collaboration with the DoD, FDA was able to authorize the use of the Ebola diagnostic test under our emergency use authorization within 24 hours of request. We authorized the use of two additional diagnostics tests developed by the CDC and these tests of course are essential for an effective public health response.

In addition, we are supporting the World Health Organization. Our scientists are providing technical advice to the WHO as it works to assess the role of convalescent plasma in treating patients with Ebola.

I recently participated in a consultation focused on Ebola vaccines in Geneva, which included dozens of experts from around the world as well as from affected and neighboring countries in West Africa. Participants agreed that promising investigational vaccines must be evaluated in scientifically valid clinical trials and in a most urgent manner. The FDA is working closely with our Government colleagues and the vaccine developers to support this goal.

It is important to note, though, that while we all want access to immediate therapies to cure or prevent Ebola, the scientific fact is that these investigational products are in the earliest stages of development. There is tremendous hope that some of these products will help patients but it is also possible some may hurt patients

and others may have little or no effect. Therefore, access to investigational products should be through clinical trials when possible. They allow us to learn about product safety and efficacy, and they can provide an equitable means for access.

FDA is working with our NIH colleagues to develop a flexible and innovative clinical trial protocol to allow companies and clinicians to evaluate multiple investigational Ebola products under a common protocol. The goal is to ensure accrual of interpretable data and generate actionable results in the most expeditious manner. It is important for the global community to know the risks and benefits of these products as soon as possible.

Until such trials are established, we will continue to enable access to these products when available and requested by clinicians. We have mechanisms such as compassionate use, which allow access to investigational products outside of clinical trials when we assess that the expected benefits outweigh the potential risks for the patient.

I can tell you that every Ebola patient in the United States has been treated with at least one investigational product. Because Ebola is such a serious and often rapidly fatal disease, FDA has approved such requests within a matter of a few hours and oftentimes in less than one hour.

There are more than 250 FDA staff involved in this response, and without exception, everyone has been proactive, thoughtful, and adaptive to the complex range of issues that have emerged. We are fully committed to sustaining our deep engagement and aggressive activities to support the robust response to the Ebola epidemic.

Thank you, and I will take your questions later.

[The prepared statement of Ms. Borio follows:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

**STATEMENT
OF
LUCIANA BORIO, M.D.
ASSISTANT COMMISSIONER FOR COUNTERTERRORISM POLICY
DIRECTOR, OFFICE OF COUNTERTERRORISM AND EMERGING THREATS
DEPUTY CHIEF SCIENTIST (ACTING)**

**FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HOUSE ENERGY AND COMMERCE COMMITTEE**

U.S. HOUSE OF REPRESENTATIVES

**"EXAMINING THE U.S. PUBLIC HEALTH RESPONSE TO THE EBOLA
OUTBREAK"**

October 16, 2014

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee. I am Dr. Luciana Borio, Assistant Commissioner for Counterterrorism Policy, Director of the Office of Counterterrorism and Emerging Threats, and Acting Deputy Chief Scientist at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to appear today to discuss FDA's response to the Ebola epidemic in West Africa.

The Ebola epidemic in West Africa is the worst in recorded history. As of October 12, 2014, there have been 8,997 reported cases, including 4,493 documented deaths, according to the World Health Organization (WHO). And as you know, a single case had been detected in the United States in an individual who was infected in Liberia and subsequently traveled to the United States and died. A nurse treating this patient has now tested positive for Ebola.

The toll of this epidemic, with so many lives lost and so many others fighting for their lives, is heartbreaking and tragic. While it appears, so far, that the outbreaks in Senegal and Nigeria have been rapidly contained by the application of standard public health techniques, widespread and intense disease transmission continues in Guinea, Liberia, and Sierra Leone. It is still the case—as Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention (CDC), has noted—that the epidemic is larger than reported and the situation is going to get worse before it gets better.

The primary approach to containing the epidemic remains standard public health measures, such as identifying and isolating infected individuals, caring for patients who are ill, ensuring that

health care workers have access to personal protective equipment and are properly trained in infection control measures, and tracing patients' contacts to detect any secondary infections as soon as possible. However, applying these public health measures on a large scale presents complex challenges because of the strains on health care and public health infrastructure within affected countries and the very limited capacity to provide medical supportive care in-country. This tragic situation is further complicated because there are no treatments or vaccines shown to be safe or effective for the Ebola virus, and products currently under development are in the very early stages of investigation. FDA is dedicated to do all that we can to respond effectively and rapidly to this epidemic.

FDA's Response to the Ebola Epidemic

This Ebola outbreak is an extraordinary global event, and FDA is taking extraordinary steps to be proactive and flexible in our response. We have a critical role in helping to facilitate the development, manufacturing, and availability of investigational products for use against Ebola virus disease. In response to this urgent situation, FDA is actively working with Federal colleagues, industry, and international organizations to facilitate development, including evaluating the safety and efficacy, of treatments and vaccines with the potential to help mitigate this epidemic.

Each Federal partner has a vital part to play in the global race to find the therapeutic solutions to this deadly puzzle. FDA participates in a cross-cutting Federal workgroup that meets regularly to provide ongoing interactions between the different Federal participants. FDA provides scientific and regulatory advice to U.S. Government agencies that support medical product development, including the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), the Biomedical Advanced Research and Development

Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR), and the U.S. Department of Defense (DoD), to help speed their development programs. We are also coordinating our activities with CDC.

In addition, we are reaching out proactively to multiple medical product developers to clarify regulatory requirements, provide input on pre-clinical and clinical trial designs (including for clinical trials that use a common protocol to test several products at once and that can be conducted in affected countries and in the United States), and expedite review of data as they are received from product developers. These efforts should help advance the development of investigational products as quickly as possible. As part of the overall response, FDA is expediting the review of Investigational New Drug (IND) applications, which are required by law for FDA-regulated clinical trials of drugs and vaccines to proceed. For example, FDA reviewed IND applications for two investigational Ebola vaccines in less than one week and, after such review, allowed them to proceed. Consequently, NIAID, which is co-developing an Ebola vaccine with GlaxoSmithKline (GSK), announced that it began Phase I clinical testing in early September of this year, and NewLink Genetics will soon proceed with Phase I clinical trials of its Ebola vaccine candidate. We also continue to work closely with therapeutic product developers to speed development of these products. To augment diagnostic capacity, we have contacted several commercial developers—entities we know are capable of rapidly developing these types of diagnostic tests—and have encouraged them to work with us to quickly develop and make available such tests. Several entities have expressed interest and have initiated discussions with FDA.

FDA also is collaborating with WHO and working with several of our international regulatory counterparts, including the European Medicines Agency, Health Canada, and others, to exchange

information about investigational products for Ebola. These efforts support regulatory collaboration to harmonize and accelerate development and, we hope, have the potential to contribute to approval of medical products in the United States and in other nations. With this important goal in mind, FDA recently entered into a confidentiality commitment with WHO to allow the exchange of non-public information concerning medical products. We believe this will facilitate international collaboration to respond to the current Ebola crisis, as well as more broadly to prepare for or respond to any future events.

I have had the opportunity to participate in WHO-sponsored consultations with my Federal colleagues, as well as representatives of the international public health community and medical product sponsors, to discuss leading investigational treatments and vaccines for Ebola and key considerations for deployment in West Africa. The most recent consultation—which was attended by 70 experts from around the world, including experts from affected and neighboring countries in West Africa—focused on Ebola vaccine development. Attendees agreed that the ultimate goal is to have a fully tested and licensed vaccine that can be scaled up for use in mass vaccination campaigns as quickly as possible. Moving forward, FDA will continue working with our international colleagues to foster development of and access to investigational products in affected countries.

While FDA is making every effort to encourage development, speed review, and use flexible approaches to authorize potential medical products to address Ebola, we cannot lose sight of the scientific fact that investigational vaccines and treatments for Ebola are in the earliest stages of development. Data on safety or effectiveness in humans are limited or lacking, and accurate assessment (especially of effectiveness) may be impossible if adequately designed clinical trials are not performed. Currently, there are only small amounts of some experimental products that

have been manufactured for testing. This supply issue constrains the options for properly assessing the safety and efficacy of these investigational products in clinical trials to respond to the epidemic, and also limits the possibilities for making products available for therapeutic use outside of a clinical trial (also known as expanded access). Nonetheless, while investigational products are being developed, with the ultimate goal of product approval and manufacturing for wide-scale use, FDA is doing all it can to facilitate access to these products when access has been granted by the sponsor and the clinical circumstances warrant. FDA has one of the most flexible regulatory frameworks in the world, which includes mechanisms to enable access to investigational medical products when appropriate, after the risks and benefits to the patient have been weighed.

In addition, under the FDA's Emergency Use Authorization (EUA)¹ authority, we can allow the use of an unapproved medical product—or an unapproved use of an approved medical product—for a larger population during emergencies, when, among other reasons, based on scientific evidence available, there is no adequate, approved, and available alternative. FDA authorized the use of an Ebola diagnostic test, developed by DoD, under an EUA to detect the Ebola virus in laboratories designated by DoD. We were able to issue this EUA, in part, because of new authorities gained under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, or PAHPRA, which provide greater flexibility in the issuance of EUAs. DoD's diagnostic test can help facilitate an effective response to the ongoing epidemic in West Africa by rapidly identifying patients infected with Ebola virus and facilitating appropriate containment measures and clinical care. The authorized test also has been made available to 14 laboratories within the United States. These laboratories are located in states that serve as major "ports-of-entry," such

¹ Under the FD&C Act, as amended by the Project BioShield Act of 2004 [PL 108-276] and PAHPRA [PL 113-5], the Secretary of HHS has the authority to authorize the "emergency use" of medical countermeasures in certain situations [21 USC § 360bbb-3].

as Texas, known to have travelers from West Africa working in the energy business. In fact, this test was used to detect Ebola in the patient from Liberia. We are encouraging other diagnostic product developers to pursue an EUA, or other appropriate mechanisms, for their investigational diagnostics to test for Ebola.

Unfortunately, during epidemics such as this, fraudulent products that claim to prevent, treat, or cure a disease rapidly appear on the market. FDA has learned of several fraudulent products that claim to prevent or treat Ebola virus infection. In response, we issued a statement, warning consumers about fraudulent Ebola treatment products, and we are taking actions against fraudulent claims to protect public health. For example, we recently issued Warning Letters to three firms marketing products that claim to prevent, treat, or cure infection by the Ebola virus.

CONCLUSION

FDA is using its authorities to the fullest extent possible to continue its mission to protect and promote the public health, both domestically and abroad. This epidemic has placed incredible demands on FDA, but our staff is fully committed to responding in the most proactive, thoughtful, and flexible manner. We have explored multiple ways to be highly responsive and adaptive to the complex range of issues that this constantly changing epidemic has presented and will continue to present.

Developing the medical products to help bring this Ebola epidemic under control is highly complex and will, unfortunately, take time. The close cooperation and collaboration within FDA, within the U.S. Government, with our international partners, and with product developers

is essential to the global response to this epidemic. FDA looks forward to playing its part as events unfold.

I would also stress that improving the medical and public health infrastructure in the affected countries is critical, not just to improve ongoing response activities, but also to enable advancing product development. In the absence of improved medical and public health infrastructure, our ability to facilitate appropriate further testing and use of these products will be extremely limited.

FDA is fully committed to sustaining our deep engagement and aggressive response activities. We will continue to work closely with our U.S. Government and international partners and with product developers to speed the development and availability of promising medical products that offer the potential to end this epidemic as quickly as possible. We fully appreciate the gravity of the situation at hand and are exercising maximum flexibility in our activities. We are singularly focused on facilitating and expediting the development of medical products to diagnose, prevent, and treat Ebola virus disease. It is our sincere hope that the global community can have access to safe and effective products for Ebola in the most expedited manner.

Thank you, and I am happy to answer your questions.

Mr. MURPHY. Thank you, Dr. Borio. Mr. Wagner, you are recognized for 5 minutes.

STATEMENT OF JOHN P. WAGNER

Mr. WAGNER. Thank you, Chairman Murphy, Ranking Member DeGette and distinguished members of the subcommittee for the opportunity to discuss the efforts of U.S. Customs and Border Protection in deterring the spread of Ebola by means of international travel.

Each day, about 1 million travelers arrive in the United States. About 280,000 of them arrive at our international airports. 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, our priority mission remains to prevent terrorists and terrorist weapons from entering the United States. However, we also play an important role in limiting the introduction, transmission and spread of serious communicable diseases from foreign countries. We have had this role for over 100 years, and in coordination with the CDC, we have had modern protocols in place for well over a decade that have guided response to a variety of significant health threats.

CBP officers at all ports of entry assess each traveler for overt signs of illness. In response to the recent Ebola virus outbreak in West Africa, CBP in close collaboration with CDC is working to ensure that frontline officers are provided the information, training, and equipment needed to identify and respond to international travelers who may pose a threat to public health.

All CBP officers are provided guidance and training on identifying and addressing travelers with any potential illness including communicable diseases such as the Ebola virus. CBP officer training includes CDC public health training, which teaches officers to identify through visual observation and questioning the overt symptoms and characteristics of ill travelers. CBP also provides operational training and guidance on how to respond to travelers with potential illness including referring individuals who display signs of illness to CDC quarantine officers for secondary screening as well as training on assisting CDC with implementation of its isolation and quarantine protocols.

Additionally, CBP provides training for its frontline personnel by covering key elements of CBP's Bloodborne Pathogens Exposure Control Plan, protections from exposure, use of personal protective equipment, other preventive measures and procedures to follow in a potential exposure incident. We are committed to ensuring our field personnel have the most accurate, updated information regarding this virus since the outbreak began. CBP field personnel have been provided a steady stream of guidance starting with initial information on the current outbreak at the beginning of April this year with numerous and regular updates since then.

Information sharing is critical, and CBP continues to engage with health and medical authorities. Since January of 2011, CDC's Division of Global Migration and Quarantine has stationed a liaison officer at our national targeting center to provide subject-mat-

ter expertise and facilitate requests for information between the two organizations.

Starting October 1st this year, CBP began providing Ebola information notices to travelers entering the United States from Guinea, Liberia and Sierra Leone. This tearsheet provides the traveler information and instructions should he or she have a concern of possible infection.

In addition to visually screening all passengers for overt signs of illness, starting October 11th CBP and CDC began enhanced screening of travelers from the three affected countries entering at JFK Airport, and today we expanded these enhanced efforts at Dulles, Chicago O'Hare, Atlanta, and Newark. Approximately 94 percent of travelers from the affected countries enter the United States through these five airports. In coordination with CDC, these targeted travelers are asked to complete a CDC questionnaire, provide contact information, and have their temperature checked. Based on these enhanced screening efforts, CDC quarantine officers will make a public health assessment.

Since the additional measures went into effect at JFK, CBP has conducted enhanced screening on 155 travelers who were identified in advance as being known to have traveled through one of these three affected countries. An additional 13 travelers were identified by CBP officers as needing additional screening during the course of our standard interview process that is applied at all ports of entry. A total of eight of these travelers have been sent to tertiary screening by CDC, and it is important to note that so far all passengers were examined and released.

While CBP officers receive training in illness recognition and response, if they identify an individual believed to be ill, CBP will isolate the traveler from the public in a designated area and contact the local CDC quarantine officer along with local public health authorities to help with further medical assessment. CBP officers are trained to employ universal precautions, an infection control approach developed by CDC when they encounter individuals with overt symptoms of illness or contaminated items in examinations of baggage and cargo. When necessary, CBP personnel will take the appropriate safety measures based on the level of potential exposure. These procedures designed to minimize risk to our officers and the public have been used collaboratively by both agencies on a number of occasions with positive results. CBP will continue to monitor the Ebola outbreak, provide timely information and guidance to our field personnel, work closely with our interagency partners to develop or adopt measures as needed to deter the spread of Ebola in the United States.

So thank you for the opportunity to testify today and the attention you are giving to this very important issue. I will be happy to answer any of your questions.

[The prepared statement of Mr. Wagner follows:]

Testimony of

**John Wagner
Acting Assistant Commissioner
Office of Field Operations
U.S. Customs and Border Protection
U.S. Department of Homeland Security
Before**

**House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

For a Hearing On

“Examining the U.S. Public Health Response to the Ebola Outbreak.”

October 16, 2014

Chairman Murphy, Ranking Member DeGette, distinguished members of the Subcommittee, thank you for inviting me to speak with you today. I appreciate the opportunity to testify on U.S. Customs and Border Protection’s (CBP) role in the Federal government’s Ebola response.

The 2014 Ebola epidemic is the largest in history with devastating impacts in multiple West African countries – the hardest hit being Liberia, Sierra Leone, and Guinea. On September 30, 2014, Centers for Disease Control and Prevention (CDC) confirmed the first travel-associated case of Ebola in the United States. The patient had traveled from Liberia to Dallas, TX, connecting through the Brussels International Airport in Belgium and Dulles International Airport in Virginia. The patient did not have symptoms when he left Liberia, nor when he entered the United States, but developed symptoms approximately four days after his arrival. In the midst of this public health event, it is important to remember that the 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 its interagency partners to prepare for and respond to Ebola and other potential threats to public health.

As you know, CBP is responsible for securing our nation’s borders and safeguarding the American homeland at and beyond our borders. In today’s remarks, I will provide an overview of CBP’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.

Screening and Observation Protocols

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, our priority mission remains to prevent terrorists and terrorist weapons from entering the United States. We also play an important role in limiting the introduction, transmission, and spread of serious communicable diseases from foreign countries. CBP works closely with CDC to recognize the signs and symptoms of international travelers who may be ill with a communicable disease of public health significance such as Ebola. 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.

CBP is continually providing updated guidance to its frontline personnel regarding Ebola, to include background on the current outbreak and impacted regions; origin, pathology, and mode of transmission; symptoms; and operational procedures and precautions for processing travelers showing signs of illness.

CBP is actively engaged with health and medical authorities at the national, state, and local levels. A CDC Quarantine Office liaison stationed at the CBP National Targeting Center continues to provide subject matter expertise and facilitate requests for information between the two organizations. Additionally, CDC provides "Do Not Board" notification to CBP regarding individuals who may be infected with a highly contagious disease, present a threat to public health, and should be prevented from traveling via commercial aircraft.

Once travelers arrive in the United States, they are subject to additional measures. As part of every inspection, CBP officers at all ports of entry – in the land, sea, and air environments – conduct surveillance of travelers, which includes routine visual observation during primary processing and notification to the CDC or U.S. public health officials, as appropriate. CBP officers are trained in illness recognition by the CDC. 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 Regional Quarantine Officers or local public health personnel for medical evaluation.

Additional Screening Measures

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, CBP is 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 has been working

with the CDC to implement additional entry screening measures for travelers entering the United States.

Specifically, CBP developed targeting rules that analyze advance passenger travel information provided by commercial airlines to identify travelers whose travel originated in or transited through Ebola-affected countries, which currently include Liberia, Sierra Leone, and Guinea.

A small number of U.S. airports receive the vast majority of travelers from the Ebola-affected countries. Beginning on October 11, at John F. Kennedy (JFK) airport in New York, CBP implemented enhanced screening of travelers from the three affected countries. These enhanced efforts roll out today at Dulles, Chicago O'Hare, Atlanta, and Newark.

In coordination with CDC, as mentioned above, CBP is implementing additional traveler screening processes when passengers traverse through primary screening. Travelers who originated from or transited through these countries and are entering the United States will be asked to complete a screening questionnaire, developed in conjunction with the CDC to further identify possible risks – even if the passenger does not display overt visual signs of illness. U.S. Coast Guard Corpsmen will assess travelers for fever until medical professionals can be contracted. Detailed supplemental contact information for each traveler will also be collected. If any of these procedures raise concerns regarding Ebola, the traveler will be referred to CDC personnel or local public health personnel for medical evaluation and assessment.

The CDC maintains jurisdiction to determine whether to detain, isolate, quarantine, or issue monitoring orders to potentially infected individuals. CBP personnel may be called upon to help with 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 United States from the Ebola-affected countries of Liberia, Sierra Leone, and Guinea. 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 the Transportation Security Administration 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.

CBP officers receive the CDC's public health training, which teaches officers 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 the CDC or local public health personnel, as

well as isolation and quarantine protocols. The health and safety of CBP employees is also our priority as CBP carries out this critical assignment. CBP officers receive training on personal protective equipment, which is available for employees at these airports along with instructions for use. 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 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.

Conclusion

CBP has worked closely with its interagency partners to develop a layered approach to identifying ill travelers and protecting the air traveling public. CBP is 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. We look forward to working with you to address any concerns. We will also continue to closely monitor the Ebola epidemic, and will evaluate additional activities as needed.

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

Mr. MURPHY. Thank you. Now we are going to recognize Dr. Daniel Varga, Chief Clinical Officer joining us from Texas on video-conference. Dr. Varga.

STATEMENT OF DANIEL VARGA

Mr. VARGA. Good afternoon, Chairman Murphy, Vice Chair Burgess, Ranking Member DeGette and members of the committee. My name is Dr. Daniel Varga. I am the Chief Clinical Officer and Senior Executive Vice President for Texas Health Resources. I am board certified in internal medicine and have more than 24 years of combined experience in patient practice, medical education, and health care administration.

I am truly sorry that I could not be with you in person today, and I deeply appreciate the committee's understanding of our situation and how important it is for me to be here in Dallas during this very challenging and sensitive time.

Texas Health Presbyterian Hospital Dallas is one of 13 wholly owned acute-care hospitals in the Texas Health Resources System. We are an 898-bed hospital treating some of the most complicated cases in north Texas. Texas Health Dallas is recognized as a magnet designated facility for excellence in nursing services by the American Nurses Credentialing Center, the Nation's leading nursing credentialing program.

Texas Health Resources is one of the largest faith-based centers not-for-profit health systems in the United States and the largest in north Texas in terms of patients served. Our mission is to improve the health of the people in the communities we serve, and we care for all patients regardless of their ability to pay. We serve diverse communities, and as such, as provide one standard of care for all regardless of race or country of origin.

As the first hospital in the country to both diagnose and treat a patient with Ebola, we are committed to using our experience to help other hospitals and health care providers protect the public health against this insidious virus. It is hard for me to put into words how we felt when our patient Thomas Eric Duncan lost his struggle with Ebola on October 8th. It was devastating to the nurses, doctors, and team who tried so hard to save his life, and we keep his family in our thoughts and prayers.

Unfortunately, in our initial treatment of Mr. Duncan, despite our best intentions and a highly skilled medical team, we made mistakes. We did not correctly diagnose his symptoms as those of Ebola, and we are deeply sorry. Also, in our effort to communicate to the public quickly and transparently, we inadvertently provided some information that was inaccurate and had to be corrected. No doubt, that was unsettling to a community that was already concerned and confused, and we have learned from that experience as well.

Last weekend, Nurse Nina Pham, a member of our hospital family who courageously cared for Mr. Duncan, was also diagnosed with Ebola. Our team is doing everything possible to help her win that fight, and on Tuesday her condition was upgraded to good, and as Dr. Fauci mentioned earlier, Nina's care continues to evolve. I can tell you that the prayers of the entire Texas Health system are with her. Yesterday, as has been noted, we identified a second care-

giver with Ebola, and I can also tell you that our thoughts and prayers remain with Amber as well.

A lot is being said about what may or may not have occurred to cause Nina and Amber to contract Ebola. We know that they are both extremely skilled nurses and were using full protective measures under the CDC protocols, so we don't yet know precisely how or when they were infected. But it is clear there was an exposure somewhere, sometime, and we are poring over records and observations and doing all we can to find the answers.

You have asked about the sequence of events with regard to our preparedness for Ebola and our treatment of Mr. Duncan. Key events from our preparation timeline are attached to our submitted statement, but here is a brief overview. As the Ebola epidemic in Africa worsened over the summer, Texas Health hospitals and facilities began educating our physicians, nurses, and other staff on the symptoms and risk factors associated with the virus. On July 28, an Infection Prevention Nurse Specialist at Texas Health received the first Centers for Disease Control and Prevention Health Advisory about Ebola virus disease and began sharing it with other Texas Health personnel. The Healthcare Advisory encouraged all healthcare providers in the U.S. to consider EVD in the diagnosis of febrile illness—in other words, a fever—in persons who had recently traveled to affected countries. The CDC advisory was also sent to all directors of our emergency departments and signage was also posted in the EDs.

On August 1, Texas Health leaders, including all regional and hospital leaders and the ED leaders across our system, received an email directing that all hospitals have a hospital epidemiologic emergency policy in place to address how to care for patients with Ebola-like symptoms. The email also drew attention to the fact that our electronic health record documentation in emergency departments included a question about travel history to be completed on every patient. Attachments to the e-mail included a draft THR epidemiologic emergencies policy that specifically addressed EVD, CDC-based poster to be posted in the ED, and the CDC advisory from 7/28.

The August 1 CDC Guidelines and Evaluation of U.S. Patients Suspected of Having Ebola Virus Disease was distributed to staff, including physicians, nurses, and other frontline caregivers on August 1st and August 4th.

Over the last 2 months, the Dallas County Health and Human Services Department communicated with us frequently as plans and preparatory work were put in place for a possible case of Ebola. We have also provided the August 27, 2014 Dallas County Health Department algorithm and screening questionnaire.

At 10:30 p.m. on September 25th, Mr. Duncan presented to the Texas Health Presbyterian Dallas Emergency Department with a fever of 100.1, abdominal pain, dizziness, nausea, and headache, symptoms that could be associated with many other illnesses. He was examined and underwent numerous tests over a period of 4 hours. During his time in the ED, his temperature spiked to 103 degrees Fahrenheit but later dropped to 101.2. He was discharged early on the morning of September 26th, and we have provided a

timeline on the notable events of Mr. Duncan's initial emergency department visit.

On September 28th, Mr. Duncan was transported to the hospital by ambulance. Once he arrived at the hospital, he met several of the criteria of the Ebola algorithm. At that time, the CDC was notified. The hospital followed all CDC and Texas Department of State Health Services recommendations in an effort to ensure the safety of all patients, hospital staff, volunteers, nurses, physicians, and visitors. Protective equipment included water-impermeable gowns, surgical masks, eye protection and gloves. Since the patient was having diarrhea, shoe covers were added shortly thereafter.

We notified the Dallas County Health and Human Services Department, and their infectious disease specialists arrived on the site shortly thereafter. On September 30th, lab testing confirmed—

Mr. MURPHY. Doctor, could you—

Mr. VARGA [continuing]. The first case of the Ebola Virus Disease diagnosed in the United States at Texas Health Dallas. Later that same day, CDC officials were notified, and they arrived on our campus October 1st. Physicians—

Mr. MURPHY. Doctor, one moment, please.

Mr. VARGA [continuing]. Nurses—

Mr. MURPHY. Could you hold one moment, please? I know we are going way over time, and we do want to hear these details, but could you wrap it up? Because a lot of members want to ask you questions as well on some of these details, sir.

Mr. VARGA. OK.

Mr. MURPHY. Thank you.

Mr. VARGA. In conclusion, I would like to underscore that we have taken all the steps possible to maximize the safety of our workers, patients and community, and we will continue to make changes as new learnings emerge. Moreover, we are determined to be an agent for change across the U.S. healthcare system by helping our peers benefit from our experience.

Texas Health Resources is an organization with a long history of excellence. Our mission and our ministry will continue, and we will emerge from these trying times stronger than ever.

Thank you for the opportunity to testify, and I'll obviously be glad to answer any questions from the committee.

[The prepared statement of Mr. Varga follows:]

Testimony of Dr. Daniel Varga

**HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS**

“EXAMINING THE U.S. PUBLIC HEALTH RESPONSE TO THE EBOLA OUTBREAK”

OCTOBER 16, 2014

INTRODUCTION

Good afternoon, Chairman Murphy, Vice Chair Burgess, Ranking Member DeGette and members of the committee.

My name is Dr. Daniel Varga. I am the Chief Clinical Officer and Senior Executive Vice President for Texas Health Resources. I am board certified in internal medicine and have more than 24 years of combined experience in patient practice, medical education and health care administration.

I'm sorry I couldn't be with you in person today. I appreciate the Committee's understanding of our situation and how important it is for me to be here in Dallas during this very challenging and sensitive time.

Texas Health Presbyterian Hospital Dallas (THD) is one of 13 wholly-owned, acute-care hospitals in the Texas Health Resources system. It is an 898-bed hospital treating some of the most complicated cases in North Texas. Texas Health Dallas is recognized as a Magnet-designated facility for excellence in nursing services by the American Nurses Credentialing Center, the nation's leading nursing credentialing organization.

Texas Health Resources is one of the largest faith-based, nonprofit healthcare systems in the U.S., and the largest in North Texas in terms of patients served. Our mission is to improve the health of the people in the communities we serve, and we care for all patients regardless of their ability to pay. We serve diverse communities, and as such we provide one standard of care for all, regardless of race or country of origin.

OVERVIEW

As the first hospital in the country to both diagnose and treat a patient with Ebola, we are committed to using our experience to help other hospitals and healthcare providers protect public health against this insidious virus.

It's hard for me to put into words how we felt when our patient Thomas Eric Duncan lost his struggle with Ebola on October 8. It was devastating to the nurses, doctors, and team who tried so hard to save his life. We keep his family in our thoughts and prayers.

Unfortunately, in our initial treatment of Mr. Duncan, despite our best intentions and a highly skilled medical team, we made mistakes. We did not correctly diagnose his symptoms as those of Ebola. We are deeply sorry.

Also, in our effort to communicate to the public quickly and transparently, we inadvertently provided some information that was inaccurate and had to be corrected. No doubt that was

unsettling to a community that was already concerned and confused, and we have learned from that experience as well.

Last weekend, nurse Nina Pham, a member of our hospital family who courageously cared for Mr. Duncan, was also diagnosed with Ebola. Our team is doing everything possible to help her win the fight, and on Tuesday her condition was upgraded to "good," so we are all very hopeful. I can tell you that the prayers of the entire Texas Health system are with her. Yesterday, we identified a second caregiver with EVD. I can also tell you that our thoughts and prayers are with her and her family as well.

A lot is being said about what may or may not have occurred to cause Ms. Pham to contract Ebola. She is known as an extremely skilled nurse, and she was using full protective measures under the CDC protocols, so we don't yet know precisely how or when she was infected. But it's clear there was an exposure somewhere, sometime. We are poring over records and observations, and doing all we can to find the answers.

SEQUENCE OF EVENTS

You have asked about the sequence of events with regard to our preparedness for Ebola and our treatment of Mr. Duncan. Key events from our preparation timeline are attached to our submitted statement, but here is a brief overview:

As the Ebola epidemic in Africa worsened over the summer, Texas Health hospitals and facilities began educating our physicians, nurses and other staff on the symptoms and risk factors associated with the virus.

- On July 28, an Infection Prevention Nurse Specialist at Texas Health received the [first Centers for Disease Control and Prevention \(CDC\) Health Advisory about Ebola Virus Disease \(also known as EVD\)](#) and began sharing it with other Texas Health personnel. The Healthcare Advisory encouraged all healthcare providers in the US to consider EVD in the diagnosis of febrile illness – in other words, a fever -- in persons who had recently traveled to affected countries.
The CDC advisory was also sent to all directors of our Emergency Departments (our EDs) and signage was also posted in the EDs.
- On August 1, Texas Health leaders, including all regional and hospital leaders and the ED leaders across our system, received an e-mail directing that all hospitals have a hospital Epidemiologic Emergency Policy in place to address how to care for patients with Ebola-like symptoms. The email also drew attention to the fact that our Electronic Health Record documentation in EDs included a question about travel history to be completed on every patient. Attachments to the e-mail included:
 - Draft THR Epidemiologic Emergencies Policy that specifically addresses EVD.
 - CDC based poster to be posted in ED admissions and other appropriate locations.
 - CDC advisory from 7/28/14.
- The August 1 CDC *Guidelines and Evaluation of US Patients Suspected of Having Ebola Virus Disease (CDCHAN-00364)* was distributed to staff, including physicians, nurses, and other frontline caregivers on August 1 and August 4.

Over the last two months, the Dallas County Health and Human Services Department communicated with us frequently as plans and preparatory work were put in place for a possible case of Ebola. We have also provided the August 27, 2014 Dallas County Health Department algorithm and screening questionnaire.

At 10:30pm on September 25, Mr. Duncan presented to the Texas Health Dallas Emergency Department with a fever of 100.1°F, abdominal pain, dizziness, nausea, and headache—symptoms that could be associated with many other illnesses. He was examined and underwent numerous tests over a period of four hours.

During his time in the ED, his temperature spiked to 103°F, but later dropped to 101.2. He was discharged early on the morning of September 26. We have provided a timeline on the notable elements of Mr. Duncan's initial emergency department visit.

On September 28, Mr. Duncan was transported to the hospital by ambulance. Once he arrived at the hospital, he met several of the criteria of the Ebola algorithm. At that time, the CDC was notified.

The hospital followed all CDC and Texas Department of State Health Services recommendations in an effort to ensure the safety of all patients, hospital staff, volunteers, nurses, physicians and visitors. Protective equipment included water impermeable gowns, surgical masks, eye protection and gloves. Since the patient was having diarrhea, shoe covers were added shortly thereafter.

We notified the Dallas County Health and Human Services Department, and their infectious disease specialists arrived on site shortly thereafter. On September 30, lab testing confirmed the first case of the Ebola Virus Disease diagnosed in the United States at Texas Health Dallas. Later that same day, CDC officials were notified, and they arrived on campus October 1.

The physicians, nurses and other caregivers at Texas Health Dallas worked diligently to provide compassionate, intensive care to Mr. Duncan. He was treated with the most appropriate and available medical interventions, including the investigative antiviral drug Brincidofovir. Mr. Duncan was the first Ebola patient to receive this drug. Mr. Duncan did not receive a serum transfusion because his blood type was not compatible with the serum donor.

REVIEW OF EVENTS IN OCTOBER

The treating personnel at Texas Health Dallas followed the CDC protocols included in the [CDC checklist](#) for patients being evaluated for EVD, including use of personal protective equipment (PPE).

Unfortunately, THD has since learned that there was an exposure during Mr. Duncan's care resulting in two of his healthcare workers testing positive for the virus. The CDC and THD are doing a thorough analysis of how this exposure occurred. We also plan to share the results of this analysis with other hospitals and providers to increase awareness in an effort to reduce the potential for future exposure of health care workers.

Today, every person at Texas Health Dallas who has had contact with a known Ebola patient is under active monitoring for 21 days after their last contact with the patient. This includes taking a temperature and assessing symptoms twice a day. We created the monitoring program based on three categories of risk as prescribed by the CDC:

- High-risk exposure;
- Low-risk exposure; and,
- No-known exposure.

All individuals in the high-risk exposure category are undergoing active monitoring by the Dallas County Health Department, are on work furlough, and are required to remain in their county of residence.

Anyone in the low-risk category is undergoing active monitoring, are able to work and have no travel restrictions.

Even those in the “no known exposure” group – those who have virtually no risk – are part of the program and are in active monitoring without work and travel restrictions.

Of note, the two caregivers who unfortunately contracted Ebola were part of this monitoring program, and as a result, were promptly and successfully isolated and diagnosed.

LESSONS LEARNED AND STEPS TAKEN

I want to emphasize that we have made a number of changes based on the preliminary lessons learned from our experience with EVD over the last two weeks:

1. Diagnosing Ebola is very different from treating Ebola

THD was and remains well prepared and equipped based upon the best available information to treat patients already identified as having EVD. Where we fell short initially was in our ability to detect and diagnose EVD, as evidenced by Mr. Duncan’s first visit to the ED.

As a result, following Mr. Duncan’s initial admission, we have changed our screening process in the ED to capture the patient’s travel history at the first point of contact with ED staff. This process change makes the travel history available to all caregivers from the beginning of the patient’s visit in the ED.

Additionally, we have modified our Electronic Health Record in multiple ways to increase the visibility and documentation of information related to travel history and infectious exposures related to EVD. These include:

- Better placement/title of the screening tool
- Expanded screening questions, which include:
 - Exposure to persons known or suspected to have EVD
 - High-risk activities for persons who have traveled to Ebola endemic areas such as: “have you touched a dead animal or helped carry someone sick”;
 - A pop up identifying the patient as high-risk for Ebola with explicit instructions for next steps if the answer to any of the screening questions is positive

2. Communication is Critical but it is No Substitute for Training

Despite the communications regarding EVD preparedness that occurred between August 1 and October 1, we realized a need for more proactive, intensive, and focused training for frontline responders in the diagnosis of EVD. Therefore an Emergency Department (ED) refresher course was provided to THD ED nurses. Additionally, an “in-service” face-to-face training was provided starting with the night shift and continued at

the start of every shift for a number of days. The education included screening of suspected patients, documenting response to travel questions in the Electronic Health Record and proper donning and doffing of PPE.

3. Ebola Extends Beyond the Walls of the Hospital

In a crisis like this, a hospital's focus needs to be on providing exceptional care. Coordination and collaboration with federal, state, and local agencies is critical to limiting the perimeter of Ebola, managing contact identification interviews, and establishing community confidence. We have been blessed with exceptional support and leadership from all of the above agencies.

CONCLUSION

In conclusion, I would like to underscore that we have taken all of these steps to maximize the safety of our workers, patients and community, and we will continue to make changes as new learnings emerge. Moreover, we are determined to be an agent for change across the U.S. healthcare system by helping our peers benefit from our experience.

Texas Health Resources is an organization with a long history of excellence, and a commitment to caring for our patients and communities. Our mission and our ministry will continue, and we will emerge from these trying times stronger than ever.

Thank you for the opportunity to testify. I would be glad to answer any questions from Committee members.

Mr. MURPHY. Thank you. We will be recognizing each person on this committee for 5 minutes of questions. We will keep a strict time on this as well.

Let me start off here with Dr. Frieden. A second nurse infected with Ebola took a flight to Cleveland after she registered a fever. We have a report that says she contacted the CDC and was told she could fly. Did she in fact call the CDC and ask for guidance on boarding a commercial flight as far as you know?

Mr. FRIEDEN. My understanding is that she did contact CDC and we discussed with her her report of symptoms as well as other evaluation.

Mr. MURPHY. Were you part of that conversation?

Mr. FRIEDEN. No, I was not.

Mr. MURPHY. Was there a pre-plan suggesting limiting her contacts with other persons?

Mr. FRIEDEN. The protocol for movement and monitoring of people potentially exposed to Ebola identifies as high risk someone who did not wear appropriate personal protective equipment during the time they cared for a patient with Ebola. On—

Mr. MURPHY. Well, let me you ask this. What specifically did she tell you? We know Mr. Duncan's medical team was was not under the same observation and travel restrictions as people he came into contact with, so what specifically did she tell you her symptoms were or what was happening?

Mr. FRIEDEN. I have not seen the transcript of the conversation. My understanding is that she reported no symptoms to us.

Mr. MURPHY. All right. Let me ask another question here quickly. With regard to the new patient being transferred to NIH, will people who come into contact with her be under any travel restrictions? Dr. Fauci, perhaps you know that? I know—

Mr. FAUCI. Well, according to the guidelines, the people who will be coming into contact with her will be physicians, nurses, and others who will be in personal protective equipment, and therefore they are not restricted.

Mr. MURPHY. Why is she being transferred to NIH and away from Texas?

Mr. FAUCI. To give the state-of-the-art care in a containment facility of highly trained individuals who are capable of taking care of her.

Mr. MURPHY. Has her condition deteriorated or improved?

Mr. FAUCI. No, it has not. I have not seen the patient yet. I will when she gets here. But at this point, from the report that we are getting from our colleagues in Dallas, it is that her condition is stable and she seems to be doing reasonably well. But I have to verify that myself when my team goes over.

Mr. MURPHY. And if other people come to Dallas or somewhere else, will they also be transferred to NIH?

Mr. FAUCI. We have a limited capacity of beds, of being able to do this type of high-level care and containment. Our total right now is two beds. She will occupy one of them.

Mr. MURPHY. Thank you.

Dr. Frieden, when we spoke on the phone the other day, you remained opposed to travel restrictions because, in your words, you said "cutting commercial ties would hurt these fledgling democ-

racies.” Now, is this the opinion of CDC? Is this your opinion or does someone also advise you, someone within the administration, any other agencies? Where did this opinion come from that that is of high importance?

