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EBOLA IN WEST AFRICA: A GLOBAL CHALLENGE AND PUBLIC HEALTH THREAT

JOINT HEARING

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
UNITED STATES SENATE

AND THE

SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES

OF THE

COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING EBOLA IN WEST AFRICA, FOCUSING ON A GLOBAL CHALLENGE AND PUBLIC HEALTH THREAT

SEPTEMBER 16, 2014

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C O N T E N T S

STATEMENTS

TUESDAY, SEPTEMBER 16, 2014

Page

COMMITTEE MEMBERS

Harkin, Hon. Tom, Chairman, Committee on Health, Education, Labor, and Pensions, opening statement 1
Alexander, Hon. Lamar, a U.S. Senator from the State of Tennessee, opening statement 3
Moran, Hon. Jerry, a U.S. Senator from the State of Kansas, opening statement 4
Reed, Hon. Jack, a U.S. Senator from the State of Rhode Island 32
Burr, Hon. Richard, a U.S. Senator from the State of North Carolina 34
Murray, Hon. Patty, a U.S. Senator from the State of Washington 36
Isakson, Hon. Johnny, a U.S. Senator from the State of Georgia 38
Casey, Hon. Robert P., Jr., a U.S. Senator from the State of Pennsylvania 40
Boozman, Hon. John, a U.S. Senator from the State of Arkansas 42
Bennet, Hon. Michael F., a U.S. Senator from the State of Colorado 43
Whitehouse, Hon. Sheldon, a U.S. Senator from the State of Rhode Island 46
Durbin, Hon. Richard J., a U.S. Senator from the State of Illinois 47
Mikulski, Hon. Barbara A., a U.S. Senator from the State of Maryland, opening statement 49

WITNESSES—PANEL I

Bell, Beth P., M.D., MPH, Director, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA 5
Prepared statement 7
Fauci, Anthony S., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD 11
Prepared statement 13
Robinson, Robin A., Ph.D., Director, Biomedical Advanced Research and Development Authority, Deputy Assistant Secretary for Preparedness & Response, U.S. Department of Health and Human Services, Washington, DC 23
Prepared statement 25

WITNESSES—PANEL II

Brantly, Kent, M.D., Former Medical Director, Samaritan's Purse Ebola Care Center in Monrovia, Liberia, Ebola Survivor, Fort Worth, TX 52
Prepared statement 55
Charles, Ishmael Alfred, Program Manager, Sierra Leone Healey International Relief Foundation, Freetown, Sierra Leone 59
Prepared statement 61

ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.:
Response by Beth P. Bell, M.D., MPH to questions of:
Senator Casey 70
Senator Bennet 71
Senator Whitehouse 72
Senator Shaheen 74
Senator Baldwin 76
Senator Warren 77
Senator Alexander 80
Senators Alexander and Burr 83
Senator Moran 84
Senator Cochran 86
Senator Shelby 87
Senator Burr 88
Senator Kirk 91
Senator Enzi 92
Response by Anthony S. Fauci, M.D., and Robin A. Robinson, Ph.D., to questions of: .....
Senator Casey 94
Senator Bennet 95
Senator Whitehouse 96
Senator Baldwin 97
Senator Warren 98
Senator Alexander 99
Senator Moran 101
Senator Shelby 102
Senator Cochran 103
Senator Burr 104
Senator Kirk 105
Response by Ishmael Alfred Charles to questions of:
Senator Casey 107
Senator Warren 108

EBOLA IN WEST AFRICA: A GLOBAL CHALLENGE AND PUBLIC HEALTH THREAT

TUESDAY, SEPTEMBER 16, 2014

U.S. SENATE JOINT HEARING,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
AND
APPROPRIATIONS SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES,
Washington, DC.

The committees met, pursuant to notice, at 2:52 p.m. in room SH–216, Hart Senate Office Building, Hon. Tom Harkin, chairman of the committee and the subcommittee, presiding.

Present: Senators Harkin, Mikulski, Alexander, Moran, Murray, Casey, Franken, Bennet, Whitehouse, Baldwin, Warren, Durbin, Reed, Pryor, Burr, Isakson, Cochran, Johanns, and Boozman.

OPENING STATEMENT OF SENATOR HARKIN

The CHAIRMAN. The Committee on Health, Education, Labor, and Pensions and the Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Services will come to order.

In March of this year, public health officials reported an outbreak of Ebola virus in the West African country of Guinea. Unlike past Ebola outbreaks that have been efficiently and effectively stopped, this outbreak has spread in ways that are potentially catastrophic for the world. Due to the gravity of the situation and the danger it poses not only to the affected region, but also to our country, I have taken the unusual step of calling together this joint hearing of both the authorizing committee I chair and the Appropriations subcommittee, which I also chair. We've come together today to learn all we can so we can work together effectively over the coming weeks to stop this deadly plague.

The extent of this epidemic is tragic and it grows more serious with each passing day. The death toll is already far greater than all other previous Ebola outbreaks combined. The World Health Organization estimates that 20,000 people may become infected by December if current control efforts are not strengthened, and we know the fatality rate, the mortality rate, is close to 50 percent, 40 to 50 percent.

We have other estimates that are much higher. And of course, the constant concern that as this virus spreads it could also start to mutate and become even more deadly or have other means of transmission other than through bodily fluids.

Ebola is just one example of a threat from infectious disease. Others include Avian flu, and the Middle East Respiratory Syndrome, or MERS. In today's globalized system of air travel and trade, health threats easily crisscross the planet. That's why I've worked hard to strengthen, all of us on both of these committees, to strengthen investments in public health preparedness and response capabilities at home.

Last year the bipartisan Pandemic and All-Hazards Preparedness Reauthorization Act was signed into law. That came through this committee, and of course I see Senator Burr here, who led a lot of effort on that on his side. Senator Alexander, Senator Enzi, Senator Casey all worked very hard on this bill. It advances national health security by strengthening CDC's public health preparedness response capabilities and ensuring that the Biomedical Advanced Research and Development Authority, BARDA, has the authority it needs to support the development of critical treatments and vaccines.

In the Appropriations Committee, we have worked together for years to secure additional funding at CDC to set up a network of disease detection centers across the globe. We now have 10, including three in Africa. We need one in every country in Africa. It is these centers that are now deploying trained epidemiologists and other staff to help in epidemic areas and those at high risk, and we'll have more discussion on that when we get to our witnesses with CDC.

I hope and expect that in the next day or two the Senate will vote in favor of the $88 million that Senator Moran and I worked to secure in the continuing resolution (CR) to do just that. This is a crucial investment that will enable 100 CDC scientists to continue working in West Africa. It will keep the ZMapp and vaccine candidates moving quickly through clinical trials.

But, as important as this is, it's just a first step. I hate to say this, but Ebola will not be conquered in the 10-weeks of the continuing resolution. When we come back to negotiate the fiscal year 2015 appropriations bills, the fight to contain Ebola must continue to be an urgent priority.

The subcommittee passed a Senate Labor-HHS bill that includes a new $40 million global health security initiative. We must carefully consider the size and goals of this initiative in light of the Ebola outbreak, while maintaining our commitment to CDC staff in the field. As this crisis illustrates, we must stop chasing diseases after the fact and start building public health systems around the globe capable of detecting and stopping diseases before they cross borders.

Last year, with the help of Senator Moran, we were able to start a new global initiative called the National Public Health Institute to do just that. This program needs to be expanded in light of this epidemic.

With these big challenges ahead of us, today's hearing is absolutely critical. We have a distinguished group here to educate us and advise us.

I will now turn to Senator Alexander and also to Senator Moran, but before that I request the record be kept open for 10 days for

Senators to submit statements and questions. With that, I'll recognize Senator Alexander.

OPENING STATEMENT OF SENATOR ALEXANDER

Senator ALEXANDER. Thanks, Mr. Chairman, and thanks to the witnesses for coming here today.

We must take the dangerous, deadly threat of Ebola as seriously as we take ISIS. Let me say that again, we must take the dangerous, deadly threat of the Ebola epidemic as seriously as we take ISIS. I think I have a reputation as a Senator who's not given to overstatement. I don't believe that's an overstatement.

The spread of this disease deserves a more urgent response from our country and other countries around the world than it's now getting. This is one of the most explosive, deadly epidemics in modern time if we do not do what we know how to do to control it. It will require a huge and immediate response. There is no known cure. There is no vaccine. Half of those who get sick die. Each sick person, according to the Centers for Disease Control and Prevention, could infect 20 or more others, including caregivers, friends, and family.

Samantha Power, the U.N. Ambassador, said to me earlier this week in a briefing that she's trying to get other countries to view this with the same urgency that we do. This is an instance, she said, when we should be running toward the burning flames with our fireproof suits on. Ebola is killing people in West Africa at alarming rates and picking up speed.

It's hard to say exactly what the number of cases is. There is an official number, a little less than 5,000 Ebola cases in Guinea, Liberia, and Sierra Leone. But the worry is that one-half of those cases were reported in the last 3 weeks. You don't have to know very much about mathematics to know that, whatever the number, if it doubles every 3 weeks, that very soon we have an out of control epidemic. And we can see easily what would happen if a single infected traveler reaches another country and begins to infect others in that country.

We'll learn more today about what we know how to do. We'll hear from a doctor who has contracted Ebola and who has recovered from it and who is here to talk about it. It's not like the flu. It can only be spread by bodily fluids, often contracted by caring for someone who's sick or through burial practices.

But with global travel, we're only one airplane ride away from a person exposed to Ebola getting on a plane to the United States and then becoming sick once they arrive, and then the mathematics of that infection could begin to develop in this country.

There's human tragedy in Africa, but it affects the rest of the world and it affects the United States. Our State is known as the Volunteer State and Dr. Brantly, who will testify here, is an Ebola patient. He was working for Samaritan's Purse. He's not a Tennessean, but his parents are graduates of Lipscomb University, which is in Nashville. He, like many Americans, go on mission trips around the world to help people who need help.

I will support the Administration's request for the $30 million Senator Harkin talked about, for the $58 million for the Biomedical Advanced Research and Development Authority. That's for vaccines

and cures and treatments. That should pass this week. There is a request to address $500 million of reprogramming in the Defense Department. Some have asked, why should our military be involved? Because they have to be involved if we want to deal with the problem. There's no way for the doctors and the nurses and the health care workers to deal with it.

I'm pleased that on both sides of the aisle we have leaders who are beginning to recognize the severity of this epidemic. Dr. Frieden and United Nations Ambassador Power are taking the lead. We look forward to learning all we can about the severity of the epidemic and what we must do to control it. But I'll end where I started, we must take the deadly, dangerous threat of the Ebola epidemic as seriously as we take ISIS.

The CHAIRMAN. Thank you, Senator Alexander.

Senator Moran.

OPENING STATEMENT OF SENATOR MORAN

Senator MORAN. Mr. Chairman, thank you very much. I very much appreciate you and your leadership, working with the Senator from Tennessee and me together, to make certain that this hearing take place.

It's very discouraging to see and know what's taking place in Africa, but it's very encouraging to know that we have the ability to make a significant difference in the outcome of what's occurring. Sometimes we face problems and we don't know exactly what to do. While I realize we haven't invented and discovered all the cures and treatments, we know a lot can be done that will save people's lives and prevent the spread of Ebola to other places in Africa and around the globe.

The encouraging thing to me is that this is an example of something where the U.S. Senate or the Congress and the President can come together and actually make a difference, something that we ought to take some satisfaction in if we are able to accomplish that.

I appreciate the leadership here today. We need to declare a war on Ebola. It's real and yet it's something that, with that war, with that campaign, we have the ability to change the people's lives who are affected and to diminish the number of people whose lives are affected in the future. This requires a global response and the United States needs to provide the necessary leadership to make certain that the war is won.

Mr. Chairman, thank you very much.

The CHAIRMAN. Thank you, Senator Moran.

We have a distinguished panel, our first panel. I'll introduce them and then we'll move ahead with the statements. First is Dr. Beth Bell, Director of the National Center for Emerging and Zoonotic Infectious Diseases at the Centers for Disease Control and Prevention. Dr. Bell is responsible for CDC's efforts in responding to a broad range of emerging and established threats. Since March, Dr. Bell has helped lead CDC's response to the Ebola outbreak in West Africa. Previously, Dr. Bell served in multiple leadership roles at CDC, including during the agency's response to the 2001 anthrax attacks and the 2009 H1N1 influenza pandemic.

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, a posi-

tion he's held since 1984, for 30 years, and has provided outstanding leadership there. At NIH Dr. Fauci oversees a wide portfolio of basic and applied research to improve our understanding of infectious diseases and applying this knowledge to develop new detection, prevention, and treatment strategies.

Dr. Fauci serves as one of the key advisers to the White House and Department of Health and Human Services on initiatives to bolster medical and public health preparedness against emerging infectious disease threats.

Finally, we extend the committee's welcome to Dr. Robin Robinson, Director of the Biomedical Advanced Research and Development Authority, BARDA, in the Office of the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. Dr. Robinson is responsible for the advanced development and acquisition of innovative medical countermeasures, including vaccines, drugs, and diagnostic tools, to protect against both man-made and naturally occurring health threats. BARDA has played a key role in ensuring the ongoing research and development of experimental Ebola treatments, and we thank you also for being here today, Dr. Robinson.

I would just ask consent that all of your statements be made a part of the record in their entirety.

Dr. Bell, we'll start with you. I know we're going to have a lot of questions from Senators, so if you sum up in 5 to 7 minutes we'd sure appreciate it.

STATEMENT OF BETH P. BELL, M.D., MPH, DIRECTOR, NATIONAL CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. BELL. I will. Good afternoon, Chairman Harkin, Ranking Members Alexander and Moran, and members of the committees. I am Dr. Beth Bell, Director of the National Center for Emerging and Zoonotic Infectious Diseases at the CDC. I appreciate the opportunity to be here today to discuss the current epidemic of Ebola in West Africa, which illustrates in a tragic way the need to strengthen global health security.

Dr. Frieden has asked me to extend his sincere regret for not being here in person and also to express his appreciation for your continuing support for CDC, enabling us to build and sustain the capacity to respond to health threats like Ebola.

The Ebola epidemic in Guinea, Liberia, and Sierra Leone is ferocious and spreading exponentially. The current outbreak is the first that has been recognized in West Africa and the biggest and most complex Ebola epidemic ever documented. As of last week, the epidemic surpassed 4,400 cumulative reported cases, including nearly 2,300 documented deaths, though we believe there is considerable underreporting and expect that the actual numbers would be two to three times higher.

We have now also seen cases imported into Nigeria and Senegal from the initially affected areas, and other countries are at risk of similar exportations as the outbreak grows. There is an urgent need to help bordering countries to better prepare for cases now

and to strengthen detection and response capabilities throughout Africa.

The secondary effects of this outbreak now include the collapse of the underlying health care systems, resulting, for example, in an inability to treat malaria or to safely deliver an infant, as well as non-health impacts such as economic and political instability and increased isolation of this area of Africa. These impacts are intensifying and not only signal a growing humanitarian crisis, but also have direct impacts on our ability to respond to the Ebola epidemic itself.

There is a window of opportunity to control the spread of this disease, but that window is closing. If we do not act now to stop Ebola, we could be dealing with it for years to come, affecting larger areas of Africa. Ebola is currently an epidemic, the worst Ebola outbreak in history, but we have tools to stop it and an accelerated global response is urgently needed.

It is important to note that we do not view Ebola as a significant public health threat to the United States. The best way to protect the United States is to stop the outbreak in West Africa. But it is possible that an infected traveler might arrive in the United States. Should this occur, we are confident that our public health and health care systems can prevent an Ebola outbreak here and recognize that the authorities in investments provided by your committees have put us in this strong position.

Many challenges remain, particularly since there is currently no therapy or vaccine shown to be safe and effective against Ebola. We need to strengthen the global response, which requires close collaboration with the World Health Organization, additional assistance from international partners, and a strong and coordinated U.S. Government response.

CDC has over 100 staff in West Africa currently and hundreds of additional staff are supporting this effort from Atlanta. CDC will continue to work with our partners across the U.S. Government and elsewhere to focus on five pillars of response:

- establishing effective emergency operations centers in countries;
- rapidly ramping up isolation and treatment facilities;
- helping promote safe burial practices;
- strengthening infection control and other elements of the health care systems; and
- improving communication about the disease and how it can be contained.

Controlling the outbreak will be costly and will require sustained effort by the United States and the world community. Within HHS, the administration recently proposed that the Congress provide $30 million for CDC's response during the continuing resolution period and for efforts to develop countermeasures, which my colleagues will describe. And last week the President indicated that the unique logistics and material capabilities of the U.S. military would be engaged in this response, and we are working across the U.S. Government to assess the full range of resources that can be leveraged to change the trajectory of this epidemic.

Working with our partners, we have been able to stop every previous Ebola outbreak and we are determined to stop this one. It

will take meticulous work and we cannot take shortcuts. As CDC Director Tom Frieden has noted, fighting Ebola is like fighting a forest fire. Leave behind one burning ember, one case undetected, and the epidemic could reignite. Ending this epidemic will take time and continued intensive effort.

This tragedy also highlights the need for stronger public health systems around the world. There is worldwide agreement on the importance of global health security, but the Ebola epidemic demonstrates that there is much more to be done. Any vulnerability can have widespread impact if not stopped at the source. As you are aware, the fiscal year 2015 President's budget includes an increase of $45 million to strengthen fundamental public health capacities around the globe. If these people, facilities, and labs had been in place in these countries currently battling Ebola, the early outbreaks would not have grown to what we are facing today. Stopping outbreaks where they occur is the most effective and least expensive way to protect people's health.

I know that many of you have traveled to Africa to see our work in global health, as have I, and we all come away with an appreciation of the enormous challenges many people and countries face. These may never have been more evident than in the current Ebola epidemic. Each day of the past several months, I have been in personal contact with our teams in the field. Their experiences reinforce the dire need and put real stories and faces on a tragedy that can't simply be reduced to numbers and facts. But these stories from the field also reinforce the unique and indispensable role that CDC and our partners are playing and the sense that with an intensified global focus we can make a real difference.

Thank you again for the opportunity to appear before you today and for making CDC's work on this epidemic and other health threats possible.

[The prepared statement of Dr. Bell follows:]

PREPARED STATEMENT OF BETH BELL, M.D., MPH

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

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

To date, the U.S. Government has spent more than $100 million to address the Ebola epidemic, and just last week the U.S. Agency for International Development (USAID) announced plans to make available up to $75 million in additional funding. In addition, we have just proposed that the Congress provide an additional $88 million through the continuing resolution process. This funding would allow us to support development and manufacturing of Ebola therapeutic and vaccine candidates

for clinical trials and to send additional response workers from CDC as well as lab supplies and equipment. If the Congress includes this additional funding, it would bring our total commitments to date to over $250 million. Last week, the President indicated the need to engage the unique logistics and materiel capabilities of the U.S. military on this response.

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

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

Ebola has an abrupt onset of symptoms similar to many other illnesses, including fever, chills, weakness and body aches. Gastrointestinal symptoms such as vomiting and diarrhea are common and severe, and can result in life threatening electrolyte losses. In approximately half of cases there is hemorrhage—serious internal and external bleeding. There are two things that are very important to understand about how Ebola spreads. First, the current evidence suggests human-to-human transmission of Ebola only happens from people who are symptomatic—not from people who have been exposed to, but are not ill with the disease. Second, everything we have seen in our decades of experience with Ebola indicates that Ebola is not spread by casual contact; Ebola is spread through direct contact with bodily fluids of someone who is sick with, or has died from Ebola, or exposure to objects such as needles that have been contaminated. While the illness has an average 8–10 day incubation period (though it may be as short as 2 days and as long as 21 days), we recommend monitoring for fever and signs of symptoms for the full 21 days. Again, we do not believe people are contagious during that incubation period, when they have no symptoms. Evidence does not suggest Ebola is spread through the air. Catching Ebola is the result of exposure to bodily fluids, which we are seeing occur in West Africa, for example, in hospitals in weaker health care systems and in some African burial practices. Getting Ebola requires exposure to bodily fluids of someone who is ill from—or has died from—Ebola.

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

Many of the health systems in these countries are weak or have collapsed entirely, and do not reach into rural areas. Health care workers may be limited (for example, we are aware of one nurse for 90 patients in one hospital in Kenema, Sierra Leone), or may not reliably be present at facilities, and those facilities may have limited capacity. Poor infection control in routine health care, along with local traditions such as public funerals and cultural mourning customs including preparing bodies of the deceased for burial, make efforts to contain the illness more difficult. Furthermore, the porous land borders among countries and remoteness of many villages have greatly complicated control efforts. The secondary effects now include the collapse of the underlying health care systems resulting for example, an inability to treat malaria, diarrheal disease, or to safely deliver a child, as well as non-health impacts such as economic and political instability and increased isolation in this area of Africa. These impacts are intensifying, and not only signal a growing humanitarian crisis, but also have direct impacts on our ability to respond to the Ebola epidemic itself.

There are three key things which we need to respond to this epidemic. The first is resources—this epidemic will take a lot of resources to confront. That is why the U.S. Government is putting our resources into this effort and asking the Congress for your assistance. The United Nations believes the cost of getting supplies needed to West African countries to get the Ebola crisis under control will be at least $600 million. I personally believe that to be an underestimate. The second is technical experts in health care and management to assist in country. Last, is a coordinated,

global unified approach, because this is not just a problem for Africa. It's a problem for the world, and the world needs to respond.

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

Many challenges remain. While we do know how to stop Ebola through meticulous case finding, isolation, and contact tracing, there is currently no cure or vaccine shown to be safe or effective for Ebola. We need to strengthen the global response, which requires close collaboration with WHO, additional assistance from our international partners, as well as a coordinated U.S. Government response. At CDC, we activated our Emergency Operations Center to respond to the initial outbreak, and are surging our response. One of the surge objectives was initial deployment of 50 disease-control experts in 30 days to the region to support partner governments, WHO, and other partners working in the region. We surpassed that goal, and as of last week, CDC has over 100 staff in West Africa, and more than 300 staff in total have provided logistics, staffing, communication, analytics, management, and other support functions. CDC will continue to work with our partners across the U.S. Government and elsewhere to focus on five pillars of response:

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

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

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

will continue to coordinate activities directly with critical Federal partners, including USAID and non-governmental organizations.

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

- Assisted with extensive screening and education efforts on the ground in West Africa to prevent ill travelers from getting on planes.
- Developed guidance for monitoring and movement of people with possible exposures, and guidance and training for partners (including airlines, Customs and Border Protection officers, and Emergency Medical Systems personnel).
- Provided guidance for travelers, humanitarian organizations, and students/universities.
- Advised United States' health care providers to consider Ebola if symptoms present within 3 weeks of a traveler returning from an affected area.
- Provided guidance for infection control practices in hospitals to prevent further spread to United States health care workers and communities.
- Developed response protocols for the evaluation, isolation and investigation of any incoming individuals with relevant symptoms.
- Expanded the capacity of our Laboratory Response Network to rapidly test suspected cases so that appropriate measures can be taken.

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

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

There is worldwide agreement on the importance of global health security, but as the Ebola epidemic demonstrates, there is much more to be done. All 194 World Health Organization Member States have adopted the International Health Regulations (IHR). Progress has occurred over the past years, but 80 percent of countries did not claim to meet the IHR capacity required to prevent, detect, and rapidly respond to infectious disease threats by the June 2012 deadline set by WHO. No globally linked, inter-operable system exists to prevent epidemic threats, detect disease outbreaks in real-time, and respond effectively. Despite improved technologies and knowledge, concerning gaps remain in many countries in the workforce, tools, training, surveillance capabilities, and coordination that are crucial to protect against the spread of infectious disease, whether naturally occurring, deliberate, or accidental. The technology, capacity, and resources exist to make measurable progress across member countries, but focused leadership is required to make it happen. If even modest investments had been made to build a public health infrastructure in West Africa previously, the current Ebola epidemic could have been detected earlier, and it could have been identified and contained. This Ebola epidemic shows that any vulnerability could have widespread impact if not stopped at the source.

Earlier this year, the U.S. Government joined with partner governments, WHO and other multilateral organizations, and non-governmental actors to launch the Global Health Security Agenda. Over the next 5 years, the United States has com-

mitted to working with at least 30 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 fiscal year 2015 Budget includes $45 million for CDC to accelerate progress in detection, prevention, and response, and we appreciate your support for this investment. The economic cost of large public health emergencies can be tremendous—the 2003 Severe Acute Respiratory Syndrome epidemic, known as SARS, disrupted travel, trade, and the workplace and cost to the Asia-Pacific region alone $40 billion. Resources provided for the Global Health Security Agenda can improve detection, prevention, and response and potentially reduce some of the direct and indirect costs of infectious diseases.

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

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

The CHAIRMAN. Thank you very much, Dr. Bell.

Dr. Fauci, welcome. Please proceed.

STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD

Dr. FAUCI. Thank you very much, Mr. Chairman, Ranking Member, members of the committee. I appreciate the opportunity to be able to speak to you today about the role of the National Institute of Allergy and Infectious Diseases in research addressing the Ebola virus disease. I have some handouts that your staff has put in front of you and it's on the visuals there.

The involvement of the NIH and NIAID in Ebola really dates back to the tragic events of 9–11–2001, which was followed closely by the anthrax attacks through the mail in letters to United States Senators as well as to members of the press, because this led to a broad, multi-agency endeavor to develop what we call biodefense against threats, not only of deliberate threats, but of unexpected naturally emerging and reemerging threats.

As you see on the right-hand side of this, there was an agenda, a research agenda involving what we called category A agents. They're listed there and they're familiar to you. They're anthrax, botulism, plague, smallpox, tularemia, and on the bottom bullet you see a category called the viral hemorrhagic fever viruses, which are Ebola, as well as Marburg, Lassa, and others.

The reason why these viral hemorrhagic fever viruses were so important and so deadly and so in need of countermeasures is that, as you mentioned in your introductory remarks, as have the other Senators, they have a high degree of lethality and infectivity. Unfortunately, the therapy is essentially mostly supportive, without specific antiviral drugs directed against the microbes in question. As we know, a vaccine for any of these is not available at present.

This is an electron micrograph of the Ebola virus, which is a filovirus, given the name because of the filamentous appearance that it has when one looks at it.

The NIH's Countermeasure Research and Development Program is ongoing and has been for several years. But before I even mention that, I wanted to underscore something that Dr. Bell said, is that right now today the best way to contain this epidemic, this outbreak, is by intensifying infection control capabilities, what we're seeing now evolve and what we've seen for some time, the ability to isolate, identify, contact trace, and protect our health care workers with personal protective equipment.

But if we want to be prepared in a durable way, we need countermeasures, and that's what I'm going to spend the next couple of minutes telling you about. What we do is basic and clinical research, but we also supply the resources for researchers in industry and in academia to get to our end game, which is better diagnostics and, of course, therapeutics and vaccines.

The product development pipeline is not unidimensional. The NIH is fundamentally responsible for developing the early concepts, doing what we call preclinical studies and early clinical studies, which I'll mention in a moment. We partner with our colleagues from BARDA, which you mentioned, who are involved in the advanced development to hand the baton over to industry for commercial manufacturing, with ultimate regulation and approval by the U.S. FDA, among other regulatory agencies, and you'll hear from Dr. Robinson shortly.

Let me spend a moment outlining some of the promising therapeutics. You mentioned and you've heard of ZMapp from Mapp Biopharmaceuticals. This is a combination of three artificially produced antibodies directed against the Ebola virus. It has been shown to be very promising in an animal model and, as you will hear from the next witnesses when Dr. Brantly speaks, that this was given for the first time in humans.

It is very, very important that we understand whether it truly works, how well it works, what's the proper dose, and is it safe. Anecdotal, we have determined that it looks like under circumstances it could be beneficial, but we don't know that, and it's our job to prove it so that we can have it readily available for larger numbers of people.

On this slide there's another couple among several interventions, one by the company BioCryst, which we're collaborating with, which is one of several novel drugs that interfere with the reproductive process of the virus. Then our Department of Defense is in collaboration with a company called Tekmira to get a drug which is actually a small inhibitory molecule, again interfering with the replication of the virus.

As I mentioned, ZMapp has been administered to seven individuals. This is probably, when you look at the animal model, a very encouraging result that we've seen in the animals. As we know, this has the potential, because it can block the virus, to do something that we hope we will be able to capitalize on, again with research ahead.

Then finally, there's the issue of vaccines. This is something that traditionally in infectious diseases has been the stalwart of preventing and protecting people. We have been working on an Ebola vaccine for several years in an iterative process that we've improved upon. We have favorable results in an animal model using

one of a few candidates, and the one I will mention in closing is the NIAID GlaxoSmithKlein candidate, which was developed at the NIH in collaboration with GlaxoSmithKlein and looked very good in an animal study. But as I have told you, Mr. Chairman and others on the committee, many times, the proof is in the pudding to show scientifically that it works.

We have actually started that process. On September 2d at the NIH Clinical Center in Bethesda, we started the first phase I study of this vaccine, aimed at vaccinating 20 normal volunteers. So far 10 of the 20 volunteers have been vaccinated and thus far there have been no red flags. Following this, which will likely end at the end of November, the beginning of December, we will expand these studies to try and prove in fact that we have a safe and effective vaccine.

In closing I'd like to reiterate what I refer to as the dual mandate of NIH and NIAID research when it comes to infectious diseases. It's our responsibility to maintain a robust basic and applied research portfolio in microbiology and infectious diseases. But also we have the other mandate, to have to respond rapidly and efficiently to emerging and reemerging infectious diseases with the kinds of countermeasures that would prevent morbidity and mortality and would have our citizens feel safe both home and abroad, and clearly Ebola is one of the most daunting of those reemerging infectious diseases. It's our aim over the next months to years to make sure that we do have the countermeasures to prepare us to address this problem.

Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Fauci follows:]

PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D.

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

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

OVERVIEW OF EBOLA VIRUS DISEASE

Viral hemorrhagic fevers are severe illnesses that can be fatal and are caused by a diverse group of viruses including Marburg virus, Lassa virus, and Ebola virus. Infection with Ebola virus typically causes fever, severe vomiting, diarrhea, rash, profound weakness, electrolyte loss, impaired kidney and liver function, and in some cases internal and external bleeding. Since the discovery of Ebola virus in 1976, outbreaks of hemorrhagic fever caused by Ebola virus have had fatality rates ranging from 25 percent to 90 percent, depending on the species of virus and the availability of medical facilities to care for infected patients. West Africa is currently experiencing the most severe Ebola epidemic ever recorded. As of last week, the epidemic surpassed 4,400 cumulative reported cases, including nearly 2,300 documented deaths according to CDC. The ongoing Ebola epidemic in Guinea, Liberia, Sierra

Leone, Nigeria, and Senegal has generated more cases and deaths than the 24 previous Ebola outbreaks combined.

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

HISTORY OF NIAID EBOLA VIRUS RESEARCH: RELATIONSHIP TO BIODEFENSE RESEARCH

The ability to safely and effectively prevent and treat Ebola virus infection is a longstanding NIAID priority. Since the 2001 anthrax attacks, NIAID has vastly expanded its research portfolio in biodefense and naturally emerging and re-emerging infectious diseases. This research targets pathogens that pose high risks to public health and national security. NIAID has designated pathogens with high mortality such as anthrax, plague, smallpox, and Ebola virus as NIAID Category A Priority Pathogens to highlight the need for medical countermeasures against these dangerous microbes.

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

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

DEVELOPMENT AND TESTING OF EBOLA MEDICAL COUNTERMEASURES

In response to the Ebola public health emergency in West Africa, NIAID is accelerating ongoing research efforts and partnering with governments and private companies throughout the world to speed the development of medical countermeasures that could help control the current epidemic and future outbreaks. NIAID research on Ebola virus focuses on basic research to understand how Ebola virus causes illness in animals and in people as well as applied research to develop diagnostics, vaccines, and therapeutics.

DIAGNOSTICS

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

THERAPEUTICS

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

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

NIAID has provided support to and collaborated with Mapp Biopharmaceutical, Inc., to develop MB–003, a combination of three antibodies that prevents Ebola virus disease in monkeys when administered as late as 48 hours after exposure. An optimized product derived from MB–003, known as ZMapp, has shown to be substantially more effective in animal models than earlier combinations and protected monkeys from death due to Ebola virus up to 5 days after infection, according to Mapp Biopharmaceutical, Inc. NIAID's preclinical services are now being used to provide pivotal safety data to support the use of ZMapp for clinical trials in humans. Mapp Biopharmaceutical, Inc., has announced that ZMapp was recently administered to humans for the first time as an experimental treatment to several Ebola-infected patients, including two Americans. It is not possible at this time to determine whether ZMapp benefited these patients. NIAID is working closely with partners at DoD, BARDA, and FDA to advance development and testing of ZMapp to determine whether it is safe and effective. BARDA has recently announced plans to optimize and accelerate the manufacturing of ZMapp so that clinical safety testing can proceed as soon as possible.

NIAID also has funded BioCryst Pharmaceuticals to develop and test BCX4430, a novel drug that interferes with the reproductive process of the virus and has activity against a broad spectrum of viruses. According to BioCryst, BCX4430 has protected animals against infection by Ebola virus and the related Marburg virus. BioCryst has announced that a Phase 1 clinical trial of this drug is expected to begin in late 2014 or early 2015.