Mr. FRIEDEN. My sole concern is to protect Americans. We can do that by continuing to take the steps we are taking here as well as—

Mr. MURPHY. Did someone advise you on that? Did someone outside of yourself, somebody else advise you that that is the position, we need to protect fledgling democracies?

Mr. FRIEDEN. My recollection of that conversation is that that discussion was in the context of our ability to stop the epidemic at the source.

Mr. MURPHY. But we can get supplies and medical personnel into the Ebola hot zones and so stopping planes—and I have heard you say this on multiple occasions, that we have 1,000-plus persons per week coming into the United States from hot zones. Am I correct on that? Coming from those areas?

Mr. FRIEDEN. There are approximately 100 to 150 per day.

Mr. MURPHY. OK. Now, the Duncan case has seriously impacted Dallas and northern Ohio but what I don’t understand, if the administration insists on bringing Ebola cases into the United States, clearly you have determined how many Ebola infection cases the U.S. public can handle. I mean, NIH can handle two of these beds. Do you know that number overall in this country, how many we can handle?

Mr. FRIEDEN. Our goal is for no patients with Ebola—

Mr. MURPHY. I understand, but as long as we don’t restrict travel and we are not quarantining people and we are not limiting their travel, we still have a risk, and so these issues of surveillance and containment I don’t understand, and this is the question the American public is asking: why are we still allowing folks to come over here and why once they are over here is there no quarantine.

Mr. FRIEDEN. Our fundamental mission is to protect Americans. Right now, we are able to track everyone who comes in.

Mr. MURPHY. But you are not stopping them from being around other people, Doctor. I understand that, and I have respect for you, but my concern is the American public, and even so, they are not limited from travel, they are not quarantined for 21 days because they could still show up with symptoms, they could still bypass all the questions that Mr. Wagner referred to and the thermometers, and this is what happened with the nurse who went to Cleveland. So I am concerned here. Is this going to be a maintained position of the administration that there will be no travel restrictions?

Mr. FRIEDEN. We will consider any options to better protect Americans.

Mr. MURPHY. Thank you. I now give 5 minutes to Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Frieden, I have got some questions for you and Dr. Varga for you, and I would appreciate yes or no answers because I have a lot to move through and only a short amount of time.

Dr. Frieden, in the spring of 2014, Ebola began spreading through West Africa, causing increasing concern within the international public health community, correct?

Mr. FRIEDEN. Correct.

Ms. DEGETTE. Ebola has an incubation period of about 21 days and is not contagious until the person with the virus begins to be symptomatic beginning often with a fever, correct?

Mr. FRIEDEN. Between 2 and 21 days, yes.

Ms. DEGETTE. Ebola is transmitted through contact with a patient's bodily fluids including vomit, blood, feces, and saliva, and the virus concentrates more heavily as the patient becomes sicker, presenting increasingly greater risk to those who may be in contact with them, correct?

Mr. FRIEDEN. Correct.

Ms. DEGETTE. Now, the CDC has developed guidance for hospitals to follow if patients present with symptoms consistent with Ebola, and it distributed them to hospitals around the country in the summer of 2014, correct?

Mr. FRIEDEN. Correct.

Ms. DEGETTE. Now, Dr. Varga, can you hear me?

Mr. VARGA. Yes, ma'am.

Ms. DEGETTE. Your hospital received the first CDC Health Advisory about Ebola on July 28th, and this advisory was given to the directors of your emergency departments and signage was posted in your emergency room. Is that right?

Mr. VARGA. Yes, ma'am.

Ms. DEGETTE. Now, was this information given to your emergency room personnel and was there any actual person-to-person training at Texas Presbyterian for the staff at that time? Yes or no.

Mr. VARGA. Was given to the emergency department.

Ms. DEGETTE. Was there actual training?

Mr. VARGA. No.

Ms. DEGETTE. On August 1st, your hospital received an email from the CDC specifying how to care for Ebola patients and advising intake personnel to ask a question about travel history from West Africa. Is that right?

Mr. VARGA. That is correct.

Ms. DEGETTE. Now, on September 25th, almost 2 months after the first advisory received by the hospital, Thomas Eric Duncan showed up at Texas Presbyterian with a fever that spiked up to 103 and he told the personnel that he had come from Liberia. Despite this, the hospital sent him home. Is that right?

Mr. VARGA. That is not completely correct.

Ms. DEGETTE. Well, they did send him home, right?

Mr. VARGA. That is correct.

Ms. DEGETTE. Now, 3 days later, on September 28th, he took a severe turn for the worse and was brought back by ambulance. The hospital staff, nurses, and everybody else wore protective equipment. Is that right?

Mr. VARGA. That is correct.

Ms. DEGETTE. And then eventually shoe covers were put on, too. Do you know how long that took them to put the shoe covers on?

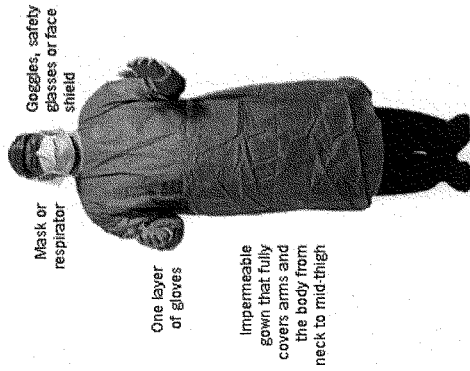
Mr. VARGA. I don't.

Ms. DEGETTE. Now, because Ebola is highly contagious when the patient is symptomatic, the protective gear has to shield them from any contact with bodily fluids. Is that right, Dr. Frieden?

Mr. FRIEDEN. Correct.

Ms. DEGETTE. Now, I have a slide I would like to put up, and I got it from the New York Times today. It is the photo of the people in the various protective gear. So the first one on the left shows what they are supposed to wear when they are not having contact with the bodily fluids. The second one shows what they are supposed to have with the bodily fluids. So I want to ask you, Dr. Varga, is what they were wearing at first before the Ebola was diagnosed, that first set of protective gear?

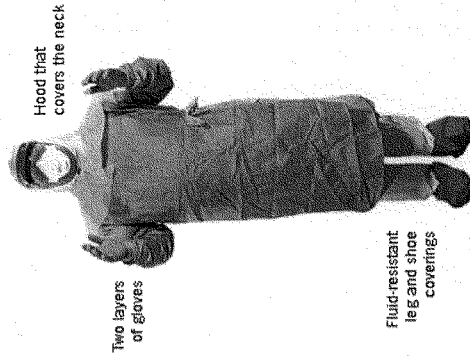
Levels of protective gear



Mask or respirator
Goggles, safety glasses or face shield

One layer of gloves

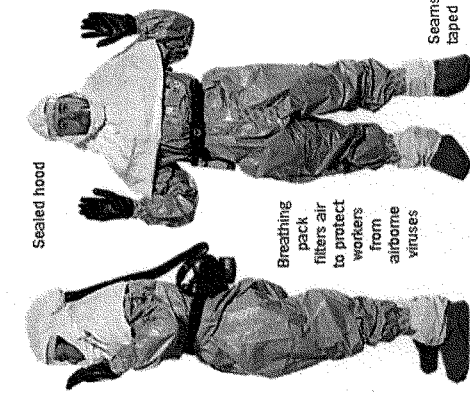
Impermeable gown that fully covers arms and the body from neck to mid-thigh



Hood that covers the neck

Two layers of gloves

Fluid-resistant leg and shoe coverings



Sealed hood

A thicker outer glove

Impermeable body suit made of material that is difficult to tear

Breathing pack filters air to protect workers from airborne viruses

Seams taped

Original C.D.C. Guidelines

The suit above represents the C.D.C.'s original guidelines for health care workers who would come in contact with Ebola patients but would not be exposed to their blood or bodily fluids.

North Shore-L.I.J. Level 2 Suit

The C.D.C. has recommended extra levels of protection, like those above, in cases where workers could come into contact with a patient's bodily fluids. Many hospitals, including the Nebraska center, have required these levels as the minimum. Before this week, this suit was used by North Shore-L.I.J. hospitals for patients who were suspected of having Ebola, but they have since decided to upgrade to the Level 3 Suit instead.

North Shore-L.I.J. Level 3 Suit

After the second nurse in Dallas was diagnosed with Ebola, the North Shore system upgraded their Level 3 suit by adding an impermeable gown on top. The suit shown above begins to approach the standard of protection used by health care workers in West Africa. The C.D.C. may soon require full-body suits in the United States.

Mr. VARGA. I am sorry. I can't see the picture right now.

Ms. DEGETTE. OK. I was told you would be able to.

Dr. Frieden, what should they have been wearing of that protective gear before the Ebola was diagnosed?

Mr. FRIEDEN. I can't make out the details, but the recommendations vary as to the risk including whether the patient is having diarrhea or vomiting and may expose health care workers to—

Ms. DEGETTE. Well, this guy, he had diarrhea and vomiting. So, in your testimony, people should have been completely covered. Is that right?

Mr. FRIEDEN. I would have to look at the exact details to know what the answer to that question would be.

Ms. DEGETTE. So you don't know whether they should have been completely covered if the patient had diarrhea and vomiting and he had come from West Africa?

Mr. FRIEDEN. If the patient had diarrhea or vomiting, then additional covering is recommended under the CDC recommendations, yes.

Ms. DEGETTE. Now, my other question that I want to ask—and I am going to have to get—Dr. Varga, I am going to have to get your testimony since you can't see my chart.

Now, subsequently, a number of people, health care workers, were put into this group, this protective work. Is that right, Dr. Frieden? People who were being monitored.

Mr. FRIEDEN. So health care—

Ms. DEGETTE. And on October 10th, Nina Pham presented with a fever, and she was admitted to the hospital. Is that right?

Mr. FRIEDEN. Yes.

Ms. DEGETTE. And then on October 13th, Amber Vinson, who was self-monitoring, she presented with a fever and she was told by your agency she could board the plane. Is that right? I just have one more question.

Mr. FRIEDEN. That is my understanding.

Ms. DEGETTE. Now, your—

Mr. FRIEDEN. I need to correct that.

Ms. DEGETTE. OK.

Mr. FRIEDEN. I have not reviewed exactly what was said but she did contact our agency and she did board the plane.

Ms. DEGETTE. And she says she was told to board the plane. Now—

Mr. FRIEDEN. That may well be correct.

Ms. DEGETTE. Now, your August 22nd protocols say people who are being monitored should not travel by commercial conveyances, don't they?

Mr. MURPHY. Time is expired. You can answer the question.

Ms. DEGETTE. That is what they say.

Mr. FRIEDEN. People who are in what is called controlled movement should not board commercial airlines.

Ms. DEGETTE. Right, and that is people who have close contact with these patients, right? That is what your guidelines say.

Mr. FRIEDEN. The guidelines say that health care workers with appropriate personal protective equipment don't need to be, but people without appropriate personal protective equipment do need to travel by controlled transportation.

Mr. MURPHY. The gentlelady's time is expired. We do need to—
Ms. DEGETTE. Mr. Chairman, I just ask for the record the interim guidance dated October 22nd, the interim guidance dated August 1st, and the CDC Health Advisory dated July 28th be included in the record.

Mr. MURPHY. Without objection, we will include it in the record.
[The information follows:]



Ebola (Ebola Virus Disease)

CDC > [Ebola \(Ebola Virus Disease\)](#) > [Healthcare Workers](#)

Safe Management of Patients with Ebola Virus Disease (EVD) in U.S. Hospitals



Frequently Asked Questions

The recent EVD outbreak in West Africa has increased the possibility of patients traveling from the impacted countries to the United States. Additionally, two American citizens with EVD were medically evacuated to the United States to receive care at Emory University Hospital in Atlanta. The following are answers to frequently asked questions about the safety of this medical evacuation and the necessary infection control procedures to protect patients and healthcare providers in U.S. hospitals.

Are U.S. hospitals ready to care for patients with Ebola virus disease (EVD)?

Yes – any U.S. hospital that is following [CDC's infection control recommendations](#) and can isolate a patient in a private room is capable of safely managing a patient with EVD. CDC recommends that U.S. hospitals isolate the patient in a private room and implement standard, contact, and droplet precautions.

What should U.S. hospitals do if they have a patient with suspect EVD?

Early recognition is critical for infection control. Healthcare providers should be alert for and evaluate any patients suspected of having EVD who have (see [EVD case definition](#)):

1. A fever of 38.0 degrees Celsius or 100.4 degrees Fahrenheit or greater, and additional symptoms such as severe headache, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage;

AND

2. Risk factors within the past 3 weeks before the onset of symptoms, such as contact with blood or other body fluids of a patient known to have or suspected to have EVD; residence in—or travel to—an [area where EVD transmission is active](#); or direct handling of bats or nonhuman primates from disease-endemic areas. Malaria diagnostics should also be a part of initial testing because it is the most common cause of febrile illness in persons with a travel history to the affected countries.

When should patients with suspected EVD in U.S. hospitals be tested?

CDC recommends testing for all persons with onset of fever within 21 days of having a high-risk exposure such as (See [CDC's laboratory testing guidance](#)):

- percutaneous or mucous membrane exposure or direct skin contact with body fluids of a person with a confirmed or suspected case of EVD without appropriate personal protective equipment (PPE),
- laboratory processing of body fluids of suspected or confirmed EVD cases without appropriate PPE or standard biosafety precautions, or
- participation in funeral rites or other direct exposure to human remains in the geographic area where the outbreak is occurring without appropriate PPE.

For persons with a high-risk exposure but without a fever, testing is recommended only if there are other compatible clinical symptoms present and blood work findings are abnormal (i.e., thrombocytopenia <150,000 cells/ μ L and/or elevated transaminases).

If a patient in a U.S. hospital is identified to have suspected or confirmed EVD, what infection control precautions should be put into place?

If a patient in a U.S. hospital is suspected or known to have Ebola virus disease, healthcare teams should follow standard, contact, and droplet precautions, including the following recommendations:

- **Isolate the patient:** Patients should be isolated in a single patient room (containing a private bathroom) with the door closed.
- **Wear appropriate PPE:** Healthcare providers entering the patient's room should wear: gloves, gown (fluid resistant or impermeable), eye protection (goggles or face shield), and a facemask. Additional protective equipment might be required in certain situations (e.g., copious amounts of blood, other body fluids, vomit, or feces present in the environment), including but not limited to double gloving, disposable shoe covers, and leg coverings.
- **Restrict visitors:** Avoid entry of visitors into the patient's room. Exceptions may be considered on a case by case basis for those who are essential for the patient's wellbeing. A logbook should be kept to document all persons entering the patient's room. See CDC's [infection control guidance](#) on procedures for monitoring, managing, and training of visitors.
- **Avoid aerosol-generating procedures:** Avoid aerosol-generating procedures. If performing these procedures, PPE should include respiratory protection (N95 or higher filtering facepiece respirator) and the procedure should

be performed in an airborne infection isolation room.

- **Implement environmental infection control measures:** Diligent environmental cleaning and disinfection and safe handling of potentially contaminated materials is of paramount importance, as blood, sweat, vomit, feces, urine and other body secretions represent potentially infectious materials should be done following hospital protocols.

Why do responders in Africa wear so much personal protective equipment (that can include full body suits) for this Ebola outbreak when CDC says hospitals here could safely manage the care of an Ebola patient without a full body suit?

There are important differences between providing care or performing public health tasks in Africa versus in a U.S. hospital.

In field medical settings, additional PPE may be necessary to protect healthcare workers. In some places in Africa, workers may not have the ability to prepare for potential exposures. For example, in some places, care may be provided in clinics with limited resources (e.g., no running water, no climate control, no floors, inadequate medical supplies), and workers could be in those areas for several hours with a number of Ebola infected patients.

Additionally, certain job responsibilities and tasks, such as attending to dead bodies, may also require different PPE than what is used when providing care for infected patients in a hospital.

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This is an official
CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
August 1, 2014 20:00 ET (8:00 PM ET)
CDCHAN-00364

Guidelines for Evaluation of US Patients Suspected of Having Ebola Virus Disease

Summary

The Centers for Disease Control and Prevention (CDC) continues to work closely with the World Health Organization (WHO) and other partners to better understand and manage the public health risks posed by Ebola Virus Disease (EVD). To date, no cases have been reported in the United States. The purpose of this health update is 1) to provide updated guidance to healthcare providers and state and local health departments regarding who should be suspected of having EVD, 2) to clarify which specimens should be obtained and how to submit for diagnostic testing, and 3) to provide hospital infection control guidelines.

U.S. hospitals can safely manage a patient with EVD by following recommended isolation and infection control procedures. Please disseminate this information to infectious disease specialists, intensive care physicians, primary care physicians, hospital epidemiologists, infection control professionals, and hospital administration, as well as to emergency departments and microbiology laboratories.

Background

CDC is working with the World Health Organization (WHO), the ministries of health of Guinea, Liberia, and Sierra Leone, and other international organizations in response to an outbreak of EVD in West Africa, which was first reported in late March 2014. As of July 27, 2014, according to WHO, a total of 1,323 cases and 729 deaths (case fatality 55-60%) had been reported across the three affected countries. This is the largest outbreak of EVD ever documented and the first recorded in West Africa.

EVD is characterized by sudden onset of fever and malaise, accompanied by other nonspecific signs and symptoms, such as myalgia, headache, vomiting, and diarrhea. Patients with severe forms of the disease may develop hemorrhagic symptoms and multi-organ dysfunction, including hepatic damage, renal failure, and central nervous system involvement, leading to shock and death. The fatality rate can vary from 40-90%.

In outbreak settings, Ebola virus is typically first spread to humans after contact with infected wildlife and is then spread person-to-person through direct contact with bodily fluids such as, but not limited to, blood, urine, sweat, semen, and breast milk. The incubation period is usually 8–10 days (ranges from 2–21 days). Patients can transmit the virus while febrile and through later stages of disease, as well as postmortem, when persons touch the body during funeral preparations.

Patient Evaluation Recommendations to Healthcare Providers

Healthcare providers should be alert for and evaluate suspected patients for Ebola virus infection who have both consistent symptoms and risk factors as follows: 1) Clinical criteria, which includes fever of greater than 38.6 degrees Celsius or 101.5 degrees Fahrenheit, and additional symptoms such as severe headache, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage; AND 2) Epidemiologic risk factors within the past 3 weeks before the onset of symptoms, such as contact with blood or other body fluids of a patient known to have or suspected to have EVD; residence in—or travel to—an area where EVD transmission is active; or direct handling of bats, rodents, or primates from disease-endemic areas. Malaria diagnostics should also be a part of initial testing because it is a common cause of febrile illness in persons with a travel history to the affected countries.

Testing of patients with suspected EVD should be guided by the risk level of exposure, as described below:

CDC recommends testing for all persons with onset of fever within 21 days of having a high-risk exposure. A high-risk exposure includes any of the following:

- percutaneous or mucous membrane exposure or direct skin contact with body fluids of a person with a confirmed or suspected case of EVD without appropriate personal protective equipment (PPE),
- laboratory processing of body fluids of suspected or confirmed EVD cases without appropriate PPE or standard biosafety precautions, or
- participation in funeral rites or other direct exposure to human remains in the geographic area where the outbreak is occurring without appropriate PPE.

For persons with a high-risk exposure but without a fever, testing is recommended only if there are other compatible clinical symptoms present and blood work findings are abnormal (i.e., thrombocytopenia <150,000 cells/ μ L and/or elevated transaminases) or unknown.

Persons considered to have a low-risk exposure include persons who spent time in a healthcare facility where EVD patients are being treated (encompassing healthcare workers who used appropriate PPE, employees not involved in direct patient care, or other hospital patients who did not have EVD and their family caretakers), or household members of an EVD patient without high-risk exposures as defined above. Persons who had direct unprotected contact with bats or primates from EVD-affected countries would also be considered to have a low-risk exposure. Testing is recommended for persons with a low-risk exposure who develop fever with other symptoms and have unknown or abnormal blood work findings. Persons with a low-risk exposure and with fever and abnormal blood work findings in absence of other symptoms are also recommended for testing. Asymptomatic persons with high- or low-risk exposures should be monitored daily for fever and symptoms for 21 days from the last known exposure and evaluated medically at the first indication of illness.

Persons with no known exposures listed above but who have fever with other symptoms and abnormal bloodwork within 21 days of visiting EVD-affected countries should be considered for testing if no other diagnosis is found. Testing may be indicated in the same patients if fever is present with other symptoms and blood work is abnormal or unknown. Consultation with local and state health departments is recommended.

If testing is indicated, the local or state health department should be immediately notified. Healthcare providers should collect serum, plasma, or whole blood. A minimum sample volume of 4 mL should be shipped refrigerated or frozen on ice pack or dry ice (no glass tubes), in accordance with IATA guidelines as a Category B diagnostic specimen. Please refer to <http://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html> for detailed instructions and a link to the specimen submission form for CDC laboratory testing.

Recommended infection control measures

U.S. hospitals can safely manage a patient with EVD by following recommended isolation and infection control procedures, including standard, contact, and droplet precautions. Early recognition and identification of patients with potential EVD is critical. Any U.S. hospital with suspected patients should follow CDC's *Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals* (<http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html>). These recommendations include the following:

- **Patient placement:** Patients should be placed in a single patient room (containing a private bathroom) with the door closed.
- **Healthcare provider protection:** Healthcare providers should wear: gloves, gown (fluid resistant or impermeable), shoe covers, eye protection (goggles or face shield), and a facemask. Additional PPE might be required in certain situations (e.g., copious amounts of blood, other body

fluids, vomit, or feces present in the environment), including but not limited to double gloving, disposable shoe covers, and leg coverings.

- **Aerosol-generating procedures:** Avoid aerosol-generating procedures. If performing these procedures, PPE should include respiratory protection (N95 filtering facepiece respirator or higher) and the procedure should be performed in an airborne isolation room.
- **Environmental infection control:** Diligent environmental cleaning and disinfection and safe handling of potentially contaminated materials is paramount, as blood, sweat, emesis, feces and other body secretions represent potentially infectious materials. Appropriate disinfectants for Ebola virus and other filoviruses include 10% sodium hypochlorite (bleach) solution, or hospital-grade quaternary ammonium or phenolic products. Healthcare providers performing environmental cleaning and disinfection should wear recommended PPE (described above) and consider use of additional barriers (e.g., shoe and leg coverings) if needed. Face protection (face shield or facemask with goggles) should be worn when performing tasks such as liquid waste disposal that can generate splashes. Follow standard procedures, per hospital policy and manufacturers' instructions, for cleaning and/or disinfection of environmental surfaces, equipment, textiles, laundry, food utensils and dishware.

Recommendations to Public Health Officials

If public health officials have a patient that is suspected of having EVD or has potentially been exposed and intends to travel, please contact CDC's Emergency Operations Center 1 (770) 488-7100.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

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##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##

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CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
July 28, 2014, 16:30 ET (4:30 PM ET)
CDCHAN-00363

Ebola Virus Disease Confirmed in a Traveler to Nigeria, Two U.S. Healthcare Workers in Liberia

Summary

Nigerian health authorities have confirmed a diagnosis of Ebola Virus Disease (EVD) in a patient who died on Friday in a hospital in Lagos, Nigeria, after traveling from Liberia on July 20, 2014. The report marks the first Ebola case in Nigeria linked to the current outbreak in the West African countries of Guinea, Sierra Leone, and Liberia. Health authorities also reported this weekend that two U.S. citizens working in a hospital in Monrovia, Liberia, have confirmed Ebola virus infection. These recent cases, together with the continued increase in the number of Ebola cases in West Africa, underscore the potential for travel-associated spread of the disease and the risks of EVD to healthcare workers. While the possibility of infected persons entering the U.S. remains low, the Centers for Disease Control and Prevention (CDC) advises that healthcare providers in the U.S. should 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.

Background

CDC is working with the World Health Organization (WHO), the ministries of health of Guinea, Liberia, and Sierra Leone, and other international organizations in response to an outbreak of EVD in West Africa, which was first reported in late March 2014. As of July 23, 2014, according to WHO, a total of 1,201 cases and 672 deaths (case fatality 55-60%) had been reported in Guinea, Liberia, and Sierra Leone. This is the largest outbreak of EVD ever documented and the first recorded in West Africa.

EVD is characterized by sudden onset of fever and malaise, accompanied by other nonspecific signs and symptoms, such as myalgia, headache, vomiting, and diarrhea. Patients with severe forms of the disease may develop multi-organ dysfunction, including hepatic damage, renal failure, and central nervous system involvement, leading to shock and death.

In outbreak settings, Ebola virus is typically first spread to humans after contact with infected wildlife and is then spread person-to-person through direct contact with bodily fluids such as, but not limited to, blood, urine, sweat, semen, and breast milk. The incubation period is usually 8–10 days (rarely ranging from 2–21 days). Patients can transmit the virus while febrile and through later stages of disease, as well as postmortem, when persons contact the body during funeral preparations.

On July 25, the Nigerian Ministry of Health confirmed a diagnosis of EVD in a man who died in a hospital in the country's capital of Lagos (population ~21 million). The man had been in isolation in the hospital since arriving at the Lagos airport from Liberia, where he apparently contracted the infection. Health authorities are investigating whether passengers or crew on the plane or other persons who had contact with the ill traveler are at risk for infection.

In addition, health authorities have reported that two U.S. healthcare workers at ELWA hospital in Monrovia, Liberia, have confirmed Ebola virus infection. One of the healthcare workers, a physician who worked with Ebola patients in the hospital, is symptomatic and in isolation. The other healthcare worker,

a hygienist, developed fever but is showing no other signs of illness. The physician is an employee of Samaritan's Purse, a North Carolina-based aid organization that has provided extensive assistance in Liberia since the beginning of the current outbreak. The other healthcare worker works with Soudan Interior Mission (SIM) in Liberia and was helping the joint SIM/Samaritan's Purse team.

The recent cases in a traveler and in healthcare workers demonstrate the risk for spread of EVD in these populations. While no EVD cases have been reported in the United States, a human case, caused by a related virus, Marburg virus, occurred in Denver, Colorado in 2008. Successful implementation of standard precautions was sufficient to limit onward transmission. Other imported cases of viral hemorrhagic fever disease were also successfully managed through effective barrier methods, including a recent Lassa fever case in Minnesota.

Recommendations

EVD poses little risk to the U.S. general population at this time. However, U.S. healthcare workers are advised to be alert for signs and symptoms of EVD in patients with compatible illness who have a recent (within 21 days) travel history to countries where the outbreak is occurring, and should consider isolation of those patients meeting these criteria, pending diagnostic testing.

For more information:

Additional information on EVD can be found at:

<http://www.cdc.gov/ebola>

Interim Guidance on EVD for healthcare workers can be found at:

<http://www.cdc.gov/vhf/abroad/healthcare-workers.html>

Travel notices for each country can be found at:

Guinea: <http://wwwnc.cdc.gov/travel/notices/alert/ebola-guinea>

Liberia: <http://wwwnc.cdc.gov/travel/notices/alert/ebola-liberia>

Sierra Leone: <http://wwwnc.cdc.gov/travel/notices/alert/ebola-sierra-leone>

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Mr. MURPHY. And Dr. Frieden, I need you and also the doctor in Texas to get back to this committee as a follow-up to her question because your comment you just made to us was that if she was wearing appropriate protective gear, she is OK to travel; if she was not, she should not have traveled. And you just told us we don't know. We need to find that out. It is an important question.

I now recognize the chairman of the committee, Mr. Upton, for 5 minutes.

Mr. UPTON. Thank you again, Mr. Chairman.

I think most Americans realize that, if you are exposed, you have 21 days. If you go beyond 21 days, you are at virtually no risk of Ebola if you go that far. But it is conceivable then that after 14 or 15 days, you in fact can still get Ebola. Is that correct?

Mr. FRIEDEN. Yes.

Mr. UPTON. So I want to go back to the restricting of travel, particularly by non-U.S. citizens, these 150 folks a day into the United States from West Africa. So the conditions as you talked about exit screening, all folks from there are exit screened, so it is perfectly conceivable that someone even after 14 days can exit screen, they are OK, no fever, and in fact, get to their destination, perhaps in the United States, and have the worst. Is that right?

Mr. FRIEDEN. Yes.

Mr. UPTON. So if our fundamental job is to protect the American public, the administration, as I understand it, because I have looked at the legal language, the President does have the legal authority to impose a travel ban because of health reasons, including Ebola. Is that not correct?

Mr. FRIEDEN. I don't have the legal expertise to answer that question.

Mr. UPTON. I saw language earlier today—we can share that with you—but he does, from what we understand, not only an Executive Order that former President Bush issued when he was President but also legal standing as well. So if you have the authority, and it is my understanding again that a number of African countries around West Africa, around particularly these three nations, in fact have imposed a travel ban from those three countries into their country. Is that not true?

Mr. FRIEDEN. I don't know the details of the restrictions. There are some restrictions.

Mr. UPTON. It is my understanding that they said no and including even Jamaica, as I read in the press earlier this week, has issued a travel ban from folks coming from West Africa. Are you aware of that?

Mr. FRIEDEN. I don't know the details of what other countries have done. I know some of the details, and some of them have been in flux.

Mr. UPTON. Well, I guess the question that I have is, if other countries are doing the same, and as you said, the fundamental job of the United States now is to protect American citizens, why cannot we move to a similar ban for folks who may or may not have a fever, knowing in fact that the exposure rate, 14 days or 15 days, is well within the 21 days and in fact knowing 150 folks coming a day, not 100 percent, it is 94 percent in terms for screening from

U.S. airports, it seems to me that this is not a failsafe system that has been put into place at this point.

Mr. FRIEDEN. Mr. Chairman, may I give a full answer?

Mr. UPTON. I look forward to it.

Mr. FRIEDEN. Right now we know who is coming in. If we try to eliminate travel, the possibility that some will travel overland, will come from other places and we don't know that they are coming in will mean that we won't be able to do multiple things. We won't be able to check them for fever when they leave—

Mr. UPTON. If I can interrupt you just for a second, do we not have a record of where they have been before, i.e., a passport or travel status as they travel from one country to another?

Mr. FRIEDEN. Borders can be porous—may I finish?

Mr. UPTON. Go ahead.

Mr. FRIEDEN. Especially in this part of the world. We won't be able to check them for fever when they leave. We won't be able to check them for fever when they arrive. We won't be able, as we do currently, to take a detailed history to see if they were exposed when they arrive. When they arrive, we wouldn't be able to impose quarantine as we now can if they have high-risk contact. We wouldn't be able to obtain detailed locating information, which we do now, including not only name and date of birth but email addresses, cell phone numbers, address, addresses of friends so that we can identify and locate them. We wouldn't be able to provide all of that information as we do now to State and local health departments so that they can monitor them under supervision. We wouldn't be able to impose controlled release, conditional release on them or active monitoring if they are exposed or to in other ways—

Mr. UPTON. My time is expired. I know I have a swift gavel over here to my left. But I just don't understand. If we have a system in place that requires any airline passenger coming in overseas with a date of birth to make sure they are not on the anti-terrorist list that we can't look at one's travel history and say, "No, you are not coming here, not until this situation"—you are right, it needs to be solved in Africa, but until it is, we should not be allowing these folks in, period.

Mr. MURPHY. The gentleman's time is expired. I recognize Mr. Waxman for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman.

Dr. Frieden, you have a difficult job. In fact, all of your colleagues who are involved from the different agencies have a difficult job because this is a fast-moving issue, and you are trying to explain things to people and educate them with limited information and partial authority. In fact, the CDC can't even do anything in a State. They have to be invited in by the State. You can't tell the States to follow your guidelines. You can give them guidelines. So you are dealing with a fast-moving situation and you have to strike a balance about informing the public on the one hand and keeping it from panicking on the other. So let us go to basics.

If people are frightened about getting Ebola, what assurances can we give them that this is not going to be a widespread epidemic in the United States, as you have said on numerous occasions?

Mr. FRIEDEN. The concern for Ebola is first and foremost among those caring for people with Ebola. That is why we are so concerned about infection control anywhere patients with Ebola are being cared for. Second, in the health care system as a whole, to think about travel because someone who has a fever or other signs of infection needs to be asked where have you been in the past 21 days, and if they have been in West Africa, immediately isolated, assessed and cared for.

Mr. WAXMAN. So we have to make sure that we monitor health care workers because they are exposed to people who have Ebola. The questions have been raised, well, what about all these people coming in from Africa from the countries where the Ebola epidemic is taking place, and you have been asked why don't we just restrict the travel either directly or indirectly from anybody coming in from those countries.

I would like to put up on the screen a map to show the passenger flows from those countries. That map shows that if you—I will hold it up here. If you are looking at those particular countries in Africa, they can go to any country in Europe. They can go to Turkey, Egypt, Saudi Arabia. They can go to China and India. They can go to other countries in Africa and then from those other countries come to the United States. So I suppose we can set up a whole bureaucratic apparatus to be sure that somebody didn't really travel from Nigeria or Cameroon or Senegal or Guinea or Sierra Leone to be sure they didn't really get here from any of those countries. That could be our emphasis, but it seems to me what you are saying is that we want to monitor people before they leave those countries to see whether they have this infection, and we want to monitor them when they come into these countries to see whether they have this infection. Is that what you are proposing to do?

Mr. FRIEDEN. That is what we are actually doing. We are able to screen on entry. We are able to get detailed locating information. We are able to determine the risk level. If people were to come in by, for example, going overland to another country and then entering without our knowing that they were from these three countries, we would actually lose that information. Currently we have detailed locating information. We are taking detailed histories and we are sharing information with State and local health departments so that they can do the follow-up they decide to do.

Mr. WAXMAN. Dr. Fauci, do you agree with Dr. Frieden on this point?

Mr. FAUCI. I do.

Mr. WAXMAN. You wouldn't put a travel ban in. It sounds like, you know, we always seal off our borders, don't let those people come in. Now, that is usually a reference to the immigration matter, not public health particularly, or it might be a tangential issue, but we know certain countries where the epidemic is originating. Why not stop them from coming in?

Mr. FAUCI. Well, I believe that Dr. Frieden and yourself just articulated it very clearly. It is certainly understandable how someone might come to a conclusion that the best approach would be to just seal off the border from those countries, but now we know what we are dealing with. If you have the possibility of doing all

of those lines that you showed, that is a big web of things that we don't know what we are dealing with.

Mr. WAXMAN. So what we know is this epidemic can spread if there is contact with body fluids from somebody who is showing the symptoms of Ebola or someone who has been exposed to that individual. If we had a travel ban, wouldn't we just force these people to hide their origin and wouldn't we also not know where they are coming from if they are going out of their way to hide it? A ban or quarantine would hinder efforts to fight the epidemic in West Africa, and the worse the epidemic becomes in West Africa, the greater it is going to be a problem all over the world including the United States.

Mr. MURPHY. The gentleman's time is expired.

Mr. WAXMAN. Is that your position? Dr. Fauci, is that your position?

Mr. FAUCI. Yes.

Mr. MURPHY. The gentleman's time is expired. Now we recognize the vice chair of the full committee for 5 minutes.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

Dr. Frieden, I want to be sure I heard you right. You just said to Chairman Upton that we cannot have flight restrictions because of a porous border, so do we need to worry about having an unsecure southern and northern border? Is that a big part of this problem?

Mr. FRIEDEN. I was referring to the border of the three countries in Africa, Liberia—

Mrs. BLACKBURN. You are referring to that border, not our porous border?

Mr. FRIEDEN [continuing]. Guinea and Sierra Leone.

Mrs. BLACKBURN. Mr. Wagner, would it help you all, the Border Patrol, if we secured the southern border and eliminated illegal entry?

Mr. WAGNER. Well, travelers coming across the southern border, like the northern border, we are going to, you know, query their information in our database. We are going to ask them their travel history, where they are coming from, how they arrived in the country they are coming from—

Mrs. BLACKBURN. Yes or no is sufficient. I need to move on.

Dr. Frieden, I want to come back to you. I would remind you that a week before last when I was at the CDC, and I thank you for letting me come down to follow up with you all on some of our committee work, that I recommended a quarantine in the affected region and hold people there, and I still think that that is something that we should consider. Quarantining people for 21 days before they leave that region, it helps every country.

I want to go back to an issue that you and I talked about at the CDC and a subsequent phone call, and that is the medical waste, and you assured me that standard protocols were being followed for disposal of this waste, and we know that 20, 25 years ago, hospitals could incinerate their waste. EPA regulations now prohibit that, and the waste has to be trucked, and they outsource the care of this medical waste and it results in that going to central processing centers. So let me ask you this. Is Ebola waste as contagious as a patient with Ebola?

Mr. FRIEDEN. Ebola waste or waste from Ebola patients can be readily decontaminated. The virus itself is not particularly hardy. It is killed by bleach, by autoclaving, by a variety of chemicals.

Mrs. BLACKBURN. OK. Is Ebola medical waste more dangerous than other medical waste?

Mr. FRIEDEN. The severity of Ebola infection is higher, so you want to be certain when you are getting rid of it that you handle it effectively.

Mrs. BLACKBURN. OK. Is the CDC assessing the capabilities of hospitals to manage the medical waste of Ebola patients and does the CDC allow offsite disposal of Ebola medical waste?

Mr. FRIEDEN. My understanding is to the latter question, yes, we worked very closely with both the Department of Transportation as well as the commercial waste management companies to ensure that capability.

Mrs. BLACKBURN. So we have an added danger in having to truck this waste and move it to facilities. Are the employees of the processing centers being trained in how to dispose of Ebola waste?

Mr. FRIEDEN. We have detailed guidelines for the disposal of medical waste from care of Ebola patients.

Mrs. BLACKBURN. All right. You and I talked a little bit about my troops from Fort Campbell that are going to be over there, and I have some questions from some of my constituents. Are the American troops going to come in contact with any Ebola patients or with those exposed to Ebola or included in any of these controlled movement groups?

Mr. FRIEDEN. As I understand it from the Department of Defense, their plans do not include any care for patients with Ebola or any direct contact with patients with Ebola. That said, we would always be careful in country because there is the possibility of coming in contact with someone with symptoms and being exposed to their body fluids, and that is why the Department of Defense is being extremely careful to avoid that possibility.

Mrs. BLACKBURN. We are still going to rely on self-reporting?

Mr. FRIEDEN. No. We are taking temperatures at many locations within the country. We are having hand-washing stations—

Ms. BLACKBURN. So you are moving away from self-reporting? Because originally it was—you said our structure was built on self-reporting when I visited with you earlier, and I found a quote from you from December 2011 at the George Comstock lecture in TB research, and I am quoting you: “Hippocrates was right: patients lie. About a third of patients don’t take medication as prescribed and a third don’t take them at all. You can either delude yourself and think that patients are taking their medications or not. In TB control, it is a simple model. If we see people take their meds, we believe they took their meds.”

Now, Dr. Frieden, relying on self-reporting and making certain that people tell us the truth before they leave and then we catch the fever at the right time if they have a temperature. We have got to do better than this. We can do better than this. We are here to work with you and we expect a better outcome. I yield back.

Mr. MURPHY. The gentlelady’s time is expired. I now recognize Mr. Braley for 5 minutes.

Mr. BRALEY. I would like to thank the panel for joining us today.

Dr. Frieden, I was happy to hear you say we will consider any options to protect Americans. I think that is the purpose of everyone here in this room today. But I do want to ask you about Texas. Are you familiar with the concept of sentinel-event reporting?

Mr. FRIEDEN. Yes.

Mr. BRALEY. Has CDC done a root-cause analysis of what happened at Texas Presbyterian and come up with an action plan on what we learned from that incident? We have the detailed hospital checklist for Ebola preparedness, which we have heard about here today. Have there been any recommendations on changing, modifying, or updating this in light of what happened at Texas Presbyterian?

Mr. FRIEDEN. We have a team of more than 20 of some of the world's top disease detectives in Texas now. We were there. We left the first day the patient was diagnosed. We identified three areas of particular focus. The first is the prompt diagnosis of anyone who has fever or other symptoms of infection and a travel history to West Africa, and Dr. Varga spoke about that issue. The second is contact tracing, and the graphic that I provided earlier outlines what we are doing there very intensively. The State of Texas and the country are doing a terrific job along with our staff making sure that every single contact of the first patient, Mr. Duncan, is monitored, their temperature taken by an outreach worker every day for 21 days. They are most of the way through that risk period. So of the 48, none have developed symptoms, none have developed fever. We are now looking at the contacts, health care workers who may have had contact as the two individuals who became infected did, and our thoughts are with them, and we are delighted that NIH is supporting the hospital in Texas and also that Emory University is doing that as well, and the third area is after identification and contact tracing is effective isolation, and we are looking very closely at what might possibly have happened to result in these two exposures.