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

VACCINES

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

The NIAID Vaccine Research Center (VRC) has a robust viral hemorrhagic fever vaccine development program. Since 2003, the VRC has evaluated three early generation Ebola vaccine candidates and one Marburg vaccine candidate in Phase 1 clinical trials at the NIH campus. An additional Phase 1 clinical trial was conducted in Kampala, Uganda, in collaboration with DoD. None of the early generation candidates raised safety concerns in these small trials; however, they did not elicit the level of immune response thought to be needed to provide protection against exposure to the virus. The data from those trials have contributed directly to the VRC's current Ebola vaccine collaboration with the pharmaceutical company GlaxoSmithKline (GSK). VRC and GSK have developed an experimental vaccine that uses a chimpanzee virus (similar to the common cold virus), Chimp Adenovirus 3 (CAd3), as a carrier, or vector, to introduce Ebola virus genes into the body; these genes code for Ebola proteins that stimulate an immune response. The vaccine candidate has shown promising results in animal models against two Ebola virus species, including the Zaire Ebola species responsible for the current epidemic in West Africa. A small Phase 1 study to examine the safety and ability of this candidate to induce an immune response in humans began on September 2, 2014, at the NIH Clinical Center in Bethesda, MD. Results from the study are anticipated by the end of this calendar year, and will help inform future development of the vaccine.

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

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

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

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

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

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

CLINICAL TRIALS

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

NIAID is committed to working with our partners to evaluate candidate drugs and vaccines for safety and efficacy. We are working to generate the evidence to show whether potential interventions are safe and effective to reassure affected communities that we are pursuing the tools needed to prevent and treat this deadly dis-

ease. 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.

ATTACHMENTS

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

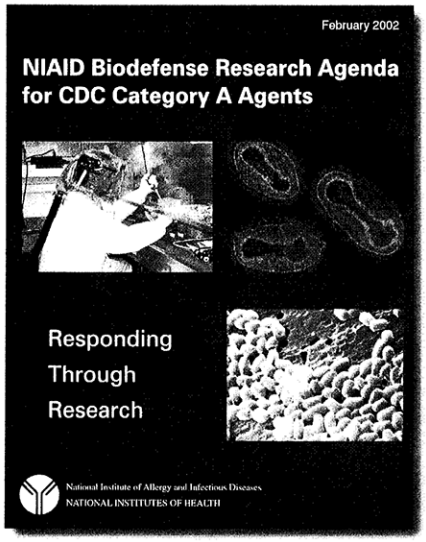
The Role of the National Institute of Allergy and Infectious Diseases in Research Addressing Ebola Virus Disease

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health

September 16, 2014

9/11 Attacks

2001 Anthrax Attacks



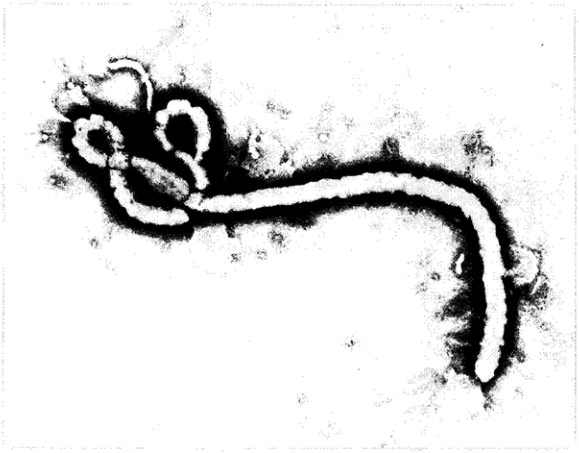
Category A pathogens

- Anthrax (*Bacillus anthracis*)
- Botulism (*Clostridium botulinum* toxin)
- Plague (*Yersinia pestis*)
- Smallpox
- Tularemia (*Francisella tularensis*)
- Viral hemorrhagic fever viruses (e.g., Ebola, Marburg, Lassa and Machupo)

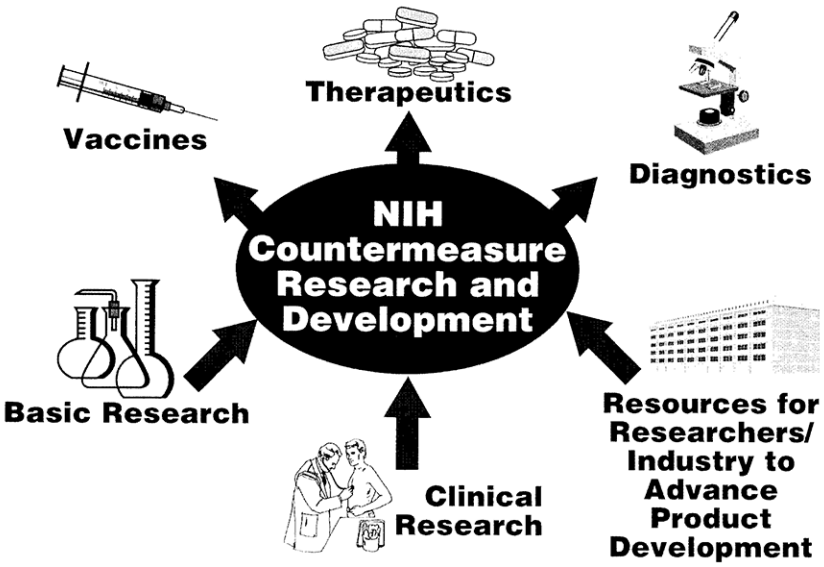
Viral Hemorrhagic Fever Viruses

- High degree of lethality and high infectivity
- Therapy: Mainly supportive
- Vaccine: Not available at present

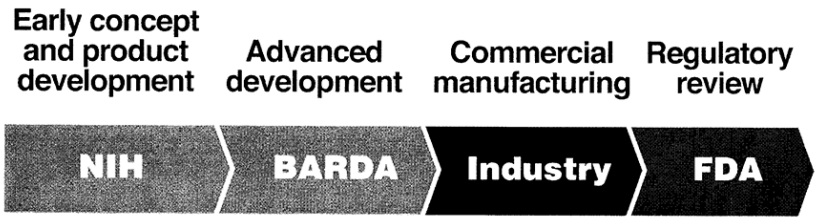
Ebola Virus



Source: CDC



Product Development Pipeline



NIAID Ebola Therapeutics in Development

- ZMapp (Mapp Biopharmaceutical)
  - Combination of 3 artificially produced antibodies directed against the Ebola virus
- BCX4430 (BioCryst)
  - A novel drug (nucleoside analogue) that interferes with the reproductive process of the virus
- TKM-Ebola (Tekmira Pharmaceuticals)
  - Small inhibitory RNA molecule that interferes with the replication of the virus (supported by the Department of Defense)

ZMapp Administered to Several Individuals

August 21, 2014
DAILY NEWS

Did Experimental Therapy Drug ZMapp Cure Two Americans with Ebola? Experts Can't Say, Yet

M Engel

August 27, 2014
Newsweek

UK Ebola Victim Treated with Experimental Drug Zmapp

Liberia: Two Ebola Patients Given All Clear after ZMapp Treatment

THE WALL STREET JOURNAL
August 13, 2014

Ebola Virus: Infected Priest Has Died in Spain

M Moffett

NIAID Ebola Vaccines in or Approaching Phase I Trials

■ NIAID/GSK (chimp adenovirus vector)	*Phase I trials initiated September 2014 at the NIH*
■ NewLink (VSV vector)	*Phase I trials expected fall 2014*
■ Crucell (adenovirus vector)	*Phase I trials expected fall 2015*

Other vaccines in development: Profectus (VSV vector); Bavarian Nordic (MVA vector); NIAID Intramural, Thomas Jefferson Univ. (rabies vector)

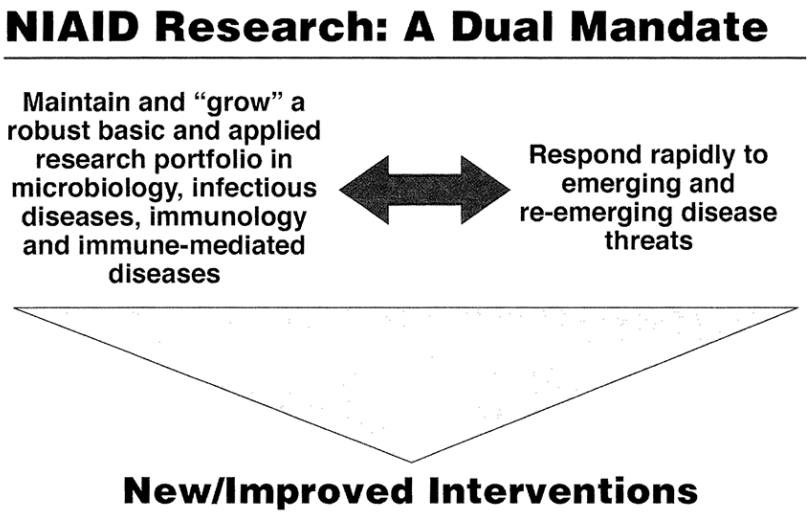
U.S. Department of Health and Human Services
NIH News
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)

September 2014

NIAID/GSK Ebola Vaccine Trial

- 20 volunteers to receive vaccine to determine safety
- First volunteer received vaccine on Sept. 2
- Thus far, 10 of the 20 volunteers in the study have received vaccine



The CHAIRMAN. Thank you, Dr. Fauci.

Dr. Robinson, please proceed.

STATEMENT OF ROBIN A. ROBINSON, PH.D., DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, DEPUTY ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. ROBINSON. Good afternoon. Thank you, Chairman Harkin, Ranking Members Alexander and Moran, and other distinguished members of the committee. We thank you for your generous appropriations over the years and the opportunity to speak with you today about our government's Ebola response efforts. I'm Dr. Robin Robinson, BARDA Director and ASPR Deputy Assistant Secretary in HHS.

BARDA, which was created by the Pandemic and All-Hazards Preparedness Act in 2006, 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 and responded to emerging threats like the HIN1 pandemic in 2009 and the Avian H7N9 outbreak last year with CDC, FDA, and NIH.

Today we face Ebola, which is simultaneously a biothreat and a material threat determination by the Department of Homeland Security in 2006 and an emerging infectious disease. As Dr. Fauci and Dr. Bell have said, when it comes to Ebola as a biothreat the best way to protect our country is to address the current epidemic in Africa, the worst in history.

BARDA works with its Federal partners to transition medical countermeasures from early development at NIH and Department of Defense and to advance 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 received FDA approval in just the last 2 years. Today we are transitioning several promising Ebola vaccine and therapeutic candidates from early development under NIH and DoD support to advanced development.

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, and FDA and industry partners, we 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, an improved framework of medical countermeasures development has been afforded to Federal and industry partners. Indeed, last year we utilized these partnerships to design, develop, manufacture, test, and stockpile five vaccine candidates in record time for the H7N9 outbreaks in China.

In the current Ebola response, we are working with a wider array of partners, including Canada, the U.K., West African countries, the World Health Organization, the Gates Foundation, and many others to make and test these Ebola product candidates.

BARDA has established a medical countermeasures infrastructure to assist product developers on a daily basis and to respond immediately in a public health emergency. Today we're using our Animal Studies Network to conduct critical animal challenge studies, our Centers for Innovation in Advanced Development and Manufacturing to expand production of Ebola monoclonal antibodies, and our Fill-Finish Manufacturing Network to fill Ebola antibody and vaccine products into vials.

Additionally, our Modeling Division, which develops computer models of the medical consequences of manmade threats on a routine basis, is coordinating international and Federal modeling efforts on the current Ebola epidemic and possible impacts of nonmedical and medical interventions. Last, BARDA supports a large-scale production of medical countermeasures as a response measure for public health emergencies.

BARDA led the vaccine manufacturing responses in the H1N1 pandemic in 2009 and the H7N9 outbreak in 2013. Today we are assisting the Ebola vaccine and therapeutic manufacturers with scaled-up manufacturing. Specifically, we are supporting the development and manufacture of the ZMapp monoclonal antibody therapy for clinical studies at one manufacturer; additionally, expanding overall manufacturing capacity of ZMapp by enlisting the help of other tobacco plant-based manufacturers; and third, seeking alternative Ebola monoclonal candidates to expand the production capacity.

Additionally, BARDA is working with the NIH and DoD and industry partners to scale up the manufacturing of two promising

Ebola candidates, one of which Dr. Fauci talked about, for clinical studies in Africa next year.

The fiscal year 2015 continuing resolution and appropriations are needed now to fund investments in these medical countermeasures candidates. BARDA faces challenges in the coming weeks and months with the manufacturing of these medical countermeasures, but the bottom line is that BARDA, with our Federal and industry partners, will use our collective capabilities to address today's Ebola epidemic and to be better prepared for future Ebola outbreaks or bioterrorism events going forward.

We thank the committee and subcommittee for your generous and continued support and the opportunity to testify, and I look forward to your questions. Thank you.

[The prepared statement of Mr. Robinson follows:]

PREPARED STATEMENT OF ROBIN A. ROBINSON, PH.D.

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

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

BARDA exists to address the medical consequences of these threats and to bridge the gap between early development and procurement of medical countermeasures for novel threats. Ebola is simultaneously a biothreat (with a Material Threat Determination issued in 2006 by the Department of Homeland Security) and an emerging infectious disease. The current Ebola epidemic is the worst on record. As CDC has said, we do not view Ebola as a significant public health threat to the United States. The best way to continue to protect our country from any domestic threat posed by Ebola is to take action to address the epidemic in Africa.

BARDA works with our PHEMCE partners in HHS and other Federal agencies to transition medical countermeasures from early development into advanced development and ultimately to Food and Drug Administration (FDA) regulatory review and approval. Advanced development includes critical steps needed for a product to be ready to use, such as optimizing manufacturing processes so products can be made in quantity to scale, creating and optimizing assays to assure product integrity, conducting late-stage clinical safety and efficacy studies, and carrying out pivotal animal efficacy studies that are often required for approval. Since 2006, BARDA has managed the advanced development of more than 150 medical countermeasures for chemical, biological, radiological, and nuclear threats and pandemic influenza. Seven of these products have received FDA approval in the last 2 years alone.

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

Working in conjunction with PHEMCE partners, BARDA uses public-private partnerships with industry to ensure that we have the medical countermeasures to protect the emergency health security of the United States. Over the past 5 years, BARDA—with NIH, CDC, FDA, and industry partners—has built a flexible and rapidly responsive infrastructure to develop and manufacture medical countermeasures. Last year, for example, in response to the H7N9 influenza outbreaks in China, the PHEMCE mobilized these partnerships to design, develop, manufacture, clinically evaluate, and stockpile several vaccine candidates in record time. In the current Ebola response, the PHEMCE is working with a wider array of partners in addition to our Federal partners. They include other countries, specifically the affected and at-risk African countries; the World Health Organization (WHO); the Bill and Melinda Gates Foundation; and others. These expanded partnerships are critical to our efforts to address the current Ebola epidemic.

BARDA has established a medical countermeasure infrastructure to assist product developers on a daily basis. The medical countermeasure infrastructure also allows for BARDA to respond immediately in a public health emergency. Today, BARDA is using this infrastructure to respond to the current Ebola epidemic by helping to develop and manufacture several investigational Ebola therapeutics and vaccines. BARDA's Animal Studies Network is conducting critical animal challenge studies for promising investigational Ebola therapeutic candidates. BARDA's Centers for Innovation in Advanced Development and Manufacturing, established in 2012, are positioned to accelerate production of Ebola monoclonal antibodies, like those in ZMapp, in tobacco plants and mammalian cells if clinical trials demonstrate that ZMapp is safe and effective. BARDA will monitor ZMapp throughout the development cycle, and, if necessary, can shift funds to test other candidate therapeutics. Our Fill-Finish Manufacturing Network, established last year for pandemic preparedness, stands ready to formulate and fill Ebola antibody and vaccine products into vials for studies and other uses. The investments we have made to create this infrastructure over the past 4 years are helping us respond to the current epidemic.

BARDA also supports large-scale production of medical countermeasures as a response measure for public health emergencies. BARDA led the manufacturing of vaccine and antiviral drugs in response to the H1N1 pandemic in 2009 and of vaccines as a preparedness measure for H7N9 in 2013. In the current Ebola epidemic, BARDA is providing assistance to vaccine and therapeutic manufacturers to scale up production from pilot scale, in which a handful of doses can be made, to commercial scale. For ZMapp, we are currently supporting the manufacture of enough doses for clinical safety studies, but we need to start now to expand the number of domestic manufacturers who can produce Ebola monoclonal antibodies using tobacco plants. Therefore, the Administration is requesting funding for this purpose through an anomaly to the fiscal year 2015 continuing resolution. Additionally, we are looking at alternative Ebola monoclonal antibody production systems, including those used for similar families of products in the commercial market, as a means of further expanding production capacity for this product. With respect to vaccines,

BARDA is working with NIH/NIAID, DoD/DTRA, and industry partners to scale up the manufacturing of the two promising investigational Ebola vaccine candidates. To enable the conduct of clinical efficacy studies for investigational Ebola therapeutics and vaccines in Africa throughout the next year, we need appropriations to fund investments in these medical countermeasure candidates now as proposed through the continuing resolution anomaly.