Mr. BRALEY. And I assume if there are any new recommendations based upon that analysis, this protocol that was sent out will be updated and redistributed?

Mr. FRIEDEN. We always look at the data to see what we can do to better protect Americans.

Mr. BRALEY. Thank you.

Dr. Fauci, you were kind enough to share with us this graphic, and in it you mentioned a company in Ames, Iowa, called NewLink, which is working on one of the vaccines that just went into Phase I clinical trials this week, correct?

Mr. FAUCI. That is correct.

Mr. BRALEY. And I had an opportunity to talk to two of their employees yesterday, and I know that they are working around the clock trying to help come up with a vaccine that will meet the protocol and the standards for scalability that I think everyone is looking for. The WHO, the Department of Defense, HHS, and the public health agency in Canada have called this vaccine one of the most advanced in the world, and they have requested contracts with HHS to expand the manufacturing, to add a third site for manufacturing, to complete the scientific studies required to scale up manufacturing, and complete the additional safety study to pro-

vide newly manufactured vaccines that are equivalent to the original vaccines, and they have also identified companies to work as subcontractors.

Dr. ROBINSON, can you tell us what HHS is doing to make sure that those contracts are moving forward as quickly as possible?

Mr. ROBINSON. Thank you, sir. We have reviewed their proposal. It looks very favorable, and we will be in the next several weeks finalizing the negotiations with them. Prior to that, we actually have been helping them with their submissions to the FDA and providing assistance onsite and also at the manufacturing sites and working with them to expand their production with other companies including a very large company here in the United States.

Mr. FAUCI. And also, Mr. Braley, the HHS is also involved in the other end of it because the trials that were started were not only in collaboration with the Department of Defense but we admitted our first VSV patient at our clinical center in Bethesda for a Phase I trial. So it is not only in the testing but also in the ultimate production.

Mr. BRALEY. And it is my understanding, Dr. Fauci and Dr. Robinson, that the ultimate goal is to also expand this clinical testing into some of the affected regions in Africa as well once we have an understanding of some of the concerns that were identified earlier in your testimonies.

Mr. FAUCI. That is quite correct. In fact, when I was saying that after we get through Phase I on the trial, I was talking about both vaccines, the GlaxoSmithKline and the NewLink both. If they are safe and induce the response we feel is appropriate, we will expand both of them into larger trials in West Africa.

Mr. BRALEY. And then Mr. Wagner, a question for you. We have heard a lot today about the issue of travel restrictions. Can you sort of walk us through the strengths and weaknesses of that approach from your standpoint in border security?

Mr. WAGNER. Well—

Mr. MURPHY. The gentleman's time is expired so if you could give a quick answer?

Mr. WAGNER. So we have the ability to use the data that the airlines give us to be able to see where travel is originating from. There are instances where travelers may go to different locations. We might not see that, but through our questioning and our review of their passport, we can identify that they have been to these affected regions or if they come through one of the borders. If they fly to Canada or Mexico it is more difficult for us to do it but the possibility is there, but the possibility is also greater that we would miss one, so I do agree with what the experts, you know, say. It is easier to manage it and control it when we know where people are coming from voluntarily and not intentionally trying to deceive us.

Mr. MURPHY. The gentleman's time is expired. The word is "voluntary."

I now recognize Dr. Burgess for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman, and I would like to stay with what Chairman Upton was talking about on the travel restriction.

The Secretary of Health and Human Services under the Public Health Service Act has the authority to issue a travel restriction. Under the pandemic plan that was adopted in 2005, the President has the ability to issue a travel restriction. Two thousand five was geared toward the pandemic avian influenza but it was amended in July of this year to include the hemorrhagic fevers. So I believe that authority very clearly exists. Now, the question is why the Executive Branch and why the agency will not exercise that authority. Mr. Chairman, I think perhaps this committee should consider forwarding to the full House a request that we have a vote on travel restriction because people are asking us to do that, and I think they are exactly correct to make that request.

Dr. Frieden, the first nurse who was infected over the weekend is now being transferred away from Presbyterian, and yet her condition has been serially reported in the news media as she is stable and she has been improving, so is the reason that she is having to be removed because the personnel are no longer willing to stay at Presbyterian to take care of her?

Mr. FRIEDEN. Texas Presbyterian is really dealing with a difficult situation. They are working very hard. Because of the events of the past week, they are now dealing with at least 50 health care workers who may potentially have been exposed. The management of those individuals, making sure that if any of them develop any symptoms whatsoever, even the slightest, they come in immediately to be assessed so that if they develop Ebola, we hope no more will, but we know that is a possibility since two individuals did become infected, others may. That makes it quite challenging to operate a hospital, and we felt it would be more prudent to focus on caring for any patients who come in, health care workers or others who might come in with symptoms.

Mr. BURGESS. I don't disagree, and you and I have talked about this, and I am fully in favor of individuals who have been diagnosed that they do be taken care of in centers. Dr. Fauci, you know that if somebody wants to do research on the Ebola, they can't just go to a regular university setting and do that. They must go to one of the laboratories where they have the capability of protecting the personnel who are not only doing the experiments but other personnel surrounding in the lab. Is it possible to get—I had a picture from the Dallas Morning News which had the CDC-recommended personal protective equipment. I think we have it there, and this not only shows the personal protective equipment, but it also details the order in which it should be put on and removed. I would know that shoe covers are not included in this graphic but you do see a fair amount of exposed skin around the eyes and the forehead and of course the neck. Now, Dr. Frieden, this is going to be hard to see, but this is your picture in western Africa, and as you can see, there is head-to-toe covering and goggles, and I believe if I understand the circumstances correctly, you were just about to be dosed with a near-toxic dose of chlorine. Is that not correct?

Mr. FRIEDEN. Yes.

Mr. BURGESS. Well, and that is why you can't have skin exposed, because it is impossible to do the disinfection, if you will, after taking care of an Ebola patient or being in an Ebola ward. It is impossible to do the disinfection if there is skin exposed because exposed

skin would be killed by the chlorine and that would not be good for the person delivering the care.

I mentioned this in my opening statement. I am so concerned. We know the numbers in western Africa are going up on Ebola. We know the case rate is going to increase. We know that 10 percent of those cases are health care workers, and we know that 56 percent of those health care workers in western Africa will succumb to the illness so that is a pretty dire warning for anyone who is involved in delivering health care. Dr. Robinson, let me ask you. What kind of stockpile of this personal protective equipment do you have available to the health care workers who are on the front line? And bear in mind, no travel restrictions so a new patient could come in tonight and go to any hospital in this country and present themselves. Are you going to be able to quickly deliver a stockpile of personal protective equipment like this?

Mr. ROBINSON. So we know from talking to the manufacturers, there are no shortages right now and that they are willing to deliver within 24 hours or less.

Mr. BURGESS. Let me just task this question, Dr. Frieden. You know, what did you think the first patient was going to look like when you knew you were going to have a patient zero at some point or that it was a possibility. We had the gentleman who died in Nigeria at the end of July who could have gotten on a plane to Minneapolis. What did you think that was going to look like? What was patient zero going to look like? And now you have seen what it really looks like—

Mr. MURPHY. The gentleman's time is expired.

Mr. BURGESS [continuing]. What is the matchup there?

Mr. MURPHY. You can go ahead and answer quickly. Thank you, Doctor.

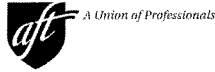
Mr. FRIEDEN. Our goal has been to get hospitals ready. The specific type of personal protective equipment to be used is not simple, and there is no single right answer, but there is a balance between protective equipment that is more familiar or less familiar, that is more flexible and less flexible, that can be decontaminated more easily or less easily, so the use of different types of protective equipment is something that obviously we are looking at very intensively now in Dallas in conjunction with the health care workers there.

Mr. MURPHY. Thank you. I now recognize Ms. Schakowsky for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

I have so many questions. I just want to begin, though, by thanking the health care professionals that are on the front line, and I would like to ask unanimous consent to put into the record, Mr. Chairman, a letter from Randi Weingarten from the American Federation of Teachers, which represents many nurses into the record. I would also like unanimous consent to put in the record the diary of Paul Farmer from Partners in Health, who has among other things said the fact is that weak health systems are to blame for Ebola's rapid spread in West Africa, and we know that West Africa has 24 percent of global disease burden, 3 percent of world health workforce, one doctor in Liberia for 90,000 people.

[The information follows:]



October 16, 2014

The Honorable Fred Upton, Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman, Ranking Member
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Ranking Member Waxman, and members of the committee:

The American Federation of Teachers represents 1.6 million members, including more than 112,000 healthcare professionals—84,000 of whom are registered nurses. As a representative of nurses and healthcare professionals, we are pleased that the committee is holding today's hearing on the U.S. public health response to the Ebola outbreak.

Preparedness and capacity have been a central focus of our healthcare members and leaders in the wake of the multiple confirmed Ebola cases in the United States. To this end, we urge you to consider the following issues and concerns as the committee undertakes its important oversight responsibilities to ensure that our government is doing everything within its power to limit exposure to Ebola.

Federal funding for public health emergencies must be increased:

The current Ebola outbreak highlights the need for greater investment in the U. S. public health infrastructure, which has eroded significantly in recent years. For instance, funding for the U. S. Hospital Preparedness Program, which helps communities and hospitals prepare for public health emergencies,¹ has been cut by 50 percent since 2003, according to the Congressional Research Service.² In addition, the Centers for Disease Control and Prevention reports that it lost nearly \$1 billion in funding due to sequestration and cuts to the Prevention and Public Health Fund.³ These cuts hamper the agency's ability to keep communities and health professionals safe.

State public health funding has likewise been slashed. According to Trust for America's Health and the Robert Wood Johnson Foundation, "33 states and Washington, D.C. decreased their public health budgets from FY 2011-12 to FY 2012-13."⁴ At a time when additional trained public health professionals are urgently needed in our communities, layoffs and attrition have reduced the number of employees at 91 percent of all state and territorial health agencies, according to the Association of State and Territorial Health Officials.⁵

¹ www.phe.gov/PREPAREDNESS/PLANNING/HPHP/pages/default.aspx

² See the Oct. 3, 2014, Congressional Research Service report, "Funding History for Public Health and Hospital Preparedness Grants to States."

³ "Fact Sheet: Impact of Sequestration and Other Budget Changes on the Centers for Disease Control & Prevention," www.cdc.gov/fmo/topic/budget%20information/appropriations_budget_form_pdf/sequester_impacts.pdf.

⁴ Trust for America's Health and Robert Wood Johnson Foundation, "Investing in America's Health: A State-by-State Look at Public Health Funding and Key Health Facts," May 2014, <http://healthyamericans.org/assets/files/FAH2014-InvestinAmericaRpt08.pdf>.

⁵ *Ibid.*

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Compounding the cuts in state and federal preparedness funding, hospitals themselves too often make decisions about emergency preparedness based on their bottom lines rather than the safety and well-being of staff, patients and communities.⁶ Hospitals and other institutions must change this status quo and put patients and communities before profits. In turn, federal and state funding for public health emergency preparedness must be made readily available to the institutions and agencies that communities rely on to keep them safe.

A robust and well-supported healthcare workforce is essential to addressing Ebola in the United States:

Nurses and health professionals are the frontlines when it comes to safeguarding the health of the public in the face of the Ebola outbreak. In order to safely care for their patients, nurses and health professionals must not be stretched too thin. Even under nonemergency situations, inadequate staffing levels too often jeopardize staff and patient safety.⁷ As we confront the Ebola outbreak, there is no excuse for inadequate healthcare staffing in our hospitals, home health agencies, nursing homes, schools and other care settings.

The time to increase healthcare staffing is now—before a patient with Ebola enters a healthcare facility. The CDC recommends the use of a “buddy system” when caring for Ebola patients and when putting on and removing personal protective equipment (PPE).⁸ Staffing must be increased for employees to be able to safely use the buddy system without rushing through the removal of PPE to get to their next patient. Immediately increasing staffing at all U. S. healthcare facilities would go a long way toward ensuring that our frontline nurses and health professionals can return safely to their homes after caring for an Ebola patient during their shifts—regardless of whether they’d expected to encounter Ebola that day.

Increased staffing at every healthcare facility is especially critical given the recent consolidation and corporatization of the healthcare industry. Smaller rural hospitals are closing after being acquired by large corporate chains, forcing some rural residents to drive for miles to get care.⁹ *Kaiser Health News* reports that “six percent of the nation’s emergency rooms have closed their doors in recent years,” at the same time that the number of ER visits has increased nationwide by 51 percent.¹⁰ This means that in the event of an Ebola outbreak, hospitals that still have emergency departments must be staffed and equipped to care for an influx of patients who previously would have gone to their own now-closed local emergency department. Thus, an immediate increase in staffing and emergency preparedness is critical for every U. S. hospital.

Every hospital must supply appropriate Personal Protective Equipment and provide high-quality, hands-on, ongoing training on its use:

Every healthcare facility must have an adequate supply of personal protective equipment—including respirators, hazmat suits, double gloves and disposable shoe covers—that meets or exceeds OSHA and CDC standards. All healthcare employees should be fitted for their PPE, and should receive high-quality, hands-on, in-person training on how to safely use the equipment. Training must be ongoing, so skills remain fresh and up-to-date, and nurses and health professionals on the frontlines feel confident in their ability to safely care for patients with Ebola.

Any healthcare professional put in precautionary quarantine should be paid at his or her normal rate for the duration of the quarantine:

Employees should be encouraged to candidly report any possible exposure to Ebola. Continuing the paychecks of

⁶ The Congressional Research Service writes, “The economics of the healthcare market push hospitals toward leanness and efficiency, and away from the redundancies and reserve capacity that a health system needs in order to surge for a mass casualty incident” (footnote 12 to the Oct. 9, 2014, CRS report).

⁷ There is a large body of evidence linking safe nurse staffing levels with improved patient outcomes. See, for example, Linda H. Aiken, Douglas M. Sloane, Luk Bruyneel et al. “Nurse Staffing and Education and Hospital Mortality in Nine European Countries: A Retrospective Observational Study,” *The Lancet* 383, issue 9931 (2014), 1824–1830; and Matthew McHugh, Julie Berez, and Dylan S. Small, “Hospitals with Higher Nurse Staffing Had Lower Odds of Readmissions Penalties than Hospitals with Lower Staffing,” *Health Affairs*, 32/10 (2013), 1740–1747.

⁸ CDC, “Detailed Hospital Checklist for Ebola Preparedness,” 3.

⁹ “Rural Hospitals Pressured to Close as Healthcare System Changes,” *Reuters*, Sept. 3, 2014, www.reuters.com/article/2014/09/03/us-healthcare-rural-insight-idUSKBN0GY14620140903.

See also, “Hospitals Continue to Shut Down in Rural America,” *Al Jazeera*, July 12, 2014, <http://america.aljazeera.com/watch/shows/fruit-lines/articles/2014/7/12/hospitals-continue-to-shut-down-in-rural-america.html>.

¹⁰ <http://capsules.kaiserhealthnews.org/index.php/2014/08/study-finds-er-closures-affect-mortality-risks-at-nearby-hospitals/>

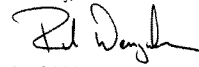
healthcare professionals during their quarantine for suspected exposure is the right thing to do, and may save money and lives in the long run.

Nurses and other frontline health professionals must be involved in public health decision-making:

As hospitals, schools and other institutions make decisions about their emergency protocols, nurses and other health professionals must have a seat at the table. One nurse in Connecticut said that he first learned about the training planned at his hospital by reading about it in the newspaper. This is simply unacceptable. Healthcare management must ensure that those who will provide the actual patient care, and potentially be exposed to the virus, are listened to and involved in every step of the planning process.

Protecting healthcare employees and incorporating their experience and expertise in preparedness plans will go a long way toward meeting the public health challenge ahead of us. We stand ready to assist you in this important work.

Sincerely,



Randi Weingarten
President

RW:am opeiu#2 afl-cio

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Paul Farmer is a professor of global health at Harvard, an infectious disease physician at the Brigham and Women's Hospital, and a co-founder of Partners in Health.

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Vol. 36 No 20 · 23 October 2014
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Diary

Paul Farmer

I have just returned from Liberia with a group of physicians and health activists. We are heading back in a few days. The country is in the midst of the largest ever epidemic of Ebola haemorrhagic fever. It's an acute and brutal affliction. Ebola is a zoonosis – it leaps from animal hosts to humans – which is caused by a filovirus (a thread-like virus that causes internal and external bleeding). It was first described in 1976 in rural Congo, not far from the Ebola River, as an acute-onset syndrome characterised by complaints of weakness, followed by fever and abdominal pain. Patients became dehydrated as a consequence of fever, vomiting and diarrhoea. Many became delirious and started to haemorrhage from the mouth, nose, vagina, at sites where intravenous lines had been placed, even from the eyes.

The Ebola virus is terrifying because it infects most of those who care for the afflicted and kills most of those who fall ill: at least, that's the received wisdom. But it isn't clear that the received wisdom is right. It's true that many of those who have died were medical professionals. The 1976 epidemic, for example, started in a mission hospital where Belgian nuns worked as nurses alongside Congolese colleagues. But even then it was known that the virus could be transmitted as the result of a failure to follow the rules of modern infection control: the nurses reused needles and did not wear gloves, gowns or masks, which were all in short supply. Nor did the nurses, still less their patients, receive what in Brussels, Boston or Paris would count as modern medical care.

Even without a specific antiviral therapy, the treatment for hypovolaemic shock – which occurs when there isn't enough blood for the heart to pump through the body and is the end result of many infections caused by bacteria and some caused by haemorrhagic viruses – is aggressive fluid resuscitation. For those able to take fluids by mouth, shock can often be forestalled by oral rehydration salts given by the litre. Patients who are vomiting or delirious are treated with intravenous fluids; haemorrhagic symptoms are treated with blood products. Any emergency room in the US or Europe can offer such care, and can also treat patients in isolation wards.

Both nurses and doctors are scarce in the regions most heavily affected by Ebola. Even before the current crisis killed many of Liberia's health professionals, there were fewer than fifty doctors working in the public health system in a country of more than four million people, most of whom live far from the capital. That's one physician per 100,000 population, compared to 240 per 100,000 in the United States or 670 in Cuba. Properly equipped hospitals are even scarcer than staff, and this is true across the regions most affected by Ebola. Also scarce is personal protective equipment (PPE): gowns, gloves, masks, face shields etc. In Liberia there isn't the staff, the stuff or the space to stop infections transmitted through bodily fluids, including blood, urine, breast milk, sweat, semen, vomit and diarrhoea. Ebola virus is shed during clinical illness and after death: it remains viable and infectious long after its hosts have breathed their last. Preparing the dead for burial has turned hundreds of mourners into Ebola victims.

Paul Farmer · Diary: Ebola · LRB 23 October 2014

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Hugh Pennington
Blaetongue

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Disease, Africa

Many of the region's recent health gains, including a sharp decline in child mortality, have already been reversed, in large part because basic medical services have been shut down as a result of the crisis. Most of Ebola's victims may well be dying from other causes: women in childbirth, children from diarrhoea, people in road accidents or from trauma of other sorts. There's little doubt that the current epidemic can be stopped, but no one knows when or how it will be reined in. As Barack Obama said, speaking at a special session of the United Nations, 'Do not stand by, thinking that somehow, because of what we've done, that it's taken care of. It's not.' Preventing the next eruption is an even more distant goal.

As of 1 October, a third of all Ebola cases ever documented were registered in September 2014. More than seven thousand cases have been recorded since March, more than half of them fatal. In epidemiological terms, the doubling times of the current Ebola outbreak are 15.7 days in Guinea, 23.6 days in Liberia and 30.2 days in Sierra Leone. The US Centers for Disease Control and Prevention suggested at the end of September that unless urgent action is taken, more than a million people could be infected in the next few months.

The worst is yet to come, especially when we take into account the social and economic impact of the epidemic, which has so far hit only a small number of patients (by contrast, the combined death toll of Aids, tuberculosis and malaria, the 'big three' infectious pathogens, was six million a year as recently as 2000). Trade and commerce in West Africa have already been gravely affected. And Ebola has reached the heart of the Liberian government, which is led by the first woman to win a presidential election in an African democracy. There were rumours that President Ellen Johnson Sirleaf was not attending the UN meeting because she was busy dealing with the crisis, or because she faced political instability at home. But we knew that one of her staff had fallen ill with Ebola. A few days ago, we heard that another of our Liberian hosts, a senior health official, had placed herself in 21-day quarantine. Although she is without symptoms, her chief aide died of Ebola on 25 September. Such developments, along with the rapid pace and often spectacular features of the illness, have led to a level of fear and stigma which seems even greater than that normally caused by pandemic disease.

But the fact is that weak health systems, not unprecedented virulence or a previously unknown mode of transmission, are to blame for Ebola's rapid spread. Weak health systems are also to blame for the high case-fatality rates in the current pandemic, which is caused by the Zaire strain of the virus. The obverse of this fact – and it is a fact – is the welcome news that the spread of the disease can be stopped by linking better infection control (to protect the uninfected) to improved clinical care (to save the afflicted). An Ebola diagnosis need not be a death sentence. Here's my assertion as an infectious disease specialist: if patients are promptly diagnosed and receive aggressive supportive care – including fluid resuscitation, electrolyte replacement and blood products – the great majority, as many as 90 per cent, should survive.

Ebola's more general effects also damage the effort to treat the disease. The closure of national borders means, among other things, that it's more difficult for the staff and the stuff to reach those most in need. Many airlines have halted services. Schools have been shut down, including medical and nursing schools. Food and fuel, much of it imported, are becoming scarce. Exxon has announced that it is delaying offshore drilling plans. Supply chains have been cut off. Hospitals and clinics have been closed.

There have been incidents of violence linked to fear and stigma. In Liberia – where we were warmly welcomed – my colleagues and I heard that seven Ebola workers, apparently including two local public-health officials, had been murdered with machetes in rural Guinea. Their bodies were discovered in the septic tank of a local primary school. Eleven years ago, four Congolese schoolteachers engaged in Ebola-awareness campaigns were also killed. The complex relationship between contagion, lethality, stigma and long neglect – most people in rural West Africa have never had access to comprehensive medical care – has yet to be laid out.

I've been asked more than once what the formula for effective action against Ebola

might be. It's often those reluctant to invest in a comprehensive model of prevention and care for the poor who ask for ready-made solutions. What's the 'model' or the 'minimum basic package'? What are the 'metrics' to evaluate 'cost-effectiveness'? The desire for simple solutions and for proof of a high 'return on investment' will be encountered by anyone aiming to deliver comprehensive services (which will necessarily include both prevention and care, all too often pitted against each other) to the poor. Anyone whose metrics or proof are judged wanting is likely to receive a cool reception, even though the Ebola crisis should serve as an object lesson and rebuke to those who tolerate anaemic state funding of, or even cutbacks in, public health and healthcare delivery. Without staff, stuff, space and systems, nothing can be done.

If such things were thin on the ground in Monrovia and Freetown, they were all but absent in rural regions. Zwedru is the capital of Grand Gedeh County in south-eastern Liberia, a region mostly covered by rainforest. Flying from Monrovia to Zwedru reminds you how vast and green – and rainy – much of the country is, especially in September. Outside the capital, paved roads are as scarce as electricity: in 2013, it was estimated that less than 1 per cent of Liberia was electrified. As Sirleaf recently pointed out, the Dallas Cowboys football stadium consumes more energy each year than the whole of Liberia. It is very difficult to take care of critically ill patients in the dark; fluid resuscitation depends on being able to place and replace intravenous lines.

In Zwedru, we visited the Grand Gedeh's only hospital. Although there have been stories of doctors and nurses fleeing their posts, the fact is that many remain. But without personal protective equipment or other supplies, there isn't a lot they can do. We didn't see any Ebola patients in the hospital. Rumour had it that the hospital administration had just sent away a carload of suspects. In Ziah Town, a small village a couple of hours away, we met some community health workers. They were a well-informed group of mostly young men and women. Kru was their native language; they spoke English just fine. They were the front line in the struggle against Ebola, the ones who could bring information and services to the rural poor. But they were isolated and badly equipped. The sun beat down on the immense forest and the dirt roads cutting through it. We were slated to leave Monrovia the following afternoon. Thunderheads blackened the eastern sky, and it wasn't clear we'd make the plane; the four-wheel-drive vehicles were having a hard time. Stuck in the mud, we wondered how the community health workers would be able to get sick patients to Ebola care centres, a series of planned but not yet constructed halfway houses.

Although the Grand Gedeh had been declared Ebola-free, it was also free of diagnostic tests. And electricity and surfaced roads. But the community health workers, like the people in Ziah Town, were plugged into the cash economy: people had cell phones (if little signal) and wore T-shirts (one of them emblazoned with the shield of a small Midwestern college); children were kicking a football around; one boy was nursing a can of Red Bull. 'How do they make a living?' I asked one of the young American volunteers. She hesitated, although she'd lived and worked in Zwedru for more than a year. 'They're great hunters,' she said. After listening patiently to our halting conversation, the driver of the jeep – we were waiting for our convoy to emerge from the mud – helped out. He was from Monrovia, he said. He'd been working in the Grand Gedeh for more than ten years, first as an officer in the disarmament programme, and then as a driver and logistician. 'It's not just hunting and small-scale farming,' he said. There were also mining, remittances from abroad and international trade. Many of the shopkeepers in town were from Guinea, Sierra Leone or Côte d'Ivoire. It may have looked like isolated rainforest, but the place is connected to the rest of West Africa.

That means it's connected to the rest of the world too. And however the epidemic started – whether through the ingestion of bush meat or an infected bit of fruit dropped by a clumsy fruit bat – it's clear enough that attempts to seal national borders won't stop it. There are no checkpoints or barriers in the forests. The day when enclosure might have worked is long gone. A CNN interviewer asked me if Ebola might spread to Europe and North America. 'Of course it will,' I replied. 'We live in a global economy.'

On 30 September, the US Centers for Disease Control and Prevention confirmed the first diagnosis of the disease in the United States. A traveller from Liberia, asymptomatic (by self-report) on boarding a flight from Monrovia to the United States on 19 September (as our team left Zwedru for Monrovia), fell ill in Dallas a few days later. His symptoms were similar to those described in every Ebola case: a fever of 40°C, weakness, abdominal pain. He had a history of exposure, having driven a young woman, pregnant and bleeding, to a hospital in Monrovia; she was turned away and later died. But on his first visit to an emergency room, his symptoms were judged 'non-specific' and the diagnosis was missed even though he had come from Liberia. Two days later, highly infectious and critically ill, he was taken by ambulance back to the same hospital and admitted to intensive care. Within hours, the cause of his illness was confirmed as Ebola, Zaire strain. He is now dying. It's unlikely that the American subplot is over. The cycle of fear and stigma, amped up by the media, will continue to spiral, even though there's little doubt that the epidemic will be contained in the US, which has the staff, stuff, space and systems.

Ebola is more a symptom of a weak healthcare system than anything else. But until this diagnosis is agreed on, there's plenty of room for other, more exotic explanations. The palaver (as Liberians say) includes a lot of talk about the 'cultural beliefs and behaviours' said to propagate the outbreak. The list usually includes activities that are not really 'behaviours', such as hunting and eating bush meat, taking part in strange funerary practices or the bizarre rituals of 'secret societies' like the Poro or the Human Leopard Societies. An obsession with funerary rituals – the more lurid the better – was characteristic of anthropology from the late 19th century on. *Tribes of the Liberian Hinterland* (1947), written in the passive voice and matter-of-fact tone typical of the genre, contains more than five hundred pages of this sort of stuff:

Formerly, only chiefs and big men were washed after they died. In Half-Grebo the corpse of a warrior who died from the effects of a gunshot wound was taken to a stream and washed. In both Grebo and Sapa, the shot was extracted in order to prevent his being reincarnated with a wound.

Now, all the dead are washed. The corpse is then laid on a mat and rolled up in it. With the corpse are put some cloths, the number varying with the rank of the person.

Despite anthropologists' fondness of recounting such practices, these rites are not suspected of having played a major role in outbreaks of Ebola in Congo, Uganda and Sudan over the last forty years. The inhabitants of coastal West Africa have eaten bush meat for centuries and they have prepared the dead for burial without taking precautions to stop transmission of a pathogen like Ebola. Even so, it isn't improbable that these practices helped to spark and then fan this outbreak, which began in the Upper Guinea Rainforest.

What accounts for Ebola's spread from Guéckédou to Monrovia and Freetown and now to Dallas? As Larry Brilliant, who helped to eradicate smallpox almost forty years ago, just as Ebola was being discovered, and now heads the Skoll Foundation's Global Threats Fund, has observed, 'Outbreaks are inevitable. Pandemics are optional.' The eating of bush meat can't possibly explain the epidemic, but grotesque and growing disparities in access to care – in the context of a globalised political economy – can. The attempt to treat Ebola patients in a weak health system – or at home – has been strongly linked to the transmission of the virus. In several West African hospitals, Ebola has ripped through the professional staff: health professionals, nurses' aides, morgue attendants. Understaffed and undersupplied, front-line health workers in West Africa have good reason to be afraid. We who aim to help them, though better equipped, are afraid too.

The others at great risk, obviously enough, are the primary caregivers of the sick: not health professionals but family members, especially women. Associated Press reported the story of a 14-year-old Liberian boy: 'Too weak to stand, they bundled him into a taxi with his backpack and a yellow plastic bucket for his vomit ... "He's been sick for a week with a runny stomach," says his distressed mother, wiping the sweat off the boy's

brow with bare hands. "We tried calling an ambulance days ago, but nobody ever came."

Who will come when we call? Who will show up not just if it's convenient or cost-effective or already budgeted? It isn't clear that all such responsibilities should be handed out to contractors or NGOs. The three countries most afflicted by Ebola are those with some of the lowest public investment in healthcare and public health in Africa. They have been wracked by war, and by extractive industries, which have never failed to turn a profit. This is one of the reasons that Liberia could boast, only a few years ago, the fastest growing GDP in the world.

For most of a century, the Firestone Rubber Company has been the largest taxpayer in Liberia. In 1926 it negotiated a million-acre concession at six cents an acre, for ninety years. By the Second World War, there was a little bit of the Liberian forest in many, if not most, American cars. Firestone is still in Liberia. It promised 350,000 jobs, but never created more than a quarter of that number. For decades, plantation workers demanded better pay, a high school and medical care. In recent years, they achieved some measure of success. But the epidemic has affected them too. At the end of March, the wife of a Firestone employee left Lofa County, which borders Guinea, not far from where the first case was recorded. She had a sudden-onset generalised weakness and fever. Eight times out of ten, the pathogens responsible would be those that cause malaria, pneumococcal pneumonia, typhoid fever, influenza or a complication of Aids. Lassa, another haemorrhagic fever, would be on the list in Liberia, but Ebola was then unknown in the region. On 31 March, the woman travelled by taxi to Monrovia with five other passengers, including her infant, but was referred back to the Firestone plantation, to Duside Hospital. By then, sick with profuse diarrhoea and vomiting, she was diagnosed with Ebola. She continued to lose vital fluids and electrolytes, and slipped into hypovolaemic shock. As her blood pressure dropped, nurses did their best to resuscitate her. Within an hour, it was all over.

Except that it wasn't. Four months later, 72 cases of Ebola were diagnosed in rapid succession at Duside; only 18 patients survived. Yet the Firestone response was considered a success, since infection control was improved during those months and transmission within the hospital declined rapidly.

Such back and forth is how Ebola got to the city and into its clinical facilities. St Joseph's Catholic Hospital, in a Monrovia slum, has lost many of its caregivers and most of its patients. Within two weeks of its first cases, the hospital director fell ill with similar symptoms. This time, they knew what was coming. But even for its most valued professionals, the hospital could not conjure proper medical care out of nothing. Two more nurses, two laboratory technicians and a social worker were all dead within a couple of months of the city's first two cases. So too were several of the nuns and priests working there. Father Miguel Pajares was airlifted home to Spain; so, later, was Father Garcia Viejo, working in a small town in Sierra Leone. Both died in Madrid. It is unlikely that we have heard the last from Spain either.

What is to be done? The only formula we've come up with is the following: you can't stop Ebola without staff, stuff, space and systems. And these need to reach not only cities but also the rural areas in which most people in West Africa still live. First, we need to stop transmission. The source of the first human cases is no longer the primary concern. Transmission is person to person, and in the absence of an effective medical system, it occurs wherever care is given: in households, clinics and hospitals, and where the dead are tended. Infection control must be strengthened in all of these places, and during burials, which requires not only training and exhortations (which are already given in cities throughout West Africa, on billboards and radio, and in community meetings) but also uninterrupted supplies of personal protective equipment. Community health workers, too, need to be better equipped, trained and paid if they are to play a role in contact-tracing and early diagnosis, as well as trying to address the mounting number of deaths caused by other conditions.

Second, we need to avoid pitting prevention against treatment. Both are necessary. Adam Levine helped to open the first Ebola Treatment Unit in Bong county, Liberia,

after working in an ETU in Monrovia. An emergency medicine specialist, he describes what it feels like to be working without the right therapies, while wearing a stifling shroud:

On my third day of training, I come across an older man, also lying motionless on his mattress. At first I think he might be dead, but as I lay my double-gloved hand gently on his shoulder, he turns his head to look up at me. His eyes are sunken and his lips parched, his skin flattening only slowly when pinched. He is severely dehydrated from the profuse diarrhoea common with Ebola. Usually a drip of intravenous fluids would be started, but the [ETU] lacks sufficient staff to safely place intravenous catheters for patients. So instead I turn the patient slowly onto his back, grab the full bottle of oral rehydration solution lying by his side, and pour a tiny capful into the man's slightly open mouth. Surprisingly, he swallows it. I pour another capful, and then another, and he keeps swallowing. Only a few hundred more capfuls to rehydrate him, but I know that in the stifling heat I am not going to last much longer in my full PPE.

Most experts don't think staff should spend more than two or three hours in PPE. Dizzied by heat, even the most cautious professionals start to make mistakes.

Equality of access to care is important if we are to encourage the sick into quarantine. Two weeks ago, a Liberian physician told me a story I won't soon forget. He and some Liberian and Ugandan colleagues were planning on opening an ETU in Monrovia after the other clinics had stopped giving intravenous fluids; patients were dying of untreated shock. When one of the European caregivers at his ETU fell ill and was about to be airlifted home, the ETU director asked him to find an infusion pump. He spent hours looking, and eventually found one, but not before the non-national was airlifted away. She survived.

Third, the rebuilding of primary care must be informed by what has been learned from the response to this outbreak. The hospital we visited in Zwedru, which has 140 beds, was technically open; staff, including the sole attending physician, were present. But there weren't many patients in the wards, or outpatients. The pharmacy had no drugs or supplies, including PPE. The laboratory was short of reagents; the recently donated digital radiography unit hadn't been installed because there weren't any batteries. There was no infection control, which was why the five Ebola suspects had been sent away (two of them died shortly afterwards of confirmed Ebola).

Fourth, the knowledge gained from the response must be built on. Every attempt to prevent the spread of Ebola should involve proper care for quarantined patients. Even without a vaccine or Ebola-specific therapies, it's possible to imagine this bringing a marked drop in case-fatality rates. But we need specific therapy, better and faster diagnosis, and effective vaccines. The vaccines and drugs required to treat so-called 'emerging infectious diseases' do not exist because of what James Surowiecki has called 'Ebolanomics'. 'When a disease's victims are both poor and not very numerous,' he says, 'that's a double whammy. On both scores, a drug for Ebola looks like a bad investment.' The *Oxion* recently ran the headline: 'Experts: Ebola vaccine at least fifty white people away.'

It needn't be this way. Several vaccines are ready for clinical trials; a number of treatments – including ZMapp, a combination of monoclonal antibodies developed by a pharmaceutical and a biodefence company, and RNA interference agents – are also ready for trial. The process should be fast-tracked, and willing Ebola survivors (who should be immune) recruited by the thousand into this work as well as into providing clinical care.

Fifth, formal training programmes should be set up for Liberians, Guineans and Sierra Leoneans. Vaccines and diagnostics and treatments will not be discovered or developed without linking research to clinical care; new developments won't be delivered across West Africa without training the next generation of researchers, clinicians and managers. West Africa needs well-designed and well-resourced medical and nursing schools as well as laboratories able to conduct surveillance and to respond earlier and more effectively. Less palaver, more action.

Paul Farmer · Diary: Ebola · LRB 23 October 2014

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Ms. SCHAKOWSKY. So I would like to focus on what we are going to do to help that infrastructure, but in my limited time I want to focus on our infrastructure here.

We have a vast infrastructure—hospitals, community health centers, I want to point out too where people may present themselves, nurses, nurses' aides, no one better than the United States, but do we have the ability to train and equip, as we talk about in military terms in Syria, and do we have the ability really to train and equip?

Let me just put a couple things on the table. In terms of the nurses, I still don't feel like we have a good answer of why nurse one and nurse two contracted Ebola. Is it because there was a problem with not following the protocols or is there something wrong with the protocols? And how are we going to ensure that even if we have the best protocols in the world that everybody knows how to use them?

Congresswoman DeGette showed the various protective gear that our nurses are supposed to have, and yet 2 days apparently went by when they were not wearing shoe covers, that their necks were not covered, that skin in fact, as Dr. Burgess was talking about, was in fact exposed, even as we knew that he had Ebola.

So how are we going to make sure despite how we are going to check at the airports—I am from Chicago. I talked to our health director today. I know what we are doing. But there is still the chance that someone could present anywhere. So how come the nurses in Dallas weren't protected and how are we going to make sure that everybody can be?

Mr. FRIEDEN. So first just to clarify one thing, those first couple of days, the 28th, 29th, 30th, were before his diagnosis was known so he had suspected Ebola. The test was being drawn and assessed but he had not yet been diagnosed with Ebola, and in our team's review—

Ms. SCHAKOWSKY. Is that—excuse me one second. Congresswoman, were you saying otherwise? Can I yield?

Ms. DEGETTE. If the gentlelady will yield, but he presented with Ebola symptoms. He had been to the emergency room just a couple of days earlier saying he had been from Africa, and I believe the CDC protocols that were given to the Dallas hospital said that people should be wearing that protective covering even before the official diagnosis. I would certainly hope—thank you for yielding, Ms. Schakowsky.

Dr. Frieden, I would certainly hope that here going forward if a patient shows up saying he is from Africa and he is vomiting and he has diarrhea, that you wouldn't say, "Well, we don't have the lab results in yet," you would start treating that person like they had Ebola.

Mr. FRIEDEN. Absolutely. I just wanted to clarify that those first couple of days, the 28th and 29th, he was being isolated for Ebola. The diagnosis was confirmed on the 30th. On the 30th we sent a team there—

Ms. SCHAKOWSKY. OK.

Mr. FRIEDEN. And when we looked at the—to answer your question—of those first couple of days, there was some variability in the

use of personal protective equipment. The hospital was certainly trying to implement CDC protocol—

Ms. SCHAKOWSKY. I know, but going forward, how are we going to assure that just trying, you know, how are we going to educate people, nurses? The nurses are saying across the country that they have not been involved and that they are not trained properly or have the equipment.

Mr. FRIEDEN. Three phases. First, think Ebola in anyone with travel history and symptoms. Second, any time a patient is suspected, isolate them, contact us, and we will talk you through how to provide care while we get the test done, and if it is confirmed, we will be there within hours with a CDC Ebola Response Team.

Ms. SCHAKOWSKY. OK. My time is expired.

Mr. MURPHY. Just in response to that, when did you come up with that plan that you just stated to Ms. Schakowsky, the plan in terms of training for nurses? When was that decided?

Mr. FRIEDEN. We look at our preparedness continuously so awareness has been something that we have been promoting in extensive ways since the outbreak—

Mr. MURPHY. I mean, she was asking specifically for those nurses. When was the plan put in place for the Texas hospitals and says you need to follow this protocol from this point on?