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

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

The CHAIRMAN. Thank you very much, Dr. Robinson. Thank you all for your very succinct summations of your statements. We'll start a round of 5-minute questions. I'm going to ask people to try to adhere to that. We have another panel that's going to be very interesting also, Dr. Brantly, who is a survivor, and Ishmael Charles, who is a worker on the ground in western Africa. We would like to get to that panel this afternoon.

I'll start a 5-minute round. Dr. Bell, these disease outbreaks seem to be becoming more common because of the close proximity of humans and animals, because of the close proximity of humans. Travel is common, and what's happened in West Africa I believe is due to a failure of the public health system or the nonexistence of a public health system in those countries.

A couple of years ago, in traveling through Africa with Dr. Frieden it occurred to me that in some of these countries they need a CDC. They need an entity that is culturally sensitive, that involves people of that country, that can detect these early, do the epidemiological work, isolate and control at the beginning. And they need to be connected with our CDC so that we can work together. Last year, Senator Moran and I put money in the appropriations bill—I forget how much it was, $10 million or something like that—to start expanding this.

Would you speak to this, and how important is it for these other countries to create their own version of the CDC so that these outbreaks can be controlled right from the beginning? In other words, every country having their own CDC.

Dr. BELL. Yes, thank you, Senator. You make some very important points. There are some fundamental capabilities that we at the CDC almost take for granted because they're so fundamental, that are really absent in many of these countries: basic laboratory capacity, rapid response teams, some understanding of what it takes to investigate an outbreak, emergency operations centers where we understand the structure that one needs in order to control, to identify and control an outbreak, telecommunications systems, some very basic capabilities.

These are capabilities that we agree with you really need—they're fundamental and really every country needs these capabilities. In many ways, that's what the Global Health Security Agenda is about.

I might give you an example from another country in Africa by way of contrast. We're in the midst now of the largest and extremely challenging Ebola outbreak, but we at the CDC have actually been investigating and stopping Ebola outbreaks in East Africa for actually quite a long time. One of the countries in which we've been working is Uganda. If you look at the list of Ebola outbreaks of the past, you'll see that many of them were in Uganda, some of the largest ones involving hundreds of people, which of course at that time we thought was a lot.

Over the last decade or so, we've been working with Uganda, with the Ministry of Health and with the Uganda Virus Research Institute to build capacity there. They now have a laboratory, which allows them to do their own testing and detect Ebola and other viral hemorrhagic fevers. They have a transportation network, which allows them to move specimens around the country

and get them to the laboratory. They have rapid response teams that know how to find Ebola outbreaks and stop them.

Consequently, what we've seen in Uganda over the last few years is more outbreaks being detected, which is good because we know that they're going on, and then they're much smaller, to the point where a year or two ago there was an outbreak of Ebola which involved one person. They were able to stop it after one person. Most of these are small clusters which are stopped quickly.

This is an example of building the kind of capacity that you're talking about, which is of benefit to the country. It helps the country solve some very fundamental health problems that they have. This is an example of the kind of thing that we think, we agree with you, really needs to be built in every country.

The CHAIRMAN. I hope this Congress and the one to follow—I won't be here, but the one that follows—will really take this up. We have spent lots of taxpayers' dollars in shoring up military operations around the globe so people could defend themselves against insurgencies, could defend themselves. Yet on this one aspect we have been woefully inadequate. It's like we expect our CDC to do everything. It can do a lot, as we've shown, but we need those other CDC's in those countries out there. Think about those as forward outposts where people can defend themselves and in turn defend us from the rapid transmission of these viruses.

I thank you very much. I thank Dr. Frieden and all of you down there for your great leadership. I hope that in the next few years we can see CDC replicated in countries around the globe.

Thank you, Dr. Bell.

Senator Alexander.

Senator ALEXANDER. Dr. Bell, you and the other witnesses have carefully explained that we know what to do about Ebola and we've demonstrated that it can be controlled. However, in talking with you and Dr. Frieden, without putting words in your mouth, I can tell you feel like this epidemic, this outbreak, is a very, very serious problem that we ought to jump all over.

Let me try to put that into some perspective. You said a moment ago that a few hundred cases would have been a big outbreak. Today the official report says you have identified a little less than 5,000 cases, correct? But it might be higher than that. Is that right? What are the chances that that's underreporting the number of cases in West Africa?

Dr. BELL. Quite likely, Senator.

Senator ALEXANDER. Quite likely higher. It's also true that, of those cases that you reported, half of them were reported in the last 3 weeks, is that correct?

Dr. BELL. More or less, yes, sir.

Senator ALEXANDER. So if the number were 10,000 or 15,000 instead of 5,000, perhaps half those cases would have been reported in the last 3 weeks.

Dr. BELL. Quite possibly.

Senator ALEXANDER. The danger is the rapid infection. Why such a worry? Is it that the infection spreads more rapidly? Is that the concern? We've had many kinds of epidemics, but why such a grim outlook about this epidemic? Why does CDC say it may be the most dangerous epidemic of modern times if it's not controlled?

Dr. BELL. Yes, sir. Thank you, Senator. As you've heard, Ebola actually is not easily transmitted. It isn't transmitted through the air and it requires direct contact with bodily fluids, with dead bodies. But what we're seeing in this outbreak is, because of right now insufficient capacity to isolate patients with Ebola, we are seeing these chains of transmission. You can imagine, as the number of cases grows, the number of contacts for each case, that these chains of transmission continue to propagate. That's how the number of cases grows and continues to grow faster as the number of cases increase.

It's really a matter of arithmetic, and it brings me to the point of what is the critical issue right now, especially in Liberia, but really in all of these countries. That is that we must come up with some ways to effectively isolate and treat Ebola patients. Right now our capacity——

Senator ALEXANDER. But first you have to find them, right? You have to chase down every infected person or person who might be infected, right?

Dr. BELL. Right now, Senator, certainly in Liberia there are patients that we know about and there are no Ebola treatment units in which to house them. So yes, we must do meticulous contact tracing. We must identify all the potential cases, isolate them, check their temperatures for 21 days to make sure that they're not infected. But right now, especially in Liberia, the problem that we have is that we don't have measures to effectively isolate cases that we do identify. That's right now the limiting factor, I would say, in Liberia.

Senator ALEXANDER. So the new cases seem to appear to double in 3 weeks, and half those infected die?

Dr. BELL. Right now it appears that's the mortality rate, that's right, sir.

Senator ALEXANDER. Dr. Fauci, I have one question for you. Dr. Bell pointed out that you don't catch Ebola by breathing on someone. It's bodily fluids, usually when someone is infected and has symptoms.

Dr. FAUCI. Right.

Senator ALEXANDER. Or someone is dead. And those two instances are most of the infections. You were quoted recently as saying it's not likely that Ebola will change how it's transmitted, which produces an even more serious set of possibilities. Are you tracking the virus in this outbreak as it affects more and more people to see if in fact it's mutating and changing in the way it's transmitted, so that we're not deceived by that?

Dr. FAUCI. Very important question, Senator. So let me just first answer the question and then I'll tell you what we're doing to make sure we're on top of this. Right now the Ebola virus is not transmitted by the respiratory route. There has been some discussion that since the virus replicates a lot—whenever you have an RNA virus, the more it replicates the greater the possibility of it mutating is. And most mutations are irrelevant mutations. They're not associated with a biological change or a biological function. So even though you see a lot of mutations, it is unlikely that there will be a change, but there's a possibility that there will be a change.

Usually when you have a change in function it could get a little bit more virulent, a little bit less virulent, be efficiently spread in the way it usually is spread or less efficient. It is an unusual situation where a mutation would completely change the way a virus is transmitted. It's not impossible, but it would be unlikely.

We never take anything like that lightly, we follow it very, very carefully. In fact, in direct answer to your first question, we have an arrangement with one of the best microbial sequencing groups in the world at the Broad Institute in Boston that is getting samples and looking at the evolution of the mutations to try and make sure that mutations are not occurring that would have an important impact on what we call a biological function, like transmissibility.

The reason I made that comment is that I wanted to make sure that people understand that changing transmissibility so that it could be transmitted by the respiratory route is obviously something that could be a frightening thing. I want to make sure that people understand that we're watching that carefully, but that's an unlikely event, not an impossible event, unlikely.

What is likely is that if we don't do what we're doing now in the sense of a major ramping up of infection control capabilities, including what we're hearing about getting the military heavily involved with all of the things they bring to the table, it is very likely if we don't stop this epidemic it's just going to get worse and worse, the way Dr. Bell said. That's the more likely phenomenon, so that's the reason why we concentrate on getting it under control so you don't give it the opportunity to mutate any more.

A virus that doesn't replicate can't mutate. So if we just put the lid on this, that'll be it.

Senator ALEXANDER. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

I will recognize Ranking Member Moran next, and in order of appearance I have here, I have then Senator Warren, Senator Burr, Senator Reed, Senator Isakson, Senator Murray, Senator Cochran, Senator Casey, Senator Johanns, Senator Bennet, Senator Boozman, and then Senator Whitehouse, Senator Pryor, and Senator Durbin.

Senator Moran.

Senator MORAN. Chairman Harkin, thank you.

Dr. Bell, thank you to you and Dr. Frieden for the visit we had in Atlanta a few days back and for the visit I had with Dr. Frieden in my office this week. At that point in time, I expressed to Dr. Frieden my request that he express gratitude on behalf of me and all of us in this country for the efforts by the people who work at CDC, who are working now globally, trying to contain and change lives. We're very grateful for what you have undertaken.

Let me ask first a question. Dr. Fauci just indicated about the potential response of use of the military. Is there something that you can say to the American people that assures them that our military men and women will be safe and secure from Ebola in the new tasks that they're now being asked to undertake?

Dr. BELL. Thank you, Senator, and thank you for the kind words about the CDC.

The CDC already has more than 100 people in the field, and this question of safety and security of our own staff or any staff or any members of the U.S. Government or many of our colleagues here, their safety and security is really our No. 1 priority. We've been actually paying a lot of attention to this issue, certainly, as I say, starting with our own staff, with making sure that the staff understands what the situation is like on the ground before they go, having them understand very clearly what are the interventions that they need to take, making sure they have the right kind of personal protective equipment, that they understand some basic strategies in terms of distancing, and that they know what to look for should they start to feel ill.

I think that the bottom line here is that it is a very dire situation. We are concerned about safety and security. We are taking that very seriously and have taken a lot of steps to do everything that we can to minimize the risk. But it is a very difficult situation and this is something that I worry about certainly every day with my own staff that are out there on the front lines.

Senator MORAN. Let me expand my expression of gratitude to the private religious charitable organizations and health care organizations that are working globally, at significant risk to themselves.

What kind of coordination, education, training, do you understand either has taken place in regard to our military and their preparation for this assignment?

Dr. BELL. Senator, I don't have any specific information about the preparation of the Department of Defense, but I will say that this is one of the areas that we at CDC have actually been working quite closely on, that being in training. Next week we'll be hosting a course in Aniston, AL, at the FEMA facility there, which is a 3-day safety training for health care workers who are planning to deploy to work for nongovernmental organizations in Liberia, Sierra Leone, or Guinea.

This is a course that our colleagues at Medecins Sans Frontieres, Doctors Without Borders, helped us develop, and the precise purpose is to explicitly teach—these are health care workers; they already know, supposedly, about infection control—but explicitly teach them about the important principles that they need to know in order to safely care for Ebola patients. There's a mock facility there and, as I say, we're hoping to actually have this course weekly over the next period of months. Our first course is actually completely full. There's a lot of interest. And we think that this kind of training is really pivotal before Americans deploy to work in treatment facilities in the region in order, to your point, to make sure that they can care for patients safely.

Senator MORAN. Dr. Bell, let me ask a broader question. How would you describe the best case scenario in regard to Ebola and its spread and consequences and the worst case scenario, and what is the difference—what is the item that makes the worst case scenario not happen, and the best case scenario to occur?

Dr. BELL. The best case scenario is that over the coming months we're able to effectively isolate and treat Ebola patients, we're able to effectively trace all of the contacts, make sure they're all followed for 21 days, and we're able to do something about safe burial practices so that we don't have bodies in the street and people are

able to respectfully bury their dead and not put themselves at risk, so that over a period of the coming months we're able to interrupt chains of transmission and start to see this increase in cases that Senator Alexander was talking about, bend that curve in the other direction.

The worst case scenario is that we continue to see the exponential rise in cases that we're currently seeing. An important corollary of that is exportation to other countries. As I mentioned, we've already had exportation to Nigeria and Senegal. I will say that the situation in Nigeria was one that we were extremely concerned about. You could imagine, in a country like Nigeria, should we have Ebola get out of control how incredibly dangerous this would be. It was an enormous effort in order to get the situation in Nigeria to the point that it is today, which is that, while we're not completely out of the woods, we do not think that there's uncontrolled transmission happening in Nigeria.

But just for an example, this involved following up on thousands of contacts, hundreds of people working in the emergency operations center in Lagos and then in Port Harcourt. So one exportation like that, it requires an enormous amount of work.

If this outbreak spirals out of control, we can expect many more of these exportations to other countries. Each one of those, as I say, requires a huge amount of work, and we have no guarantee that we'll be successful. You could imagine the outbreak spreading outside of the borders of the countries that are currently affected as certainly part of a worst case scenario.

Senator MORAN. Thank you, Dr. Bell.

The CHAIRMAN. I'm going to recognize Senator Reed. Before I do it, I just have one clarification. Dr. Fauci, you said this was nonrespiratory communicable. But what if someone sneezes on somebody?

Dr. FAUCI. Mr. Chairman, there is no evidence, with a lot of experience over multiple outbreaks, including the current outbreak, that respiratory spread occurs, or if it does it's extraordinarily rare. You never say never in biology, but people who have been in situations in which that particular phenomenon would have been noticed clearly indicate that that's not the case.

The CHAIRMAN. Got it. Thank you.

Senator Reed.

STATEMENT OF SENATOR REED

Senator REED. Thank you very much, Mr. Chairman.

Let me first thank you and your colleagues for your extraordinary service to the Nation and to the world. One of the reasons that this issue is so important in Rhode Island is that we have a large Liberian community, probably the largest Liberian community per capita in the United States, and they are hardworking and they are terribly concerned about their families in Liberia.

I want to thank, Dr. Bell, you and Dr. Moro, because Dr. Moro actually participated in a conference call with our Liberian leaders. Senator Whitehouse and I were both involved in setting it up. Thank you very, very much.

I also want to join Senator Moran in saluting those volunteers. We have two doctors on the Brown University faculty, Dr. Tim

Flanagan and Adam Levine, who are in the country giving their skills and courageously working on behalf of the people of Liberia. Thank you for that.

One other point I'll make, and this is something of an aside. A number of the Liberians in Rhode Island and across the country are here legally on a status of deferred enforced departure, but let me make the point: That status expires September 30th unless the President extends it. I would hope that he would do so because to send people back to this, literally, danger would be I think inappropriate.

But let me ask Dr. Fauci and Dr. Robinson, you talked about a vaccine. Do you have sort of a sense of how fast this could be deployed in West Africa? And second, would you reach the point where you basically said, it's a huge risk, but it has to be done, even if you don't have all of the usual protocols completed?

Dr. FAUCI. Excellent question, Senator Reed. The standard way of implementing a vaccine in the field and deploying it is to go through a series of steps of what I just described—phase I, show is it safe and does it or does it not induce unexpected reaction, a hypersensitivity reaction or whatever; then find out what the right dose is and does it induce the right immune response. Then you go to larger numbers of people, because now you're pretty sure it's safe, you can do larger numbers of people in what's called a phase IIA or IIB.

Then, depending on the disease, you can go out in the field and test if it works, because the worst thing that you'd want is have a vaccine that you're deploying that you think works, but it doesn't work, or even one that would be even more terrible is a vaccine that actually makes things worse.

So we have to consider all of that. But when you have an emergent situation like this, where you have the desire to get people protected if in fact the vaccine is protective, there are ways to get the answers, not as definitively as if you did a pristine type of a trial, but if you would then employ the people who are needing the vaccine as part of the clinical trial, where you either compare one vaccine against another or one dose against another, so that you accomplish two things. You try and determine if it's safe and effective, even though it isn't as definitive as the pristine trial, but at the same time by getting people into these expanded trials you actually make it available.

Right now the thought is once we get this situation where we can say we know what the dose is and we know it's safe, to have an expanded trial and within the context of that trial more people would get the opportunity to be vaccinated.

I might say that the target of the vaccinations is clearly directed, among others, to the health care workers, the people on the front line, the emergency responders, because those are the ones that put themselves at risk, as did Dr. Brantly, in taking care of individuals.

Senator REED. So if you can prove, which is what you're trying to do right now, that it's safe, but I don't know if it's effective, you can try to prove its effectiveness by inoculating the health care workers and others.

Dr. FAUCI. Right.

Senator REED. It's better than nothing, but it's not quite definitive.

Dr. FAUCI. Right. Fully knowing that you're not going to get a definitive answer. But still, when you're in an emergent situation you've got to do the best with what you have.

Senator REED. Briefly, any further comments, Dr. Robinson?

Mr. ROBINSON. Commensurate with those clinical trials that Dr. Fauci is talking about is that we have to have the product there, the vaccines, to be made available. Part of that is taking these products that are very early in development, that are pilot scale, and making sure we can go to commercial scale and produce those in large quantities, so that these studies can be done and after that, if they are shown to be well tolerated and immunogenic and protective, that there's more vaccine available.

Senator REED. Thank you all for your extraordinary work, and please thank your colleagues, particularly those who are in the field at risk.

Thank you.

The CHAIRMAN. Thank you very much.

Senator Burr.

STATEMENT OF SENATOR BURR

Senator BURR. Mr. Chairman, thank you.

Thank you to this panel, the next panel, and thousands who will be called into action over the next weeks and months, hopefully not years.

Dr. Bell, you said if we don't act now. Can you define "now" for me from the standpoint of a time line? At what point will we have reached where we said we've missed our opportunity? How long is that?

Dr. BELL. Senator, I wish I had a crystal ball and could tell you precisely the answer to that. But the situation is quite fluid and I think it's quite hard to predict with any kind of precision. I certainly can say that speed and scale is of the essence.

Senator BURR. You used the term several times "controlling the outbreak." Is controlling the outbreak the same or do you use that the same way you do "containment"?

Dr. BELL. Yes, sir, more or less, yes.

Senator BURR. How do you achieve containment on a disease that's already broken the containment?

Dr. BELL. You can think of this as bending a curve. A curve is going in one direction. We want to make it go in the other direction. In order to do that, what we have to do is break these chains of transmission. The way we break the chains of transmission is by having effective ways, to isolate patients so that they can't transmit and to make sure that there isn't ongoing transmission happening, for example in health care facilities or from unsafe burial practices.

Senator BURR. Let's just take Liberia as an example, 1,383 cases in the last 21 days, and we're surging through DoD the capacity for 1,700 beds in a country where they have zero now. My math is not great, but my math says we're going to be behind the eightball on day one because we won't have enough beds.

Dr. Fauci, I'm told the most infectious tool or method in these countries today is the back of a cab, where individuals ride with their family to find that there are no beds in the clinic and they ride home. Let me ask you, how long can the virus survive, whether it's on a cab seat or whether it's on a sheet or whether it's on a table? How long can it infect somebody?

Dr. FAUCI. There have not been definitive studies giving a timeframe. It is not very durable, it's somewhat of a fragile virus. But we do know that people get infected from touching the dead bodies of people who have the virus—probably contaminated with blood or bodily fluids. It certainly is within the timeframe of when someone dies to a funeral, because that's when people have been documented to get infected.

I don't think we could go, Senator Burr, beyond, giving you days, weeks, or whatever. But it clearly is not instantaneous, where once the virus gets out of the body it's gone, because we know people have been infected at funerals by touching the body.

Senator BURR. I understand on previous Ebola outbreaks we've seen five generations of transmission. How many generations of transmission have we seen so far with this epidemic and how many mutations are we seeing as the virus continues to spread with each chain of transmission?

Dr. FAUCI. I can't give you a number on that, but when you have an RNA virus it notoriously is a bad reproducer. It makes mistakes, and when it makes mistakes it mutates. Most of the mutations don't mean anything. They're just irrelevant. They're called synonymous mutations. They don't mean anything.

Some of them, rarely, do mean something. Sometimes it means that it kills the virus. Other times it maybe modifies some of its biological function.

I can't tell you how many generations, but that could mathematically likely be figured out on the basis of a paper that just came out about a couple of weeks ago from Boston, where they looked at 78 people and the virus taken from them, and if you did a mathematical computerized informatics you'd be able to say how many replications. I don't have that number for you now, but you can determine that.

Senator BURR. If you'd get that to us, I'd appreciate it.

Dr. FAUCI. I will.

Senator BURR. Dr. Bell, in recent days there have been reports of modeling that suggest we could see 20,000 cases a month and that the outbreak may last 12 to 18 months, which would calculate to roughly 360,000 cases. Again, I think we continue to be a step behind up until this point, this response point. On what projected number of cases and period of outbreak did the administration base its response strategy to date and the latest actions announced today?

Dr. BELL. As you say, Senator, there have been a number of models out there and we ourselves have been working on a model, and I think it is certainly true that a number of these models predict without additional effective interventions that we could see hundreds of thousands of cases. So all of those modeling exercises I think have certainly been taken into account as we've been calling for additional interventions in these countries.

I think the critical point here is that those models for the most part, as I say, are based on not scaling up and what we're doing right now is scaling up. In addition to all the things that the U.S. Government is doing to scale up, including the announcements from the Department of Defense, there are also many other international partners who are also scaling up—the World Health Organization, other countries, many nongovernmental organizations, some of our colleagues here that will be testifying in the next panel. There's also more financing that's become available, for example from the World Bank. The United Nations is becoming involved.

I think that it's fair to say that there is a general mobilization of forces here and what we're looking for is, with that mobilization of forces, these models, what they're predicting is not in fact what we're going to see happen.

Senator BURR. Dr. Bell, I appreciate that and follow it very closely, and I know the mobilization of most other countries and the United Nations is not near the timeframe that ours is, and that's why it scares me to death.

Mr. Chairman, thank you for your generosity, but let me ask Dr. Robinson, does BARDA have the resources it needs?

Mr. ROBINSON. To begin the medical countermeasure development or advanced development, yes, for this fall. We don't have going forward for Ebola next year to produce more vaccines and more therapeutics if we actually want to do more than just Zmapp for therapeutics. There are others that we have under consideration that Dr. Fauci has talked about. So we and others will need more funding, there's no doubt about that.

Senator BURR. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Murray.

STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much to the panel and Mr. Chairman for having this hearing.

I'm very proud to represent a State that is producing some truly incredible research in the biomedical field, including several ongoing studies and efforts that are aimed at curing Ebola. We've got World Vision, which is supporting the Ministries of Health, the Geneva Foundation, which is working on a treatment drug. Washington State University's Paul G. Allen School for Global Animal Health, they're looking at some culturally appropriate ways to prevent further transmissions; and of course the University of Washington Katz Lab which is looking at some vaccines and drug development. We're doing a lot out there.

But the reality is that we all have to do more. I think it's important to mention that one of the reasons I fought so hard to roll back sequestration in the Bipartisan Budget Act was to provide certainty for organizations like NIH and CDC, which have had to deal with, as we all know, some very steep and harmful budget cuts. I believe it's going to be very critical that we continue to focus on rolling back this trend of disinvestment in research and development so we can ensure that our country continues to produce the

kind of live-saving, world-changing research that we know we're capable of. But I am very concerned—I just need to say this—that fiscal austerity and the return of sequestration is going to continue to weaken our ability to respond to needs like this.

Dr. Fauci, while you're here, I wanted to ask you, can you talk a little bit about how the lack of budget certainty and sequestration and the budget fights of the last 2 years have really impacted the U.S.'s ability to respond to the Ebola situation?

Dr. FAUCI. Thank you for the question, Senator Murray. I'd have to tell you, honestly, it's been a significant impact on us, as you well know, and I know you've been fighting for us for quite a long period of time. Our budget has been flat since the end of the doubling in 2003, with the 2-plus percent inflationary index, that over a 10-year period we've lost about 22 percent in our purchasing power.

That was the left hook. The right cross was the sequestration that came in and pulled out a significant amount of money, $1.5 billion, of which we got reconstituted not all of it. We try to preserve the fundamental basic research of the investigators, the bright ideas that people have. If you want to preserve that, the money that you have for initiatives such as the development of vaccines and the development of drugs suffers, because it's a balance. There's programmatic initiatives and there's investigator-initiated awards, and when you shrink the budget or don't give even an inflationary increase all of that starts to whittle away and you get even secondary effects, like disincentives of getting bright people involved from your State or any State, who feel that there's a disincentive to get involved.

It has both in an acute and in a chronic insidious way eroded our ability to respond in the way that I and my colleagues would like to see us be able to respond to these emerging threats. In my Institute particularly, that's responsible for responding on the dime to an emerging infectious disease threat, this is particularly damaging.

Senator MURRAY. I hope that all of us keep that in mind moving forward.

Again, I'm proud of the folks in my State. The Bill and Melinda Gates Foundation gave $50 million to scale up emergency operations. Paul G. Allen Foundation has contributed $9 million to open emergency operations sites in three of the most affected countries.

Dr. Robinson, Director Bell, knowing that the Gates and Allen Foundations have stepped up that way and the money that is going to be included in this CR—thank you to our Appropriations chair who's sitting next to me—is that enough money and global support to stop this outbreak?

Dr. BELL. I'll answer, Senator, for the CDC. We do appreciate the $30 million that's in the CR. That amount of money is enough to keep us operating through the end of the continuing resolution on December 11th. It will allow us to keep our people in the field, to pay for our staff, and to begin to scale up in a way that we think is necessary.

We will be kind of considering over the time period of the CR what additional resources we will need for the rest of the fiscal

year in order to fulfil our responsibilities and response to the Ebola outbreak in the way that we need to.

Senator MURRAY. Dr. Robinson.

Mr. ROBINSON. The $50 million that we requested will get us through this fall. If we want more vaccines and more therapeutics, there will have to be more funding for us to go forward.

Senator MURRAY. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray.

Senator Isakson.

STATEMENT OF SENATOR ISAKSON

Senator ISAKSON. Thank you, Mr. Chairman.

Dr. Bell, I want to echo what Senator Moran, Senator Harkin, Senator Alexander, and Senator Reed said about how proud we are of CDC. As one of Georgia's two Senators, however, I want to add how proud we are of Emory University and Dr. Jim Wagner and the staff there—I know Dr. Brantly would probably feel the same way—as well as Phoenix Air, which I believe was the contractor from Bartow County, Georgia, that brought the patients back from Liberia to the United States. That was a tremendous effort.

For the committee's benefit, Saxby was gone when this happened, so I was the only Senator reachable by the press the day it was announced they were coming to Emory University. The press immediately looked for the wisdom in bringing an Ebola patient back to the United States, whether or not we had the capability of preventing the disease from spreading while we were treating Ebola patients. Emory University and the CDC did a marvelous job of making those transfers seamless and complete and proving to the media, that was trying their best to start a riot, I think, that the Ebola virus was going to be safely contained, that they were in the best place in the world. So you deserve a tremendous amount of credit. I just wanted to say that. I just wanted to say that publicly to you.

Dr. BELL. Thank you, Senator.

Senator ISAKSON. Tell me. You said this is by far the worst outbreak you've ever seen. What was the next worst before it in terms of numbers?

Dr. BELL. Let's see.

Dr. FAUCI. Uganda in 2000.

Dr. BELL. Yes. That was about 400 and some cases.

Senator ISAKSON. Here's my question, what makes this one so different?

Dr. BELL. There are a number of factors, Senator, that has made this one quite a bit different. No. 1, this is the first time we've seen Ebola in a large urban setting. Our previous experience with Ebola outbreaks has been primarily in rural areas, and there are many, many different factors that come into play when you have Ebola in a situation with people packed very closely together in a large city. That's one thing.

Another issue that has been challenging is that the area, the sort of three-country area where the outbreak sort of began and has been propagating from, is an area with communities that are sometimes not very receptive to interventions by either government or by public health officials.

A third point is that these are countries with very, very weak infrastructure to start with. They've just been emerging from decades of war. They have very weak health systems and very little capabilities, to Senator Harkin's point about public health capabilities, but even health care capabilities, so very little with which to battle this outbreak from the beginning.

Senator ISAKSON. I've traveled extensively in West Africa and I've seen firsthand exactly—they're almost bereft of health care facilities, of anything close to what we would consider to be reasonable.

Which brings me to this question. When you described containment, you described a very labor-intensive process. You talked about people taking temperatures for 21 days to see if somebody who's been exposed had been infected. You talked about monitoring. You talked about isolating. We're sending 3,000 American troops to West Africa as I understand it. We've got 100 CDC personnel. We have NGO's and other volunteers. But it seems like to me it's going to take a lot bigger labor force just to contain the disease at its current level; am I correct?

Dr. BELL. Yes, sir. There's lots of different settings that we can talk about, but for example in the Ebola treatment units 90 percent of the staff are local. I think it is important to remember that the governments, the people in the countries and the governments themselves, are stepping up and, with assistance from those of us that have the technical capabilities, are really able to fill many of these roles and responsibilities. As I say, some of the work in the treatment units, much of this going out into communities every day and checking in with contacts to see how they're doing, these are roles that the people themselves, the local people themselves in these countries, can undertake, as I say, with some technical guidance from some of us that have this experience.

This is not to minimize the scale of the human resources that will be needed to contain this. But as I say, I think that there are many of these sorts of functions that we're already seeing the local people help with. There's also other groups around Africa, the African Union, many of our field training programs from around Africa, that are also stepping up.

It is an enormous job, but it's a job where I think there are lots of different sectors and parts of the local community in addition to the international community that can work together to address this.

Senator ISAKSON. I know my time's up, but I wanted to make a comment. At the Africa Summit, which was here just about a month ago, I had the privilege of participating in a lot of that with some of the West Africa leaders. I noted how they were begging—not begging, but they were wanting so much American knowledge, CDC, NIH, all the technology, but they seemed very—even the bordering countries seemed like they were very willing to provide manpower, but they badly needed leadership in terms of health care. Is that correct?

Dr. BELL. Yes, sir. We've actually made quite a bit of progress in that regard over the last month or so and are working very closely with the African Union to have them deploy staff to the area.

Senator ISAKSON. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Before I recognize Senator Casey, you mentioned all these different entities. Addressing this we have CDC, USAID, State Department, World Health Organization, and Doctors Without Borders. Can you tell us who's in charge of coordinating our government's response effort in Africa?

Dr. BELL. Yes, sir. In terms of the U.S. Government, in each of the countries there is the Disaster Assistance Response Teams, the DART. This is a USAID umbrella under which all of the U.S. Government efforts are coordinated. We are quite well coordinated with the USG organizations.

In the larger sort of undertaking, in each of these countries people are getting organized, generally speaking with the government.

The CHAIRMAN. The USAID is in charge intra-country, in a country. But overall who is in charge of coordinating?

Dr. BELL. The three countries together are all under the umbrella of the USAID DART.

Senator MIKULSKI. Of USAID?

Dr. BELL. Yes.

The CHAIRMAN. I'm startled to find that out, that USAID would be in charge of coordinating.

Dr. BELL. Well, it's a disaster. When a disaster is declared—I don't know; as we scale up, I'm sure that there'll be other mechanisms for the various parts of the government to collaborate and coordinate with each other. But there is this kind of structure on the ground which is meant to——

The CHAIRMAN. I think this requires further looking into by this committee, by both these committees.

Senator Casey.

Senator MIKULSKI. I would concur, Mr. Chairman.

The CHAIRMAN. Thank you.

STATEMENT OF SENATOR CASEY

Senator CASEY. Mr. Chairman, thank you very much.

I want to thank the members of the panel, Dr. Bell, Dr. Fauci, and Dr. Robinson, for being here. I also want to note the good work that's been done by this committee and members of this committee for a lot of years, the chairman, Chairman Harkin, Senator Mikulski as well with her experience; grateful to work with them; Senator Burr, who has spent a lot of time on this and a lot of time on these issues and has become such a leading voice on this.

I don't want to plow ground that's already been plowed through. I apologize for having to juggle two hearings. But I wanted to ask Dr. Bell. I know that one of the fundamental questions you're asked is what's the threat to the United States, if any, and how you articulate that. Let's just say—for purposes of process and the mechanics of confronting this kind of a threat were it to arise here—pick a town in Pennsylvania. I won't pinpoint one, but if there was a patient at a hospital in that town and they tested positive for Ebola, what would be the steps that would be undertaken at that point?

Dr. BELL. Yes, thank you, Senator. We have been working quite closely here in the United States to prepare for this sort of eventuality that you describe. As we've mentioned, Ebola really is not easily transmitted.

I think in terms of helping to understand the context to answering this question, I just want to say a word or two about what a hospital in these countries in Africa looks like, as a way of contrasting. When we think of a hospital, we think of a shiny, clean building with lots of equipment. Most of the hospitals in this region, as many of you that have traveled to this area are aware, oftentimes there's no running water, there is no soap, there may not even be beds. There may be mattresses on the floor. Every health care worker is caring for a large number of patients. There'll be beds around them. They may not have the appropriate personal protective equipment, like gloves and gowns and masks.

That's the environment in Africa where Ebola is currently raging. In the United States, by contrast, we have many, many protocols in place, and with these protocols most hospitals that can isolate a patient in a private room with their own bathroom and can follow very strict and meticulous infection control practices which have been well outlined and which health care workers are quite aware of, can safely take care of Ebola patients.

I'll mention that, while we haven't taken care of any Ebola patients prior to this outbreak here in the United States, we have safely cared for at least five patients in recent years who have had other viral hemorrhagic fever, what we call Marburg virus and Lassa fever. In each of these circumstances, these patients were cared for quite safely in our hospitals around the country and we didn't see any ongoing transmission.