Mr. FRIEDEN. The day the diagnosis was confirmed, we sent a team to Texas.

Mr. MURPHY. Thank you. Dr. Gingrey is recognized for 5 minutes.

Mr. GINGREY. Well, first of all, I want to thank, of course, Chairman Murphy for calling the subcommittee back to Washington to hold today's hearing on our collective response to the ongoing Ebola outbreak and commend my colleagues on both sides of the aisle, your near-unanimous attendance to this hearing.

Since my time is very limited, of course, I would like to get directly to my questions, and this is kind of a follow-on maybe to what Ms. Schakowsky was asking, and I don't think we ever got around to an answer on that, and I am going to direct the question to Dr. Frieden and to Dr. Varga, maybe first to Dr. Varga.

As we know from new reports yesterday, there has been a second health care worker who has contracted Ebola, Ms. Amber Vinson. Now that she is receiving isolated treatment at Emory University containment unit in Atlanta, we must examine the protocol breakdowns that resulted in the contraction of Ebola by these two nurses who were directly in contact treating Thomas Duncan.

Dr. Varga, in your written testimony you say that the first nurse, Ms. Pham, to contract Ebola was using full protective measures under the CDC protocol while treating Mr. Duncan. Has your organization in Texas identified where the specific breaches in protocol were that resulted in her infection or, alternatively, the inadequacies of the protocol? Dr. Varga, that question is for you.

Mr. VARGA. Thank you, sir. We are investigating currently the source of this obvious exposure and contraction of the illness. We have confirmed that Nina through her care with Mr. Duncan was wearing protective patient equipment through the whole period of time. As Dr. Frieden already mentioned, with the diagnosis of the Ebola confirmed, the level of personal protective equipment was

elevated to the full hazmat style. We don't know at this particular juncture what the source or the cause of the exposure that caused Nina to contract the disease was.

Mr. GINGREY. Dr. Varga, I am going to interrupt you just for a second because of limitation of time. I want to now go to Dr. Frieden.

Dr. Frieden, as Dr. Varga just stated, health care personnel were following CDC protocols while treating Mr. Duncan, which include the use of so-called PPE, personal protective equipment. Do the CDC guidelines, your guidelines, on the use of PPE mirror current international standards that by the way are being adhered to, those international standards, in West Africa in those three countries, Sierra Leone, Guinea, and Liberia?

Mr. FRIEDEN. The international standards are something that evolve and change. We use different PPE in different settings. There is no single right answer, and this is something we are looking at very closely. Our current guidelines are consistent with recommendations from the World Health Organization. That is my understanding.

Mr. GINGREY. I would think that there would need to be, Dr. Frieden, and I commend you for the job that you are doing and I know these are tough times for all of us, but I think some consistency is what we need, and that brings me to my next question and my last question, and again, it is to you, Dr. Frieden.

This issue of elevated temperature, is it 100.4, is it 101.5, is it 99.6? I think there is some great confusion because initially when people were screening, Mr. Wagner, at the airports in West Africa, the temperature threshold was 101.5, and then I think now the screenings that we are doing at these five major airports including Hartsfield International in Atlanta, it is now 100.4. When Mr. Duncan came for the first time to the Texas Presbyterian Hospital, his temperature was, what, 100.1, and within 24 hours, of course, it was 103. So when mom and dad are out there when their child has a temperature and this fall is flu season and they are going to the doctor, they are going to demand being checked for Ebola. Give us some guidelines on what is elevated temperature and when should parents be concerned?

Mr. FRIEDEN. Well, first, parents should not be concerned about Ebola unless you are living in West Africa or the child has had exposure to Ebola, and right now the only people who have had exposure to Ebola in the United States are people who either are providing care for Ebola patients or the contacts of the three Ebola patients, and I outlined those in this sheet. For our screening criteria, we are always going to try to have an additional margin of safety and so we look at that, and we would rather check more people and assess, so we are going to always have that extra margin of safety for our screening.

Mr. GINGREY. Thank you, and I yield back.

Mr. MURPHY. I now recognize Ms. Castor for 5 minutes.

Ms. CASTOR. Thank you all for tackling this important public health issue of the Ebola virus, and I want to thank the experts at the Centers for Disease Control and the NIH and medical professionals across the country, especially those at Emory University

Health Care who have been proactive in containing and treating the virus.

I agree with President Obama and all of you. We have to be as aggressive as possible in preventing any transmission of the disease within the United States and boosting containment in West Africa.

But I also think we need to pause here. This is a wakeup call for America that we cannot allow NIH funding to stagnate any longer. Earlier this year in the Budget Committee, I offered an amendment to the Republican budget to restore the cuts to NIH, the budget cuts that have been inflicted over the past 2 years and repair the damage of the Government shutdown of last year. Unfortunately, it did not pass on a party-line vote. We will only save lives if we can robustly fund medical research in America and keep America as the world leader.

So I would like to turn to some of that research that is going on now because it is going to be research that will be our longer-term response to Ebola. It will be the vaccines to prevent the disease and the drugs to treat it. So I want to walk through a basic point here, that the development of vaccines and treatments for Ebola is different from the development of many other drugs. There is not a large private market for Ebola drugs, so the development requires leadership of our country, and NIH, as Dr. Fauci has testified, has been working on a vaccine for many years, and he reported today they have now moved into some Phase I clinical trials.

Dr. Fauci, can you explain to us why Government support is so important for developing Ebola vaccines and treatments?

Mr. FAUCI. Well, when you have a product that you want to develop, there is not a great incentive on the part of the pharmaceutical companies because it is a disease whose characteristics are not a large market. We had the experience when you are dealing with emerging and reemerging diseases, be it influenza or be it a rare disease that could either be used deliberately in bioterror or a rare disease like Ebola, that if you look prior to the current epidemic, there were 24 outbreaks since 1976. The total number of people in those outbreaks was less than 3,000. It was about 2,500. So we were struggling for years to get pharmaceutical partners ourselves who were doing the fundamental basic and clinical research, and then we did get some pharmaceutical partners like we have now with GlaxoSmithKline and the NewLink Corporation, which is the reason why we are now moving along. So that is one of the reasons why we have BARDA, so I showed that slide, Ms. Castor, with the NIH and the researchers at this end, and then you have to push the envelope further to the product to de-risk it on the part of the companies. Companies don't like to take risks when they don't have a—

Ms. CASTOR. So can you quantify a timeline for an Ebola vaccine to be on the market? Is it feasible for any vaccines to be approved in time to assist in the current outbreak?

Mr. FAUCI. Well, your question has a couple of assumptions. The first is that the vaccine is safe and it works. The second is going to be, how long is this outbreak going to last at this level. If you look at the kinetics and the dynamics of the epidemic, it looks very serious. Our response to it—when I say “our,” I mean the global

response—has not kept up with the rate of expansion. If that keeps up as the CDC has projected, we may need a vaccine to actually be an important part of the control of the epidemic itself as opposed to what the original purpose of it was, to protect health care workers alone, but now if you have a raging epidemic—and to be quite honest with you, Ms. Castor, I cannot predict when that will be.

If you have a lot of rate of infection, a vaccine trial takes a much shorter time to give you the answer. If it slows down, it is a much longer time. If you have a lot more people in your vaccine trial, it takes less time. If we have trouble logistically, which we might, of getting people into the trial, it might take longer. So I would like to give you a firm answer but we can't right now.

Ms. CASTOR. In addition to the vaccines, part of controlling the virus is early diagnosis and treatment. I know there are some diagnostic tests that are being developed. Can you speak to the prospects of improved diagnostics that can assist in this outbreak?

Mr. FAUCI. Right. Well, there are a couple of us, and when I say "us" I mean agencies that are working on diagnostics. Dr. Frieden's group at the CDC has actually played a major role in leadership. We have several grants and contracts out to try and get earlier and more sensitive diagnostics.

Ms. CASTOR. Thank you.

Mr. MURPHY. Thank you. I now recognize Mr. Gardner for 5 minutes.

Mr. GARDNER. Thank you, Mr. Chairman, and I thank the witnesses for joining us today and the work that you are undertaking.

Dr. Frieden, I want to clarify something that you had said earlier. I believe you mentioned that there are approximately 100 to 150 people a day coming into the United States from the affected areas?

Mr. FRIEDEN. That is my understanding, yes.

Mr. GARDNER. And to Mr. Wagner, you had mentioned that we are screening 94 percent of those people?

Mr. WAGNER. As of today with the expansion to the four additional locations. That covers about 94 percent.

Mr. GARDNER. OK. So of the 100 to 150, 94 percent are being covered. That means that somewhere between 2,000 and 3,000 people a year are coming into this country without being screened from the affected areas?

Mr. WAGNER. Well, they would undergo a different form of screening. We are still going to identify that they have been to one of those three affected regions, and we are still going to ask them questions about their itinerary. We are going to be alert to any overt signs of illness and coordinate with CDC and public health if they are sick, and we are also going to give them a fact sheet about Ebola, about the symptoms, what to watch for, and most importantly, who to contact—

Mr. GARDNER. Would we be checking their temperature?

Mr. WAGNER. We will not be checking their temperatures or having them fill out a contact sheet about—

Mr. GARDNER. So there are 2,000 to 3,000 people entering this country a year without checking their temperature, without having the contact sheet that 94 percent of those affected people—

Mr. WAGNER. They are going to arrive at hundreds of different airports throughout the United States.

Mr. GARDNER. OK. I want to talk a little bit more about the travel restrictions.

Dr. Frieden, how many non-U.S. military flights, commercial flights, are currently going into the affected countries?

Mr. FRIEDEN. I don't have the exact numbers.

Mr. GARDNER. Does anyone on the panel know how many commercial flights are going into these areas? Mr. Wagner, you don't know?

Mr. WAGNER. From the United States or from anywhere?

Mr. GARDNER. From the United States into those areas.

Mr. WAGNER. There are no direct flights, commercial flights, from those three affected areas to the United States.

Mr. GARDNER. And into the area, into West Africa.

Mr. WAGNER. There are flights into West Africa.

Mr. GARDNER. How many?

Mr. WAGNER. That I don't have offhand.

Mr. GARDNER. Anybody on the panel know how many? How many coming back into the United States?

Mr. WAGNER. There are no commercial flights coming directly into the United States from those three areas.

Mr. GARDNER. And what about Europe?

Mr. WAGNER. There are hundreds of flights a day coming from there.

Mr. GARDNER. OK. So people traveling from West Africa to Europe to here?

Mr. WAGNER. That is generally how they would get here.

Mr. GARDNER. And 94 percent screening. How many flights are required daily, every other day, or weekly to get the supplies and personnel to the affected areas?

Mr. FRIEDEN. The quantity of supplies is quite large. I would have to get back to you in terms of the numbers. But there are huge quantities needed, but it is not just supplies. It is also personnel who need to move back and forth.

Mr. GARDNER. Well, if you could get back to me with that number, I would appreciate it.

Now, Dr. Frieden, are you aware if Nigeria has a travel ban from the countries affected with the outbreak right now?

Mr. FRIEDEN. I believe that is not the case.

Mr. GARDNER. They do not? OK.

Dr. Frieden, one of the issues that has been brought up regularly to me back in the district when I go home, what should I tell my local hospital and local doctors that they need to do to address Ebola?

Mr. FRIEDEN. The single most important thing they need to do is to make sure that if anyone comes in with fever or other symptoms of infection, they need to ask where they have been for the past 21 days and whether they have been in West Africa.

Mr. GARDNER. And the training that a small local district hospital would receive, is that the same kind that a major metropolitan hospital would receive?

Mr. FRIEDEN. There are a variety of forms of training. We support hospitals. Hospitals are regulated by States, not by CDC.

Mr. GARDNER. Dr. Frieden, what do we need to do? We are entering the flu season now, as somebody else on the panel had mentioned. What do we need to do to make sure that people understand that there could be similar conditions, similar circumstances so that we don't have a situation where people are indeed panicked?

Mr. FRIEDEN. The key issue, it is, as you point out, getting into flu season. By all means, get a flu shot. And for health care workers, any time someone comes in with a fever or other signs of infection, take a travel history. That is really important.

Mr. GARDNER. Dr. Frieden, I just want to go back to what I said at the beginning. You mentioned that we can't have a travel ban because you are afraid of the impact that it would have but you don't know how much personnel, equipment, and flights are currently in use.

Mr. FRIEDEN. My point earlier on was that, if passengers are not allowed to come directly, there is a high likelihood that they will find another way to get here and we won't be able to track them as we currently can.

Mr. GARDNER. But we are talking about supplies, equipment, and personnel, how many? How many flights? How many personnel? How much equipment?

Mr. FRIEDEN. The point I made earlier was if we are not able to track people coming directly, we will lose that ability to monitor them for fever, to collect their locating information, to share that with local public health authorities and to isolate them if they are ill.

Mr. GARDNER. Mr. Chairman, I yield back.

Mr. MURPHY. The gentleman's time is expired. Thank you. I now recognize Mr. Welch for 5 minutes.

Mr. WELCH. Thank you.

I want to follow up on some of Mr. Gardner's questions. First of all, I want to understand this. There has been one person that came to the United States and then he infected two health care workers in Dallas, correct?

Mr. FRIEDEN. At this point, none of the 48 contacts he had before getting isolated have developed symptoms and they are mostly well past the maximum incubation period, although not completely out of the woods.

Mr. WELCH. All right. And for everybody on the panel, it is Code Red. We have had two instances of infection here in the United States, but this is such a highly contagious disease that we are on full alert, correct?

Mr. FRIEDEN. It is a very severe disease. It is not nearly as contagious as some other diseases, but any infection in a health care worker is unacceptable.

Mr. WELCH. That is right, and there is an enormous, enormous amount of public concern and apprehension about this so we appreciate the full-on efforts that you are making. There has been some lessons learned from what happened in Dallas. The hospital has been forthcoming about mistakes that were made, and now what you are telling us is that there has been information provided to all our hospitals in the country about what protocols to follow, correct?

Mr. FRIEDEN. Correct.

Mr. WELCH. Now, just on a practical level, is it feasible that all our hospitals are going to be in a position to provide state-of-the-art treatment or does it really as a practical matter make sense for hospitals to contact you when they have a potential infection for you to come and then for us to have centers to which that individual who is infected can be treated?

Mr. FRIEDEN. Every hospital needs to be able to think it may be Ebola, diagnose it, to call us as they do—we have had hundreds of calls—and then we will send a team to determine what is best for that hospital and that patient.

Mr. WELCH. And then what we have also heard—Ms. Schakowsky asked this question—this is absolutely a public health infrastructure issue where it gets out of hand, correct?

Mr. FRIEDEN. Public health measures can control Ebola.

Mr. WELCH. Right. And they have had effective measures in Nigeria where they have been able to contain it but they have no public health infrastructure in these three countries where the epidemic is now getting some headway, correct?

Mr. FRIEDEN. Exactly.

Mr. WELCH. And then in the United States, of course, we are fortunate to have a pretty good infrastructure but we do have to have an answer, I think, to this question that is being asked about travel. That is a concern that people have because it is seen as a quote, easy answer, and I just want to understand what the debate is within the medical community. For a lot of us sitting up here, we are hearing from our constituents. It sounds like something that we can do and that will eliminate any possibility of an infection coming here, but that may be a psychological answer but not necessarily an effective medical answer.

All of us have been asking you to give your explanation, and anyone else can come in, as to why from a medical standpoint you have concluded that a total travel ban is inappropriate and not effective.

Mr. FRIEDEN. First off, many of the people coming to the United States from West Africa are American citizens, American passport holders, so that is one issue just to be aware of, but—

Mr. WELCH. All right. And then by the way, I don't have much time, but our health care workers, even if there some risk of infection, if we are going to encourage people to go and do the important work including our military personnel, we have got to take them back and make sure we can treat them if in fact they do get the illness, correct?

Mr. FRIEDEN. People travel, and people will be coming in.

Mr. WELCH. And as I understand it, you say there is basically a tradeoff. If you have a full-on ban, there is going to be ways around it and then you are going to lose the benefit of being able to track folks who may be infected and then that could lead to a greater incidence of outbreak, so it is a tradeoff. Is that essentially what is going on?

Mr. FRIEDEN. We are open to any possibility that will increase the safety of Americans.

Mr. WELCH. Right. So are there some midpoints that in terms of travel restrictions as opposed to a travel ban that may make sense

to you in coordination with your colleagues, particularly Mr. Wagner?

Mr. FRIEDEN. We would look at any proposal that would improve the safety of Americans.

Mr. WELCH. All right. This isn't about funding so I am not going to ask you because I think we would know what your answers would be, but I just want to share my concern that was expressed by Ms. Castor.

Mr. Chairman, we may want to have a hearing at some point about what is the funding requirements to make certain that the infrastructure this country needs to be in place before something happens is robust, it is strong, we have got people who are trained, they are ready to do the job and they have everything that they need. So that is not today's hearing but I think it is a question that we should address because with 20 percent across-the-board funding at NIH, I find that to be a reckless decision with 12 percent at CDC. I think that is definitely the wrong direction. I think this Congress has to revisit our priorities on making certain that we have the public health infrastructure to be prepared to protect the American people.

Mr. MURPHY. If I could just say, we are planning a second hearing, and in preparation for that we will also ask if NIH does have the flexibility now to transfer funds as well as HHS.

I now recognize Mr. Griffith for 5 minutes.

Mr. GRIFFITH. Thank you, Mr. Chairman.

I believe we should have reasonable travel restrictions. Dr. Frieden, in answering a question of my colleague from Colorado, Mr. Gardner, you indicated that Nigeria didn't have any restrictions, and that is accurate, but I have in my possession, and I would ask that it be submitted to the committee for the record, a letter from delegate Robert G. Marshall of Manassas, Virginia, to Governor Terry McAuliffe, Governor of the Commonwealth, and in that he cites the International SOS, a prominent medical and travel security services company with more than 700 locations in 76 countries, reports that African countries have imposed total air, land, and water travel bans by persons from countries where Ebola is present. The countries include Kenya, Cape Verde, Cameroon, Mauritius, South Sudan, Namibia, Gambia, Gabon, Cote d'Ivoire, Rwanda, Senegal, Chad and Kenya. South African development community members, 14 countries, only allow highly restricted entry from Ebola-affected regions with monitoring for 21 days and travel to public gatherings discouraged.

[The information follows:]



ROBERT G. MARSHALL
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HOUSE OF DELEGATES
 RICHMOND

COMMITTEE ASSIGNMENTS:
 FINANCE
 COUNTIES, CITIES AND TOWNS
 SCIENCE AND TECHNOLOGY

October 16, 2014

Governor Terry McAuliffe
 Office of the Governor
 Patrick Henry Building, 3rd Floor
 1111 East Broad Street
 Richmond, Virginia 23219

Dear Governor McAuliffe:

We are writing to you to urge you as Governor to act promptly and decisively to protect the people of the Commonwealth of Virginia from unnecessary risk of exposure to the Ebola virus.

It is increasingly clear to the American people that the Obama Administration has failed to properly respond to the Ebola crisis. This failure includes the refusal to ban flights into the United States from West Africa and impose an embargo on the issuance of visas for travel from persons in these countries.

The Obama Administration appears to view these steps as unwarranted, even though such restrictions have been successfully employed by a number of African nations in stopping the spread of Ebola. Nigeria and Senegal imposed travel bans from Ebola-affected countries and appear to be Ebola free. USA Today (9/30/14) reports: "The Ebola outbreak may be over in two countries – Nigeria and Senegal ... No new Ebola cases have been diagnosed in Nigeria since Aug. 31, suggesting that the outbreak has been contained, according to a report Tuesday from the Centers for Disease Control and Prevention. The only case confirmed in Senegal was reported Aug. 28 in a man who survived."

The CDC is fully aware of what these countries have done, but still opposes bans on travelers from Ebola affected countries, relying only on fever screening at selected airports, including at Dulles Airport, to detect active Ebola carriers. Of course, fever screening will not detect active Ebola carriers who are successfully masking their fever with drugs. Moreover, *there is no reason to trust such measures, as Thomas Duncan was asymptomatic when he passed through Dulles Airport on his way to Dallas where he died.*

International SOS, a prominent medical and travel security services company with more than 700 locations in 76 countries, reports that African countries have imposed total air, land and water travel bans by persons from countries where Ebola is prevalent. The countries include: Kenya, Cape Verde, Cameroon, Mauritius, South Sudan, Namibia, Gambia, Gabon, Côte d'Ivoire, Rwanda, Senegal, Chad and Kenya. Southern African Development Community members (14 countries) only allows highly restricted entry from Ebola-affected regions with monitoring for 21 days and travel to public gatherings discouraged.
https://www.internationalsos.com/ebola/index.cfm?content_id=435&language_id=ENG

International SOS also reports the following foreign Airlines have suspended flights to countries where Ebola is prevalent: Air France, Asky Airlines (Togo), Arik Air (Nigeria), Gambia Bird and Kenya Airways, British Airways (thru 12/31/14), Emirates Airlines, Korean Air, and Senegal Airlines.

With the failure of the federal government to act, it is our belief that Virginia should do no less than being done by other countries. Indeed, the Commonwealth of Virginia has a solemn duty to protect its citizens from infectious and contagious diseases. In carrying out this duty Virginia may act on the mere supposition of a threat to public safety. See, *Smith v. Wm. Turner of the Port of New York*, 48 U.S. 283 (1849) and *Norris v. The City of Boston*, 48 U.S. 283 (1849).

In the recent Arizona case, the U.S. Supreme Court held that even when courts are conducting a preemption analysis, the courts should assume that the 'historic police powers of the States' are not superseded "unless that was the clear and manifest purpose of Congress." *Arizona v. The United States*, 567 U.S. ____ (2012) (U.S. Supreme Court Docket No. 11-182); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

Health laws and quarantine laws have been passed by the legislatures of the States for the protection and welfare of their citizens. It follows that the Chief Executives of these States may act, in fact, have a solemn duty to act, to enforce these protective laws. See, *Smith v. Wm. Turner, supra*; *Norris v. The City of Boston, supra*. Indeed, in *Smith v. Turner* the U.S. Supreme Court held: "They (the States) may guard against anything which may ... endanger the health or lives of its citizens." *Smith v. Wm. Turner, supra*, at 400).

Supreme Court Justice James Wayne, posed and answered the question regarding the retention of police powers by the states. "How much of it have the States retained? I answer, unhesitatingly, all necessary to their internal government . . . all not yielded by them under the Constitution of the United States. *Norris v. The City of Boston, supra*.

Justice Wayne also noted, "Among them, qualified rights to protect their inhabitants by quarantine from disease. ... But, further, by the police power in the States they have reserved the right to be informed of the name and quality of every foreigner that arrives in the State." *Norris v. The City of Boston, supra*, at 425; see also *Smith v. Wm. Turner, supra*, at 404).

We strongly urge you to use the police powers of Virginia to protect our citizens and residents from exposure to Ebola even if it means a timely court challenge against passenger airlines or the federal government if they continue to permit entry into Virginia of passengers flying from Ebola affected areas. We also ask you to take similar measures to protect our seaports. Indeed, **Government travel restrictions were used to limit Severe Acute Respiratory Syndrome (SARS).**

African nations which have effected Ebola travel prohibitions have seen the number of persons infected by Ebola drop precipitously or vanish altogether. While we support vigorous contact tracing of exposed individuals, even highly accurate contact tracing merely identifies Ebola carriers, it does not prevent the introduction of new Ebola carriers into Virginia. Ebola has NO practical cure. Avoiding exposure is the only way to protect the health and lives of Virginians.

The Director of the CDC claimed recently that a Texas nurse who recently was identified as infected with Ebola must have violated CDC infectious disease protocols. Yet, that CDC Director noted (10/14/14) that the CDC will

October 16, 2014

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Marshall

have to revisit all Ebola infection protocols. In essence, he said health care workers will be safe if they follow CDC rules, but CDC rules now need to be tightened to protect health care workers.

The actions of the CDC have fueled a lack of public confidence in the Obama Administration's policy to permit travel to the US from Ebola affected countries as long as a single symptom body temperature is monitored for passengers arriving at airports.

New Jersey officials issued a mandatory quarantine order Friday night for an entire NBC news crew that was exposed to a cameraman with Ebola because a voluntary 21-day isolation agreement was violated.

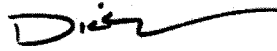
Please advise us of what you intend to do to protect Virginians. With the World Health Organization announcing that Ebola has a 70 percent death rate, clearly, first priority must be on prevention. Should you as Governor of the Commonwealth of Virginia chose not to act in the face of such a crisis, you will be without excuse.

Thank you for your timely attention to this request. If you have any questions please contact me at 703-853-4213.

Sincerely,



Delegate Bob Marshall



Senator Dick Black



Delegate Mark Berg, M.D.

RGM/ccg

Mr. GRIFFITH. I find that interesting, Dr. Frieden, because some of those countries have had previous outbreaks of Ebola themselves. Wouldn't you agree that some of those countries have had to face Ebola before?

Mr. FRIEDEN. I would have to check the list carefully to know, but I will take your word for it.

Mr. GRIFFITH. All right. I will tell you that this is a concern to a lot of our constituents and to mine as well, and I was checking my Facebook page recently when I saw that a Facebook friend of mine, a father from Virginia, asked for prayers for his daughter because she lives in the apartment complex with the first nurse, Nurse number one, as I think somebody referred to earlier, and was very concerned, and while I think I know the answer, I would like to get your answer so that I can reassure this father and that is, his question is, if I count to 21 days and my daughter is not infected, at that point can I exhale and breathe a sigh of relief?

Mr. FRIEDEN. Not only can he do that but he can do that now because the first nurse only exposed one person, one contact, and that was only in the very early stages of her illness, so at most, one person from the community was exposed.

Mr. GRIFFITH. And I appreciate that. He also asked a second question. He said there is some suggestion coming out of Dallas that the patient's dog may be infected and may have infected other dogs through actual contact or by feces. Can the virus be transmitted by dogs? And I will tell you that I did some homework on this because I thought it was an interesting question and found a CDC publication from March of 2005 that did a study on dogs in Africa in the affected areas and a study in France as a control group, and they found that while dogs show antibodies for Ebola, they are asymptomatic, but the study went further to say that there is really a lot of questions about how Ebola is transmitted, and in some instances, Gabon in 1996 and 2004, Republican of Congo likewise in 2004 and the Sudan, that there is a question mark as to whether or not, or how that Ebola outbreak occurred. It wasn't in the normal or standard ways. It wasn't human to human. And this report indicates that dogs might be—might be—I don't want to scare folks—might be suspect.

I guess my question to you is, isn't it true that we really don't know a whole lot about the various outbreaks of Ebola and so when we are trying to assure the American people just like previously we didn't think it would come to this country and then we thought if it did get to this country, we wouldn't have any problems controlling it. Now we have got all kinds of people being monitored. Isn't it true there are still a lot of questions about how Ebola is spread?

Mr. FRIEDEN. Although we are still learning a lot about Ebola and every other organism that we study and that we control, we have a lot of information about Ebola. We have a good sense of how it is controlled, and we have looked at the issue of exposure to animals. We know that in parts of Africa, consumption of forest-living animals can be a cause. We don't know of any documented transmission from dogs to humans, but that is why the authorities with our agreement have quarantined a dog, and we are helping them to assess that situation.

Mr. GRIFFITH. And it is also true that while we have no evidence of transmission from human to dogs, we really don't know if there can be. We have what we call in the law—I used to be a lawyer—you have a lack of evidence as opposed to negative evidence. We don't have clear evidence that you can't transmit it either. And what is interesting is, that raised the question for me about, OK, we have got no restrictions on travel of human beings, how about the dogs? I called Customs. They said, well, our experts are there, and then after pushing them a little bit, they said that is USDA. We call USDA, and Dr. Frieden, they said that would be CDC.

So I understand all your reasons, and while I don't agree with completely, I understand the concerns about humanitarianism, et cetera, but don't you think we ought to at least restrict travel of dogs?

Mr. FRIEDEN. We will follow up in terms of what is possible and indicated.

Mr. MURPHY. I now recognize Mr. Yarmuth for 5 minutes.

Mr. YARMUTH. Thank you, Mr. Chairman, and before I begin my questioning, I would like to submit for the record an article titled "Will America's fragmented public health system meet the Ebola challenge?" by Mark Rothstein, who is the Director of the Institute of Bioethics at the University of Louisville Medical School. I would like to submit that for the record. Thank you.

[The information follows:]



WILL AMERICA'S FRAGMENTED PUBLIC HEALTH SYSTEM MEET THE EBOLA CHALLENGE?

by Mark A. Rothstein, University of Louisville School of Medicine

The recent first diagnosis of Ebola illness on U.S. soil brought into sharp focus the weaknesses as well as strengths of the U.S. public health system. Even as national authorities touted America's capacities to deal with Ebola, the Texas Health Presbyterian Hospital in Dallas, Texas, failed to properly handle a man, avowedly recently arrived from Liberia, who arrived at the emergency room complaining of Ebola symptoms. Thomas Eric Duncan was refused admission for two days, putting dozens of contacts needlessly at risk; and even after he was admitted, family members were left penned up in an infected apartment for nearly a week. When Mr. Duncan later died his relatives were left to wonder whether the delay in treatment contributed to his death.

Excellence and Fragmentation

The United States certainly has the advanced health care facilities, equipment, and personnel to handle Ebola infections and stop them from spreading. Nevertheless, the decentralized and fragmented nature of the U.S. public health system requires challenging coordination by many separate agencies and officials. Unlike many other industrialized countries, the United States has no central public health agency with comprehensive authority.

To be sure, the U.S. Centers for Disease Control and Prevention is responsible for controlling the international and interstate spread of disease, and it also supplies expertise, guidance, laboratory services, data collection, and other technical assistance to the states. But federal authority is limited on the front lines, where state and local governments must see to crucial tasks such as isolating infectious patients, quarantining exposed individuals, issuing public health orders, administering vaccines and medications, overseeing emergency services and health care providers, and directing law enforcement.

In addition, officials at all levels must navigate divisions of responsibility. At the federal level, to give just a few examples, the Centers for Disease Control and Prevention must coordinate with the Food and Drug Administration on issues of experimental medications, with the Department of Homeland Security on issues of screening international passengers, and with the Department of Transportation on identifying potentially exposed passengers on commercial airlines. Similarly, at the state level officials must orchestrate the activities of state, county, and municipal public health departments, law enforcement agencies, emergency management offices, and offices overseeing transportation, utilities, and public services. Government officials also need to coordinate with the armed forces and nongovernmental groups such as the Red Cross.

Phases and Parts of a Coordinated U.S. Effort

The U.S. response to the arrival of Ebola shows the range of efforts that have to unfold in a coordinated manner.

- **America's initial prevention strategy is to keep infected individuals from entering the country.** West African countries are using temperature screening and health questionnaires to prevent infected people from traveling abroad. But even though nearly 100 individuals have already been pulled out of airport lines in Africa, Ebola has a 21-day incubation period when travelers may not know they are infected; and of course some who suspect they are ill may try to reach countries where their chances of advanced treatment are better. U.S. authorities are now instituting more detailed screenings before passengers are admitted to the United States.
- **The next line of defense involves first responders – health care workers, and hospitals responsible for diagnosing, transporting, and treated men or women with suspected and confirmed Ebola infections.** Preparation and flawless communication are essential. When the man with a fever who reported arriving recently from Liberia came to that Dallas hospital emergency room, nurses and doctors needed to suspect Ebola and take immediate precautions. And after he was finally admitted for treatment in quarantine, local authorities should have been better prepared to help his contacts and remove infectious materials from his family apartment.
- **Once an Ebola case is confirmed, public health officials immediately begin "contact tracing" – identifying and interviewing all individuals who may have been exposed. Contacts need to be monitored and those with a likelihood of exposure placed in quarantine.** But the requirements are more complicated than simply telling people to stay home. The health of quarantined individuals must be monitored and those who show symptoms must be transported to a hospital at once. Quarantined individuals need food, medicines, or housing, and some may have special needs, such as people with disabilities, pregnant women, and people with mental illness. And of course front-line workers need to know how to protect their own health as they enforce rules and provide logistical support.

Ebola calls for even more preparation by local and state authorities. Officials need to know what to do about people who violate quarantine, and they need to decide in advance whether to ignore the law-breaking status of people such as undocumented aliens or criminal fugitives, in order to encourage them to enter quarantine rather than possibly spread disease. And new state laws may be desirable. During the epidemic spread of Severe Acute Respiratory Syndrome in 2003, governments in Asia and Canada enacted laws to replace wages and prevent discrimination in employment for people in quarantine. Without such protections many low-income and self-employed persons not yet showing symptoms may break quarantine to go to work. Unfortunately, few states have any such protections. Given the lengthy 21-day quarantines needed for Ebola contacts, states should act now.

Thus far, the United States has been fortunate to escape the ravages of the Ebola outbreak devastating West Africa. But even though we have the facilities, equipment, and personnel to stymie Ebola, our public health system remains vulnerable because it is so decentralized and fragmented. Advance planning, communication, coordination, and vigilance are essential until the Ebola epidemic is brought under control in all countries of our highly connected world.

Read more in Mark A. Rothstein, "From SARS to Ebola: Legal and Ethical Considerations for Modern Quarantine." *Indiana Health Law Review* 12, no. 1 (forthcoming).

Mr. YARMUTH. I would like to thank the panel for their testimony and answering the questions, and this has been a very enlightening hearing. I also want to acknowledge at the beginning that the Kentucky Air National Guard, which is based in my district, is in Senegal right now providing the infrastructure for the 101st in their efforts, so I want to acknowledge their participation in this effort.

At the risk of displaying my ignorance, we apparently know that you cannot detect the Ebola until the same time it becomes symptomatic when it becomes contagious. Is there any other kind of test that would indicate whether anything is going on in the body? I know that sometimes my doctor will say, well, you have got an elevated white blood cell count, something is going on there, and may not know exactly what it is. Is that true of the Ebola or would that not indicate that something is going on?

Mr. FRIEDEN. At this point we don't have a test that would identify it before someone has symptoms. In fact, the test only turns positive when they are sick, and the test is for the virus itself and that is why—that is another reason besides the patterns of disease that we are confident that it doesn't spread. We can't even find tiny amounts of it in people's bodies until they get sick.

Mr. YARMUTH. Is there any research being done as to a possible test, earlier test for this?

Mr. FRIEDEN. There is a lot of research being done to try to understand and diagnose and treat and prevent better.

Mr. YARMUTH. Good. I am a media person by background. That is where I spent most of my career, so I am very sensitive to how the media treat situations like this, and certainly the media can be a very important part of providing public information about a potential threat to public safety as this is. But they can also go overboard, as we know, and I am curious because I see every day comments in the media about the spread of Ebola and outbreaks of Ebola, and while yes, technically it has spread from one person to two health care workers, I know that the public may hear that very differently and perceive there to be a much broader and widespread incident of Ebola in the country, and I see things like, for instance, in the Washington Post today the picture of the woman at Dulles Airport who looks like she is mummified because of her concern of contracting Ebola, and I know that now one survey showed 98 percent of the American people are aware of the Ebola situation and not even 50 percent know there is an election coming up in 3 weeks. So the media has certainly let the public know that there is something going on.

My question to you is, has the media coverage so far been helpful or harmful in your efforts to have the public have an appropriate concern and awareness of what the situation is?

Mr. FRIEDEN. Well, anytime health care workers become infected and ill in this country, it is unacceptable, and our thoughts are with the two infected health care workers in hoping for their recovery. So it is certainly understandable that there is intense media interest. It is new to the United States. It is a scary disease, had a movie made about it, and it is important to have that attention so that we as a society pay attention, and doctors in hospitals and community health clinics, and primary care practices think of the possibility of Ebola that we generate the societal will and resources

to both protect Americans and stop it at the source because it has got to be stopped at the source to make us completely safe.

Some of the coverage, I think many would agree, may exaggerate the potential risks or may confuse people about the risks. There really is a lot we know about Ebola. CDC has an entire branch, entire group of professionals who spend their careers working on Ebola and other similar infections. They go out and stop outbreaks all the time. We have stopped every outbreak of Ebola until the current one in West Africa. There is zero doubt in my mind that barring a mutation which changes it, which we don't think is likely, there will not be a large outbreak in the United States. So I think we welcome the attention. It would be important at times to put it in perspective.

Mr. YARMUTH. I appreciate that. I agree totally.

One final question in the last 30 seconds. Is there any additional authority that CDC would find more helpful in conducting or meeting the responsibilities? I know most of yours is guidance and information, but is there any specific authority that Congress could grant you that would make it easier for you to do your job?

Mr. FRIEDEN. We are looking at a variety of things, emergency procurement, for example, to see in conjunction with the administration whether there are some changes that might allow us to respond more quickly and effectively.

Mr. YARMUTH. Thank you. I yield back.

Mr. MURPHY. I recognize Mr. Johnson for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman, and Dr. Frieden, thank you for being here. I thank all of you on the panel for being here today.

You know, this is not about politics, it is not about international diplomacy. It is about public health and protecting the public safety of the American people particularly our health care workers, who if I understood correctly, you have acknowledged are some of the high-risk folks to be exposed.

You know, one of my main concerns, Dr. Frieden, is that we don't know what we don't know. Throughout testimony and questioning today, I have heard you say multiple times "I don't know the details of this, I don't know the details of that," and I think what the American people are wanting is some assurance that somebody does know the details.

So let me ask you a question. Do we know yet how the two health care workers in Dallas contracted the virus? Was it a breakdown in the protocol? Was it a breakdown in the training of the protocol? Do we know whether or not the protocol works?

Mr. FRIEDEN. The investigation is ongoing. We have identified some possible causes. We are not waiting for the investigation to be completed—

Mr. JOHNSON. So we don't know?

Mr. FRIEDEN. We are immediately—

Mr. JOHNSON. OK.

Mr. FRIEDEN [continuing]. Going to take safety measures.

Mr. JOHNSON. I get that. We don't know. You know, the people in Ohio are concerned, especially now that we know that one of those health care workers traveled through Ohio, even spent some

time in Akron with family members. I applaud Governor Kasich's immediate actions to try to address the situation.

You know, in my experience as a military war planner, 26 ½ years in the military, and I know we have got military engaged in this process overseas, we don't wait until the bullets start flying to figure out whether our war plan is going to work.

Dr. Frieden, when did the CDC find out that there was an outbreak of Ebola in West Africa?

Mr. FRIEDEN. Late March.

Mr. JOHNSON. Late March. One of the things that we do in the military is that we conduct what is called operational readiness inspections. We give real-world scenarios in controlled environments, no notice so that those who are going to be responsible for executing a war plan know what to do when the first shot is fired, no panic, no second guessing; they know what to do. Has the plan to address an Ebola outbreak ever been tested by the CDC in a real-world environment?

Mr. FRIEDEN. Not only has the plan been tested but outbreak control has been done multiple times in parts of Africa. What had not been done is in this part of Africa which had never seen—

Mr. JOHNSON. No, I am talking about here in America.

Mr. FRIEDEN. In America also we do a series of preparedness plans, for example—

Mr. JOHNSON. Do you know of any hospitals in eastern and southeastern Ohio that have participated in any kind of real-world scenario of an Ebola outbreak?

Mr. FRIEDEN. I can't speak to that specific example, no.

Mr. JOHNSON. OK. Let me go a little bit further. You mentioned earlier that 150 per day roughly are coming in from West Africa. I think Mr. Wagner indicated 94 percent screening. Let me give you a scenario. Let us say a person comes in to the country from West Africa, and let us assume that everything in the screening process works right. They are maybe in day 14 of having been exposed to Ebola in West Africa. They show up here in America with no symptoms. They go through the screening process, and so they go on about wherever they go—Akron, Cleveland, Cincinnati, Los Angeles, wherever. Day 17 or 18 they start getting ill and they start seeing a spike in their temperature. If they walk into any emergency room in Appalachia Ohio and start throwing up, having symptoms, does your plan identify that and does your plan tell that hospital emergency room what to do in that scenario? They don't know that person came from Liberia or any other place.

Mr. FRIEDEN. We have detailed checklists and algorithms that we have distributed widely, provided repeated training and information so that health care providers throughout the country have a detailed checklist of what to do step by step by step to determine whether the person has Ebola, if they do, to call for help and we will be there.

Mr. JOHNSON. Mr. Chairman, I yield back.