While this is certainly something to be taken quite seriously and we're doing a lot to educate health care workers, to educate laboratory workers, and to answer people's questions, to sensitize them to these issues, really most hospitals in the United States with these sort of basic capabilities should be able to safely care for Ebola patients.

Senator CASEY. Thank you, doctor.

I have limited time, but I wanted to ask Dr. Fauci one question. You noted in your testimony there are a number of Ebola therapeutics and vaccines in development. Recognizing that all these products are still rather early in their development, do any of them have clear advantages or disadvantages over the others? Can you make that assessment yet?

Dr. FAUCI. No, I don't think, honestly, Senator Casey, we can say that, because apart from ZMapp and one other perhaps, they have not really been in humans. We have in the past had experience where things look really good in an animal and then when they get into the human for one reason or other it doesn't work or it's too toxic.

It would be premature—I can say that there are a number of candidates that look favorable enough in an animal model that we're enthusiastic about moving them into a phase I and then beyond that. So there are a number of candidates that have a favorable profile in an animal model. But I think it would be unwise to

say this one looks a little better than this one, because it just is too premature to do that.

Senator CASEY. I know I'm out of time, but I hope there's nothing that the Congress has not done, not been able to achieve, that would be an impediment for you to be able to answer that question down the road and to be able to make the progress you want to make on these developments, because we have an obligation, I believe, to fund NIH and to fund this research in a manner that leads to the result that we hope. I think that's a bipartisan obligation and I say it for the record.

Thanks, doctor.

Dr. FAUCI. Thank you. We appreciate it very much, sir.

Senator CASEY. Thank you.

The CHAIRMAN. Thank you, Senator.

Senator Boozman.

STATEMENT OF SENATOR BOOZMAN

Senator BOOZMAN. Thank you, Mr. Chairman, and thank you very much for having this hearing, you and the rest of the leadership on both sides. This is so important.

To you all, we appreciate you being here. All of you have just sterling, excellent reputations and we appreciate the fact that you're working very, very hard to keep us safe.

From what I've read and from the testimony, it seems like speed is important, education is important, coordination is important. We have the CDC involved. We have the NIH. We have the DoD. We have the Department of State. Samantha Power is calling the Security Council for the first time ever in an event like this.

I would like to get into this a little deeper—we heard that USAID was distributing stuff over there. Who's in charge of all of that at the Washington level? Who's taking this on so that we can get coordination, so we can get speed and get the education component done? Is that CDC? Are you doing that, Ms. Bell? Dr. Bell, I'm sorry.

Dr. BELL. That's OK. We at CDC have the lead on the public health aspects of the response. The DoD and USAID have the lead on logistics and material. The National Security Council is coordinating, certainly from Washington, and it's really important that we draw on all of our assets from all of the different agencies working in our particular lanes and coordinating all together.

There is very strong inter-agency coordination. The NSC is deeply involved in bringing all the agencies together, and we at CDC take the lead in the public health aspect.

Senator BOOZMAN. Good. I hope we get this worked out where we actually have somebody that we can point to, an individual that's kind of in charge of coordinating, because the same thing that's going on on the ground, that needs to be going on over there, is simply not going to happen without that happening here.

One thing that's happened, Dr. Bell, Dr. Fauci, there's an Ebola outbreak going on in the Democratic Republic of the Congo. Is that related to this or is this a whole separate thing that we've seen in the past?

Dr. BELL. I'll say something. I'm sure Dr. Fauci can add. This outbreak is not related to what we're seeing in West Africa. As you

say, Senator, this area of DRC is an area in which we've seen many Ebola outbreaks in the past, and this outbreak is of a strain that's quite similar to those outbreaks. So while we are taking it very seriously, and actually CDC have sent a team into that area, we don't think that that outbreak is at all connected. We're actually aware of the individual case that began that outbreak and it had no relationship to what's been going on in West Africa.

Dr. FAUCI. I agree with Dr. Bell that that will be determined. It does not look like it's the same. The extraordinary ability to do rapid deep sequencing of the genome of these viruses can actually pinpoint whether or not they're related. It's very interesting that the study that was done and published very recently showed the exact point introduction of what we're seeing in West Africa and how it went from Guinea to Sierra Leone to Liberia, and it doesn't look like the strain that is in the Democratic Republic of the Congo is in that lineage, even though it's the same general strain.

Senator BOOZMAN. Dr. Bell, can you reassure the—I know the public is concerned about bringing it into the country. Can you talk to us a little bit about the steps with helping those that are at the airports and identifying people that possibly have the virus?

Dr. BELL. Yes, Senator. It's certainly quite understandable why people would be concerned. The images that we're seeing are quite alarming. As you know, we have been working in the countries to improve their abilities to do exit screening. We have teams in each of the countries and we've really been able to help them improve their capability to do exit screening considerably over the last month or so and are quite pleased with the progress in these countries.

They have equipment. They understand what they're supposed to do. They have the protocols in place and they are really moving forward.

In addition, I'll mention that we also have been doing a lot of work with our own border agencies, so with the TSA and with the CBP, to train them so that they understand what to look for and they understand when they need to call on us—as you know, CDC has quarantine stations in the major airports around the country—so that they also are sensitized to what needs to be done.

Then the final point I guess I would make on this topic to Senator Casey's point is that we've done a lot of work here in the United States with health care providers, even with just citizens, so that they know what to look for, to remember to ask for a travel history. There are a number of our Laboratory Response Network laboratories around the country who now have the capacity to test for Ebola, and then the health care facilities themselves are very tuned into the appropriate isolation methods that would be needed should they have a suspected Ebola patient.

Senator BOOZMAN. Thank you, Mr. Chairman.

Thank you.

The CHAIRMAN. Thank you, Senator Boozman.

Senator Bennet.

STATEMENT OF SENATOR BENNET

Senator BENNET. Thank you, Mr. Chairman. Thank you very much for holding this hearing.

Dr. Bell, you mentioned in your opening comments a particular problem in Liberia of there being a lack of isolation capacity. I wonder if you could describe for us—if everything actually worked the way it's supposed to work to make the decision, to make these fundings, first of all, what the experience of somebody today who's infected with Ebola is in Liberia if they don't have access to an isolation chamber; and then second, what you would expect to be the progress points we need to see in order to know that we're actually creating an infrastructure that really can change the outcomes, the course of the disease?

Dr. BELL. Yes, thank you, Senator. As you mentioned, there are not enough treatment facilities, isolation facilities, in Liberia right now to take care of all of the cases. Because of that, there is ongoing transmission that's occurring because we can't isolate them. So we're working on this in a number of fronts.

First, as many of the Senators have mentioned, we will be building more Ebola treatment units, and in addition a number of other entities, including the government of Liberia, are also building Ebola treatment units. So there will be a scale-up of Ebola treatment units. Medecins Sans Frontieres is building another. There's a number of groups that are actually working to scale it up.

In the mean time, there are a number of interim measures that we're also going to be taking so that people can be isolated safely not in a treatment unit. So there's a number of ways to approach that. There are community sort of holding centers, for lack of a better term, where people can be isolated safely with one caregiver and that caregiver can be provided with the appropriate personal protective equipment that they need to prevent transmission to themselves.

There are also some efforts afoot to do that in households, where a caregiver in a household would be given a kit which provided all the equipment that the person would need to protect themselves and also some of the medications, such as oral rehydration for example, Tylenol to help with fever, that the patient themselves could use during their illness.

There's a number of different kinds of interim measures that we're working to scale up now at the same time as we're working on building additional isolation facilities in Liberia.

Senator BENNET. How are you or with whom are you working to make sure that that work is actually happening, rather than just being thought about?

Dr. BELL. There is actually quite a bit going on right now. Actually, USAID has been working with a number of nongovernmental organizations, including MSF. They've actually produced tens of thousands of these kits and have a plan in place to scale them up to hundreds of thousands in the near future.

Senator BENNET. Thank you. In his first question or one of his first questions the chairman talked about the need to have a CDC or something like it in every country, and that is something I think we ought to aspire to. We have a long way to go to get there. I just wondered if you could talk a little bit about the efforts that you're making to create a more global, interoperable network of real-time detection of diseases and collaboration among these various countries in our response?

Dr. BELL. Yes. Part of our response here is to buildup these basic capacities in these countries. In addition, right now as an urgent matter we're working to buildup these capacities in the bordering countries—laboratory capacity, emergency operations centers, rapid response teams, beginning planning on what they would need to do in terms of isolation should they need to do that, working on culturally appropriate burial practices.

In those bordering countries that's an urgent priority for us. Then across the rest of Africa we're also working to harden the countries' ability to be able to recognize imported cases, to know who is the incident manager, how is their emergency operations center going to work, and what are the steps that they would take in order to respond to an additional case. Do they know how to do contact tracing? Who would be responsible for the contact tracing? Where would they isolate the patients? These are all things that we're working on now in the context of this outbreak.

In the bigger picture, these are basic capabilities that the Global Health Security Agenda, for example, has been calling for. As you probably know, we at CDC have been working with a number of countries in a pilot kind of way over the last couple of fiscal years to show the proof of principle of what global health security can mean, to detect, to respond, and to prevent these outbreaks with basic capabilities around laboratory capacity, around communications strategies, around emergency operation centers, basic epidemiology.

These are all fundamental capabilities that country by country we really need to build if we want to prevent this kind of thing from happening again in the future.

Senator BENNET. Thank you. I appreciate that testimony. Thank you for your testimony.

Thank you, Mr. Chairman.

The CHAIRMAN. I would say to my colleague from Colorado that last year the Appropriations Committee put in $6 million to start this process of establishing CDC's in key countries designated by CDC. I understand that some time this fall, the CDC will announce those initial grants.

We put $10 million in the appropriations bill this year to continue that effort. In light of the Ebola outbreak and others, I am hopeful that maybe we can take a second look at this if in fact we do have an omnibus appropriations bill that we can do, that we might want to put some more in there, understanding of course you can't do it all at once, but still so that the pipeline is there, that we can start bringing people to train them, train them in laboratory procedures, start buying the equipment they need, to kind of get a jump start on even more countries next year.

Senator BENNET. I appreciate that. I think there are a number of us that would love to work with you and the chair of the Appropriations Committee on this.

The CHAIRMAN. We need the money, that's right. Thank you very much.

Senator Whitehouse.

STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Two questions. I'm not expert in epidemics and I don't know if there are accepted stages in the acceleration of an epidemic, when it goes from just an outbreak to a full epidemic to a raging out of control forest fire. If there are, what are the red flags that we should be looking for that this epidemic has gone to the next stage in terms of the threat that it presents?

Dr. BELL. There are some key indicators that we use. It sort of depends on the situation what the indicators are. In this situation, certainly there are some basic indicators, like the number of cases and the number of cases per week, as Senator Alexander has discussed. There are other indicators, for example the number of cases in health care workers. We should not be seeing cases in health care workers if our infection control interventions are working.

After that, I think that we are working to track things like whether patients that need to be isolated have a way to be appropriately isolated, whether or not we stop seeing bodies that can't be picked up in a timely fashion, and a number of different sort of indicators like that that we use to help us understand if in fact we're bending the curve and whether it's going in the right direction.

Senator WHITEHOUSE. When you consider the existing effort, which has been heroic, but measured against the threat has obviously not kept it from accelerating, how many multiples of the existing level of effort do you think are required to be able to get ahead of this and bring it back under control? Ten times the effort, a hundred times the effort?

Dr. BELL. I would say a very large increase in the effort, and also a very large increase in the effort with a sense of urgency, so that the increase happens very quickly. It's hard to say how many multiples, but there needs to be—and I think we can safely say that there is——

Senator WHITEHOUSE. We're not even close to meeting the threat right now?

Dr. BELL. I would say that the sorts of interventions and scale-up that we've been hearing about in recent days is the sort of scale that we need in order to address this outbreak, this epidemic.

Senator WHITEHOUSE. Dr. Fauci I guess might be the best person to answer this question. Is this a virus that is capable of being manipulated by humans? Could one go into it if one had a sample of the Ebola virus and meddle with a portion of the DNA strain that relates to how it's transmitted? Could somebody up to mischief try to make something that was more transmittable out of this existing virus?

Dr. FAUCI. Theoretically, you can manipulate almost any virus to change it any way you want. That's a question that always raises red flags about it, but the fact is yes. The only trouble is it wouldn't be easy for somebody to do that in their laboratory backyard. They would probably kill themselves doing that.

Senator WHITEHOUSE. It would take a nation State to do that?

Dr. FAUCI. Yes, it would take a state-type thing. I don't know whether you were here when I made my opening presentation, Senator Whitehouse, but I mentioned that our getting involved in the

hemorrhagic fever viruses was part of a biodefense agenda because way back during the cold war it was clear from intelligence and proven that the Soviets were stockpiling hemorrhagic fever viruses and things like that for just the purpose that you make.

So it would have to be a State thing. I don't think you're going to get some rogue person being able to do that.

Senator WHITEHOUSE. Senator Burr and Senator Casey and others and I, would love to work with you on trying to explore that further. Thank you very much.

The CHAIRMAN. Thank you, Senator.

Senator Durbin.

STATEMENT OF SENATOR DURBIN

Senator DURBIN. Dr. Bell, is CDC working with the World Health Organization?

Dr. BELL. Yes, we are, Senator, very, very closely.

Senator DURBIN. It is my understanding that the President submitted the name of Dr. Frieden from the CDC to be our representative to the World Health Organization in July of this year and it is still lost somewhere in the U.S. Senate. I would hope before this week ends and we return home that we might consider bringing this to the floor on a bipartisan basis and expedite the appointment of Dr. Frieden, whom we know well and we have studied, we know his background, so that he can be with the WHO and not wait for 2 months or more for us to return and consider that nomination. I'd like to suggest that to the chairman and see if we can get that done.

I'd like to ask a second question of Dr. Fauci, following up on what Senator Casey said, which was:

> "I hope that there's nothing that's been done on a budgetary basis that has slowed down the development of an Ebola vaccine or a response that might be helpful."

You've talked about a 22 percent decline in the funding in NIH research over the last 10 years and the impact of sequestration. Has there been to your knowledge any shortage of funds which has led to a delay in testing or development of an Ebola vaccine?

Dr. FAUCI. I think one could say honestly, Senator, that everything really over the last several years, with few exceptions, has been at a level less productive than we would been, purely on the basis of significant constraints. I don't think we can say that there's been a serious delay in this particular vaccine. I think that would be an overexaggeration. I would have to put it under the umbrella of the entire effort that we've been putting forth over the last several years have had to be muted somewhat by a budget that in real dollars is shrinking.

Senator DURBIN. It's my understanding, based on WHO statistics that I've read, about the physicians per capita that in my home town of Springfield, IL, with about a population of 100,000, there would be expected to be 240 physicians, in Sierra Leone two physicians for 100,000 people, and in Liberia one physician for 100,000 people.

That I think is an indication, at least a few years ago, a snapshot of the scarcity of medical professionals at the highest level, doctors

and such. I have been working and we included in the immigration bill which passed the U.S. Senate a provision which provided in one respect if you are medically trained in Africa and have promised to serve in Africa for a certain period of time before going anywhere else that we would honor that, respect that, and not allow people to be recruited into the United States when they still had an obligation to their country; and second, that doctors in the United States would be able to serve in these crisis situations overseas without jeopardizing their immigration status. That passed the Senate. That was in the immigration bill. It was never called for consideration in the House of Representatives.

Speak to, not just the terrible infrastructure when it comes to hospitals, but the medical professionals and the health workers available in these countries that are facing this.

Dr. BELL. Yes, Senator, you're right that the number of doctors in Liberia and in Sierra Leone is extremely small. In Liberia I think the number of doctors before the outbreak numbered in the hundreds, as you say. Tragically, because of sort of the lack of infection control and the very, very poor conditions in the health care facilities and the inability of the health care workers to recognize Ebola patients when they came with a fever, and you think it's malaria, it turns out it's Ebola, and the fact that the health care workers were not able to protect themselves, tragically, a lot of these sort of scarce health care workers have died in the context of the Ebola outbreak.

Many of these facilities now, that already were very rudimentary, are closed. This is one of the things that we need to do, is to train in infection control, provide appropriate personal protective equipment, and get the facilities back up and running safely, so that we don't continue this spiral of not only the Ebola outbreak, but also many other conditions that are actually not getting treated right now in these countries.

Senator DURBIN. We've learned the hard way that these countries with very few medical resources, when they face this kind of epidemic challenge, are only a 10-hour plane ride away from the United States.

Thank you.

The CHAIRMAN. Senator Durbin, I must say that when you talked about Dr. Frieden's nomination I thought that we'd dropped the ball on this. How could we have dropped the ball on something like this? I just found out that it does not come to this committee, but to the Foreign Relations Committee. So hopefully, hopefully——

Senator ALEXANDER. Mr. Chairman, the information we have is the President didn't nominate him until the end of July. We were gone in August. The Foreign Relations Committee staff is meeting with him tomorrow. They're doing that in a bipartisan way. They could move him. I heard Senator McConnell say on the floor this morning that he supported President Obama's proposals to deal with Ebola. I know of no reason why the Majority Leader and the Whip couldn't work with Senator McConnell and bring it up before we leave.