Mr. MURPHY. Thank you. Mr. Green is next in line, but we are looking for him, so Mr. Matheson is next for 5 minutes.

Mr. MATHESON. Well, thank you, Mr. Chairman. I have a number of questions. I will try to move through them quickly.

Dr. Frieden, as was mentioned by a couple people in their opening statements, it strikes me that controlling the outbreak in West Africa is really one of the real key issues to keeping Americans safe. There are reports that indicate we may still be losing some ground in Liberia, so I guess I would ask the question, what would enhance the international community's ability to gain control of the situation in West Africa in terms of actions and resources?

Mr. FRIEDEN. The fight against Ebola in West Africa is challenging. The health systems are weak. What we are finding is that it is moving quickly and there is a real risk it will spread to other parts of Africa. Therefore, the key ingredient to progress there is speed. Because the outbreak is increasing so quickly, the quicker we surge in a response, the quicker we blunt the number of cases and the risk to other parts of the world including the United States decreases.

Mr. MATHESON. And are you resource-constrained in that context?

Mr. FRIEDEN. Congress has provided money or approval or agreement to use money for the Department of Defense. USAID has resources going in. At CDC, we received through an anomaly \$30 million for the first 11 weeks of this fiscal year, which we appreciate.

Mr. MATHESON. Let me ask you, you have a number—CDC has an unprecedented number of people in the field right now in West Africa and in Texas. How many people do you have deployed doing airport screenings?

Mr. FRIEDEN. I would have to get back to you with the exact number. We are working both to oversee the screenings in West Africa and make sure they are done correctly and to screen individuals here, collect information on them and transfer that information—

Mr. MATHESON. I need you to get that number and also find out if those resources are best used there or elsewhere with your limited number of people. That would be interesting to hear.

Following up on Mr. Yarmuth's questioning, is there a development of a more rapid test to determine if someone has Ebola than what we use today?

Mr. FRIEDEN. A more rapid test would be very helpful. The U.S. Navy has a pilot test in development. We are currently testing that in parts of West Africa. It is simpler, quicker and would be very helpful, even if it isn't quite as sensitive in West Africa, but we are working with a number of commercial manufacturers also on a more rapid test than there is currently.

Mr. MATHESON. It seems to me that when it comes to infection control and prevention and hospital epidemiology standards, I think they vary widely from hospital to hospital in this country. What legislative or regulatory actions could strengthen these systems? I mean, how can we reduce this variability among hospitals in our country?

Mr. FRIEDEN. Infection control in our hospitals generally is a challenge and something that CDC works hard with hospitals and State health departments and State governments to improve. Hospitals are regulated by the States within which they operate, and the issue of what could be done to improve infection control is com-

plex. CDC has a large hospital infection prevention program, and there we support regional efforts to share lessons and figure out new ways to do things better to prevent infection, and that kind of center-of-excellence model is a very important one.

Mr. MATHESON. But you are suggesting that while you can provide the information and the expertise and the guidance, the actual implementation and responsibility is still a State function more than a Federal function. Do you think we should be looking at that issue?

Mr. FRIEDEN. In the United States, we have a federalist system. The CDC provides information and input. There are roughly 5,000 hospitals in the country. We are not a regulatory agency.

Mr. MATHESON. Right. One other line of question. There is no good news about Ebola, but at least it is not transmitted as an airborne entity. It is clear that we don't want to underestimate its ability to be transmitted, and while the focus is on Ebola and rightly so for this hearing, there are other airborne transmissible pathogens that ought to be of great concern to everyone including this Congress that exist around the globe today, MERS being one of them. Is this experience we have had with Ebola, how do we learn from it to make sure we are prepared for other human-to-human-transmissible pandemics that may be a higher rate of transmission than Ebola?

Mr. FRIEDEN. I think there are two major lessons, first, to prevent it at the source. If we had had the basic public health system in place in these three countries a year ago to find it, stop it, and prevent it, it would be over already, and second, within our country, to continue to support hospital preparedness, community preparedness and fundamentally the public health measures to find, stop and prevent health threats.

Mr. MATHESON. OK. Thanks, Mr. Chairman.

Mr. UPTON [presiding]. Mr. Long is recognized for 5 minutes.

Mr. LONG. Thank you, Mr. Chairman, and today we have referred to—people on the panel, people up here have referred to Nurse One and Nurse Two, and these are two young women that have dedicated their lives to helping other people, sick people, and to refer them as Nurse One and Nurse Two just doesn't set well with me. It is kind of reminiscent of Dr. Seuss Thing One and Thing Two. These are not things. So for the record, I would like to state that the first nurse to contract Ebola was Nina Pham, and the second nurse was Amber Joy Vinson. These are young women with families. I know one in particular has a fiancé. And so I think that it would serve as well to remember that these are human beings that have dedicated—young women that have dedicated their lives to helping other people, and for them and nurses everywhere and their families, I would just like to open with that.

Dr. Frieden, you said in your testimony earlier that only by direct contact can you contract Ebola. Do you stand by that statement?

Mr. FRIEDEN. Direct contact with someone who is ill or died from Ebola or their body fluids.

Mr. LONG. And it is not airborne, Congressman Matheson just said, and you agreed it is not an airborne—cannot be contracted airborne.

Mr. FRIEDEN. Ebola spreads person to person, not by the airborne route, so it is not like——

Mr. LONG. Do you need personal contact?

Mr. FRIEDEN. Yes.

Mr. LONG. If you need personal contact with bodily fluids, why is there an airliner in the Denver Airport right now that Frontier Airlines has scrubbed four times? Aren't they wasting money? Why can't they get that back into service? If you have to have bodily contact, close contact, why scrub that airliner?

Mr. FRIEDEN. I understand that people are very concerned about Ebola. It is a scary disease. I can't comment——

Mr. LONG. So it is just for public perception? I mean, they really don't need to be doing that, right?

Mr. FRIEDEN. We have detailed guidelines along with the EPA for how to clean airliners.

Mr. LONG. Do you need a fever to be contagious?

Mr. FRIEDEN. You need to be sick. Generally the first symptom of illness is fever.

Mr. LONG. So do you need a fever to be contagious?

Mr. FRIEDEN. Late in the disease when people are deathly ill, they may not have fever but they would be likely be unable to walk at that point.

Mr. LONG. This 21-day period that you need to show symptoms within 21 days from exposure, during that period could you be contagious the third day of that point?

Mr. FRIEDEN. Only if you were sick, only if you had symptoms.

Mr. LONG. OK. And the incubation period is anywhere from zero to 21 days?

Mr. FRIEDEN. Two to 21 days, generally within the first 10 days or so.

Mr. LONG. You said here today that there are 100 to 150 people a day coming from West Africa into the United States. You are opposed to travel restrictions, which the constituents in the 7th District in Missouri are very much in favor of travel restrictions. I predict you are going to put on or the President is going to put on travel restrictions. I don't know if it is going to be today or tomorrow or 2 weeks or a month from now but I think that they are coming and I think sooner rather than later. If there are 150 a day, and you rationalize, well, we don't really need to worry about that because they could get across borders, they could go by land and then get here. With that 100 to 150 a day, don't you think that number might be reduced to five or ten a day if we did put on travel restrictions?

Mr. FRIEDEN. I can't comment on what numbers would——

Mr. LONG. If someone had to make an effort other than going out to their local airport and jumping on a plane, if they really had to try to get here, don't you think that number would dramatically drop?

Mr. FRIEDEN. I know that people do come back, and right now we are able to screen them, collect their information——

Mr. LONG. What if they don't come back? A lot of people come in this country and we lose track of them. They don't come back. What happens then? My point is, if you have got 150 a day coming in or you have five coming in a day, I and my constituents would

rather have five a day coming in, and this thing of checking for temperatures like it is going to help is kind of like scrubbing a plane that doesn't need to be scrubbed.

But I would like to recommend the folks reading this copy of Bloomberg Business Week "Ebola is coming, coming to America. The United States had a chance to stop the virus in its tracks but it missed." That issue came out before Mr. Duncan came to this country and before he was diagnosed with Ebola. There is some good reading in there that I would recommend.

I would also recommend to you if you want to Google a hospital from hell, it is swamped by Ebola in the New York Times just a few days ago, hospital from hell, if you get a chance to read that. I think that everyone would be in favor of the travel restrictions we have talked about here today, and today OSHA, Occupational Safety and Health Administration, just today said that Customs and Border Patrol immigration enforcement agents are at risk of coming into contact with Ebola.

Mr. Wagner, are we prepared for that? Are your agents, are they protected to the fullest extent what they need?

Mr. WAGNER. We—

Mr. LONG. This just came out today.

Mr. WAGNER. We issue them personal protective gear and we train them on how to wear it and what circumstances to wear it, but they encounter all different kinds of travelers with a whole host of different potential communicable diseases. So you know, we are aware and we do train to recognize signs of overt illness and we have the protocols with health professionals to get those travelers into that care and to protect our employees.

Mr. LONG. To me, they fall in the same category of the nurses. They are there to save us and help people and protect people in this country, so God bless, and I will yield back.

Mr. UPTON. The gentleman's time has expired. The gentlelady from North Carolina, Mrs. Ellmers.

Mrs. ELLMERS. Thank you so much, Mr. Chairman, and I have a number of questions.

I would like to start with Dr. Varga in regard to the two nurses that were exposed. My understanding is, one of the nurses, the first nurse, Ms. Pham, was exposed in the emergency room. Is that correct?

Mr. VARGA. I am sorry. Could you repeat the question, please?

Mrs. ELLMERS. The first nurse was exposed in the emergency room. Is that correct?

Mr. VARGA. No, that would not be correct. Nina was one of our ICU nurses and came in contact with Mr. Duncan when Mr. Duncan was transferred from the emergency department up to the ED.

Mrs. ELLMERS. So that was sometime from September 28th to the 30th. Is that correct?

Mr. VARGA. That is correct.

Mrs. ELLMERS. OK. And then the second nurse, Ms. Vinson, was she also an ICU nurse?

Mr. VARGA. That is correct.

Mrs. ELLMERS. OK. So they were exposed after the point that we would have already started recognizing that Ebola was being questioned. Is that correct?

Mr. VARGA. No, that is not correct. The nurses in the MICU from the time they had first contact with Mr. Duncan were in personal protective equipment according to the CDC guidelines. Nina cared for Mr. Duncan—

Mrs. ELLMERS. OK. Dr. Varga, I am going to stop you right there. So they were already using universal precautions but also were using some of the more isolation? And just answer yes or no.

Mr. VARGA. Yes.

Mrs. ELLMERS. OK. To that, I would like to move on to Dr. Frieden. On October 6th, I sent a letter to the CDC, to CBP, and HHS calling for travel restrictions. So there is no question I believe travel restrictions need to be put in place, and now after having this subcommittee hearing, I believe even more strongly that we need them, and I just want to back up to a couple questions for Dr. Frieden and Dr. Fauci. Are there multiple strains of Ebola?

Mr. FRIEDEN. There are five different subspecies. This outbreak is one particular subspecies, Ebola Zaire, and all of the strains that we have seen have been closely related.

Mrs. ELLMERS. OK. So we know that it is isolated to one particular strain?

Mr. FRIEDEN. Yes.

Mrs. ELLMERS. Now, you had mentioned, and I believe the quote was, “unless it mutates, there will not be an outbreak here in the United States.” Is that correct?

Mr. FRIEDEN. There will not be a large outbreak here barring a mutation.

Mrs. ELLMERS. Well, the question I have is, when the nurses were using the protective gear then, how is this that this has happened? It tells me that something is changing here, and are we currently looking into this situation right now?

Mr. FRIEDEN. We are absolutely looking for other mutations or changes. What we have seen is a very little change in the virus. We don't think it is spreading by any different way.

Mrs. ELLMERS. And you have already said a couple of times that you don't believe that this is airborne, and yet I know how nurses are. I was one for 21 years before coming to Congress. You are protecting yourself. You are protecting your patient. You are protecting your family. They followed precautions, I am sure, and now we are having this conversation, and I am very concerned about that.

Mr. FRIEDEN. We are confident that this is not airborne transmission. These nurses were working very hard. They were working with a patient who was very ill, who was having lots of vomiting, lots of diarrhea. There was a lot of infectious material, and the investigation is ongoing but we immediately implemented a series of measures to increase the level of safety.

Mrs. ELLMERS. OK. I am going to move on.

Dr. Borio, in the discussion of fast tracking a test for Ebola, where is the FDA on that? Is there a fast-track process right now that you know of?

Ms. BORIO. For diagnostic tests?

Mrs. ELLMERS. Yes.

Ms. BORIO. So there are three diagnostic tests that are authorized for use under our EUA authorities, and we have also taken

some practice steps by contacting manufacturers, commercial manufacturers, who we know have potential interest in technologies to be brought to bear here, and we reached out to a handful who might be interested in working with us.

Mrs. ELLMERS. OK. So you are in the process of looking towards a fast-track process?

Ms. BORIO. Yes. We would expedite every such test.

Mrs. ELLMERS. Great. Thank you.

And then Dr. Frieden, lastly, I am speaking on behalf of my constituents and every American in this country. I just don't believe that it is acceptable that the quote that you had given us, "we won't be able to track them," is the reasoning for why we should not implement travel restrictions. I do believe we can, and Mr. Wagner, as far as our Customs and Border Patrol, do you believe that there is a way that we can implement tracking?

Mr. WAGNER. Tracking?

Mrs. ELLMERS. Tracking of individuals if we do not allow them to come—

Mr. WAGNER. Yes, we have ways to determine a person's itinerary and travel history through the questioning or review of the passport. It is easier when they are coming on a direct ticket from those places—

Ms. ELLMERS. True, but as you pointed out, they are coming from—

Mr. MURPHY. The gentlelady's time is expired.

Mrs. ELLMERS. Thank you, Mr. Chairman. I thank you for indulging my overtime here.

Mr. MURPHY. I now recognize Mr. Scalise for 5 minutes.

Mr. SCALISE. Thank you, Mr. Chairman. I appreciate you holding this hearing, and I want to thank all of the panelists for coming and participating, and I have talked to a number of health care professionals as well as many constituents and listened to the panel as well. I want to join with Chairman Upton in urging the President to immediately institute a travel ban until such time that they can firmly and scientifically prove that Americans are safe from having more Ebola patients coming into the United States, and Dr. Frieden, you expressed disagreement with that. Have you all had any conversations within the White House about a travel ban and whether or not the President has the authority, because many of us have said the President does have the authority to do it today.

Mr. FRIEDEN. From the point of view of CDC, we are willing to consider anything that will reduce risk of—

Mr. SCALISE. But have you considered that and have you ruled it out or have you not considered it at all? Have you had conversations with the White House about a travel ban? That is a yes or no question. Have you had conversations with the White House about a travel ban?

Mr. FRIEDEN. We discussed many aspects—

Mr. SCALISE. How about a travel ban? Have you had that conversation—

Mr. FRIEDEN. We have had discussions on the issue of travel to and from West Africa.

Mr. SCALISE. And have you all ruled it out?

Mr. FRIEDEN. I can't speak for the White House. I can tell you that—

Mr. SCALISE. You can speak for the CDC. If you were in those conversations, maybe they had their own conversations without you but if you were involved in conversations with the White House about a travel ban, did they rule it out? Are they still considering it?

Mr. FRIEDEN. From the CDC's perspective, we will consider anything that will better protect—

Mr. SCALISE. So are you going to answer the question about your conversations with the White House? Is the White House considering a travel ban?

Mr. FRIEDEN. I can't speak for the White House.

Mr. SCALISE. Do you know if they have ruled out a travel ban?

Mr. FRIEDEN. I can't speak for the White House.

Mr. SCALISE. Have you had conversations with them about it?

Mr. FRIEDEN. We have discussed the issue of travel.

Mr. SCALISE. All right. I would urge you at a minimum, if you have ruled out a travel ban, if you don't think it is the right way to go, there are a lot of people that would disagree with you. At a minimum, you ought to look at least immediately suspending visas to non-U.S. nationals seeking to travel into the United States from Sierra Leone, Liberia, and Guinea. Have you all considered that or discussed it or ruled it out?

Mr. FRIEDEN. At CDC, our authority is to quarantine individuals who require isolation.

Mr. SCALISE. But earlier you said you don't think there should be a travel ban. What about at least looking at suspending visas to non-U.S. citizens? Have you looked at that?

Mr. FRIEDEN. CDC doesn't issue visas.

Mr. SCALISE. But you can make a recommendation to the White House that it would be in the best interest of the American people to have that kind of suspension issue, can't you? Are you not aware of that?

Mr. FRIEDEN. We would certainly consider anything that will reduce risk to Americans.

Mr. SCALISE. Let me ask you this. Do you have a high level of confidence that our U.S. troops that are over there right now—I have got estimates that are around 350 U.S. troops are already in those three affected countries. Up to 3,000 troops are going to be sent over by President Obama. Do you have a high level of confidence that those U.S. troops are protected with all the protocols in place so that they will not contract Ebola?

Mr. FRIEDEN. We have worked very closely with DoD on their protocols and—

Mr. SCALISE. So do you have a high level of confidence that they are protected?

Mr. FRIEDEN. I would not say that there is zero risk. They are in those countries but they are not participating in high-risk activities that—

Mr. SCALISE. Are you consulting with DoD? Who establishes the protocols in that case? Is the CDC involved in that?

Mr. FRIEDEN. They are following the CDC's protocols but they follow their own—

Mr. SCALISE. Let me ask you about the protocols because I have read reports that some people with some of the other organizations that have been over there for a while—you have got the group Samaritan's Purse, a gentleman by the name of Sean Kaufman, who is involved with some of the doctors that have been over there that have gotten infected. They have been working for decades in some cases. He said that he warned your agency that the guidelines that you had on Ebola were lax and his response was, "They kind of blew me off," meaning your agency blew him off when he was warning you that your protocols were lax. Are you aware of that?

Mr. FRIEDEN. I saw that quotation. We take all suggestions—

Mr. SCALISE. Have you identified who blew him off in your agency?

Mr. FRIEDEN. I don't know that that occurred.

Mr. SCALISE. Well, I would hope that you would go and find out because there is a real concern. You know, one of the biggest concerns I get from the hospitals in my district that I have talked to, and I have talked to a number of hospital officials, medical officials, professionals in my district. They are concerned that they haven't had consistent protocols. There has been at least four just in the last few weeks where the protocols keep changing. Now, with the nurse, the first nurse that was infected, I believe you personally said that the protocols were breached originally. Have you backed away from that?

Mr. FRIEDEN. We are looking at what might—

Mr. SCALISE. You said the protocols were breached. Were the protocols breached with the first nurse that was infected? Yes or no.

Mr. FRIEDEN. Our review of the records suggests that in the first few days of—

Mr. SCALISE. If you didn't know for a fact, you shouldn't have said it.

Mr. MURPHY. The gentleman's time is expired.

Mr. SCALISE. Do you withdraw that statement, or do you still stand by the statement that protocols were breached by the first nurse?

Mr. FRIEDEN. There was a definite exposure that resulted—

Mr. SCALISE. Were protocols breached, yes or no?

Mr. MURPHY. The gentleman's time is expired.

Mr. SCALISE. Yield back.

Mr. MURPHY. Thank you.

It is the tradition of this committee that the ranking member and the chairman have a final 2-minute wrap-up. Ms. DeGette, 2 minutes.

Ms. DEGETTE. Dr. Frieden, would it be fair to say that it looks like the first nurse, Ms. Pham, was exposed in the first couple of days before the diagnosis came in?

Mr. FRIEDEN. That is our leading hypothesis at this point.

Ms. DEGETTE. Thank you.

Now, Dr. Varga, we have still got you, I hope.

Mr. VARGA. Yes, I am here.

Ms. DEGETTE. Have you now seen my chart from the New York Times about the protective gear?

Mr. VARGA. Yes, ma'am.

Ms. DEGETTE. Do you know which of these types of protective gear Ms. Pham and the other health care workers were wearing during those first 2 days?

Mr. VARGA. Ms. Pham would have been wearing or Nina would have been wearing the second garb. The folks in the ED most likely would have been wearing the first picture.

Ms. DEGETTE. OK. Thank you. So it is your testimony you don't really know how Ms. Pham was—well, either one of these wonderful nurses were exposed. Is that correct?

Mr. VARGA. That is correct.

Ms. DEGETTE. OK. I just want to say one last thing. I think that we have had a lot of discussion today about a lot of issues, and my takeaway is this—and Dr. Frieden, I am going to make a statement and I would ask you to comment on it. It seems to me that, aside from trying to stop this Ebola in Africa, the thing we can do here is, number one, we can give better training to the people in our emergency rooms and our first responders, not just send them out emails or bulletins. Number two, we can have more robust protective gear at an early stage if somebody looks like they might have a risk for Ebola, and number three, I think it might be really useful to put CDC on the ground much earlier. Here, they didn't come into this Dallas hospital until after the diagnosis. So there were 2 days when people were moving in and out of Mr. Duncan's room, and we don't know exactly what happened. Dr. Frieden, could you comment very briefly on that?

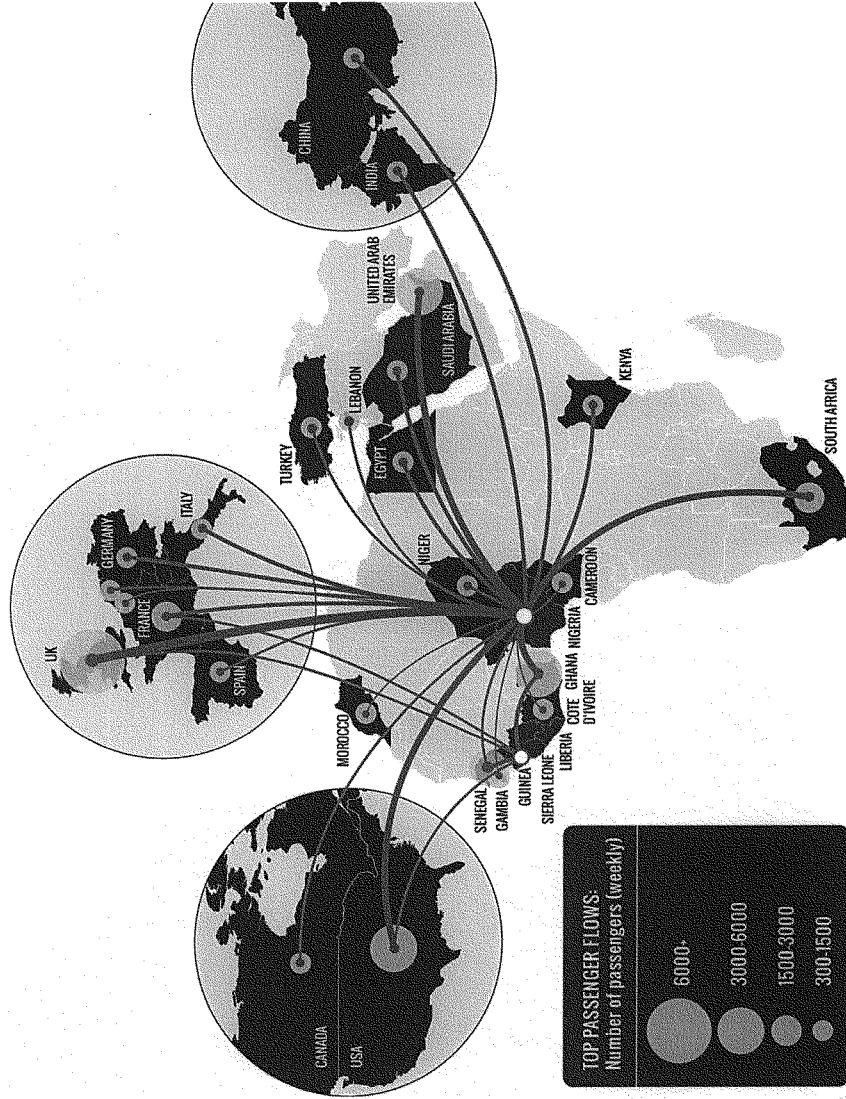
Mr. FRIEDEN. I will agree completely on the training. We are looking very carefully at the personal protective equipment issue. We consult immediately every time, and there have been more than 300 consultations for hospitals that have thought they might have a patient with Ebola. Only Mr. Duncan was confirmed to have Ebola.

We can't be everywhere. Everyone has to do their part but we will do everything we can to support the front lines.

Ms. DEGETTE. And Mr. Chairman, I would ask for both this protective gear chart and also our map of the flights to be included in the record, and I would also ask—

Mr. MURPHY. Without objection.

[The map follows:]



Ms. DEGETTE. I would also ask all of our witnesses if they would continue to keep this committee updated as to changes in procedures or developments that are made as we go along, and I would ask unanimous consent to put in the other members' opening statements in the record.

Mr. GRIFFITH. Mr. Chairman, I had previously asked for unanimous consent for the letter that I quoted from.

Mr. MURPHY. Yes, that was granted.

Mr. GRIFFITH. I don't think we ever agreed on it but—

Mr. MURPHY. It is so ordered.

Mr. GRIFFITH. Thank you.

Mr. MURPHY. I now recognize myself for a final 2 minutes.

So having listened to all your testimony, a couple of things that stand out for me. One, I appreciate Dr. Daniel Varga's statement of honesty that we made mistakes. I didn't hear that from any of you, and that troubles me. Because what has happened here, is your protocol depends on everyone being honest 100 percent of the time. I am not a medical expert. I study behavior as a psychologist. People are not honest 100 percent of the time.

Secondly, it relies on tools for taking temperatures, which have their own reliability and validity issues, a 1 in 21 chance during those 21 days it may register something, and a person can mask it with some analgesics, so that is not helpful.

We also have to recognize human behavior, that protocols may not be followed. That is why you have a failsafe system of basically a buddy watching you put on your garb, watch you take it off, making sure you use other things, and I think the example of how this failed was, there is an assumption in the travel—Dr. Frieden, you said CDC granted her travel with the assumption that she used all the right protective gear but we have looked at this, and you are not aware of what she wore and it does not appear she wore the proper ones. So to this extent, these are my recommendations based on what we have heard in this hearing.

I believe we need an immediate ban on commercial non-essential travel from Guinea, Liberia, and Sierra Leone until we have an accurate and thorough screening process and we treat this disease. Number two, a mandatory quarantine order for any American who was treated an Ebola patient or has traveled to and returned from the Ebola hot zone countries. This includes a prohibition of domestic travel because of an assumption, and without this assumption of what they wore was donned and removed properly. Number three, immediate training and thorough training for U.S. health care hospital workers to include a review of personal protective equipment used in the treatment of possible Ebola-infected patients, their wear and removal. Number four, identify and designate specific medical centers equipped and trained to treat potential Ebola patients and expansion of those as soon as possible. Number five, identify gaps in statutory language that may prevent CDC and any other Federal agency including BARDA, FDA, and NIH from taking more aggressive and immediate action to protect public health from Ebola including letting us know of any abilities now to transfer funds immediately or any other action Congress needs to do to facilitate your needs. Number six, accelerate directives on development and deployment of clinical trials for all prom-

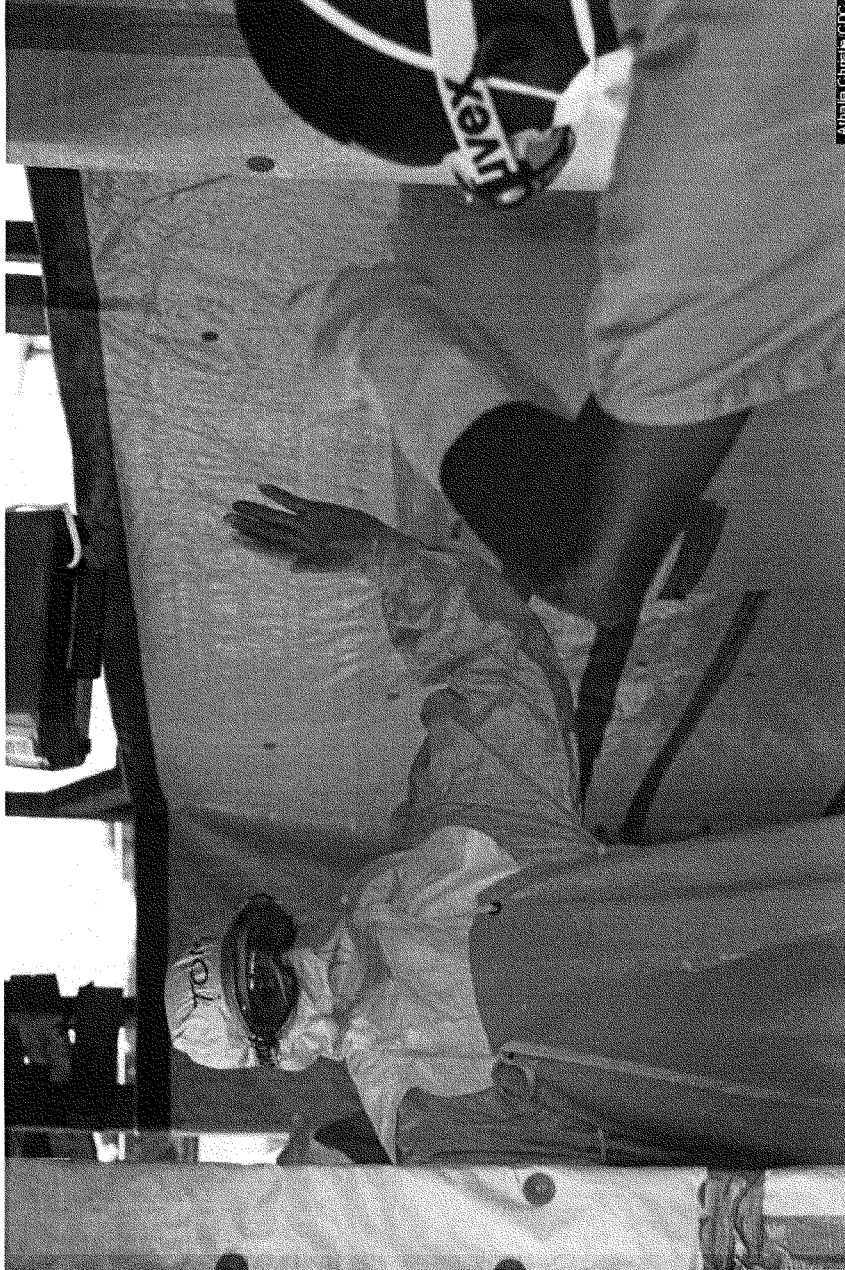
ising Ebola vaccines, investigational drugs, and diagnostic tests. Number seven, acquisition of additional airplanes and vehicles capable of transporting American medical and military personnel who may have contracted Ebola in Africa to return to the United States beyond the current capacity of two. Number eight, additional contact tracing and testing resources for public health agencies, and number nine, to provide information to Congress regarding any resources needed to assist health interventions, aggressive health interventions in Africa so we can stop Ebola there.

I appreciate all the members coming back today for this hearing, and I particularly appreciate the testimony of the panel. I ask unanimous consent that the members' written opening statements be introduced into the record. Without objection, the documents will be entered into the record.

Mr. BURGESS. Yes, I have a document to enter into the record, the Office of Inspector General, Department of Homeland Security, and then the photograph that I demonstrated earlier today.

Mr. MURPHY. So ordered. That will be included in the record.¹
[The photograph follows:]

¹The information has been retained in committee files and also is available at <http://docs.house.gov/meetings/IF/IF02/20141016/102718/HHRG-113-IF02-20141016-SD010.pdf>.



Again, I thank all the witnesses and members——

Ms. SCHAKOWSKY. Mr. Chairman.

Mr. MURPHY [continuing]. Who have participated in the hearing.

Ms. SCHAKOWSKY. Mr. Chairman, I just want an acknowledgment that the things I wanted included in the record——

Mr. MURPHY. Yes, those are included, as well.

Ms. SCHAKOWSKY. Thank you.

Mr. MURPHY. We will also have a hearing in November. We will follow up. We will notify members of the participants in that and when that will be.

I ask all members to submit questions for the record and ask that the witnesses please agree to respond promptly to the questions, and with that, this hearing adjourned.

[Whereupon, at 2:55 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**Statement for the Record
The Honorable Frank Pallone, Jr.
House Energy and Commerce Committee
Oversight and Investigations Subcommittee Hearing
“Examining the U.S. Public Health Response to the Ebola Outbreak”**

October 16, 2014

Thank you Chairman Murphy for holding today’s important hearing on the U.S. public health response to the Ebola outbreak. I think we can all agree that this is a serious issue that deserves the federal government working together, including Congress and the global health community to ensure the safety of not only Americans but people all over the world.

Two contracted cases of Ebola in the United States is two too many. But two cases is by no means a domestic pandemic of Ebola. It is important as we examine the current state of affairs that we maintain this perspective. Furthermore, I think we must assume going forward that there may be additional cases but the spread of the disease can and will be contained in the United States.

Ebola, as I’m certain we will here from our experts today, is transmitted only through direct contact with body fluids, such as blood, saliva, feces and urine. It is not considered to be highly infectious and it is important to note for the American public it is not spread through the air and proper infection control in hospitals can prevent its spread.

It is my hope that Dr. Frieden and Dr. Fauci, as well as the other witnesses here today, can help us understand the short term risks and long term risks of this disease. This Committee’s hearings should be aimed at understanding the immediate needs of our public health system, as well as applying lessons learned to prevent future outbreaks from reaching the magnitude of the current epidemic.

According to the World Health Organization, the death rate in the Ebola outbreak has risen to 70 percent, and there could be up to 10,000 new cases a week by December. The death toll is now over 4,000 people, nearly all of them in West Africa, out of a total of 8,400 cases. Unfortunately, these statistics may significantly underestimate the actual number of cases, which many believe is several times higher.

The Centers for Disease Control and Prevention (CDC) and other federal and local public health officials appear to be taking all of the appropriate steps to stop the disease and prevent its spread in our country. Still, there are many questions about the cases in Dallas and how the health workers treating an infected patient from Liberia became infected themselves.

Meanwhile, it’s becoming increasingly clear that the global community waited too long to respond, and even now I question whether enough is being done by other countries. This is not only a United States problem. This is a global problem that deserves a global response. Specifically, I remain increasingly concerned that the collapsing public health infrastructure in the West African countries not only has so

far prevented them from successfully implementing methods to control the outbreak, but that routine medical problems are becoming deadly for thousands of West Africans.

But we must not look back – we need to look forward and understand whether our public health system is adequately prepared for Ebola cases or for other emerging public health issues. And what more must be done by the international community to fight this outbreak.

First and foremost, we need to have a serious discussion about resources and funding. The very agencies responsible for handling the crisis, the National Institute of Health (NIH) and the Center for Disease Control (CDC), have been starved of resources in the past four years. The CDC's role in addressing this crisis is to protect the public health—they control the spread of diseases and support our local public health systems. The NIH's role is in the discovery of new cures and treatments for diseases. Together, they represent our core public health infrastructure.

But unfortunately, the purchasing power of the NIH has been cut ten percent over the last 4 years. In fact, in a response to a question about the crisis, Dr. Francis Collins, the Director of NIH stated, "if we had not gone through our 10-year slide in research support, we probably would have had a vaccine in time for this [Ebola crisis] that would have gone through clinical trials and would have been ready."

The cuts to the CDC and HHS have been more severe. For example, since 2010, the Hospital Preparedness program has been cut by an astounding 44 percent, when adjusted for inflation. These agencies have been short-changed, and we must find ways to make them whole again.

Secondly, while treatments for infectious diseases and, in particular, Ebola are critical part of our response to the disease, their development, because the market for these treatments is small and sporadic, is entirely driven by government activity. I am pleased to hear that there are several therapies and vaccines at various stages of development. However, the path to effective treatments on a mass scale is unlikely in the near future.

Mr. Chairman, we should absolutely address these issues in a thorough and appropriate way. Yet we must be cognizant that our investigation be focused so to ensure that we are not unnecessarily diverting the time or resources of public health leaders at a critical time. I want to thank everyone for being here today. Thank you for your public service. We appreciate everything you and your staffs are doing to address this disease.

Finally, Mr. Chairman, we by no means should use this public health crisis as a scare tactic, or to use the response of the federal government as a political tool against this Administration. Too many Republicans in Washington have been quick to criticize the government's efforts. I'm confident we will hear assurances today that we are equipped to stop the spread of this disease here at home.

Thank you.

Representative Gene Green (TX-29)
Opening Statement
O&I Subcommittee: "Examining the US Public Health Response to the Ebola Outbreak"
October 16, 2014

Thank you for yielding.

The Ebola epidemic in West Africa is the worst in recorded history.

Since the outbreak came to the attention of the global community, we have seen an exponential rise in the number of cases and fatalities.

This is a growing situation that requires a swift and robust response from the global community.

This outbreak has cast a glaring light on the fragile and failing health systems in Africa, and revealed shortcomings in our public health infrastructure here at home.

Today, I am interested in better educating myself and the general public on what protocols have been updated since the first travel associated case was diagnosed in the U.S. and what protocols were in place when it happen.

It is important to gain clarity on where the CDC's authority begins and ends, and where regulatory and enforcement responsibilities lie with state and local institutions, and hospitals.

We must learn from what has happened and improve protocols, address education gaps, and give providers and physicians the tools they need.

Thank you and I look forward to hearing from our witnesses.

I yield back.

**THE COMMITTEE ON ENERGY AND COMMERCE****MEMORANDUM**

October 14, 2014

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing on “Examining the U.S. Public Health Response to the Ebola Outbreak”

The Subcommittee on Oversight and Investigations will hold a hearing on Thursday, October 16, 2014, at 12:00 p.m. in 2123 Rayburn House Office Building, entitled “Examining the U.S. Public Health Response to the Ebola Outbreak.” This hearing will focus on the role of U.S. public health agencies and their efforts to prevent the spread of Ebola within the U.S. The preparedness of United States ports, points of entry, healthcare facilities and other institutions to identify, diagnose, isolate, and treat Ebola patients in a safe and appropriate manner also will be evaluated.

I. WITNESSES

- Dr. Thomas R. Frieden, Director, Centers for Disease Control and Prevention;
- Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health;
- Dr. Luciana Borio, Assistant Commissioner, Counterterrorism Policy, U.S. Food and Drug Administration;
- Dr. Robin Robinson, Director, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services;
- Mr. John P. Wagner, Acting Assistant Commissioner, Office of Field Operations, U.S. Customs and Border Protection, U.S. Department of Homeland Security; and
- Dr. Daniel Varga, Chief Clinical Officer and Senior Vice President, Texas Health Resources.

II. BACKGROUND**A. About Ebola Virus Disease**

Ebola is a deadly disease caused by infection with an Ebola virus strain.¹ According to the Centers for Disease Control and Prevention (CDC), Ebola is not airborne and asymptomatic individuals are not contagious.² Ebola was first discovered in 1976,³ and there have been sporadic Ebola outbreaks in several African countries⁴

The average incubation period for Ebola is eight to ten days, but symptoms may appear anywhere from two to twenty-one days post-exposure.⁵ The nonspecific nature of Ebola symptoms makes diagnosing Ebola difficult, particularly when a person has been infected for just a few days.⁶ Ebola symptoms include fever, headache, muscle pain, weakness, diarrhea, vomiting, abdominal pain, and unexplained hemorrhaging.⁷ Ebola is spread through direct contact with blood or bodily fluids of an infected person, infected animals, and objects contaminated with the virus.⁸ Healthcare providers, family, and friends in close contact with Ebola patients are at the highest risk for infection, as they are most likely to come in contact with a patient's infected blood or bodily fluids.⁹

B. The 2014 Ebola Epidemic

The World Health Organization (WHO) announced on March 23, 2014, that forty-one people had contracted Ebola in Guinea — the apparent starting point of West Africa's first Ebola outbreak — and twenty-nine had died from the virus.¹⁰ WHO estimated that the outbreak likely began in December 2013;¹¹ the organization posited that detection was delayed due to poor disease surveillance and detection capacity.¹² By mid-August, Ebola had spread to Sierra Leone, Liberia, and Nigeria, infecting more than 2,000 people and killing more than half, according to reports.¹³

¹ CDC, Ebola (Ebola Virus Disease), About Ebola Hemorrhagic Fever, <http://www.cdc.gov/vhf/ebola/about.html>.

² Id.

³ CDC, Ebola (Ebola Virus Disease), About Ebola Hemorrhagic Fever, <http://www.cdc.gov/vhf/ebola/about.html>.

⁴ CDC, Ebola Hemorrhagic Fever, Risk of Exposure, www.cdc.gov/vhf/ebola/exposure/index.html.

⁵ CDC, Ebola Hemorrhagic Fever, Transmission, www.cdc.gov/vhf/ebola/transmission/index.html.

⁶ Id.

⁷ Id.

⁸ CDC, Ebola Hemorrhagic Fever: Transmission, www.cdc.gov/vhf/ebola/transmission/index.html.

⁹ Id.

¹⁰ WHO, Global Alert and Response, Ebola virus disease in Guinea, <http://www.afro.who.int/en/clusters-a-programmes/dpc/epidemic-a-pandemic-alert-and-response/outbreak-news/4063-ebola-hemorrhagic-fever-in-guinea.html>; CRS, The 2014 Ebola Outbreak: International and U.S. Responses (R43697). Current case counts are available at: <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html>.

¹¹ WHO, Global Alert and Response, Ground zero in Guinea: the outbreak smolders — undetected — for more than 3 months, <http://who.int/csr/disease/ebola/ebola-6-months/guinea/en/>.

¹² CDC, Ebola (Ebola Virus Disease), 2014 Ebola Outbreak in West Africa - Case Counts,

<http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html>.

¹³ Id.

The 2014 Ebola epidemic in West Africa is now the largest in recorded history. According to CDC, three countries in West Africa —Guinea, Liberia, and Sierra Leone — are experiencing widespread transmission.¹⁴ As of October 8, 2014, there were 8,011 total cases and 3,857 known deaths in these countries alone.¹⁵ The outbreak has not been contained and transmission rates are high in Guinea, Sierra Leone, and Liberia.¹⁶

1. United States Importation

On September 30, 2014, the CDC confirmed the first travel associated case of Ebola to be diagnosed in the United States.¹⁷ On October 12, 2014, the CDC announced that a healthcare worker who had been providing care for the first U.S. case also had tested positive for Ebola.¹⁸ Additionally, several individuals who contracted the disease in Africa have been transported into the United States and Europe for treatment.¹⁹

2. Treatment Options

There is no FDA-approved vaccine or therapy available for Ebola, but numerous experimental products have been and are under development.²⁰ ZMapp, for instance, is an experimental treatment being developed for use in Ebola-infected individuals.²¹ At least two American missionaries who contracted the disease while working in Liberia were given ZMapp and have since recovered. Other experimental products, such as TKM-Ebola and Brincidofovir, have also been used to treat Ebola patients in the United States.²²

Urgently needed, but not-yet approved drugs can be made available to the public in some circumstances. For instance, the FDA can authorize access to potentially promising products through various mechanisms such as an Emergency Investigational New Drug (EIND) application.²³ Practical limitations, such as drug availability and manufacturing capacity, may limit access to experimental treatments.²⁴

¹⁴ CDC, Ebola (Ebola Virus Disease), First Imported Case of Ebola Diagnosed in the United States: <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html>.

¹⁵ CDC, Ebola (Ebola Virus Disease), 2014 Ebola Outbreak in West Africa - Case Counts, <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html>.

¹⁶ *Id.*

¹⁷ CDC, Ebola (Ebola Virus Disease), Cases of Ebola Diagnosed in the United States, <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html>.

¹⁸ CDC, Media Statement, Texas Reports Positive Test for Ebola in Health Care Worker, October, 12, 2014, <http://www.cdc.gov/media/releases/2014/s1012-texas-health-care-worker.html>.

¹⁹ *Id.*

²⁰ CDC, Ebola Hemorrhagic Fever, Questions and Answers on Experimental Treatments and Vaccines for Ebola, <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/qa-experimental-treatments.html>.

²¹ *Id.*

²² See Patterson Clark, Experimental Drugs Used to Treat Ebola, The Washington Post, October 7, 2014, <http://apps.washingtonpost.com/g/page/national/experimental-drugs-used-to-treat-ebola/1361/>.

²³ Public Health Emergency, Ebola Experimental Treatments & Vaccines, <http://www.phe.gov/Preparedness/mcm/Pages/ebola-factsheet.aspx>.

²⁴ Publicly and in private meetings with Committee staff, FDA has referenced these and other practical limitations to explain limited access to various Ebola drugs. See, e.g., FDA, Emergency Preparedness and Response, 2014 Outbreak in West Africa,

CDC emphasizes that supportive therapy (which includes balancing fluids and electrolytes, maintaining oxygen status and blood pressure, and treating for any complicating infections) remains the standard treatment for Ebola.²⁵ If utilized early, these basic interventions can significantly improve chances of survival.²⁶

C. U.S. Response to the Ebola Epidemic

In August 2014, (U.S. Agency for International Development (USAID) activated a Disaster Assistance Response Team (DART) to assess and identify priority needs and coordinate key areas of the U.S. response to the West Africa Ebola outbreak, including planning, operations, and logistics.²⁷ Under the DART structure, the U.S. Department of State is leading diplomatic engagements; USAID is coordinating U.S. responses, as well as providing financial and material support; CDC is leading public health and medical response activities; and the U.S. Department of Defense (DOD) is providing logistical and operational support.²⁸ The U.S. Public Health Service (PHS) will staff a DOD-built hospital for health workers, which is currently under construction.

As of October 6, 2014, the U.S. government had committed over \$350 million towards efforts to combat the outbreak in West Africa, more than \$111 million of which took the form of humanitarian aid.²⁹

The sections below provide further detail about the involvement and relevant authorities of key agencies involved in the public health response to Ebola. The following information was relayed to Committee staff during an extensive series of briefings and is now largely reflected in public information disseminated by CDC and other Federal agencies involved in response efforts.³⁰

1. U.S. Centers for Disease Control and Prevention

In March 2014, CDC teams traveled to West Africa to help the Health Ministries of Guinea and Liberia characterize and control the outbreak by collecting case reports, interviewing

<http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/ucm410308.htm>; also see Medscape, FDA Expert Interview, Responding to the Ebola Outbreak: The View from FDA, August 20, 2014, <http://www.medscape.com/viewarticle/830142>.

²⁵ CDC officials have made this point repeatedly in meetings with Committee staff, congressional teleconferences and public statements. See, e.g., CDC, Ebola Hemorrhagic Fever, Questions and Answers on Experimental Treatments and Vaccines for Ebola, <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/qa-experimental-treatments.html>.

²⁶ Id.

²⁷ USAID, Ebola, <http://www.usaid.gov/ebola>.

²⁸ Id.

²⁹ The White House, Office of the Press Secretary, FACT SHEET: The U.S. Response to the Ebola Epidemic in West Africa, <http://www.whitehouse.gov/the-press-office/2014/10/06/fact-sheet-us-response-ebola-epidemic-west-africa>.

³⁰ Committee staff has been carefully monitoring the Ebola outbreak since July 2014. Staff has been in frequent contact with various groups and agencies involved in the response in order to understand issues related to international and domestic preparedness and response.

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patients and family members, coordinating contact tracing, and consolidating data into centralized databases.³¹ Initial efforts in the region seemed to slow the outbreak for a time, but new cases arose.³² CDC has since deployed several teams to West Africa to help coordinate the response at the national level, assist with database management, and deliver health education.³³

Although CDC is not providing direct care to Ebola patients, the agency has approximately 150 personnel on the ground in West Africa and hundreds of personnel are providing around-the-clock logistics, staffing, communication, analytics, management, and other support functions from the CDC Emergency Operations Center in Atlanta.³⁴ CDC is assisting with exit screenings and communication efforts in West Africa to prevent sick travelers from boarding planes, and has issued guidance for airline flight crews, cleaning personnel, cargo personnel, colleges, universities, and students regarding travel to the region.³⁵ CDC also developed recommendations for humanitarian aid workers traveling Guinea, Liberia, Sierra Leone, and Nigeria, including steps to take before departure, during travel, and upon return to the U.S.³⁶

CDC has been working with U.S. Customs and Border Protection (CBP) and other partners at U.S. ports of entry to use routine processes to identify travelers with signs of infectious disease.³⁷ CDC is beginning to implement a new layer of entry screenings this week at five U.S. airports, which receive approximately 94% of travelers from Guinea, Liberia, and Sierra Leone.³⁸ As part of this new process, CDC will be responsible for training CBP officers, conducting enhanced passenger screenings, investigating any exposed travelers, notifying appropriate public health officials and working with airlines, Federal partners, and State, and local health departments to take appropriate public health action.³⁹ Related CDC authorities — such as a public health “Do Not Board” list, foreign airport screening authority (to identify travelers with communicable disease and alert local authorities), and the authority to impose isolation and quarantine measures — may help to prevent the spread of infectious diseases.⁴⁰

CDC is also responsible for preparing both U.S. healthcare facilities and emergency medical service systems to safely manage patients with suspected Ebola.⁴¹ CDC is in charge of enhancing domestic surveillance and laboratory testing capacity, and developing guidance and

³¹ CRS, *The 2014 Ebola Outbreak: International and U.S. Responses* (R43697).

³² *Id.*

³³ *Id.*

³⁴ CDC Director Tom Frieden, Press Briefing, Update on Dallas Ebola Response, October 13, 2014 (12:00 PM EST); The White House, FACT SHEET: US Response to the Ebola Epidemic in West Africa, September 16, 2014, <http://www.whitehouse.gov/the-press-office/2014/09/16/fact-sheet-us-response-ebola-epidemic-west-africa>.

³⁵ *Id.*

³⁶ *Id.*

³⁷ CDC, Press Release, Enhanced Ebola Screening to Start at Five U.S. Airports and New Tracking Program for all People Entering U.S. from Ebola-affected Countries (October, 8, 2014).

³⁸ CDC, Ebola Hemorrhagic Fever, Outbreaks, <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/index.html>.

³⁹ *Id.*

⁴⁰ CRS, Legal Sidebar, *The Ebola Outbreak: Select Legal Issues* (posted October 6, 2014, 3:33 p.m. by Jared P. Cole).

⁴¹ *Id.* CDC guidance and recommendations for U.S. healthcare workers and settings is available at: <http://www.cdc.gov/vhf/ebola/hcp/index.html>.

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tools for health departments to conduct public health investigations and improve communications and recommendations for healthcare infection control.⁴² The agency has developed guidance to provide public health authorities and other local, State, and Federal partners with a framework for evaluating exposure levels and initiating appropriate public health actions, based on exposure level and clinical assessment.⁴³

2. U.S. National Institutes of Health (& Biomedical Advanced Research and Development Authority)

The National Institutes of Health (NIH) is developing an investigational Ebola vaccine and supporting efforts to develop additional Ebola antivirals and therapeutics candidates.⁴⁴ Among other things, NIH is working to evaluate the safety and efficacy in healthy adults of an experimental vaccine, which it co-developed with GlaxoSmithKline, through trials at the NIH Clinical Center in Bethesda, Maryland.⁴⁵

Although the Defense Threat Reduction Agency (DTRA) within DOD and the National Institute of Allergy and Infectious Diseases (NIAID) within NIH supported initial work on Zmapp, HHS announced on September 2, 2014, that Biomedical Advanced Research and Development Authority (BARDA) will provide funding, subject matter expertise, and technical support for manufacturing, regulatory, and nonclinical activities.⁴⁶ The 18-month, \$24.9 million contract with Mapp Biopharmaceutical Inc. aims to accelerate the development of Zmapp.⁴⁷ BARDA plans to work closely with those agencies and the company to optimize and accelerate the manufacturing for trials.⁴⁸ The Assistant Secretary for Preparedness and Response (ASPR) may extend the contract up to \$42.3 million.⁴⁹

3. U.S. Food and Drug Administration

There are no approved drugs on the market to treat or prevent Ebola, and many of the investigational drugs that might be used are in short supply.⁵⁰ This dynamic makes FDA's

⁴² CRS, Legal Sidebar, The Ebola Outbreak: Select Legal Issues (posted October 6, 2014, 3:33 p.m. by Jared P. Cole).

⁴³ Id.; see CDC, Ebola (Ebola Virus Disease), Information for Healthcare Workers and Settings, <http://www.cdc.gov/vhf/ebola/hcp/index.html> (including guidance, recommendations, checklists and other information). For additional information about what CDC is doing, see: <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/what-cdc-is-doing.html>.

⁴⁴ See NIH, News & Events, NIH to Launch Human Safety Study of Ebola Vaccine Candidate, August 28, 2014, <http://www.nih.gov/news/health/aug2014/niaid-28.htm>.

⁴⁵ HHS, Public Health Emergency, Medical Countermeasures: Ebola Experimental Treatments and Vaccines, September 3, 2014, <http://www.phe.gov/Preparedness/mcm/Pages/ebola-factsheet.aspx>.

⁴⁶ Id.; CDC, Ebola Hemorrhagic Fever, Treatment, <http://www.cdc.gov/vhf/ebola/treatment/index.html>.

⁴⁷ Id.; HHS, News, HHS Contracts with Mapp Biopharmaceutical to Develop Ebola Drug, September 2, 2014, <http://www.hhs.gov/news/press/2014pres/09/20140902b.html>.

⁴⁸ Luciana Borio, FDA Works to Mitigate West Africa Ebola Outbreak, FDA Voice, August 22, 2014, <http://blogs.fda.gov/fdavoices/index.php/2014/08/fda-works-to-mitigate-the-west-africa-ebola-outbreak/>.

⁴⁹ Id.

⁵⁰ Id.

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authorities and flexible regulatory framework – which include mechanisms to allow access to available investigational products when appropriate – extremely important.⁵¹

Under certain circumstances, clinicians may request the use of EIND application⁵² to help their patient access investigational products outside of clinical trials.⁵³ Per FDA's Emergency Use Authorization (EUA) authority,⁵⁴ when there are no adequate, approved, and available alternative, the agency can allow use of an unapproved medical products (or unapproved use of an approved product) for a larger population during emergencies.⁵⁵ In fact, FDA authorized use of a DOD-developed Ebola diagnostic test under an EUA to facilitate Ebola virus detection in DOD-designated laboratories.⁵⁶

FDA has reported to Committee staff that it is working closely with other U.S. government agencies that support medical product development, medical product sponsors, WHO, and international regulatory counterparts to speed product development and facilitate investigational product access where appropriate.⁵⁷

4. U.S. Customs and Border Protection

Recently, it was announced that the CDC and U.S. Customs and Border Protection (CBP) will add new layers of entry screening at five U.S. airports that receive approximately 94% of travelers from Guinea, Liberia, and Sierra Leone.⁵⁸ The new measures begin with CBP officers reviewing travelers' passports.⁵⁹ After passport review, travelers from Guinea, Liberia, and

⁵¹ Id.

⁵² 21 CFR 56.102(d). The emergency use provision in 21 CFR 56.104(c) (FDA regulations) is an exemption from prior review and approval by the Institutional Review Boards. FDA, Guidance, Emergency Use of an Investigational Drug or Biologic – Information Sheet, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm>.

⁵³ Id; also see, FDA, Emergency Investigational New Drug (EIND) Applications for Antiviral Products, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm090039.htm>.

⁵⁴ 21 U.S.C. § 360bbb-3, available at: <http://www.gpo.gov/fdsys/granule/USCODE-2010-title21/USCODE-2010-title21-chap9-subchapV-partE-sec360bbb-3/content-detail.html>.

⁵⁵ See FDA, Emergency Preparedness and Response, Emergency Use Authorization, <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm>.

⁵⁶ HHS, Notice, Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus, 79 FR 47141, August 12, 2014, available at: <http://www.gpo.gov/fdsys/pkg/FR-2014-08-12/pdf/2014-19026.pdf>; also see DOD, News, DOD Medical Countermeasures Find Use in Ebola Outbreak, October 8, 2014, <http://www.defense.gov/news/newsarticle.aspx?id=123371>.

⁵⁷ Committee Staff Briefing by FDA and NIH on Ebola-Related Issues, Ford House Office Building, October 2, 2014. Also see Luciana Borio, FDA Works to Mitigate West Africa Ebola Outbreak, FDA Voice, August 22, 2014, <http://blogs.fda.gov/fdavoices/index.php/2014/08/fda-works-to-mitigate-the-west-africa-ebola-outbreak/>.

⁵⁸ CDC, Enhanced Ebola Screenings to Start at Five U.S. Airports and New Tracking Program for all People Entering U.S. from Ebola-affected Countries, October 8, 2014, http://www.cdc.gov/media/releases/2014/p1008_ebola_screenings.html.

⁵⁹ See DHS, News, Fact Sheet: Screening of Travelers at Airports, October 8, 2014, <http://www.dhs.gov/news/2014/10/08/fact-sheet-screening-travelers-airports>; also see, CDC, Press Release, Enhanced Ebola Screening to Start at Five U.S. Airports and New Tracking Program for All People Entering U.S. from Ebola-affected Countries, October 8, 2014, <http://www.cdc.gov/media/releases/2014/p1008-ebola-screening.html>.

Sierra Leone will be escorted by CBP to an area of the airport that is set aside for screening.⁶⁰ Trained CBP staff will observe them for signs of illness, ask a series of health and exposure questions and provide health information and reminders to self-monitor for Ebola symptoms.⁶¹ Medical staff trained by the U.S. Coast Guard will then take travelers' temperature with a non-contact thermometer. If the travelers have fever or other symptoms, or the health questionnaire reveals possible Ebola exposure, they will be evaluated by a CDC quarantine station public health officer.⁶² The public health officer will again take a temperature reading and make a public health assessment.⁶³

Ill travelers may be transferred to a health care facility for further evaluation, examination, testing, and treatment.⁶⁴ Travelers without symptoms but with a possible Ebola exposure will be linked with a health department for active monitoring for 21 days.⁶⁵ Regardless of symptoms or exposure, all travelers from Guinea, Sierra Leone, and Liberia will be required to complete a daily temperature log.⁶⁶

D. Dallas Ebola Cases

Our investigation of the facts surrounding of the first two Ebola diagnoses in the U.S. — both of which involve patients at Texas Health Presbyterian Hospital of Dallas (Texas Presbyterian) located in Texas — is ongoing. Set forth below is a summary of the facts and circumstances of the Texas Ebola cases.

1. Index Patient⁶⁷

On September 30, 2014, CDC confirmed that a person, later identified as Thomas Eric Duncan, departed from Liberia on September 19, 2014, on an indirect flight to Dallas, Texas, via Brussels and Dulles. Duncan arrived in the United States on September 20, 2014.

Duncan sought treatment at Texas Presbyterian on the evening of September 25, 2014. According to the hospital, he was sent home in the early morning on September 26, 2014, with antibiotics after "a four-hour evaluation and numerous tests."⁶⁸ According to medical records, Duncan had a fever of 103°F and complained of abdominal pain, dizziness, headache, and decreased urination.⁶⁹

⁶⁰ Id.

⁶¹ Id.

⁶² Id.

⁶³ Id.

⁶⁴ Id.

⁶⁵ Id.

⁶⁶ Id.

⁶⁷ Unless otherwise noted, information in this section is from CDC or the Texas Department of State Health Services.

⁶⁸ Texas Health Resources, Ebola Update, Oct 9, 3:01 CDT, Statement Regarding Mr. Thomas Eric Duncan, <http://www.texashealth.org/blank.cfm?print=yes&action=detail&id=1629&ref=1879>.

⁶⁹ Emily Schmall et al., Ebola Patient's temperature spiked to 103 degrees, AP, October 10, 2014, http://hosted2.ap.org/APDEFAULT/3d281c11a96b4ad082fe88aa0db04305/Article_2014-10-10-US-Ebola-Medical-

Duncan returned to Texas Presbyterian via ambulance on September 28, 2014.⁷⁰ He was extremely ill at the time of transport to the hospital, with symptoms now including severe vomiting and diarrhea. Hospital officials testified that he was kept in the emergency department until a contact and droplet isolation area was established in the intensive care unit, at which time he was admitted to the hospital and put into isolation.⁷¹

The hospital notified Dallas County Health and Human Services (DCHHS) on Monday, September 29, 2014, whose personnel arrived on site shortly thereafter.⁷² CDC officials were notified later on September 29, but did not arrive at the hospital campus until October 1, 2014.⁷³ CDC and Texas Department of State Health Services (DSHS) laboratory testing confirmed the diagnosis of Ebola on Tuesday, September 30, 2014.⁷⁴

DCHHS states it is the lead agency charged with the ongoing contact investigation to determine who may have been exposed to Duncan while he was contagious.⁷⁵ The investigation has, thus far, identified forty-eight individuals out of a broader group with risk of exposure. Ten individuals are considered to be at high risk. These forty-eight contacts are being monitored for twenty-one days from their time of exposure.

Four close family members of the patient, believed to be amongst the “high risk” contacts, were asked to stay home at least until October 19, when the 21-day incubation period for the virus would have lapsed. After failing to comply with this request, they were formally ordered to remain confined to their apartment. The family was forced to remain in the apartment for days, despite the fact that it was contaminated with Duncan’s waste product and bodily fluids. The family has since been moved to an undisclosed location.

Duncan received an experimental drug during the course of his treatment. He was also intubated and on dialysis for an unknown period of time.

2. Infected Healthcare Worker⁷⁶

On October 11, a healthcare worker who cared for Duncan at Texas Presbyterian Hospital reported having a low grade fever overnight and referred for testing.⁷⁷ The Texas Department of

[Records/id-e6b6ef8e892548298ea4ecba7c493f85](#); also see Amy Ellis Nutt, *In Dallas, a focus on how hospital treated victim*, The Washington Post, A4, October 11, 2014.

⁷⁰ Testimony of Dr. Gary Weinstein, Chief of Pulmonology and Critical Care Medicine for Texas Health Presbyterian Hospital Dallas, Senate Health and Human Services Committee (October 7, 2014).

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Texas Department of State Health Services, *Ebola Case in Texas: Overview*, October 5, 2014.

⁷⁶ Unless otherwise noted, information in this section is from CDC or Texas Department of State Health Services. See generally, CDC, *Ebola (Ebola Hemorrhagic Fever), Cases of Ebola Diagnosed in the United States*, <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html>.

⁷⁷ CDC, *Media Statement, Texas Reports Positive Test for Ebola in a Health Care Worker*, October 12, 2014, <http://www.cdc.gov/media/releases/2014/s1012-texas-health-care-worker.html>.

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State Health Services' laboratory returned a preliminary test that was positive for Ebola at approximately 9:30 p.m. on October 11. CDC testing performed on October 12 confirmed this result. This patient was isolated and interviewed by CDC to identify any contacts or potential community exposures. To date, CDC officials have identified one close contact, who is being monitored for fever and other symptoms.

CDC Director Tom Frieden has attributed the healthcare worker's infection to a "breach in protocol," but says officials do not know yet what protocol was breached.⁷⁸ A CDC investigation is ongoing.

III. ISSUES

The following issues will be examined at the hearing:

- What have we learned from the two Ebola cases in Dallas, and how can we use this information to improve protocols, training, guidance, hospital preparedness, patient care, and safety going forward, both in the U.S. and in West Africa?
- The global health community has not been able to control the ongoing Ebola outbreak. Why has this outbreak been so difficult to control, and is the current containment strategy appropriate?
- Is the United States adequately prepared to help contain the outbreak in West Africa, and what impact will these efforts have on American health systems?
- Screening procedures did not prevent an individual infected with Ebola from entering the United States on September 20, 2014. What were these procedures, and why did they fail to identify Mr. Duncan? Are the additional screening procedures announced this month adequate to prevent another importation?
- Are America's hospitals and health care workers adequately prepared for Ebola patients? What adjustments can be made to protocols, training, and guidance to enhance preparedness and safety now and in the future?
- What treatment options and diagnostics are available for Ebola, and what can be done to speed their development?
- What resources will the CDC and other impacted government agencies require when current funding expires?

⁷⁸ Marshall Cohen, Face in the News: CDC under fire as Ebola spreads, CBS News, October 13, 2014, <http://www.cbsnews.com/news/face-in-the-news-cdc-under-fire-as-ebola-spreads/>; also see Lisa Maria and Terry Wade, U.S. needs to rethink Ebola infection controls CDC chief says, Reuters, October 13, 2014, <http://uk.reuters.com/article/2014/10/13/us-health-ebola-idUKKCN0J21M020141013>.

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IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Emily Newman, Alan Slobodin, Sean Hayes, or Karen Christian at (202) 225-2927.

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November 10, 2014

Dr. Thomas R. Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Frieden:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, October 16, 2014, to testify at the hearing entitled "Examining the U.S. Public Health Response to the Ebola Outbreak."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Monday, November 24, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

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DOL/OSHA COMMENTS APPEAR BELOW

Dr. Thomas R. Frieden, M.D., M.P.H.

Director, Centers for Disease Control and Prevention

"Examining the Public Health Response to the Ebola Outbreak"

Before the House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

October 16, 2014

Attachment 1- Additional Questions for the Record

The Honorable Michael C. Burgess

1. We have learned a great deal about the difficulty of cleaning a room that has been utilized by an Ebola patient. What are the current standards for sterilizing a room in a health care or hospital facility?
 - a. When were these regulations last updated?
 - b. Will additional steps be taken to sterilize a room with an Ebola patient?
 - c. Will you be updating these guidelines to better reflect the realities of an Ebola case?

Response: CDC does not have regulatory authority over hospitals. CDC released guidance titled, "Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus" to provide information and recommendations to health care facilities. The guidance was last updated on October 3, 2014. Guidance for U.S. hospitals on environmental cleaning and disinfection was first released on August 1, 2014 in guidance *Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals*. On August 20, 2014, based on questions from facilities and external groups, CDC released expanded guidance on environmental infection cleaning and disinfection that provided additional detail to guide implementation titled, *Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus*. This guidance will be revised as additional scientific information about methods needed to clean and disinfect a hospital room that has been utilized by an Ebola patient becomes available.

Ebola viruses are transmitted through direct contact with blood or body fluids/substances (e.g., urine, feces, vomit) of an infected person with symptoms or through exposure to objects (such as needles) that have been contaminated with infected blood or body fluids. The role of the environment in transmission has not been clearly established. Limited laboratory studies under favorable conditions indicate that Ebola virus can remain viable on solid surfaces, with concentrations falling slowly over several days. However, in a study to assess contamination of the patient care environment during an outbreak, virus

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was not detected in any of 31 samples collected from sites that were not visibly bloody. Virus was detected on a blood-stained glove and bloody intravenous insertion site. There is insufficient epidemiologic evidence of Ebola virus transmission via the environment to strongly implicate surfaces that are not visibly soiled or fomites that could become contaminated during patient care (e.g., bed rails, door knobs, laundry) as sources of environmental exposure.

Nonetheless, given the apparent low infectious dose, potential of a high concentration of virus in the blood of ill patients, and disease severity, higher levels of precaution are currently recommended for cleaning and disinfection of potentially contaminated surfaces in the patient care environment.

As part of the care of patients who are persons under investigation, or confirmed to have Ebola virus infections, it is currently recommended that hospitals:

- Be sure environmental services staff wear and are trained in the use of recommended personal protective equipment (PPE) to protect against direct skin and mucous membrane exposure of cleaning chemicals, contamination, and splashes during environmental cleaning and disinfection activities. If reusable heavy-duty gloves are used for cleaning and disinfecting, they should be disinfected immediately after use and kept in the room or anteroom. Be sure staff are supervised in the proper use of personal protective equipment including safe removal to prevent contaminating themselves or others in the process, and that contaminated equipment is disposed of appropriately.
- Use a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) to disinfect environmental surfaces in rooms of patients with suspected or confirmed Ebola virus infection. Although there are no products with specific label claims against the Ebola virus, enveloped viruses such as Ebola are very susceptible to a broad range of hospital disinfectants used to disinfect hard, non-porous surfaces. In contrast, non-enveloped viruses are more resistant to disinfectants. As an extreme precaution, disinfectants with a much higher potency than what is actually required for an enveloped virus are being recommended at this time.
- Avoid contamination of reusable porous surfaces that cannot be made single use. Use only a mattress and pillow with plastic or other covering that fluids cannot get through. Do not place patients with suspected or confirmed Ebola virus infection in carpeted rooms and remove all upholstered furniture and decorative curtains from patient rooms before use.
- Maintain constant cleaning and disinfection of the PPE doffing area. Routine cleaning of the PPE doffing area should be performed at least once per day and after each doffing of grossly contaminated PPE. Cleaning should be performed by a health care worker (HCW) wearing clean PPE. An EPA-registered hospital disinfectant with label claims against non-enveloped viruses (e.g., norovirus, rotavirus, adenovirus, poliovirus) should be used for disinfection. When cleaning and disinfection are complete, the HCW should carefully doff PPE and perform hand hygiene.
- To reduce opportunities for exposure of staff to potentially contaminated textiles (cloth

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products), linens, non-fluid-impermeable pillows or mattresses, and textile privacy curtains should be discarded after use in accordance with state and local waste management regulations, or packaged and transported in accordance with Department of Transportation/Pipeline and Hazardous Materials Safety Administration's Hazardous Materials Regulations (49 CFR 100-185) and the Department of Labor (DOL)/Occupational Safety and Health Administration (OSHA)'s Bloodborne Pathogens standard (29 CFR 1910.1030).

For cleaning and disinfecting the room of a patient with suspected or confirmed Ebola virus infection, CDC recommends daily cleaning and disinfection of hard, non-porous surfaces (e.g., high-touch surfaces such as bed rails and over bed tables, housekeeping surfaces such as floors and counters). Before disinfecting a surface, cleaning should be performed. In contrast to disinfection where products with specific claims are used, any cleaning product can be used for cleaning tasks. Use cleaning and disinfecting products according to label instructions. Check the disinfectant's label for specific instructions for inactivation of any of the non-enveloped viruses (e.g., norovirus, rotavirus, adenovirus, poliovirus) and follow label instructions for use of the product that are specific for inactivation of these non-enveloped viruses. Use disposable cleaning cloths, mop cloths, and wipes and dispose of these in leak-proof bags. Use a rigid waste receptacle designed to support the bag to help minimize contamination of the bag's exterior.

Additional guidance on cleaning and decontamination can be found on the CDC website and is updated as new information or recommendations emerge.

- d. Some Veterans Affairs facilities and other hospitals are currently using pulsing xenon UV light to disinfect rooms--are any of you familiar with this technology?**
- i. If yes, do you believe this may have a higher success rate in disinfecting rooms and preventing further infection?**
 - ii. Do you believe that this technology could be useful if deployed more widely in the United States?**
 - iii. What about in combating the outbreak in Africa--would it be possible to utilize this technology to fight the outbreak?**
 - iv. Will you please have someone on your staff review the regulations on sterilizing rooms in regards to this method?**

Response: CDC is aware of this technology and has had direct demonstrations from several manufacturers.

CDC is aware of these newer technologies that are being investigated for room decontamination (e.g., UV light, ozone mists, vaporized hydrogen peroxide). CDC is staying abreast of this evolving clinical research that will clarify effectiveness and reliability, and limitations of these new technologies, for making future recommendations. UV devices may be part of an integrated approach to use in the terminal cleaning of rooms in conjunction with physical cleaning. Existing UV technologies still require that organic material be cleaned from surfaces to ensure optimal effectiveness. At this time there are insufficient data to inform national or international recommendations for these technologies. CDC continues to consider several automated and non-contact approaches to environmental decontamination, including UV devices.

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

Response: CDC is focused on reducing the risk of transmission for all potential infections and to interrupt transmission at the sources of the outbreak in West Africa. CDC issued guidance titled, "Ebola-Associated Waste Management" to provide key information about the safe handling, transport, and disposal of waste generated from the care of persons diagnosed with or suspected of having Ebola Virus Disease. CDC is also evaluating the need to provide additional guidance for these groups.

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

Response: State and local health agencies have authority over public health quarantine and isolation issues. In the days following the case in Dallas, CDC developed Interim Guidance for the U.S. Residence Decontamination for Ebola Virus Disease (Ebola) and Removal of Contaminated Waste to provide recommendations for public health, state and/or local authorities who may have to decontaminate or arrange for a contract company to decontaminate a U.S. residence and remove contaminated waste because someone living there was confirmed to have Ebola. These recommendations list effective disinfectant products, procedures, and guidance for contract companies to follow in dealing with contaminated wastes, and guidance on how to use personal protective equipment (PPE).

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

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

Response: CDC is working to establish material transfer agreements (MTAs) with 7 companies for the production of improved Ebola diagnostic tests. The MTA enables the exchange of proprietary material for research purposes and dictates the terms of the exchange. The goal is to collaborate on the development of assays which can be used to test for the presence of Ebola in multiple types of specimens, including saliva, whole blood, and blood spots. CDC will test the prototypes compared to CDC's validated assays. CDC will analyze the effectiveness of various measures of functionality, including the sensitivity, specificity and end-point dilution curves of the prototypes. If a prototype is shown to have greater effectiveness and/or ease of use than current diagnostic tests, CDC plans to test the most promising candidate/s in West African pilot studies. CDC is eager to work with any company having promising diagnostic test prototypes.

- 5. Can you provide a timeline that describes the variability of the PPE being used at Texas Health Dallas in the time period from when Mr. Duncan was admitted, to his death? Please provide the rational (sic) or impetus behind these changes.**

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Response: Since the time of the first patient with Ebola in the United States, CDC expanded previous infection control guidance for health care workers caring for patients with Ebola, to ensure there is no ambiguity and provide an increased margin of safety. We may never know exactly how two health care workers became infected. The Dallas experience showed that taking care of a patient with Ebola is challenging.

The revised guidance focuses on improving the consistency with which personal protective equipment (PPE) is used and offers detailed step by step instructions for how to put the equipment on and take it off safely. Recent experience from safely treating patients with Ebola at Emory University Hospital, Nebraska Medical Center and National Institutes of Health Clinical Center are reflected in the guidance. The enhanced guidance is centered on three principles:

- All health care workers undergo rigorous training and are practiced and competent with PPE, including putting it on and taking it off in a systematic manner
- PPE covers the wearer completely and prevents unrecognized self-contamination
- All workers are supervised by a trained monitor who watches each worker putting PPE on and taking it off.

All patients treated at Emory University Hospital, Nebraska Medical Center and the National Institutes of Health Clinical Center have followed similar principles. None of the workers at these facilities have contracted the illness.

- 6. Where is the PPE that our hospitals are using being manufactured? Are they American companies or companies from overseas? Please outline to the best of your ability these sources of PPE.**

Response: The types of PPE used in U.S. hospitals are manufactured in various locations across the world, including the United States. CDC's understanding is that product manufacturing varies greatly depending on the product and the manufacturer. Products may range from 100% production in one country, to partial manufacturing in multiple countries. For example, three components of a respirator produced in one country could be fully assembled in another. The selection of specific PPE brands and models for hospital procurement is made at the discretion of the individual hospital to meet facility requirements and preferences. Employers, including hospitals, are required under the Occupational Safety and Health Act of 1970 and OSHA standards promulgated under authority of the act to select and provide PPE for workers to protect them from recognized occupational safety and health hazards. While CDC does not recommend or endorse specific brands or manufacturers of PPE broadly, CDC through its National Institute for Occupational Safety and Health (NIOSH), certifies respirators recommended in the guidance (i.e., NIOSH certified powered air purifying respirators (PAPRs) or NIOSH-certified N95 filtering facepiece respirators), and maintains a list of those meeting the preferred Ebola configuration. NIOSH worked closely with OSHA both to develop recommendations for PPE ensembles, including respirators, and ensure recommendations met the requirements of OSHA standards.

- 7. We realize the focus is on Ebola at present, and rightly so. But CDC has other public health**

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responsibilities, and as we enter the flu season I am curious how CDC is managing these other responsibilities while meeting the considerable demands imposed by the Ebola response.

Response: CDC is actively prioritizing the work allocation to critical, non-Ebola related public health issues in the midst of an evolving situation. Efforts on non-critical activities have been shifted to provide greater support to essential operations. Challenges exist around the sustainability of a large-scale response.

8. Why aren't other patients also cured with ZMapp not donating their plasma?

- a) Are they and is it not being publicized?
- b) If so, is this a result of patient privacy laws?

Response: Some survivors of Ebola virus disease in the U.S., including recipients of ZMapp, have donated convalescent plasma that has been used to treat other patients. Details have not been publicized due to privacy laws. Individually-identifiable information about patients with Ebola virus disease, as for all other patients, is confidential. In addition, it is not clear whether ZMapp (and/or other treatment received) affected either the survival of the plasma donors or the potential value of the donated plasma as treatment for others.

9. Is there a way to encourage donation so that if future cases arise we can have a small reserve of convalescent serum to use for infected individuals?

Response: In addition to donor plasma discussed in the previous answer, further donations are being encouraged. Several patients who have survived Ebola virus disease in the United States are still recovering at home and are likely to donate their plasma in the months to come. However, it is unknown whether convalescent plasma treatment is beneficial. The only way to know is for controlled clinical trials to be conducted. Such studies are planned to be implemented in West Africa.

10. What is the reason for the transfusions being so successful? Is it because the blood or serum donated has both immune response created antibodies and the antibodies from ZMapp?

Response: There are no FDA-licensed or -approved vaccines or therapeutics available for prevention, post-exposure, or treatment for Ebola virus infection. Clinical management of EVD should focus on supportive care of complications. Several investigational drugs and convalescent plasma from recovered Ebola virus disease patients have been used to treat patients with EVD during the current outbreak, but no controlled clinical trials have been conducted to date. Therefore, there are no data on the safety, efficacy or effectiveness of any experimental drugs or convalescent plasma for treatment of patients with EVD. Since these investigational treatments are still at early stages of development and production, the availability of these products varies. This holds true for the experimental drug known as ZMapp. A recent scientific article published in the New England Journal of Medicine posits that survival of EVD patients likely was due to effective supportive clinical management with intravenous fluids and electrolyte

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replacement.

We do not know whether convalescent plasma treatment is successful or not. Convalescent plasma collected from survivors of Ebola virus disease is expected to contain antibodies to Ebola virus that may help to reduce the amount of Ebola virus in the blood of an infected patient when used as treatment. Seven patients with Ebola virus disease in the U.S. have received convalescent plasma, but they have also received other experimental treatments and excellent clinical care. Although only one of these EVD patients who received convalescent plasma died, it is impossible to know the benefit of convalescent plasma treatment in these patients without a controlled clinical trial. Two survivors who received ZMapp have donated plasma approximately 1-2 months after their hospital discharge for treatment of other EVD patients in the U.S. Although it is unknown whether their plasma contains any residual ZMapp antibodies, it is unlikely as such antibodies are expected to decay over several weeks. Controlled clinical trials in relevant settings including West Africa are needed to determine the benefit of convalescent plasma treatment for Ebola virus disease.

11. We understand the guidance and protocols for health professionals are shifting in light of the recent infections of two health care workers in Dallas. How, and how quickly, are the changes being communicated to local health care providers? Do the local providers have an opportunity to provide input and feedback or ask questions?

Response: CDC is actively working to bring updated recommendations and information to U.S. health care workers. We provide these through regular outreach via the website, industry calls and meetings, trainings, and social media communication. Opportunities for feedback and questions are provided. CDC efforts to reach health care workers in the United States include:

- Educating and answering questions from clinical partners. CDC has reached over 326,700 individuals through conference calls to provide training and updates on CDC guidance.
- Hosting live events to educate health care workers and others about infection control principles and demonstrate appropriate use of PPE.
 - NYC event on October 21st with over 5,400 people in-person, 53 media outlets, and at least 20,000 people on livestream in 10 countries. The event was co-hosted by the Partnership for Quality Care (PQC) and the 1199SEIU/Greater New York Hospital Association Healthcare Education Project.
 - Los Angeles Event on November 7th with over 1,000 people in-person, a dozen media outlets, and thousands of people on live stream in hundreds of health care facilities across the country. The event was co-hosted by Kaiser Permanente, the Coalition of Kaiser Permanente Unions, the Partnership for Quality Care, and United Nurses Associations of California/Union of Health Care Professionals, Service Employees International Union (SEIU) – United Healthcare Workers West, SEIU Local 721 and Los Angeles County Department of Health.
 - American Medical Association meeting on November 9th that was live streamed to thousands of individuals.
- Collaborating with online clinical communities (e.g., Medscape) to provide education and tools directly to health care workers. Medscape has also streamed CDC live events. Through

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Medscape training alone CDC has been able to reach 298,000 health care professional with online health care training resources.