I would hope so, and I would be glad to support that, as I imagine the chairman would.

The CHAIRMAN. I would support him. I'm not on the committee, but you know, one of those little meetings in back of the Senate floor, like we do all the time; get that job done in a hurry.

Our wonderful chairman of the full Appropriations Committee, Senator Mikulski.

OPENING STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. Thank you very much, Mr. Chairman. First of all, thank you for organizing this hearing of both the authorizing and the appropriations committee, and to my colleagues for such strong bipartisan participation in this.

I want to thank the people at the head table and all who work behind them for the outstanding job they're doing to organize the American government's response to this, and also to Dr. Brantly and Mr. Charles, representatives of the people who are really in Africa trying to help people in this most horrific of challenges facing not only the countries, but the people, and particularly the workers who are there that must be facing just incredible stress.

This is such a grim, horrific proportion, and they're working 36-hour days, just as you are. We want to acknowledge that and thank them.

Mr. Charles, it's wonderful to have you here. Dr. Brantly and Mrs. Brantly, good to see you. What's so great about seeing you, Dr. Brantly, is, one, that you're well enough to be here, you were well enough to travel here, and you're well enough that we're not afraid to have you here. We can smile, but this is a stunning, stunning, stunning accomplishment. But again, we're glad to see you.

Mrs. Brantly, you look so much like Samantha Power, I said, what is Samantha Power doing sitting next to Dr. Brantly? We could send you to the U.N. and I bet you'd have a lot to say that would shake them up in helping them respond. We're glad that you're here.

I want to make a couple of comments and then a few questions if I could. First of all on this issue of who's in charge that was raised by both Senator Harkin and Senator Boozman, I think USAID is in charge of responding in a disaster—an earthquake, in Haiti, the many disasters—and they're to be acknowledged for their ability to do that. But the size and scope and multiple government agencies involved in this I think needs a higher authority that actually can command personnel and organize, working with us on, again, a bipartisan basis, for the kind of resources to do this, because just listening to what we're doing today, we need the HELP Committee, we need Labor. Now go to the Appropriations Committee. We're going to need Foreign Ops and we're going to need DoD. Within the Labor-HHS subcommittee, it's CDC, it's NIH, it's FDA.

Mr. Chairman, working across the aisle, we should ask the President, through whatever mechanism they're going to say, we need a point person in addition to OMB, which will be here, to do this.

Dr. Bell, do you want to comment?

Dr. BELL. I thank you, Senator. I just wanted to make sure that I didn't create a misconception in what I said about the DART. What I meant was on-the-ground coordination in the middle of that area USAID is coordinating. But I take your point and I think——

Senator MIKULSKI. Well, here is my point.

Dr. BELL. Yes, ma'am.

Senator MIKULSKI. That presuming that there is a bipartisan group and there is the will here—we have one of the leading Senators within the Republican Party. Senator Burr has been one of the leading experts on biohazards. We worked together to create BARDA. If we wanted to meet with the person in charge, who would be the person in charge? AID? Frieden? Dempsey? Kerry?

Dr. BELL. I take your point, Senator.

Senator MIKULSKI. Dr. Rice? We want to maximize and leverage everything we have and also create that sense of urgency.

Let's talk about resources. I'll be leaving shortly, so, Dr. Brantly, if you see me go before you give your testimony it's because I'm going to work on the continuing resolution so we can, on a bipartisan basis, bicameral basis, pass that.

But I'm looking ahead to December 11th and also the 2016 fiscal year. So the CR is really a down payment to keep your current response functioning, but it is not of the size and scope that you need to respond in Africa and prevent it from spreading globally. Am I correct in that?

Dr. BELL. From the CDC perspective, yes. The CR will allow us to continue our field operations through the end of the CR, but the situation is very fluid and we're assessing what we would need for the rest of the year.

Senator MIKULSKI. Dr. Bell, when did you have to submit to OMB your fiscal 2016 request?

Dr. BELL. I'm sorry, Senator. I don't know the answer to that question.

Senator MIKULSKI. Well, let me tell you.

Dr. BELL. I thought you might be able to.

[Laughter.]

Senator MIKULSKI. It was a few months ago. So whatever Dr. Frieden told OMB and the White House that he needed for CDC, it is really 3 to 5 months behind. As we get ready to work, we're encouraging OMB—this is our administration here—to go back and say, what is it that you need for the CR and omnibus, which I hope we can achieve, but also a look ahead at fiscal 2016, presuming we can find a way to cancel sequester.

I would say to all of the agencies involved, look at that and revisit that. And it's our job to get OMB to give you the latitude to come back because of this new need.

Dr. Fauci, wherever there's been an infectious disease crisis you've been in the forefront of trying to find solutions for 30 years, since AID to now. We're so lucky to have you in all of these. But you spoke to us eloquently a few years ago about a pandemic, that when you have a global infectious disease crisis you need to have an infrastructure to be able to respond. Am I correct?

Dr. FAUCI. Correct.

Senator MIKULSKI. This is contained to one continent and one part of a continent. Do you think we're heading to a pandemic with this?

Dr. FAUCI. No, I don't, Senator Mikulski, because, as we have mentioned, the spread of this in the West African countries is really a reflection of the extraordinary disparity of lack of health care

infrastructure—to be able to handle an outbreak, to get the people isolated, taken care of, contact traced, so that you don't have essentially unfettered spread.

In a country like the United States and other developed countries, we may, and it's entirely conceivable, have someone get on a plane infected in a West African country, be asymptomatic and land in Washington or New York or Paris or London, get out of the plane, get sick, and perhaps go to an emergency room, and even infect a person or two because someone didn't take a travel history. But at that point, once it's recognized, the kinds of capabilities we have would make it almost impossible to have the kind of outbreak that you're seeing in a country in which the outbreak is driven by a lack of ability to handle infection control, and we have that.

Senator MIKULSKI. Well then, let's go to the disease. If this disease mutates, would mutation be of concern to you? And if it would mutate, do the current suggested treatments, possible treatments, become ineffective because it's a new disease, and then could it even become airborne?

Dr. FAUCI. Any hypothetical you say, we'd have to say it's not impossible, though I think as a person who's been dealing with viruses for so long, do I think that this is likely that this is going to happen? No. You never rule anything out, Senator. You always keep an eye out on it, and we are following the genetic moveability or mutation of this very, very carefully.

When people ask me this question, I say what I know will happen, not hypothetical, is that unless we get control of this it will continue to not only devastate, but it will be much more difficult to ultimately get in control. So although we always in the back of our mind are concerned about mutations, right now today, in September 2014, mutation is not the problem. The problem is the full court press we need to put on getting this under control by standard classical infection control methods.

Senator MIKULSKI. Which is a public health infrastructure——

Dr. FAUCI. Exactly.

Senator MIKULSKI [continuing]. In this country and helping other countries?

Dr. FAUCI. Quite correct.

Senator MIKULSKI. Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Mikulski.

I want to thank this panel. We're running very late, but it's been very informative. We thank you all very, very much for your great leadership, and the record will remain open, as I said, for 10 days, and I hope that we can continue to call upon you for advice and consultation as we move ahead on this.

Dr. FAUCI. Thank you.

The CHAIRMAN. Thank you, Dr. Fauci.

Dr. BELL. Thank you very much.

The CHAIRMAN. Thank you, Dr. Bell.

Mr. ROBINSON. Thank you, chairman.

The CHAIRMAN. Now we'll call our second panel, Dr. Kent Brantly and Ishmael Charles. Dr. Brantly served as the Medical Director for the Samaritan's Purse Ebola Care Center in the Liberian capital of Monrovia. In July, Dr. Brantly's life changed abruptly when he contracted the Ebola virus while treating patients in Li-

beria. We're thankful that he's recovered and is feeling well enough to offer his unique insight as both a provider and a patient. Dr. Brantly, as Senator Mikulski pointed out, is joined today by his wife Amber and we welcome you here also. Dr. Brantly, thank you for being here.

Ishmael Charles is a survivor of Sierra Leone's 11-year brutal civil war. He is a Program Manager for Healey International Relief Foundation in Sierra Leone. In that capacity he manages and monitors all Healey International Relief Foundation projects in Sierra Leone, including an Ebola awareness and prevention project in 11 communities in the rural western district of Sierra Leone. Thank you, Mr. Charles, also for being here today.

We'll start again with Dr. Brantly. Dr. Brantly, your statement will be made a part of the record in its entirety, as will yours, Mr. Charles. Again, I apologize for the long period, but, as you can tell, people here are very interested in what's happening with Ebola, and you do bring a very unique perspective. You had, you've contracted Ebola. You're alive and well today. You are a provider. Dr. Brantly, welcome. Please proceed as you so desire.

STATEMENT OF KENT BRANTLY, M.D., FORMER MEDICAL DIRECTOR, SAMARITAN'S PURSE EBOLA CARE CENTER IN MONROVIA, LIBERIA, AND EBOLA SURVIVOR

Dr. BRANTLY. Chairman Harkin, esteemed Senators, guests of this committee, I'm grateful for the opportunity to testify before you today about the unprecedented Ebola virus outbreak that's occurring in West Africa, that has already claimed thousands of lives and threatens to kill tens of thousands more.

Let me also take this opportunity to thank each and every one of you. I know there were many people, maybe some of you on this committee, who helped play a role in bringing me home when I was so sick, and I just want to say thank you.

On October 16, 2013, I moved to Liberia with my family to serve as a medical missionary at ELWA Hospital in the capital city of Monrovia. I worked as a physician to support the woefully inadequate health care system in a country that is still struggling to recover from a brutal civil war. In late March of this year, we learned that there were cases of Ebola in our region and we began preparing our staff as well as our facility to be ready to care for patients in the safest way possible should that need arise.

Three months later in June, our hospital had the only available Ebola treatment unit in southern Liberia and I was one of only two physicians to treat the first infected individuals in that area. From June 11th when we received our first patient until July 20th, the number of cases continued to grow at an incredible rate. The disease was spiraling out of control and it was clear that we were not equipped to fight it effectively on our own. We began to call for more international assistance, but our pleas appeared to fall on deaf ears.

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

Then, on July 23d I fell ill. Three days later, I learned that I had tested positive for Ebola virus disease and I came to understand firsthand what my patients had suffered. I was isolated and unsure if I would ever see my family again. Even though I knew most of my caregivers, I could see nothing but their eyes through their protective goggles when they came to treat me. I experienced the humiliation of losing control of my bodily functions and I faced the horror of vomiting blood, a sign of the internal bleeding that could have led to my death.

I'm grateful to the team that worked tirelessly to keep me alive in Liberia, despite a severe lack of medical resources. They were courageous.

I was then evacuated to Emory University Hospital, where I eventually became one of the few to recover from Ebola. As a survivor, it is not only my privilege, but it is my duty, to speak out on behalf of the people of West Africa who continue to face unspeakable devastation because of this horrific disease.

This unprecedented outbreak received very little notice from the international community until those events of mid-July when Nancy Writebol and I became infected. Since that time, there has been intense media attention and increased awareness of the situation on the ground in West Africa. The response to date, however, has remained sluggish and unacceptably out of step with the scope and the size of the problem that is now before us. The U.S. Government has been closely following these events in West Africa since that time, if not before, and only now are we seeing a significant commitment to a solution.

I had the privilege and honor of meeting with President Obama this morning and we discussed his commitment of more military and medical resources to fight this epidemic. He has also requested increased funding for the CDC. I thanked him for entering into this battle with us in a larger way. Now it is imperative that these words are backed up by immediate action.

To control this outbreak and save the lives of thousands of West Africans and possibly many Americans, we need the promised Ebola treatment units, the surge in health care workers, the U.S. military regional command and control center, and we need it immediately. We also need the 400,000 home treatment kits that have been committed to be sent without delay.

There is no time to waste if we are to contain Ebola and adequately care for the thousands of people that epidemiologists are now predicting will fall victim in just the next few weeks. The U.S. military must establish and maintain an air bridge to deliver critically needed personnel and medical supplies and to continue bringing in more resources in the future. We cannot turn the tide of this disease without regular flights of personnel and large cargo loads of equipment and supplies.

I am grateful to the President for his decision to send tens of thousands of Ebola test kits to the region, but these will only be helpful if we also deploy all available mobile laboratories and increase funding for more to be built as quickly as possible. During my time in Liberia, the laboratory we used to confirm Ebola virus infection in patients was 45 minutes away from our hospital and it was inadequately staffed. The turnaround time to positively iden-

tify an Ebola case was anywhere from 12 to 36 hours after the blood was drawn. If a patient is not infected with the virus, that can be a life-threatening delay. More kits are not effective unless we have the facilities and the staffing to use them.

As the first human being to ever receive the experimental drug ZMapp, I am a strong advocate for the CDC and the NIH as they research vaccines and drugs, as we've just heard about, and these drugs can give patients hope for recovery. I'm deeply grateful to the personnel at Mapp Biopharmaceuticals who, even before this outbreak, dedicated their lives to combating Ebola.

We cannot wait, however, for a magic bullet to halt the spread of this virus in West Africa. The current epidemic is beyond anything we have seen before and it's time to think outside the box. I realize that home health care interventions can be controversial. However, we know that many Ebola-positive people are staying at home and even hiding after they become infected. Because of fear and superstition, their families either abandon them or they lovingly care for them in ways that almost always result in infection of the caregivers. This is a major contributor to the spread of Ebola and we cannot contain the disease without addressing this problem head on.

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

Admittedly, home care is less ideal than treatment in an isolation unit. In the home it's impossible to administer IV fluids and other supportive medical interventions. However, there are not enough beds in the Ebola treatment units right now and many infected people are choosing to suffer and die at home. The least we can do is try to give their caregivers the information and resources they need to protect themselves from this deadly virus.

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

One of my patients in Liberia was a man named Francis. Like most patients, at first he was fearful. But eventually he shared the story of how he contracted the disease. He said to me:

> "Doc, I remember who the man was that I got this infection from. He was sick at home and his condition worsened, and when he began vomiting blood everyone around him fled."

But his wife was determined to get him to the hospital. Since no one else was around to help, Francis went to this man's house and helped carry him out of the house and put him in a taxi. On the way to the hospital, that man died.

If someone had come alongside Francis and given him a little bit of education and provided him with the personal protective equip-

ment he needed, his family would still have their father and their son and their brother, and the world might still have this good samaritan. But unfortunately, Francis fell victim to Ebola and died.

Many, including one of the Senators today, used the analogy of a fire burning out of control to describe this unprecedented Ebola outbreak. Indeed, it is a fire. It is a fire straight from the pit of hell. We cannot fool ourselves into thinking that the vast moat of the Atlantic Ocean will protect us from the flames of this fire. Instead, we must move quickly and immediately to deliver the promises that have been made and to be open to practical, innovative interventions. This is the only way to keep entire nations from being reduced to ashes.

Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Brantly follows:]

PREPARED STATEMENT OF KENT BRANTLY, M.D.

SUMMARY

Background

In July of this year, my organization, Samaritan's Purse, took over responsibility for all direct clinical care of those infected with Ebola in the Nation of Liberia. I was appointed Medical Director of what would become the only isolation unit in the Monrovia area.

On July 26, I learned that I had tested positive for Ebola Virus Disease. Eventually, I was evacuated to Emory University Hospital where I was given world-class medical treatment and beat the odds to become one of the few who recover from Ebola.

As a survivor of this horrific disease, I feel it is my duty to speak out on behalf of the people of West Africa. The response of the international community is still unacceptably out-of-step with the size and scope of the problem now before us. The only way to combat this unprecedented outbreak is for the U.S. Government to take the lead.

Key Points

- The United States must begin providing large treatment facilities, skilled personnel, medical supplies, logistical support, mobile laboratories, and security. This will require the deployment of military personnel and other assets. Congress must also increase funding for the Centers for Disease Control and other agencies.
- We have to consider the role of home-based care and other outside-of-the-box methods as critical community interventions. Those caring for family members at home must be trained and given basic equipment—gloves and masks at a minimum—to protect themselves. The United States should provide advisors and experts and support the delivery of supplies to affected areas.
- The U.S. military is the only global force with the capacity to immediately mobilize the kind of support needed to defeat the scourge of Ebola. If we do not deploy military assets now, the situation could quickly become a matter of U.S. national security—whether that means a regional war in West Africa or the spread of Ebola into America.

Closing

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

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

On October 16, 2013, I moved to Liberia with my family to serve as a medical missionary at ELWA Hospital in the capital city, Monrovia. I worked as a physician to support the woefully inadequate healthcare system of a country still struggling

to recover from a brutal civil war. Resources were limited, and we often saw patients die of diseases that would be easily treatable in the United States. It was a challenging job to provide quality care even before the Ebola virus tore through the country.