- Contracting with Johns Hopkins University to create additional training videos for donning and doffing PPE guidance, including videos tailored to emergency departments (ED) and outpatient staff.
- Disseminating guidance through CDC's website and promoting it through CDC email distribution lists, plus additional partner outreach. For example, the PPE videos have been viewed over 225,000 times. Viewers logged more than 150,000 minutes (or 2500 hours) watching the videos
- Working with state and local health departments, public health partners, and professional organizations to improve and accelerate implementation of effective infection control measures for emergency departments and outpatient settings.

CDC is working to ensure that health care workers are receiving information about Ebola in a manner that raises their level of awareness.

12. What have you learned about failures of isolation and personnel protection from the experience at Texas Health Resources' Presbyterian hospital and what have you shared with other hospitals about how to avoid the same errors? Have you provided other hospitals with specific information about the failure of the procedures at THR?

Response: Enhanced guidance is based on the breadth of existing knowledge including patients who have been cared for at Texas Health Presbyterian Hospital, Emory University Hospital, NIH, and Nebraska Medical Center. CDC continues to work closely with hospitals and health care facilities to update guidance and recommendations, including expanding previous infection control guidance for health care workers caring for patients with Ebola to ensure there is no ambiguity and to better emphasize the importance of training, practice, competence, and observation of health care workers in correct donning and doffing of PPE selected by the facility.

CDC has formed Rapid Ebola Preparedness (REP) and Infection Control Assessment and Response (ICAR) teams that deploy to pre-identified facilities to work with local health officials and hospitals in assessing their readiness for caring for patients with Ebola. REP teams are composed of CDC experts in infection control, occupational health, and laboratory issues; other HHS personnel including National Hospital Preparedness Program Field Project Officers and other regional staff; federal and state OSHA staff; and external local experts. State health officials and candidate hospitals determine the hospitals in their state or region where patients suspected of having Ebola will be transported for treatment for the full course of illness. During the visit, the REP team identifies areas that pose challenges and provide technical assistance and support to gain readiness in the areas identified. While implementation and adherence to CDC recommendations lies with individual hospitals, a positive corollary of the intensive training and preparation at these facilities may be increased readiness for other disease outbreaks in the future.

In the event of a confirmed Ebola case, CDC will immediately deploy a CDC Ebola Response Team (CERT) to provide on the ground technical assistance and clinical support to the treatment hospital and the health care community.

13. Will the temperature screeners be maintaining the recommended distance barrier (3ft) for evaluation and if so, how will they use the infrared devices effectively?

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Response: Use of the noncontact thermometers correctly requires that the screener be briefly less than three feet from the person being screened. Screening staff are wearing personal protective equipment that protects their hands and mucous membranes.

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The Honorable Marsha Blackburn

1. Dr. Frieden, are you aware of a detection system called Canary made by Isomark?

It is my understanding that this test can detect infections up to two days before current practices. It is a non-invasive and inexpensive breath test. Preclinical and clinical work has demonstrated proof of concept. The company has been awarded a \$1.7 million from NIH and is launching a human subject study.

When you speak of looking at all options to stop the Ebola epidemic, is this one of the options that you have looked at?

Response: At this time, work on development of this technology is appropriately on investigating its efficacy. CDC would become engaged later in the process.

2. Dr. Frieden, are you aware of a kit called Film Array, produced by a company called BioFire, subsidiary of bioMerieux?

Response: It is my understanding that this kit is currently used by the military to screen for Ebola in Africa, as well as other respiratory and gastrointestinal illnesses with a 90-percent sensitivity.

3. When you speak of looking at all options to stop the Ebola epidemic, is this one of the options that you have looked at?

Response: CDC submitted a material transfer agreement (MTA) to work with BioFire, which is currently under review. The MTA enables the exchange of proprietary material for research purposes and dictates the terms of the exchange. CDC is planning to procure one of their instruments to establish sensitivity and specificity data to provide evidence for the potential effectiveness of their test in the field.

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The Honorable Morgan Griffith

1. **Dr. Frieden, we realize the focus is on Ebola at present, and rightly so. But CDC has other public health responsibilities, and as we enter the flu season and with enterovirus cases continuing to grow, I am curious how CDC is managing these other responsibilities while meeting the considerable demands imposed by the Ebola response.**

- a. **How strained are CDC's resources right now?**

Response: CDC received \$30 million to support Ebola response activities in the FY 2015 Continuing Resolution (CR). The CR funding was a stop-gap amount to keep CDC engaged in the first 11 weeks of FY 2015. The \$30 million will not provide the necessary public health support to contain the spread of the disease in West Africa or scale preparedness efforts here in the United States. CDC work needs to include the countries with active epidemics as well as those most at risk for imported cases that could become outbreaks. CDC also needs to ensure that Ebola and other emerging infectious disease outbreaks do not go undetected in the future.

CDC has undertaken the largest global response in the agency's history, with over 160 staff deployed in West Africa, and more than 1,000 staff involved in the Emergency Operations Center (EOC) to help coordinate technical assistance and control activities with partners. On August 6, CDC elevated the EOC to a Level 1 activation, its highest level, because of the significance of the outbreak. Hundreds of CDC staff members have provided logistics, staffing, communication, analytics, management, and other support functions for the response. 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.

The Administration's Emergency Request for Ebola funding included \$1.83 billion for CDC to fight Ebola on all fronts, with the goals of stopping the Ebola epidemic at its source; supporting immediate and decisive response to any domestic case; and preparing for & responding to disease threats around the world – to prevent the next Ebola or other emerging health threat and implement the Global Health Security Agenda.

- b. **Will the new Ebola SWAT teams and everything else you now have to activate detract from keeping track of enterovirus and other public health threats?**

Response: CDC is continuing our work in critical areas other than Ebola including enterovirus D68 (EV-D68). Every year, enteroviruses and rhinoviruses cause millions of respiratory illnesses in children. This year, EV-D68 has been the most common type of enterovirus identified, leading to increases in illnesses among children and affecting those with asthma most severely.

CDC continues to collect information from states and assess the situation to better understand EV-D68 and the illness caused by this virus and how widespread EV-D68 infections may be within states and the populations affected. We are also helping states with diagnostic and molecular typing for EV-D68. A huge increase in testing for enterovirus meant that some of our laboratory staff worked weekends and nights for nearly two months without a break. We are working with state and local health departments and clinical and state laboratories to enhance their capacity to identify and investigate outbreaks and perform diagnostic and molecular typing tests to improve detection of enteroviruses and enhance surveillance.

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Even as they were testing specimens, the CDC laboratory staff developed, and started using on October 14, a new, faster lab test that can detect EV-D68. The new test has fewer and shorter steps than the test that CDC and some states were using previously during this EV-D68 outbreak. CDC has made the protocols publically available on its website (<http://www.cdc.gov/non-polio-enterovirus/hcp/EV-D68-hcp.html>) and is exploring options for providing test kits to state public health labs. In addition, we are providing information to health care professionals, policymakers, the general public, and partners in numerous formats, including Morbidity and Mortality Weekly Reports (MMWRs), health alerts, websites, social media, podcasts, infographics, and presentations. Other CDC activities include obtaining one complete genomic sequence and six nearly complete genomic sequences from viruses representing the three known strains of EV-D68 that are causing infection at this time and posting these sequences on Gen Bank. Comparison of these sequences to sequences from previous years shows they are genetically related to strains of EV-D68 that were detected in previous years in the United States, Europe, and Asia.

c. With EV-D68, what can we do to protect kids who seem to be the most vulnerable to this virus?

Response: The same measures that are used to prevent other infections are important for preventing EV-D68:

- Wash hands often with soap and water for 20 seconds
- Avoid touching eyes, nose and mouth with unwashed hands
- Avoid close contact such as kissing, hugging, and sharing cups or eating utensils with people who are sick, or when you are sick
- Cover your coughs and sneezes with a tissue or shirt sleeve, not your hands
- Clean and disinfect frequently touched surfaces, such as toys and doorknobs, especially if someone is sick
- Stay home when you are sick
- There is no vaccine for EV-D68, but it is important to stay up to date on other vaccinations including flu vaccine.

Children with asthma are at risk for severe symptoms from EV-D68 and other respiratory illnesses. Parents should follow CDC's guidance to maintain control of their children's illness:

- Discuss and update their child's asthma action plan with their primary care provider.
- Provide prescribed asthma medications as directed, especially long term control medication(s).
- Be sure to keep their reliever medication with the child.
- Parents and children should receive flu vaccine.
 - If a child develops new or worsening asthma symptoms, follow the steps of their asthma action plan. If the symptoms do not go away, call the doctor right away.
 - Parents should make sure the child's caregiver and/or teacher is aware of his/her condition, and that they know how to help if the child experiences any symptoms related to asthma.

d. Has CDC figured out if there is a link between the virus and the cases of paralysis that have occurred?

Response: Every year, children in the United States develop this type of neurologic illness, and often the

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causes are not identified. CDC is working with health care professionals and state and local health departments to investigate all the reported cases since August. The investigation of these cases is allowing us to better understand the illness, who is affected, how often the illness occurs, and potential causes; such investigations take time to conduct thoroughly.

Among other possible causes, CDC is investigating whether the cases of neurologic illness may be linked to the outbreak of severe respiratory illness caused by enterovirus D68 (EV-D68) that the United States experienced this year. Enteroviruses most commonly cause mild illness, sometimes aseptic meningitis, less commonly encephalitis, and rarely, acute myelitis and paralysis. We are aware of only two published reports of children with neurologic illnesses confirmed as EV-D68 infection from cerebrospinal fluid testing. Historically, it has been challenging to identify causes of illness with muscle weakness.

CDC understands that Americans may be concerned about these illnesses. Severe illness is always a concern to us, especially when children are affected. We will continue to share information as soon as we have it, and post updates at <http://www.cdc.gov/ncird/investigation/viral/sep2014.html>.

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The Honorable Ben Ray Lujan

1. As you know, we have a responsibility to ensure that our hospitals and our front-line health care professionals are capable of safely handling a potential Ebola case. Recently, I heard from a constituent whose daughter had worked in a state public health lab and had experience training lab workers how to properly respond if they found dangerous biohazard threats, such as Ebola. She conveyed to my office that, in her experience, it was difficult to find protective gear that fit certain body types, particularly smaller individuals. Ill-fitting gear exacerbated the challenges associated with conducting activities that, even in properly fitting safety gear can be difficult for those with limited experience wearing such gear in the first place.

In addition, after a recent scare at the Christus St. Vincent Regional Medical Center in Santa Fe, the hospital's nurses expressed concerns with the adequacy of their training and preparation. Before this incident, the hospital had not held a drill simulating a biological or chemical disaster or provided training to emergency staff on using their protective gear since April.

Dr. Frieden, can you detail the steps the CDC is taking to ensure that our nation's hospitals and front-line health care workers are prepared and have the proper resources, included adequate protective gear? What lessons have you learned from the mistakes made at Texas Health Presbyterian Hospital? And, do you believe the CDC needs any additional authorities or resources?

Response: Enhanced guidance is based on the breadth of existing knowledge including patients who have been cared for at Texas Health Presbyterian Hospital, Emory University Hospital, NIH, and Nebraska Medical Center. CDC continues to work closely with hospitals and health care facilities to update guidance and recommendations, including expanding previous infection control guidance for health care workers caring for patients with Ebola. CDC is actively working to educate U.S. state and local health departments on CDC guidelines for Ebola applicable to public health preparedness national standards for state and local planning.

CDC has formed Rapid Ebola Preparedness (REP) and Infection Control Assessment and Response (ICAR) teams that deploy to pre-identified facilities to work with local health officials and hospitals in assessing their readiness for caring for patients with Ebola. REP teams are composed of CDC experts in infection control, occupational health, and laboratory issues; other HHS personnel including National Hospital Preparedness Program Field Project Officers and other regional staff; federal and state OSHA staff; and external local experts. State health officials and candidate hospitals determine the hospitals in their state or region where patients suspected of having Ebola will be transported for treatment for the full course of illness. During the visit, the REP team identifies areas that pose challenges and provide technical assistance and support to gain readiness in the areas identified. Implementation and adherence to CDC recommendations lies with individual hospitals. A positive corollary of the intensive training and preparation at these facilities may be increased readiness for other disease outbreaks in the future. In the event of a confirmed Ebola case, CDC will immediately deploy a CDC Ebola Response Team (CERT) to provide on the ground technical assistance and clinical support to the treatment hospital and the health care community.

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With the magnitude of this unprecedented response, the Administration's Emergency Request for Ebola funding included \$1.83 billion for CDC to fight Ebola on all fronts, with the goals of stopping the Ebola epidemic at its source; supporting immediate and decisive response to any domestic case; and preparing for and responding to disease threats around the world and implement the Global Health Security Agenda. In addition to resources, the Emergency Funding Request contains several authorities important to CDC's domestic and overseas response:

- 1) **Funding transfer authority:** Transfer authority would allow CDC to move these funds across CDC accounts to be able to more quickly respond to health security issues. The authority requires CDC to notify Congress promptly of any transfers made.
 - 2) **Adding to the Strategic National Stockpile:** The proposed Ebola funding specifically authorizes that "products purchased with these [ebola] funds may... be deposited in the Strategic National Stockpile."
 - 3) **Personal service contract authority:** This authority would authorize CDC to use personal service contracts for Ebola response staffing domestically
 - 4) **Expanded overseas facilities authority:** This proposal would allow CDC to "acquire, lease, construct, alter, renovate, equip, furnish, or manage facilities" overseas.
 - 5) **Overseas auto purchase and insurance authority** was added to the CDC-Wide Ebola response proposal to allow Ebola funds to be used overseas for car purchase and usage (CDC's global health account already has this authority).
2. **Recently, the Liberian government published a list of supplies that it believes it needs to address the Ebola outbreak. That list included a request for nearly 85,000 additional body bags.**

Clearly, the Ebola outbreak in West Africa represents a major humanitarian crisis-one that we have a moral obligation to forcefully address. And, as you said in your testimony, "the most effective step we can take to protect the United States is to stop the epidemic where it is occurring."

Can you provide us with an update on what CDC is seeing on the ground in West Africa? Considering the state of these countries' health infrastructure, what challenges are you facing? And are there any additional steps that Congress should be considering to address this crisis?

Response: The situation in West Africa continues to be of significant concern. EVD transmission remains widespread in Sierra Leone and Liberia, and in several critical areas of Guinea, as well as new cases emerging in Mali. CDC staff is actively working with local authorities and United States Government and non-governmental organization partners to respond by supporting the coordination of the response by local authorities, supporting surveillance, laboratory and infection control activities, conducting contact tracing, and developing risk reduction messages and communication strategies. There is evidence that the activities we have undertaken to respond to the outbreak have had a positive impact as two countries in Liberia have seen decreasing rates of EVD. Despite the positive movement, new and often more remote

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areas continue to be heavily affected. As such, we must continue to mount a response that is both fast and flexible in order to respond to the response as it evolves. As of November 17, 2014, there continue to be a number of challenges in combatting the EVD outbreak, including:

- A shortage of health care workers and epidemiologists;
- Need for infection control procedures to be improved, especially in non-Ebola Treatment Unit (ETU) health care facilities;
- Need to maintain supplies of personal protective equipment (PPE) in ETUs;
- A lack of PPE in appropriate quantities in non-ETU health facilities;
- Few health care facilities outside of major population areas;
- Too few vehicles are available for contact tracing, safe burials and patient transport,
- Little road infrastructure limiting access to remote communities;
- Lengthy timeframes in transporting specimens to laboratories from remote areas,
- Unreliable communications networks;
- Few non-governmental organizations with the ability to implement public health or medical response activities to augment existing Ministry of Health-run facilities;
- Partner organizations with needed skills are interested but underutilized: they either do not have existing presence in West Africa, or if they have a presence, are unable to take on additional activities; and
- Need to balance health needs in the region, i.e., deploying CDC to respond to the Ebola outbreak while or instead of maintaining other important health projects such as on malaria or immunizations.

As a result, supplies and staff have to be brought in from outside of the affected countries and staff in country must be trained. This is often complicated by lengthy hiring processes; lacking medevac assurances for foreign medical providers; and the small number of partners in West Africa with absorptive capacity or partners with the ability to start new operations in the near future to take on some of the additional public health activities needed to support the response.

As future trends in the outbreak cannot be predicted with certainty, it is important that the United States Government remain committed to fighting the outbreak until the last case has been treated and released. The United States Government must also remain committed to assembling a nimble, flexible response that includes, but is not limited to, funding with availability for longer time horizons, special hiring authorities to ensure that needed staff can be quickly hired, support for medevac for health care providers back to their home country, and other future needs. As responses in Nigeria and Senegal have shown, a fast and flexible effort can contain EVD. A consistent long term commitment must be made to the highly impacted countries and neighboring countries to help them prepare and respond. Our global health security depends on it.

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

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Response: Even before the Ebola epidemic, CDC recognized the need to expand the Global Health Security Agenda, and proposed an increase in resources in the FY 2015 President's Budget. The Ebola epidemic made the need for global health security an urgent need. This epidemic starkly demonstrated the difference between nations with and without public health capacity—Nigeria was able to halt its epidemic, while Liberia and the other two nations did not. We recognize that the United States cannot wait years to begin efforts that can prevent the next outbreak that will threaten the nation and the world.

The United States significantly enhanced its preparedness in the years following the September 11th attacks, when funds were provided for enhancing public health preparedness. State and local health departments have greatly increased their capacity to respond to an array of hazards, which is evidenced through states' proven success in responding to critical events without requesting direct federal financial support for public health. Ebola virus disease response requires additional equipment, facilities, and specialized training beyond what is typically required for all hazards preparedness. The unique nature of this disease requires additional steps to enhance our response measures to ensure whole community preparedness.

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The Honorable Paul Tonko

1. **Protecting the United States population from Ebola outbreak should be the number one priority of the CDC. In light of this, many have called for a travel ban for those traveling into or out of the affected countries. In your opinion, at this time would a travel ban increase or decrease the risk of the United States being exposed to an Ebola outbreak?**

Response: The Administration does not recommend stopping travel from countries with Ebola outbreaks. Travel restrictions balance the public health risk to others, the rights of individuals, and the impact of the recommendations on the welfare of the countries with Ebola outbreaks. They are based on the least restrictive means necessary to protect the public's health. The key to controlling this epidemic is to focus on stopping the spread at its source, and international humanitarian assistance must continue.

Every day, CDC works closely with partners at U.S. international airports and other ports of entry to look for sick travelers with possible contagious diseases. From August 2014 (as of November 17, 2014), CDC has deployed 45 staff members to five West African countries including: Guinea, Liberia, Nigeria, Senegal and Sierra Leone to develop and implement exit screening of all departing international travelers. Currently, there are six CDC staff deployed internationally supporting airport exit screening programs, and CDC has recently added staff to assist with exit screening in Mali.

CDC and the Department of Homeland Security (DHS) are conducting enhanced entry screening at five U.S. airports (New York's JFK International, Washington-Dulles, Newark, Chicago-O'Hare, and Atlanta) for all U.S.-bound air travelers who have been in Liberia, Sierra Leone, Guinea, and Mali. Entry screening helps prevent further spread of Ebola and protect the health of all Americans by identifying travelers who may be sick with Ebola or may have had an exposure to Ebola, and to ensure that these travelers are directed to appropriate care, if needed.

Active post-arrival monitoring is occurring in all states. Active post-arrival monitoring means that health officials maintain daily contact with travelers from Guinea, Liberia, Sierra Leone, and Mali for 21 days following their last date of exposure to Ebola. Post-arrival monitoring is an added safeguard that complements existing exit screening protocols, which require all outbound passengers from the affected West African countries to be screened for fever.

On October 27, CDC released Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure to protect Americans from Ebola. This updated guidance focuses on strengthening monitoring of people potentially exposed to Ebola and for evaluating their intended travel, including the application of movement restrictions when indicated. This interim guidance has been updated by establishing a "low (but not zero) risk" category; adding a "no identifiable risk" category; modifying the recommended public health actions in the high, some, and low (but not zero) risk categories; and adding recommendations for specific groups and settings.

Through these changes, CDC and state and local health departments seek to support people who may have been exposed to Ebola, while also continuing to stop Ebola at its source in West Africa through the valor of our health care workers who serve. These changes will help systematize monitoring of any symptoms they might develop and quick referral when they need to be routed to care. These actions will better protect potentially exposed individuals and the American public as a whole.

NOTE: CONTENT ACCURATE AS OF NOVEMBER 17, 2014**2. How does the Ebola response compare to U.S. efforts to prevent other highly infectious diseases from entering the U.S., such as SARS or H1N1? Did we rely on a multi-layered approach to screen for those viruses? Was travel restricted?**

Response: CDC relies on multi-layered, proven strategies for responding to public health emergencies. It is important to note that the circumstances, including epidemiologic, geographic, social and cultural, among others, of each emergency play key roles in how CDC responds. The outbreak of Severe Acute Respiratory Syndrome (SARS), pandemic (H1N1) 2009 influenza, and Ebola Virus Disease (EVD) differ in key ways, including method of transmission, incubation period, infection rates, and affected areas. CDC's response to EVD is the largest global response in the agency's history with over 160 staff deployed in West Africa, more than 1,000 staff involved in the Emergency Operations Center (EOC) to help coordinate technical assistance and control activities with partners.

CDC travel recommendations and procedures in response to EVD are different than those employed during the response to SARS and pandemic (H1N1) 2009 influenza. All air travelers entering the United States who have been in Guinea, Liberia, Sierra Leone, and Mali are being routed through five U.S. airports (New York's JFK International, Washington-Dulles, Newark, Chicago-O'Hare, and Atlanta) for enhanced entry screening as described above. These inbound travelers receive Check and Report Ebola (CARE) Kits that contain further information about Ebola. This kit includes a health advisory infographic about monitoring for Ebola symptoms for 21 days, pictorial description of symptoms, a thermometer with instructions for how to use it, a symptom log, and a wallet-sized card that reminds travelers to monitor their health and provides information about who to call if they have symptoms.

In the United States, SARS was a travel-associated illness. During the investigation into the SARS outbreak, CDC's public health staff at United States ports of entry:

- Provided information to returning travelers arriving in the United States either directly or indirectly from Hong Kong, Guangdong Province, People's Republic of China and Hanoi, Vietnam on airplanes, cargo ships or cruise ships;
- Distributed health alert notices to those travelers advising them that they may have been exposed to people who had SARS and recommending they monitor their health for at least 7 days and to contact their physicians if they become ill with a fever accompanied by a cough or difficulty breathing;
- Boarded airplanes and ships with travelers reported to be ill to assess whether their symptoms match the case definition of SARS;
- Provided timely updates to government agencies partnering in these activities as well as to travel industry organizations; and
- Worked with CDC's SARS investigation team and local and state health departments to assist in the investigation of suspected cases of SARS.

In response to pandemic (H1N1) 2009 influenza, CDC issued a travel health warning recommending that United States travelers postpone all non-essential travel to Mexico. This issuance was based on reports of widespread influenza-like-illness and many severe illnesses and deaths in Mexico. CDC provided information to the traveling public and travel industry partners. As in past influenza seasons, CDC urged the public and especially those people at highest risk of influenza-related complications, to protect themselves by taking antiviral drugs early in their illness when recommended by their doctor; CDC also advised that everyone take every day preventive actions like covering coughs and sneezes and staying

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home from work and school when ill to help reduce the spread of illness.

3. What are the CDC's recommended procedures on the protective measures to be taken when a potential Ebola case is diagnosed? Is the patient put into isolation at this time? Is the hospital staff alerted to wear full body personal protective equipment?

Response: CDC has provided guidance on the protective measures to be taken when a potential Ebola case is identified. Details can be found in the document "Emergency Department Evaluation and Management of Patients with Possible Ebola Virus Disease" on the CDC website. Early recognition is critical to controlling the spread of Ebola virus. Health care providers should evaluate the patient's epidemiologic risk, including a history of travel to a country with widespread Ebola virus transmission or contact with a person with symptomatic Ebola within the previous 21 days. CDC developed an evaluation algorithm to determine if testing for Ebola is indicated.

If a diagnosis of Ebola is being considered, the patient should be isolated in a single room, and health care personnel should follow standard, contact, and droplet precautions, including the use of appropriate personal protective equipment (PPE) as detailed in the guidance document. Infection control personnel and the health department should be contacted immediately. The need for Ebola virus testing and initiation of identification of contacts will be determined in consultation with health department officials. Health departments should immediately report any persons under investigation by calling CDC's Emergency Operations Center.

Detailed guidance, a checklist, an algorithm, and frequently asked questions can be found on the CDC website.

4. What is the CDC doing to ensure that hospital staff is complying with best practices for preventing infection? Will there be trained compliance staff on the ground at future outbreaks to ensure compliance with safety procedures?

Response: CDC continues to work closely with hospitals and health care facilities to update guidance and recommendations, including expanding previous infection control guidance for health care workers caring for patients with Ebola. CDC is actively working to educate U.S. state and local health departments on CDC guidelines for Ebola applicable to public health preparedness national standards for state and local planning, and to bring updated recommendations and information to U.S. health care workers. CDC efforts to reach health care workers in the United States include:

- Educating and answering questions from clinical partners. CDC has reached over 326,700 individuals through conference calls to provide training and updates on CDC guidance.
- Hosting live events to educate health care workers and others about infection control principles and demonstrate appropriate use of PPE.
 - NYC event on October 21st with over 5,400 people in-person, 53 media outlets, and at least 20,000 people on livestream in 10 countries. The event was co-hosted by the Partnership for Quality Care (PQC) and the 1199SEIU/Greater New York Hospital Association Healthcare Education Project.

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- Los Angeles Event on November 7th with over 1,000 people in-person, a dozen media outlets, and thousands of people on live stream in hundreds of health care facilities across the country. The event was co-hosted by Kaiser Permanente, the Coalition of Kaiser Permanente Unions, the Partnership for Quality Care, and United Nurses Associations of California/Union of Health Care Professionals, Service Employees International Union (SEIU) – United Healthcare Workers West, SEIU Local 721 and Los Angeles County Department of Health.
- American Medical Association meeting on November 9th that was live streamed to thousands of individuals.
- Collaborating with online clinical communities (e.g., Medscape) to provide education and tools directly to health care workers. Medscape has also streamed CDC live events. Through Medscape training alone CDC has been able to reach 298,000 health care professional with online health care training resources.
- Contracting with Johns Hopkins University to create additional training videos for donning and doffing PPE guidance, including videos tailored to emergency departments (ED) and outpatient staff.
- Disseminating guidance through CDC's website and promoting it through CDC email distribution lists, plus additional partner outreach. For example, the PPE videos have been viewed over 225,000 times. Viewers logged more than 150,000 minutes (or 2500 hours) watching the videos
- Working with state and local health departments, public health partners, and professional organizations to improve and accelerate implementation of effective infection control measures for emergency departments and outpatient settings.

CDC is working to ensure that health care workers are receiving information about Ebola in a manner that raises their level of awareness.

CDC has formed Rapid Ebola Preparedness (REP) teams that deploy to pre-identified facilities to work with local health officials and hospitals in assessing their readiness for caring for patients with Ebola. REP teams are composed of CDC experts in infection control, occupational health, and laboratory issues, other HHS personnel including National Hospital Preparedness Program Field Project Officers and other regional staff, and external local experts. State health officials and candidate hospitals determine the hospitals in their state or region where patients suspected of having Ebola will be transported for treatment for the full course of illness. During the visit, the REP team identifies areas that pose challenges and provide technical assistance and support to gain readiness in the areas identified. While implementation and adherence to CDC recommendations lies with individual hospitals, a positive corollary of the intensive training and preparation at these facilities may be increased readiness for other disease outbreaks in the future.

In the event of a confirmed Ebola case, CDC will immediately deploy a CDC Ebola Response Team (CERT) to provide on the ground technical assistance and clinical support to the treatment hospital and the health care community.

5. **Aid groups working in Africa, such as Samaritan's Purse and Doctors without Borders have criticized the CDC's guidelines for being too lax. Has the CDC consulted with these groups as to best practices and what can be done to improve CDC's guidelines so that no cases of Ebola**

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are transmitted within the United States?

Response: CDC's Guidance for U.S. health care settings is similar to Doctors Without Borders guidance, and reflects 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 health care workers in correct donning and doffing of PPE selected by the facility.

- 6. Ebola is categorically different the type of airborne diseases that hospital isolation units were built to accommodate. Do we need to rethink our approach with Ebola isolation procedures and look to some of the practices on the ground in West Africa when treating these patients?**

Response: Ebola virus is not an airborne disease. It is transmitted by direct contact with blood or body fluids of a person who is sick with Ebola or with objects (like needles and syringes) that have been contaminated with the virus. The experience of the U.S. hospitals that have successfully treated patients with Ebola without further transmission supports that current guidance is an effective approach.

- 7. Your testimony states that Nigeria and Senegal have implemented proven practices such as contact tracing, monitoring, and isolation to contain the spread of the virus. With these nations on the verge of being declared Ebola free, how similar are domestic protocols to the ones successfully implemented overseas? What lessons have we learned that can be incorporated to our domestic procedures?**

Response: CDC is incorporating lessons learned as the response evolves and has adjusted guidance, recommendations, and procedures based on developing information and knowledge. CDC's current guidance for domestic response reflects best practices in public health strategies as appropriate and feasible for the environment and settings in the United States. Effective approaches in the fundamental public health activities are in use domestically and internationally.

- 8. Public health experts, including yourself, have testified that the only way we will ultimately be able to keep Americans safe from Ebola is eradicating the disease at its source in West Africa. What are the major challenges for getting ahead of this disease in West Africa, and is the current response adequate to meet the needs?**

Response: As of November 17, 2014, there continue to be a number of challenges in combatting the EVD outbreak, including:

- A shortage of health care workers and epidemiologists;
- Need for infection control procedures to be improved, especially in non-Ebola Treatment Unit (ETU) health care facilities;
- Need to maintain supplies of personal protective equipment (PPE) in ETUs;
- A lack of PPE in appropriate quantities in non-ETU health facilities;
- Few health care facilities outside of major population areas;
- Too few vehicles are available for contact tracing, safe burials and patient transport,
- Little road infrastructure limiting access to remote communities;
- Lengthy timeframes in transporting specimens to laboratories from remote areas,
- Unreliable communications networks;
- Few non-governmental organizations with the ability to implement public health or medical

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- response activities to augment existing Ministry of Health-run facilities;
- Partner organizations with needed skills are interested but underutilized: they either do not have existing presence in West Africa, or if they have a presence, are unable to take on additional activities; and
- Need to balance health needs in the region, i.e., deploying CDC to respond to the Ebola outbreak while or instead of maintaining other important health projects such as on malaria or immunizations.

In order to halt the outbreak, we must work with partners, local staff and governments in West Africa and United States Government agencies to continue contact tracing, surveillance and case identification, risk communication, infection control, Emergency Operations Center development, laboratory testing, care and treatment, exit screening, and in activities to mitigate second order impacts.

As future trends in the outbreak cannot be predicted with certainty it is important that the USG remain committed to fighting the outbreak until the last case has been treated and released and the health systems in these countries can identify future outbreaks. CDC is undertaking a response that is both fast and flexible. And as such, new needs will periodically be identified as the outbreak changes and new barriers to implementation are identified. As responses in Nigeria and Senegal have shown, it is possible to contain EVD. Our response (and the resources that it requires) needs to be thought of as a marathon and not a sprint. A consistent long term commitment must be made to the highly impacted countries and neighboring countries to help them prepare and respond.

- 9. It is estimated that Liberia has only one doctor for every 100,000 people. What are the challenges CDC has faced in training health care workers in a country with poor public health and physical infrastructure? What efforts have been made to get more personnel and resources to rural and isolated communities?**

Response: There was a severe shortage of health care centers and health care providers before the Ebola outbreak. Health care workers have been especially ravaged by Ebola Virus Disease (EVD); over 300 have died as a result of providing care to EVD patients. The risk of Ebola and lack of personal protective equipment (PPE) for non-Ebola Treatment Unit (ETU) settings has further reduced the willingness of health care providers to provide health care for conditions other than EVD.

In coordination with USAID, Ministries of Health and non-governmental organization (NGO) partners, CDC has developed and is implementing infection control training programs in the affected countries.

In order to increase the personnel and resources for remote communities, CDC is working with organizations such as the African Union and Partners in Health to recruit and station personnel in West Africa. The African Union will support both epidemiologists and clinicians to participate in the response. CDC will also maintain a cadre of staff in country to address issues at the national and local level.

Transportation via helicopter is an urgent need for personnel and resources to arrive in remote communities and for specimens from these communities to be transferred to laboratories in a timely manner for testing. For example, while some treatment for health care workers who contract Ebola while treating patients is available in Monrovia and Freetown, few medevac and high-level treatment options are open to health care providers treating Ebola patients. This limits health care providers' willingness to

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travel to the affected countries.

10. Can you please provide specific details about the work being done by U.S. personnel on the ground in West Africa? Is CDC directly monitoring exit screenings to identify potentially infected passengers before they attempt to leave the country?

Response: Hundreds of CDC staff members have provided logistics, staffing, communication, analytics, management, and other support functions for the response. CDC has deployed several teams of public health experts to the West Africa region. CDC staff are deployed to Guinea, Liberia, Nigeria, Senegal, and Sierra Leone to assist with response efforts, including surveillance, contact tracing, data management, laboratory testing, and health education. CDC supports countries with widespread Ebola transmission in establishing their own national and sub-national EOCs. All three West African countries at the center of the epidemic now have established an Incident Manager position, reporting to the presidents of the countries, to lead response efforts. Some specific activities include:

- CDC experts have been deployed to non-affected border countries in West Africa, including Cote d'Ivoire, to conduct assessments of Ebola preparedness in those countries.
- CDC staff are 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 countries with widespread Ebola virus transmission.
- CDC's health promotion teams, consisting of health communicators and public health advisors deployed to Guinea, Liberia, and Sierra Leone, are working closely with country embassies, UNICEF, WHO, ministries of health, and nongovernment organizations to develop public health messages and implement social mobilization activities.
 - In all three countries, CDC health communicators are meeting with local community leaders beyond capital cities.
 - CDC is partnering with major telecommunications companies in the affected countries (ORANGE and Cellcom in Guinea; Africell in Sierra Leone; and Cellcom and Lonestar in Liberia).
 - CDC engaged with UNICEF and Focus 1000 in the development of a Knowledge, Attitudes, and Practices (KAP) study in Sierra Leone and is using the results to inform future message strategies.
 - In Liberia, CDC supports the Carter Center's trainings for chiefs in 15 counties to improve Ebola response activities.
 - CDC's Ebola radio spots for West African communities are broadcast throughout the day by UNICEF, the U.S. Embassy, and other distribution outlets for public dissemination on radio and megaphones in churches, trucks, and public buildings in Freetown and Kenema, Sierra Leone.
 - CDC is working with UNICEF and WHO in Sierra Leone and Liberia to develop national key messages.
 - CDC is working with USAID and UNICEF to prepare communication strategies to educate local populations on community care centers and home health and hygiene kits disseminated by other agencies.

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- CDC and the Carter Center developed PSAs recorded by President Jimmy Carter for audiences in West Africa.
- CDC, the U.S. embassy, and UNFPA developed a distribution plan for messages by President Obama in Guinea, translated into French.
- An Ebola Field Communications Site provides resources and information to support CDC staff working in West Africa. It serves as a knowledge management platform to inform and coordinate the development of communications content and strategies with CDC staff working in the Emergency Operations Center in Atlanta.
- CDC is 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.
- CDC, in partnership with WHO's Global Outbreak Alert and Response Network and the U.S. National Institutes of Health (NIH), has provided a field laboratory to Liberia to increase the number of specimens being tested for Ebola.
- The DART continues to support the Government of Liberia (GoL) and U.N. agencies to plan, construct, and run Ebola Treatment Units throughout Liberia.
- USAID/OFDA contributed \$2.2 million to UNICEF to procure and distribute 50,000 household protection kits in Liberia. An initial 9,000 of those kits have been delivered.

CDC also is 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;
- Training staff on exit screening protocols and appropriate PPE use; and
- CDC has issued a Warning, Level Three notice for U.S. citizens to avoid nonessential travel to the West African nations of Guinea, Liberia, and Sierra Leone. CDC has issued an Alert Level Two notice for U.S. citizens to practice enhanced precautions when traveling to Mali.

NOTE: CONTENT ACCURATE AS OF NOVEMBER 17, 2014

The Honorable Gene Green

- 1. Dr. Frieden, what is the process and timeline for updating and communicated (sic) changes in protocols to local health care providers?**

Response: CDC continues to work closely with hospitals and health care facilities to update guidance and recommendations, including expanding previous infection control guidance for health care workers caring for patients with Ebola to ensure there is no ambiguity and to better emphasize the importance of training, practice, competence, and observation of health care workers in correct donning and doffing of PPE selected by the facility. Enhanced guidance is based on the breadth of existing knowledge including patients who have been cared for at Texas Health Presbyterian Hospital, Emory University Hospital, NIH, and Nebraska Medical Center.

CDC is actively working to bring updated recommendations and information to U.S. health care workers. We provide these through regular outreach via the website, industry calls and meetings, trainings, and social media communication, and notify partners through well-established communication channels as soon as guidance, recommendations or information is updated. CDC efforts to reach health care workers in the United States include:

- Educating and answering questions from clinical partners. CDC has reached over 326,700 individuals through conference calls to provide training and updates on CDC guidance.
- Hosting live events to educate health care workers and others about infection control principles and demonstrate appropriate use of PPE.
 - NYC event on October 21st with over 5,400 people in-person, 53 media outlets, and at least 20,000 people on livestream in 10 countries. The event was co-hosted by the Partnership for Quality Care (PQC) and the 1199SEIU/Greater New York Hospital Association Healthcare Education Project.
 - Los Angeles Event on November 7th with over 1,000 people in-person, a dozen media outlets, and thousands of people on live stream in hundreds of health care facilities across the country. The event was co-hosted by Kaiser Permanente, the Coalition of Kaiser Permanente Unions, the Partnership for Quality Care, and United Nurses Associations of California/Union of Health Care Professionals, Service Employees International Union (SEIU) – United Healthcare Workers West, SEIU Local 721 and Los Angeles County Department of Health.
 - American Medical Association meeting on November 9th that was live streamed to thousands of individuals.
- Collaborating with online clinical communities (e.g., Medscape) to provide education and tools directly to health care workers. Medscape has also streamed CDC live events. Through Medscape training alone CDC has been able to reach 298,000 health care professional with online health care training resources.
- Contracting with Johns Hopkins University to create additional training videos for donning and doffing PPE guidance, including videos tailored to emergency departments (ED) and outpatient staff.

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- Disseminating guidance through CDC's website and promoting it through CDC email distribution lists, plus additional partner outreach. For example, the PPE videos have been viewed over 225,000 times. Viewers logged more than 150,000 minutes (or 2500 hours) watching the videos
- Working with state and local health departments, public health partners, and professional organizations to improve and accelerate implementation of effective infection control measures for emergency departments and outpatient settings.

CDC is working to ensure that health care workers are receiving information about Ebola in a manner that raises their level of awareness.

CDC is actively working to bring updated recommendations and information through regular outreach via the website, industry calls and meetings, trainings, and social media communication, and notify partners through well-established communication channels as soon as guidance, recommendations or information is updated.

2. What have we learned about failures of isolation and personnel protection from the experience at Texas Health Resources' Presbyterian hospital? And have these lessons been shared with other hospitals so we can avoid the same errors in the future?

Response: Enhanced guidance is based on the breadth of existing knowledge including patients who have been cared for at Texas Health Presbyterian Hospital, Emory University Hospital, NIH, and Nebraska Medical Center. CDC continues to work closely with hospitals and health care facilities to update guidance and recommendations, including expanding previous infection control guidance for health care workers caring for patients with Ebola. CDC is actively working to educate U.S. state and local health departments on CDC guidelines for Ebola applicable to public health preparedness national standards for state and local planning.

CDC has formed Rapid Ebola Preparedness (REP) teams that deploy to pre-identified facilities to work with local health officials and hospitals in assessing their readiness for caring for patients with Ebola. REP teams are composed of CDC experts in infection control, occupational health, and laboratory issues, as well as external local experts. State health officials and candidate hospitals determine the hospitals in their state or region where patients suspected of having Ebola will be transported for treatment for the full course of illness. During the visit, the REP team identifies areas that pose challenges and provide technical assistance and support to gain readiness in the areas identified. While implementation and adherence to CDC recommendations lies with individual hospitals, a positive corollary of the intensive training and preparation at these facilities may be increased readiness for other disease outbreaks in the future.

In the event of a confirmed Ebola case, CDC will immediately deploy a CDC Ebola Response Team (CERT) to provide on the ground technical assistance and clinical support to the treatment hospital and the health care community.

3. I understand CDC is not a regulatory agency. Can you provide clarity over CDC's authority and responsibilities in the setting and enforcement of protocols?

Response: CDC's regulatory responsibilities are limited. For example, CDC administers and enforces the

NOTE: CONTENT ACCURATE AS OF NOVEMBER 17, 2014

quarantine and isolation regulations found at 42 CFR parts 70 and 71, as authorized by section 361 of the Public Health Service Act. In the context of health care settings, CDC does not administer regulations. CDC frequently publishes guidelines and recommendations for health care workers and related work forces on topics including Management of Hospitalized Ebola Patients, Personal Protective Equipment (PPE), Medical Transport, Specimen Collection and Testing, Handling Human Remains, and Environmental Infection Control.

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Attachment 2-Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Tim Murphy

1. Who is subject to controlled movement and monitoring requirements under the August 1, 2014 guidelines?

a. How if at all, did this change under the October 22, 2014 guidelines?

Response: With the complex nature and seriousness of the outbreak, CDC has created interim guidance for monitoring people potentially exposed to Ebola and for evaluating their intended travel, including the application of movement restrictions when indicated, titled "Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure." It provides recommendations for monitoring people potentially exposed to Ebola. This interim guidance has been updated by establishing a "low (but not zero) risk" category; adding a "no identifiable risk" category; modifying the recommended public health actions in the high, some, and low (but not zero) risk categories; and adding recommendations for specific groups and settings.

2. Did Nurse Amber Vincent (sic) wear protective gear while treating Mr. Duncan during all stages of Mr. Duncan's treatment?

Response: Ms. Vinson reported that she wore PPE while caring for Mr. Duncan during all stages of his treatment. No other healthcare personnel who worked with Ms. Vinson have indicated otherwise. CDC personnel did not observe her interactions with Mr. Duncan or her use of PPE and therefore cannot determine exactly how she was exposed. However, we suspect the exposure occurred during the complex processes of putting on (donning) and removing (doffing) the PPE. To minimize the chance of any future exposures, CDC issued revised Guidance on "Personal Protective Equipment To Be Used by Health care Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing)" on October 20, 2014, shortly after the two health care worker cases were confirmed.

a. Was Amber Vincent (sic) told by a CDC official that she could travel on a commercial passenger plane?

Response: Ms. Vinson's risk status changed between her flight to Ohio on October 10 and her return on October 13, since during that period it was learned that another nurse performing similar work had become infected with the Ebola virus. This infection called into question the effective use of personal protective equipment by the caregiving staff. Ms. Vinson was monitoring her temperature and symptoms and was in contact with health officials in Dallas. Because of the change in her risk status, CDC could have – and should have – prevented her from flying on October 13. Unfortunately, that direction was not provided to Ms. Vinson. Since that time, CDC has issued revised written guidelines for monitoring and movement of individuals that makes clear that an individual with the same

NOTE: CONTENT ACCURATE AS OF NOVEMBER 17, 2014

circumstances as Ms. Vinson's should not fly on a commercial aircraft. Although the risk to other passengers on the return flight was very low, out of an abundance of caution, CDC worked with state health departments to track contacts of Nurse Vinson including those on her flight; none developed Ebola.

The Honorable Corv Gardner**1. How many commercial flights, both passenger and cargo, fly to and from Liberia, Sierra Leone, and Guinea?**

Response: No data is available for cargo flights. None of the affected countries in West Africa have direct flights into the United States. During the November-January period, the average volume of monthly departing passenger flights from the affected countries with connections to the United States is:

- From Guinea: 69 departing flights per month
- From Liberia: 26 departing flights per month
- From Sierra Leone: 38 departing flights per month

2. How many flights are required daily, every other day, or weekly to get supplies and personnel to the affected areas?

Response: CDC is not aware of an estimate of the number of flights required to move personnel and supplies from all responding entities into and out of the affected countries. With respect to CDC's own logistical requirements, at this time, CDC is primarily relying on one commercial carrier, Brussels Air, which makes two flights per week between Brussels, Belgium, and each of the three affected countries (Guinea, Sierra Leone, and Liberia) to transport personnel. There are no United-States-based airlines currently flying into any of these countries. CDC is currently using six flights per week to get staff into the three countries. The number of staff deployed each week varies. The current level of commercial service is adequate to meet deployment needs.

CDC occasionally uses one additional commercial carrier, Royal Air Maroc (RAM), which flies from Casablanca to each of the affected countries. RAM is used mainly for CDC staff being deployed from other CDC international offices due to the challenges in making flight connections from those locations. This is sporadic use, averaging less than once per week.

For supply and equipment movement, CDC averages five shipments per week to the three affected countries. These are carried out through commercial shippers that either obtain space on Brussels Air or may have their own cargo flight going into the area.

The Honorable Morgan Griffith**1. Has there been any discussion or consideration of the possibility of a travel restriction for dogs until we learn more about interspecies transmission?**

Response: CDC's current dog-import regulations require that all dogs appear to be healthy and show no

NOTE: CONTENT ACCURATE AS OF NOVEMBER 17, 2014

signs of carrying a communicable disease upon arrival in the United States. Any dog that appeared ill would be excluded from the United States unless the owner of the dog can present findings of a veterinary examination that indicate that the dog is not carrying a communicable disease.

At this time, there is no evidence that dogs that are not showing any signs of illness are capable of transmitting the Ebola virus. Also, there is currently no evidence that dogs play a significant role in the transmission of Ebola virus in this epidemic. Presently, CDC does not believe further restrictions on the import of dogs that appear healthy are warranted. If evidence were identified that suggests that dogs that appear healthy can transmit Ebola virus, CDC would have the authority to further restrict the importation of dogs from the affected region at that time. CDC has posted information related to dogs and Ebola on the CDC website.

The Honorable Jim Matheson**1. How many people has CDC deployed for the purpose of conducting or supporting airport screenings in the United States and abroad?****a. How has CDC's support of airport screenings in West Africa impacted CDC's limited resources, including workforce capacity?**

Response: As of November 17, 2014, CDC has deployed 110 total staff to support airport screening measures both domestically and abroad, including 65 staff deployed domestically to five U.S. airports in support entry screening of passengers from the Ebola affected region. Currently, there are 48 CDC staff supporting domestic entry screening. From August 2014 (as of November 17, 2014), CDC has deployed 45 staff members to five West African countries including: Guinea, Liberia, Nigeria, Senegal and Sierra Leone to develop and implement exit screening of all departing international travelers. Currently, there are six CDC staff deployed internationally supporting airport exit screening programs.

Significant support for these teams was provided domestically including the development of trainings, communication messages, guidance documents, and logistical support. In order to continue these robust efforts, as well as to support the other needs of the response, CDC will require additional resources and support for workforce capacity.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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November 10, 2014

Dr. Anthony Fauci
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Fauci:

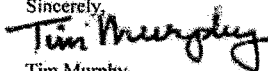
Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, October 16, 2014, to testify at the hearing entitled "Examining the U.S. Public Health Response to the Ebola Outbreak."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, November 24, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman

Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

**Attachment – Additional Questions for the Record
Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
"Examining the Public Health Response to the Ebola Outbreak"
Before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
October 16, 2014**

The Honorable Michael C. Burgess

- 1. We have learned a great deal about the difficulty of cleaning a room that has been utilized by an Ebola patient. What are the current standards for sterilizing a room in a healthcare or hospital facility?**
 - a. When were these regulations last updated?**
 - b. Will additional steps be taken to sterilize a room with an Ebola patient?**
 - c. Will you be updating these guidelines to better reflect the realities of an Ebola case?**
 - d. Some Veterans Affairs facilities and other hospitals are currently using pulsing xenon UV light to disinfect rooms – are any of you familiar with this technology?**
 - i. If yes, do you believe this may have a higher success rate in disinfecting rooms and preventing further infection?**
 - ii. Do you believe that this technology could be useful if deployed more widely in the United States?**
 - iii. What about in combating the outbreak in Africa – would it be possible to utilize this technology to fight the outbreak?**
 - iv. Will you please have someone on your staff review the position of the NIH on this technology and whether it will be helpful?**

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

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

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

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

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

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

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

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

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

¹ <http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html>

² https://www.osha.gov/Publications/OSHA_FS-3766.pdf

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

NIAID Response: CDC makes resources available to state and local governments with regard to preventing, preparing for, and managing cases of Ebola virus disease in the United States.

NIH was not involved in the treatment of Mr. Duncan or matters involving his family, quarantine, or disposal of medical waste. NIH did not provide information or guidance to any state or local official in this case.

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

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

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

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

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

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

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

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

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

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

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

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

The Honorable Ben Ray Luján

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

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

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

The Honorable Paul Tonko

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Honorable Gene Green

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

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

NIAID is an active participant in the PHEMCE, an interagency effort led by HHS's ASPR that coordinates Federal activities to increase preparedness against chemical, radiological, nuclear, and biological threats, including Ebola virus. As an active member, NIAID participates in multiple teams and committees to ensure coordination of scientific activity with PHEMCE partners, including BARDA, FDA and DOD. In addition, NIAID participates in the Ebola Medical Countermeasures Senior Steering Group, coordinated by OSTP. Senior staff from all agencies participating in the Ebola response meet twice weekly to discuss medical countermeasures for Ebola virus in the context of the U.S. response to the Ebola epidemic.

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

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

continue to coordinate closely with BARDA to transition these candidates for advanced development.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2027
Minority (202) 225-3641

November 10, 2014

Dr. Robin Robinson
Director
Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
2000 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Robinson:

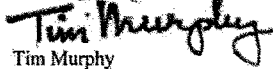
Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, October 16, 2014, to testify at the hearing entitled "Examining the U.S. Public Health Response to the Ebola Outbreak."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, November 24, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

Robin A. Robinson, Ph.D.

Deputy Assistant Secretary and BARDA Director

Office of the Assistant Secretary for Preparedness and

Response

"Examining the Public Health Response to the Ebola Outbreak"

Before the House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

October 16, 2014

Burgess

1. Can you describe what impact the Ebola outbreak has had on BARDA's advanced research and development budget?

Response: The Biomedical Advanced Research Development Authority (BARDA) redirected \$24.9 million of its Fiscal Year (FY) 2014 advanced research and development (ARD) funding in September 2014 to support the development and manufacturing of the Ebola monoclonal antibody therapeutic candidate, ZMapp, for Phase 1-2 clinical trials. As a result, funding of select activities in BARDA's broad spectrum antimicrobials and radiological and nuclear therapeutics portfolio was shifted to FY 2015. Since rapid acceleration of the development and manufacturing of other Ebola vaccine and therapeutic candidates was needed to address the escalating United States Government response to the evolving Ebola epidemic, BARDA requested additional funding for Ebola medical countermeasure (MCM) advanced development and manufacturing in the FY 2015 Continuing Resolution (\$58 million) and the President's emergency funding request (\$157 million).

**2. Have you had to shift funding to Ebola projects from other previously planned programs?
a. if so, how costly will it be to start them up again?**

Response: In FY 2014, BARDA had originally planned to expend \$8 million in MCM research and development for viral hemorrhagic diseases. To meet the \$24.9 million level necessary to support the first contract for ZMapp development and manufacturing in September 2014, BARDA delayed spending on planned actions to support antibiotic and radiation therapeutic candidate-development projects until FY 2015. Given the urgency and increasingly rapid spread of the Ebola virus in West Africa, BARDA shifted \$17 million in FY 2014 to support the development of ZMapp.

In the absence of funds (\$157 million) for Ebola MCM development and manufacturing that BARDA asked for in the President's emergency funding request, BARDA has determined that

reprogramming FY 2015 funds away from ongoing CBRN MCM activities would have an exceedingly detrimental effect on those projects. Companies developing these CBRN MCMs could abandon these MCM candidates and move resources onto the development of more lucrative and stably-funded commercial product candidates. Not only would BARDA potentially lose these MCM candidates in the pipeline, but earlier investments that BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) had previously made would be lost as well. BARDA would have to start over with new companies and repeat these same investments. Additionally, some clinical trials are already underway and would need to be stopped, which would not only harm the product development (loss of valuable data to move products to the next level of development), but it would also be unethical to treat the study participants in this manner. For example, the projects below are planned for funding in FY 2015 and build upon approximately \$177 million in prior investments. Shifting funds would jeopardize those prior investments as discussed above.

Existing BARDA Projects requiring FY 2015 Funding	
Threat Area	Description of Projects
Anthrax	Development of lyophilized formulation of Raxibacumab (anthrax antitoxin)
Broad Spectrum Antimicrobials	pediatric clinical trials, novel antimicrobials
Radiation/Nuclear	clinical studies for treatment of radiation effects; nonclinical trials and manufacturing of pediatric radiation treatment

3. Have development projects against other threats-like smallpox and anthrax- been shut down as a result?

Response: To date, no BARDA medical countermeasure development projects have been shut down to support Ebola response activities, though staff and resources have been stretched to accommodate the increased workload.

4. What additional funds do you need to develop Ebola countermeasures?

Response: The Office of the Assistant Secretary for Preparedness and Response (ASPR)/BARDA needs additional funding (\$157 million) for the Ebola response to continue supporting the accelerated development of promising vaccine, therapeutic, and antibody candidates that may

be used in the current Ebola epidemic in West Africa. The successful development of MCMs against Ebola could be instrumental in protecting health care workers, decreasing the mortality rate of people infected with Ebola, and ultimately halting the spread of the disease. Furthermore, these MCMs and corresponding manufacturing capabilities will be key to not only resolving the current Ebola epidemic, but extremely important to helping address the medical consequences of future Ebola outbreaks.

This request will fund BARDA's support of promising Ebola vaccine and therapeutic candidates. These candidates were previously supported during early development by NIAID and/or the Department of Defense's Defense Threat Reduction Agency (DoD/DTRA) and can now be transitioned to BARDA for advanced development and manufacturing as part of ASPR's response to the current Ebola epidemic. Building on development activities funded during FY2014 and during the FY2015 Continuing Resolution, the request will support the following (see **Table 1**):

- Advanced development and manufacturing of Ebola monoclonal antibodies produced in tobacco plants (ZMapp) and CHO mammalian cells for Phase 2/3 clinical trials for efficacy in affected West African countries in 2015 and scaling up manufacturing from pilot scale to commercial scale;
- Advanced development of other Ebola therapeutic candidates (small molecule antiviral drug therapeutic candidates) for Phase 2 clinical trials in affected West African countries in 2015;
- Advanced development of Ebola vaccine candidates (adenovirus and MVA-vectored vaccines) for Phase 2 clinical trials to evaluate efficacy in affected West African countries in 2015, including freeze-dried formulation development for field administration, and scaling up manufacturing from pilot scale to commercial scale; and,
- Fill-finish manufacturing of Ebola vaccine and therapeutic candidates for clinical trials in 2015, using BARDA's Fill-Finish Manufacturing Network.

The request will also subsequently support Phase 2/3 clinical trials to evaluate the safety and efficacy of these Ebola vaccine and therapeutic candidates in affected West African countries and, if the resulting data are sufficiently encouraging, submissions for Food and Drug Administration (FDA) approval.

Table 1. BARDA FY2014-2015 budgets for Ebola medical countermeasure development and manufacturing activities (in million dollars)

BARDA Ebola MCM Activity	FY 2014	FY2015			FY14-15
	Sept	CR Anomaly	Supplemental	FY 2015 Total	2-Yr Total
<i>Therapeutics</i>	24.9	1.5	141.0	142.5	167.4
Ebola antibody product development (ZMapp & CHO cell mAbs)	24.9	1.5	116.0		
Ebola small molecule antiviral drug therapeutic candidate development			25.0		
<i>Vaccines</i>		53.5	15.0	68.5	68.5
rVSVΔG EBOV (Newlink Genetics/Merck)		30.5			
cAd3 EBOV (GSK)		17.0			
AdVac/MVA EBOV (J&J/BN)			15.0		
rVSVN4CT1 EBOV (Profectus)		6.0			
<i>Other Activities</i>		3.0	1.0	4.0	4.0
Ebola MCM Fill finish manufacturing	0	3.0	1.0		
Total	24.9	58.0	157.0	215.0	239.9
Note: FY 2015 CR anomaly provides \$58 million for Ebola.					
THIS TABLE DOES NOT CONTAIN FUNDING REQUESTS FOR COMMERCIAL SCALE MANUFACTURING OF VACCINES FOR MASSIVE VACCINATION CAMPAIGNS.					

The President submitted a request to Congress in October 2014 for Ebola Supplemental Appropriations (\$6.2 B) to address domestic and international responses to the current Ebola epidemic.

The present Ebola epidemic is similar to other biotreats, as they are caused by infectious agents and are considered bioterrorism threats. Unlike smallpox or anthrax, where the former was eradicated in the 1970s and the latter occurs infrequently from handling contaminated hides (among other means), Ebola still persists with outbreaks in Africa over the past forty years and now as an emerging epidemic in West Africa.

Lujan

1. Can each of you discuss if budget cuts have had any impact on our response to the Ebola outbreak in West Africa or impacted the handling of the cases here in the United States?

Response: To date, no BARDA medical countermeasure development projects have been shut down to support Ebola response activities, though staff and resources have been stretched to accommodate the increased workload.

In FY 2014, BARDA had originally planned to expend \$8 million in MCM research and development for viral hemorrhagic diseases. To meet the \$24.9 million level necessary to support the first contract for ZMapp development and manufacturing in September 2014, BARDA delayed spending on planned actions to support antibiotic and radiation therapeutic candidate-development projects until FY 2015. Given the urgency and increasingly rapid spread of the Ebola virus in West Africa, BARDA shifted \$17 million in FY 2014 to support the development of ZMapp.

In the absence of funds (\$157 million) for Ebola MCM development and manufacturing that BARDA asked for in the President's emergency funding request, BARDA has determined that reprogramming FY 2015 funds away from ongoing CBRN MCM activities would have an exceedingly detrimental effect on those projects. Companies developing these CBRN MCMs could abandon these MCM candidates and move resources onto the development of more lucrative and stably-funded commercial product candidates. Not only would BARDA potentially lose these MCM candidates in the pipeline, but earlier investments that BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) had previously made would be lost as well. BARDA would have to start over with new companies and repeat these same investments. Additionally, some clinical trials are already underway and would need to be stopped, which would not only harm the product development (loss of valuable data to move products to the next level of development), but it would also be unethical to treat the study participants in this manner. For example, the projects below are planned for funding in FY 2015 and build upon approximately \$177 million in prior investments. Shifting funds would jeopardize those prior investments as discussed above.

Existing BARDA Projects requiring FY 2015 Funding	
Threat Area	Description of Projects
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Broad Spectrum Antimicrobials	pediatric clinical trials, novel antimicrobials
Radiation/Nuclear	clinical studies for treatment of radiation effects; nonclinical trials and manufacturing of pediatric radiation treatment

Green

1. Dr. Robinson, can you please tell us which US agency or agencies are responsible for the development of vaccines and therapies to treat Ebola? Do you think sufficient resources are available to successfully develop these needed products?

Response: ASPR/BARDA and the National Institutes of Health (NIH)/NIAID are the Department of Health and Human Services agencies that hold primary responsibility for the development of Ebola vaccines and therapies. The Centers for Disease Control and Prevention (CDC) and the Department of Defense also play important roles in Ebola vaccine and therapy development. Specifically, BARDA is responsible for the advanced development and manufacturing of the Ebola vaccine and therapeutic candidates for clinical trials and possible large scale administration campaigns.

At this point, the Administration has submitted an emergency funding request \$6.1 billion to augment FY 2015 available funds to meet the additional development and manufacturing needs of these medical countermeasures for response in West Africa.

2. As we know, the development of a medical countermeasure for a biological threat agent can take a decade or more, and a billion dollars, to develop. Ebola will be no different. The US government research program on Ebola countermeasures goes back a decade. But the level of financial priority and urgency on getting these countermeasures developed and stockpiled was insufficient to prepare us for the situation we currently face. Most would agree we are only aggressively pressing forward into clinical trials now because of the gravity of the situation. Approximately how much funding do you think is needed to invest in development of Ebola vaccines and drugs to give us the best chance of developing one new vaccine and one new therapy?

Response: In addition to budget requests from NIAID and CDC for Ebola vaccine and therapeutic development and clinical trials, BARDA seeks \$157 million in funding through the President's emergency funding request to further the advanced development and manufacturing of at least four Ebola vaccine candidates, two or three Ebola monoclonal antibody therapeutic candidates, and at least two Ebola small molecule antiviral drug candidates for clinical trials in West Africa that will determine whether these candidates work, are safe, and to ensure that these Ebola product candidates can be made at commercial scale if mass administration campaigns are needed in 2015.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2827
Minority (202) 225-3641

November 10, 2014

Dr. Luciana Borio
Assistant Commissioner
Counterterrorism Policy
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Borio:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, October 16, 2014, to testify at the hearing entitled "Examining the U.S. Public Health Response to the Ebola Outbreak."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, November 24, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

MAR 31 2015

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the October 16, 2014, hearing before the Subcommittee on Oversight and Investigations, entitled "Examining the U.S. Public Health Response to the Ebola Outbreak." This is the response for the record to questions posed by two Committee Members, in a letter we received on November 10, 2014.

Please let us know if you have any further questions.

Sincerely,



Thomas A. Kraus
Associate Commissioner for Legislation

cc: The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Page 2 – The Honorable Tim Murphy

We have restated your questions below in bold, followed by our responses.

The Honorable Ben Ray Luján

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

FDA has not sustained funding cuts related to the programs listed here or to programs to prepare for and respond to the types of public health emergencies that include the current Ebola epidemic.

The Honorable Paul Tonko

- 1. By all accounts, the FDA has worked at an unprecedented speed to aid in bringing an Ebola vaccine to market. Instead of lengthy reviews taking months or years, the potential treatments have cleared FDA hurdles in days. Given the urgency of this need, is there anything else that Congress can do to support this critical mission?**

As it has done in the past, with other urgent public health situations such as SARS and the 2009 H1N1 influenza pandemic, FDA has responded to the current Ebola outbreak with a sense of urgency appropriate to the nature of the events. In 2010, Congress provided additional resources to FDA to launch its Medical Countermeasures Initiative. These resources have allowed FDA to increase its capacity to prepare for and respond to public health emergencies such as the Ebola epidemic. In responding to public health emergencies, FDA operates within current resources and uses a variety of regulatory tools to expedite review of candidate products. However, maintaining due attention to multiple priorities simultaneously can stress the available resources. The recent appropriation of \$25 million in one-time emergency supplemental funds for increased work at FDA related to the ongoing Ebola epidemic, and for increased medical countermeasures activities, will help FDA continue response and preparedness activities while maintaining our ongoing regulatory oversight of products that are important to public health.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641
November 10, 2014

Mr. John P. Wagner
Acting Assistant Commissioner
Office of Field Operations
U.S. Customs and Border Protection
U.S. Department of Homeland Security
Washington, D.C. 20528

Dear Mr. Wagner:


Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, October 16, 2014, to testify at the hearing entitled "Examining the U.S. Public Health Response to the Ebola Outbreak."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Monday, November 24, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

1/20/2015 10:47 AM

Authorizing Questions For the Record (QFR) Summary

House Committee on Energy and Commerce – Subcommittee on Oversight and Investigations

Hearing Date: October 16, 2014

Hearing Title: “Examining the U.S. Public Health Response to the Ebola Outbreak”

DHS Witnesses: John Wagner – CBP

Total QFRs Received: 5

Date Received: 11/13/2014

IQ/ECT Workflow: 1052769

QFR Breakdown by Sen. /Rep.:

1 question from Rep. Lujan (D-NM)
3 questions from Rep. Tonko (D-NY)
1 question from Rep. Gardner (R-CO)

Question#:	1
Topic:	Ebola cases
Hearing:	Examining the U.S. Public Health Response to the Ebola Outbreak
Primary:	The Honorable Ben Lujan
Committee:	ENERGY & COMMERCE (HOUSE)

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

Response: DHS defers to HHS and other agency witnesses to address this question.

Question#:	2
Topic:	estimate
Hearing:	Examining the U.S. Public Health Response to the Ebola Outbreak
Primary:	The Honorable Paul Tonko
Committee:	ENERGY & COMMERCE (HOUSE)

Question: It has been estimated that 100 to 150 people whose travel originated in or transited through Liberia, Sierra Leone, and Guinea arrive in the United States daily. Do you have an estimate as to how many are U.S. citizens?

Response: From June 1, 2014, through November 30, 2014, a total of 19,805 travelers arrived in the United States from Liberia, Sierra Leone, and Guinea. U.S. persons, either U.S. citizens (USCs) or Lawful Permanent Residents (LPRs), accounted for 14,204 (or 71.7 percent) of those travelers. Broken down further, 9,666 (or 48.8 percent) were USCs, and 4,538 (or 22.9 percent) were LPRs with passports issued in one of the Ebola affected countries.

Question: How many are traveling on a passport not issued by one of these three nations?

Response: From June 1, 2014, through November 30, 2014, a total of 19,805 travelers arrived in the United States from Liberia, Sierra Leone, and Guinea. Of these, 5,601 (or 28.3 percent) were traveling on passports issued by countries other than Liberia, Sierra Leone, and Guinea, or the U.S.

Question#:	3
Topic:	screening individuals
Hearing:	Examining the U.S. Public Health Response to the Ebola Outbreak
Primary:	The Honorable Paul Tonko
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Your testimony references a multi-layered approach to screening individuals. Can you explain the various layers to the screening that a traveler will pass through before entering the United States?

Response: Ensuring the safety of the American public is of paramount concern. U.S. Customs and Border Protection's (CBP) approach ensures there are multiple points at which an infected individual can be identified by systematically employing a number of layered and pre-planned measures to minimize the risk of introducing Ebola Virus Disease (Ebola) to the United States.

1. Closest Point of Source:

CBP's first line of defense is to inhibit the spread of Ebola from the closest point to the source of infection. DHS, through authorities implemented by the Transportation Security Administration and CBP, will deny boarding to passengers who have been identified by the CDC or other appropriate medical authority to have a communicable disease that constitutes a public health threat, and therefore should be prevented from traveling via commercial aircraft. Additionally, officials in Guinea, Liberia, Mali and Sierra Leone have instituted exit screening of all individuals departing the respective countries to identify potentially symptomatic travelers prior to departure. At present, there are no direct commercial flights from the affected countries to the United States. Governments at major transit points along routes from the affected countries to the United States, including Nigeria, Senegal, Ghana, Morocco, France, Belgium, and the UK, have also implemented screening to identify potentially symptomatic travelers on arrival.

2. Passenger Travel Data:

CBP leverages advance passenger data to identify travelers destined to the U.S. that are traveling from or through Ebola-affected countries, have recently traveled to the Ebola-affected countries, or are traveling on a passport issued by one of the Ebola-affected countries. Such travelers are identified for additional questioning

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upon arrival in the United States and referral for enhanced screening, as appropriate.

3. Entry Point Control (Funneling):

On October 21, 2014, the Secretary for Homeland Security announced all passengers with itineraries originating in the Ebola-affected countries of Liberia, Sierra Leone, and Guinea would be required to enter the United States at one of the five designated airports performing enhanced screening protocols. The five designated airports are JFK Airport in New York, Chicago's O'Hare International Airport, Dulles International Airport in Virginia, Hartsfield Jackson International Airport in Atlanta, and Newark International Airport in New Jersey. CBP implemented measures to ensure that commercial air and general aviation passengers identified as having a travel nexus to one of the Ebola-affected countries within the previous 21 days are routed to make first entry into the United States at one of the five designated airports for screening. On November 17, DHS expanded these enhanced screening and funneling procedures to include travelers arriving to the United States from or traveling through Mali. On January 6, 2015 Mali was removed from the list of Ebola-impacted countries and enhanced screening for those passengers ceased.

At present, there are no direct commercial flights from the affected countries to the United States. If a traveler wants to fly to the United States from Guinea, Liberia, or Sierra Leone, the airlines will not permit the passenger to fly on a connecting flight to any U.S. airport other than one of the five with the enhanced screening. This is an appropriate part of our layered approach to security and the protection of the American people. This requirement has also been expanded to General Aviation.

4. Routine Screening:

Within CBP's broad responsibility, our priority mission remains to prevent terrorists and terrorist weapons from entering the United States. We also play an important role in limiting the introduction, transmission, and spread of serious communicable diseases from foreign countries. CBP works closely with CDC to

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recognize the signs and symptoms of international travelers who may be ill with a communicable disease that raises public health concerns, such as Ebola.

CBP and the CDC have closely coordinated to develop policies, procedures, and protocols to identify such travelers to the United States, 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.

CBP personnel review all travelers entering the United States for general overt signs of illnesses (visual observation, questioning, and notification to CDC as appropriate) at all U.S. ports of entry, including all federal inspection service areas at U.S. airports that service international flights, land-border crossings and seaports.

5. Enhanced Primary and Secondary Screening at All Ports of Entry:

The enhanced primary inspection consists of a thorough interview, examination of documents, and query through CBP systems to identify travelers who originated from or transited airports in the West African countries of Guinea, Liberia, and Sierra Leone. The primary CBP officer will observe the traveler for overt signs of illness. Any traveler identified as having travel nexus to affected countries or exhibiting overt signs of illness will be referred for secondary screening.

The goal of these procedures is 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 the passenger in the future. If there is reason to believe a passenger has been exposed to Ebola, either through personal contact, the questionnaire, temperature check, or overt symptoms, the passenger will be referred to tertiary screening in a separate area where CDC personnel conduct an evaluation. Contracted emergency medical technicians are utilized for enhanced screening services at the five designated airports.

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6. In the Maritime Context:

CBP works with the U.S. Coast Guard, CDC, and other federal, state and local port partners to ensure the safe and secure arrival of passengers and crews into U.S. ports, including those aboard cruise ships. All U.S. Ports of Entry, including all seaports, have protocols in place with respect to handling passengers and crews who may present a contagious illness. CBP Officers are advised to coordinate any possible potential isolation and response with local public health officials.

Before any vessel docks at a U.S. port, vessel operators are required to provide advance information about the vessel's last five ports of call, crew and passenger manifests, embarkation ports of crewmembers, and hazardous conditions to include any illness aboard. This is a mandatory requirement of large vessels, including cruise ships, which must notify the Coast Guard and CBP 96 hours before arrival to a U.S. Port. In consultation with the CDC and the Coast Guard, CBP can restrict a vessel's entry at U.S. ports, should there be concern about a possible virus presence on board.

If there is a concern about a communicable disease on board, CBP, in conjunction with the Coast Guard, manages the vessel's arrival in order to allow CDC to implement appropriate screening procedures and allow for decontamination if necessary. Based on the outcome of initial screening, CDC and the Coast Guard can order vessels into quarantine at special anchorages outside the port. CDC will determine if passengers and crewmembers require evacuation and coordinate with state and local partners if hospitalization is required.

These established procedures are yet another measure to ensure that vessels, cargo, and their passengers entering the United States will be appropriately screened for the safety of all.

Question: What screenings occur when a traveler is leaving Liberia, Sierra Leone, or Guinea?

Response: Since the beginning of August, CDC and the Department of State have been working with airlines, airports, ministries of health, and other partners to provide technical assistance to countries with Ebola outbreaks. CDC has helped affected countries screen departing travelers from these countries (exit screening).

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Exit screenings are conducted at airports in these outbreak-affected countries to look for sick travelers or travelers exposed to Ebola and to delay them from boarding an airplane until it is safe for them to travel.

DHS defers to the Department of State and/or the Department of Health and Human Services with regard to more specific information regarding screening of passengers leaving Ebola-affected countries.

Question: How do those procedures compare to the screenings at U.S. points of entry?

Response: The majority of travelers arriving from the Ebola-affected countries transit through major hubs in Western Europe including London, Brussels and Paris, as well as via Casablanca, Morocco. These countries conduct varying degrees of screening. During the week of October 19, DHS met with a range of European partners with direct flights from affected areas to discuss screening. We will continue to work with them to ensure we are doing everything necessary to protect the American and traveling public.

Question#:	4
Topic:	CBP officers
Hearing:	Examining the U.S. Public Health Response to the Ebola Outbreak
Primary:	The Honorable Paul Tonko
Committee:	ENERGY & COMMERCE (HOUSE)

Question: You stated in your testimony that CBP officers receive training on protective equipment and universal precautions developed by the CDC. How often is that training administered?

Response: U.S. Customs and Border Protection (CBP), Office of Field Operations (OFO), in coordination with the Office of Training and Development (OTD) and Office of Human Resource Management (HRM), developed a comprehensive training plan for OFO frontline employees in response to the enhanced screening for Ebola. The training plan includes on-site training at the five airports conducting the enhanced screening and the immediate completion of computer based training courses on Blood Borne Pathogens and Tuberculosis Prevention. The successful completion of these computer based courses is part of each officer's annual training requirements. The DHS Office of Health Affairs deployed subject matter experts to select airports as the Department rolled out enhanced Ebola screening in October, working with CDC to train CBP agents on proper use and removal of personal protective equipment. Additionally, CBP has developed a subsequent instructional video on the donning and doffing of personal protective equipment for enhanced screening for Ebola. All training and instructional videos are updated, as necessary, and are provided to CBP OFO frontline employees.

Question: Have additional protocols or equipment been sent to CBP officers in light of the increased risk from Ebola?

Response: CBP OFO and HRM Occupational Health and Safety have implemented procedures for the procurement of appropriate PPEs for all OFO ports of entry. OFO Field Offices have been instructed to purchase and maintain a 60 day supply of the appropriate PPEs.

Question#:	5
Topic:	commercial flights
Hearing:	Examining the U.S. Public Health Response to the Ebola Outbreak
Primary:	The Honorable Cory Gardner
Committee:	ENERGY & COMMERCE (HOUSE)

Question: During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

How many commercial flights, both passenger and cargo, fly to and from Liberia, Sierra Leone, and Guinea?

Response: There are no direct commercial flights, either passenger or cargo, from the three primary Ebola-affected countries of Guinea, Liberia, and Sierra Leone to the United States. This is also true for Mali, which has experienced a small number of infections to date. The majority of travelers arriving from the affected countries transit through major hubs in Western Europe, including London, Brussels and Paris, as well as via Casablanca, Morocco.

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November 10, 2014

Dr. Daniel Varga
Chief Clinical Officer and
Senior Executive Vice President
Texas Health Resources
612 E. Lamar Boulevard
Arlington, TX 76011


Dear Dr. Varga:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, October 16, 2014, to testify at the hearing entitled "Examining the U.S. Public Health Response to the Ebola Outbreak."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, November 24, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

DR. VARGA'S RESPONSES TO ADDITIONAL QUESTIONS FOR THE RECORD**The Honorable Marsha Blackburn****Question: Dr. Varga, who paid the medical bills for Thomas Duncan's care?**

Texas Health Resources is a faith-based, nonprofit health care system dedicated to its mission of improving the health of the people in the communities it serves. As such, we maintain a policy to provide care for all individuals in need of charity assistance. Texas Health Resources applied its charity care policy to Mr. Duncan's care and did not bill Mr. Duncan or his family.

Question: Who is covering the cost of care for your two nurses who were stricken with Ebola?

Texas Health Resources is treating the costs of treating the nurses as a work related injury issue.

THE HONORABLE BILLY LONG**Question: The US Government has invested billions of dollars in assisting hospitals with implementing Electronic Health Records (EHR). In this instance, do you believe your hospital's EHR failed to catch Mr. Duncan's illness on his first visit, and if so, why?****Question: Will you please explain what your health system has done to address these clear shortcomings in the design of your Electronic Health Records?**

We do not believe our Electronic Health Record (EHR) failed. However, following Mr. Duncan's initial admission, we changed our screening process in the Emergency Department (ED) to capture the patient's travel history at the first point of contact with ED staff. This process change makes the travel history available to all caregivers from the beginning of any patient's visit in the ED.

Additionally, we modified our EHR in multiple ways to increase the visibility and documentation of information related to travel history and infectious exposures related to EVD. These include:

- Better placement/title of the screening tool
- Expanded screening questions, which include:
 - Exposure to persons known or suspected to have EVD
 - High-risk activities for persons who have traveled to Ebola endemic areas such as: "have you touched a dead animal or helped carry someone sick";
 - A pop up identifying the patient as high-risk for Ebola with explicit instructions for next steps if the answer to any of the screening questions is positive

THE HONORABLE BEN RAY LUJAN

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

The response to Ebola in West Africa is outside of our scope, but we do not believe budget cuts had an impact on our response to the EVD cases at Texas Health Dallas.

In a crisis like this, a hospital's focus needs to be on providing exceptional care. Coordination and collaboration with federal, state, and local agencies is critical to limiting the perimeter of Ebola, managing contact identification interviews, and establishing community confidence.

THE HONORABLE PAUL TONKO

Question: What type of guidance did you receive from the CDC prior to the first Ebola patient arriving at Texas Presbyterian Hospital? What form was this guidance in (handout, webinar, etc?)

We received the CDC health advisories via email entitled *Centers for Disease Control and Prevention (CDC) Health Advisory about Ebola Virus Disease*¹ on July 28, and the August 1 *CDC Guidelines and Evaluation of US Patients Suspected of Having Ebola Virus Disease (CDCHAN-00364)*².

Question: After the first diagnosis, do you feel your hospital had adequate guidance from the CDC on how to handle the infected patient?

CDC guidance did evolve through the course of our experience with treating the first patient diagnosed with EVD and as the CDC issued updates, we followed their guidelines. The hospital followed CDC and Texas Department of State Health Services recommendations in an effort to ensure the safety of all patients, hospital staff, volunteers, nurses, physicians and visitors.

Question: Did CDC's guidance require personal protective equipment with full body coverage – meaning no exposed neck or wrist?

When the CDC recommended that nurses wear isolation suits, the nurses raised questions and concerns about the fact that the skin on their neck was exposed. The CDC recommended that they pinch and tape the necks of the gown. Because our nurses

¹ <http://emergency.cdc.gov/han/han00363.asp>

² <http://emergency.cdc.gov/han/han00364.asp>

continued to be concerned, particularly about removing the tape, we ordered hoods for their use even though it exceeded current CDC guidelines.

Question: Reports have indicated that Nina Pham was not wearing protective gear when she first treated Thomas Duncan on September 29. Is this true? If so, why was she allowed in the treatment room without personal protective equipment?

No, Nina Pham was wearing protective gear. The treating personnel at Texas Health Dallas followed the CDC protocols included in the *CDC checklist*³ for patients being evaluated for EVD, including use of personal protective equipment (PPE). Nurses who interacted with Mr. Duncan wore PPE consistent with the CDC guidelines.

Question: Did you conduct training for medical personnel on how to comply with the CDC's isolation procedures?

One of the lessons we learned is that communication is critical but it is not a substitute for training. Despite the communications regarding EVD preparedness that occurred between August 1 and October 1, we realized a need for more proactive, intensive, and focused training for frontline responders in the diagnosis of EVD. Therefore an Emergency Department (ED) refresher course was provided to THD ED nurses. Additionally, an "in-service" face-to-face training was provided starting with the night shift and continued at the start of every shift for a number of days. The education included screening of suspected patients, documenting response to travel questions in the Electronic Health Record and proper donning and doffing of PPE.

Question: Do you have enough personal protective equipment to accommodate all health care workers who come into contact with an Ebola patient, and would you have enough to deal with a larger outbreak?

We have enough personal protective equipment to accommodate all health care workers who may care for an Ebola patient and we have enough personal protective equipment for the health care workers who would care for a larger number of Ebola patients.

³ <http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html>