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

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

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

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

Then on July 23, I started to feel ill. Three days later, I learned that I had tested positive for Ebola Virus Disease. I became a patient, and I came to understand firsthand what my own patients had suffered. I was isolated from my family, and I was unsure if I would ever see them again. Even though I knew most of my caretakers, I could see nothing but their eyes through their protective goggles when they came to treat me. I experienced the humiliation of losing control of my bodily functions and faced the horror of vomiting blood—a sign of the internal bleeding that could have eventually led to my death.

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

This unprecedented outbreak began 9 months ago but received very little attention from the international community until the events of mid-July when my friend and colleague, Nancy Writebol, and I became infected. Since that time, there has been intense media attention and therefore increased awareness of the situation on the ground in Liberia, Guinea, Sierra Leone and neighboring countries. The response, however, is still unacceptably out-of-step with the size and scope of the problem now before us.

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

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

Treating Ebola patients is not like caring for other patients. It is grueling work. The personal protective equipment (PPE) we wore in the Ebola Treatment Unit becomes excruciatingly hot, with temperatures inside the suit reaching up to 115 degrees. It cannot be worn for more than an hour and a half. Because of the elaborate safety protocols involved in treating an Ebola patient, each one takes an average

of 30 minutes of time from a team of three to five people. It is easy to see that a significant influx of medical personnel will be needed to adequately care for the thousands of people that epidemiologists now are predicting will fall victim to the disease in the coming weeks.

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

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

A surge in medical treatment capacity also must include the deployment of all available mobile laboratories and increased funding for more to be built as quickly as possible. During my time in Liberia, ELWA Hospital was the only Ebola Treatment Unit for all of Monrovia and the surrounding area—serving a population of more than 1 million. The laboratory we used to confirm Ebola Virus Disease in patients was 45 minutes away and inadequately staffed. A patient would arrive at our center in the afternoon, and their blood specimen would not be collected until the following morning. We would receive results later that night at the earliest. This means that the turn-around time to positively identify Ebola cases was anywhere from 12 to 36 hours after the blood was drawn. If a patient is not infected with the virus, that can be a life-threatening delay.

I remember one patient who presented with symptoms of Ebola—fever, diarrhea, and vomiting. She was in our unit 36 hours before we received confirmation that she was not infected with the virus. We were then able to determine that she was actually suffering from diabetic ketoacidosis. Her treatment had been delayed for a day and a half because of inadequate laboratory support. Amazingly, she survived, but she was in a coma for 3 weeks. That didn't have to happen.

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

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

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

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

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

vide much-needed support to those who are trying to do what is best for their loved ones.

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

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

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

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

The World Health Organization has laid out a roadmap similar to what I have just described, but they are so bound up by bureaucracy that they have been painfully slow and ineffective in this response. Their recommendations for home care were made August 28, and I am not aware of any significant progress in the implementation of their plan to date. It is imperative that the United States take the lead instead of relying on other agencies.

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

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

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

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

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

The CHAIRMAN. Thank you, Dr. Brantly. Thank you for your courage and for being here, being an example. Thank you.

We'll get on to questions, but, Mr. Charles, welcome and please proceed.

STATEMENT OF ISHMAEL ALFRED CHARLES, PROGRAM MANAGER, SIERRA LEONE, HEALEY INTERNATIONAL RELIEF FOUNDATION, FREETOWN, SIERRA LEONE

Mr. CHARLES. Thank you very much. Chairman Harkin, honorable Senators, Dr. Kent Brantly, and fellow guests of this committee, thank you for the opportunity to allow me to come all the way from West Africa and testify in front of you today.

My name is Ishmael Alfred Charles, a resident of Freetown, Sierra Leone. I'm married and a father of two children, two girls, 9 months and 10 years. I arrived yesterday morning around 2 a.m. to share with you what my country is currently dealing with on a daily basis with the current Ebola outbreak, while still trying to rebuild from the brutal civil war. Unlike the civil war, in Sierra Leone the outbreak creates more fear to the entire population at one go. In the civil war it was at a time a certain population would be afraid of the attack. Today the general atmosphere in my country and among all Africans within the West African region, they are afraid of fear—the biggest crisis that we have ever faced, bigger than even the civil war.

As a former child soldier, I was able to survive the war. But I fear that this is going to be worse than the war.

The Healey International Relief Foundation, based in Lumberton, NJ, supports the rebuilding of health care services in Sierra Leone and provided relief and other supports to war-torn countries like Sierra Leone, and they have been working in Sierra Leone for more than 12 years. The foundation's mission is to invest and support families and individuals affected by disaster, war, and adverse socioeconomic conditions, through the delivery of health care, food, and training and other kinds of programs. Hence, the mandate is to empower communities and build the capacity to become self-sustaining.

The foundation partners with Caritas Freetown, which I am placed with, and Caritas Freetown runs all the foundation's projects in Sierra Leone. Caritas Freetown, whose mission is to eradicate poverty, corruption, injustice, improve equality, advance good governance, and achieve peace and human rights, empower women and the disabled.

As the spokesperson for the Healey International Relief Foundation in Sierra Leone, I feel privileged to share with you our experience on the ground in the war front. As it is today, Sierra Leone is considered to be a war front, and so is Liberia, Guinea, and the other West African countries that are threatened. Since the outbreak, we have been implementing the Ebola Outbreak Response Project in the western area rural and urban districts. We work closely with the Ministry of Health and Sanitation, Ministry of Social Welfare, and the Emergency Operations Centers.

What this essentially shows is that small organizations with lower human capacity and budgets are able to make impacts at the lowest community level because they live within the community and they understand the reality on the ground.

As part of this project, we have been working with a number of communities in the western area rural districts with a catchment of about 219,000 people, raising awareness, providing chlorine, which serves as a detergent to kill the virus, soap and buckets to

police stations and police posts. In addition, we have a strong national media campaign in collaboration with our counterpart Caritas organizations in the other regions of the country.

The growing number of cases recorded on a daily basis has made the situation in Sierra Leone very scary. Each day the situation becomes worse and the effect of Ebola cannot be overemphasized, as Dr. Brantly has painted a picture very clearly for you to see.

When I was about to leave, my 10-year-old daughter asked me, she said:

> "Dad, are you going to leave us in this country and go to America, where they say there is no Ebola?" I stared at her for a minute and said, "Maa"—as I call her—"my trip is for the general good of the family and for your future. I will be back in 2 weeks." And she said again, "Are you sure, because every day flights are being canceled?"

As I speak, there are only two flights going to Sierra Leone or Liberia.

Similarly, my wife said:

> "Dear, the money you used to leave normally when you travel is not going to be enough this time around, because the price of commodities has tripled."

What I'm trying to say in essence, the situation in Sierra Leone is getting very difficult every day, and so it is in the other countries that have been faced with the current outbreak challenge. And the economic burden is getting very heavy on a number of people.

As I was about to leave, my biggest stress was in the situation if anyone gets sick behind me, the health system is not functional. When you go to a hospital, the doctors are not there any more. And even when they are there, they deny that they are doctors, because they are afraid that they might be infected and they're not sure what sort of sickness a patient might have come in with.

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

The State is overwhelmed and unable to coordinate effectively the Ebola response. People are losing their confidence every day. The Ebola crisis has escalated into widening economic situations and has damaged further the health care systems, which are not prepared to manage such a difficult situation.

Harvests have been canceled because too many farmers are dying. In the capital, Freetown, hotels have very few number of guests. A very big hotel that might have the capacity to house 300 guests will only have 4 guests or even less. And these hotels keep dropping their staff every day because they don't have the money, the resources, to take care of the staff. And this staff that they're dropping are parents who have families they need to take care of.

In a country with 70 percent illiteracy, schools have been closed indefinitely because of Ebola. We have no idea when we're going to reopen schools. Our country has a high orphan population and Ebola is increasing that on a daily basis. Through the foundation, we are able to make donations to the Ministry of Social Welfare and support the Ministry of Social Welfare, who are currently taking care of the Ebola orphans, while we are also very careful that

these orphans will be stigmatized and at the same time could be positive. It's a very delicate situation.

People do not have the free will to bury their loved ones any more and show the compassion and care and emotional love to those who are sick which normally help people to recover very fast when you know that you have a social support around you.

Flights have been canceled. The economic situation is getting worse every day. As a result, households are struggling. Not just the Ebola is killing people in Sierra Leone. Poverty, hunger, lack of medical facilities. Families go hungry when the breadwinner dies or gets sick or loses their job, which is happening on a daily basis.

With the support of the United States, the international community, and the spirit of Sierra Leoneans, we believe we will put Ebola at our back. However, a decade's progress will have been lost, especially so when already the health facilities were in bad shape before the outbreak.

I plead to this house and to the United States and the international community not to leave Sierra Leone when the outbreak may subside. We will need help investing in Sierra Leone so that we can be able to be self-reliant again because we will not need to continue to rely on international support. But if we are self-sustainable, we will be able.

I've heard about the CDC report that Dr. Bell spoke about. She gave a number of incidents or instances specifically talking about Liberia. Every picture that she painted is equally as devastating in Sierra Leone and probably even worse. The numbers that the government gives on a daily basis of infected people, is definitely much less than what is really happening on the ground, for various reasons, and the health facilities or the support that we have currently does not really match with the number of infections that we have.

Last, I want to thank this house for listening to me, and please, we will look forward to the continued support of the United States in Sierra Leone. I thank you very much for your attention and for the privilege you give me in listening to me. Thank you.

[The prepared statement of Mr. Charles follows:]

PREPARED STATEMENT OF ISHMAEL ALFRED CHARLES

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

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

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

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

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

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

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

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

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

The growing number of cases recorded on a daily basis has made the situation in Sierra Leone very scary. Each day the situation becomes worse and the effects of the Ebola cannot be over emphasized. When I was about to leave, my 10-year-old daughter asked "Dad are you leaving us here in this difficult situation with this Ebola, they said there is no Ebola in America, why can't you take us along?" I starred at her for a minute and said "Maa," as I call her, "my trip is for the general good of all our family and your future. I will be back in 2 weeks." She asked again, "Are you sure when flights are being cutoff daily?"

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

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

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

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

- Harvests are being canceled because so many farmers had died;
- In the capital, Freetown, patrons are sparse at hotels and restaurants especially those catering to the expatriates. Hotel occupancy rates have dropped and large hotels have only 4 guests and these hotels are laying off staff daily;
- In a country with 70 percent illiteracy, schools are closed indefinitely;
- Our country's high orphan population, is increasing every day;
- People do not have the free will to bury their loved ones, and even the sick ones are deprived of the emotional care from their family needed to recover;
- Many companies are laying off staff amidst the slowdown in commerce, restrictions on travel and decrease in other economic activity.

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

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

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

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

I thank you for your attention.

The CHAIRMAN. Thank you, Mr. Charles. It's always important to put a human face on matters like this. I think people read about it, you get the numbers, you say it's horrible. But one has to understand the human impact and what this is doing to families in your country, in Liberia, and other countries, and the nature that I am now beginning to understand is, if we don't get it controlled soon, it will spiral out of control and it will have the devastating effects that Mr. Charles is talking about. No more people will go there. Business will end. The whole economy will start grinding to a halt.

Dr. Brantly, I'm sure I can speak for many in America and around the world when I say thank you. Thank you for being such an example for all of us on how to serve others. We regularly thank our soldiers for marching into harm's way, rightfully so. Let me say this is no different. You and others like you run toward the risk

to help those standing in the path of this terrible disease. So I want to include you and others like you in that pantheon of American heroes. You do us proud, real proud.

I have so many questions, but I know we're running out of time. Dr. Brantly, what I would ask you first is, with all that you know, and you've been there with your family, you know what the situation is like, give me one, two, three, what's the most important thing we could do now? What's the most important response that we could do now?

Dr. BRANTLY. Thank you, Mr. Chairman.

The CHAIRMAN. If you were in charge and you had a magic wand, what would you do with it?

Dr. BRANTLY. I think one of the most important points is in your very question. We have to do it now. This has been in the eye of the government for months. We can't afford to wait months or even weeks to take action, to put people on the ground, to begin opening those logistical bridges and pathways, to begin going out into the communities and educating caregivers.

It's not that we're trying to keep people at home, but we need to increase the capacity to care for them in facilities. And that means not only creating more beds, but having the staff to care for them in those beds. Putting them in a bed may keep them from giving the disease to someone else, but it does nothing to improve their chances of survival unless they're receiving good quality supportive care.

So we need more capacity in Ebola treatment units, but we must have the staff for those units as well. And we need to start educating people right now in their communities about how to safely care for their family members who are hiding at home and dying from Ebola and ashamed or scared of their own situation.

The CHAIRMAN. You must have a valuable perspective on Liberian culture and society, having been there. We send in a lot of people. Maybe they're not culturally sensitive. I don't know exactly what I mean by that, but they don't understand the situation; and could people actually become more afraid of the workers that we send in if they're not adequately trained and equipped?

Dr. BRANTLY. I think that's a very real possibility, Mr. Chairman. I think that, yes, Liberia's civil war ended 10 years ago, but think about the situation in the United States 10 years after our own Civil War. There was still a lot of tension, and in Liberia there is still a lot of tension between people, groups, and society in general, and there's a sense of distrust, distrust of government, distrust of authority, distrust of foreigners.

So yes, people will be resistant to help. But I think because of the devastation of this outbreak even those people who have been resistant to help are starting to see the need for some assistance. I think that's why it's important that we don't just march in there with our military and take over, but we partner with the NGO's, like Doctors Without Borders and Samaritan's Purse, and the Ministry of Health of Liberia, so that it's a partnership and we're using people like the survivors from Ebola.

There are more and more survivors every day in places where they can get good, supportive care, and those survivors are the ones who can go out and, in what you refer to as a culturally ap-

propriate way, educate and support the communities and distribute the needed personal protective equipment to protect those home care providers. I think that is very much an important part of the strategy.

But again, it has to start now. It has to start in a matter of days. From the time I fell sick just less than 2 months ago, the death toll has tripled. If we take 2 months to get our response up and going, even if we only maintain that rate of growth, we're looking at thousands and tens of thousands. And 9 months down the road, we're looking at hundreds of thousands of not only cases of Ebola, but deaths. And we can't afford that.

The CHAIRMAN. That's where I hope our military airlift capability will come in and start moving material and personnel over there.

Senator Alexander.

Senator ALEXANDER. Dr. Brantly, Mr. Charles, let me thank you both. Mr. Charles, thank you for your work in prevention and bringing awareness here. Dr. Brantly, thanks for your being a good samaritan. We greatly admire what you've done.

You're a survivor of Ebola. Is that like cancer? Is that in remission, or are you cured, or do you know?

Dr. BRANTLY. Thank you, Senator. I'm cured from Ebola.

Senator ALEXANDER. So you don't have it—it's gone from you?

Dr. BRANTLY. Yes. When a person survives Ebola, when they recover they're not a carrier of the virus. Dr. Ribner at Emory University was very clear to say that Nancy Writebol and I posed no public health risk. So there's no risk to the public from a survivor. There's a lot of stigma attached to being a survivor of Ebola, but we——

Senator ALEXANDER. Can an Ebola survivor become infected once again, or are you immune then from Ebola?

Dr. BRANTLY. In theory and I think in practice, I am immune to the strain of Ebola that I was infected with. But there are five different strains of Ebola, so if I went to the Democratic Republic of the Congo I may not be immune to the strain that's causing the outbreak there.

Senator ALEXANDER. You talk about how you treated a lot of patients. Would you say it's accurate that about half the patients who are infected died, or is it higher or lower than that?

Dr. BRANTLY. Unfortunately, Senator, in my experience we did not have a 50 percent mortality rate of 50 percent survival rate in our facility. As we saw patients early on in the outbreak, they were usually showing up very late in their course, and in the month and a half that I was treating Ebola patients we had one survivor.

Senator ALEXANDER. From the time you discover an infection until death, how long is that typically?

Dr. BRANTLY. That varies greatly depending on how early the person seeks care. We had some people who came and died in a matter of hours from the time they presented, and we had others who were under our care for a matter of days, 4 or 5 or 6 days, before they passed away.

Senator ALEXANDER. But it's not months?

Dr. BRANTLY. No. The illness generally is a 2-week course, and by the end of 2 weeks the person has either died or they're on the road to recovery.

Senator ALEXANDER. Which is one reason there's such concern, because it's so explosive, it moves so rapidly. Is that right? As I listen to you, I hear you talking about lots of people at home sick for a variety of reasons. We've heard the official statistics say there are less than 5,000 infections. It sounds to me like there might be many more.

Dr. BRANTLY. I think that's very accurate, sir. As many of the witnesses today have said, those numbers are based on the cases we have tested and identified or are housing in isolation units. But there are many, many more at home.

Senator ALEXANDER. So there are many more, and what you're saying is the course of the disease might run a couple of weeks and you're either dead or a survivor after that period of time. In your experience, all but one died. Others, they say half. The official statistics say the cases have doubled over the last 3 weeks. So you don't have to do much math to see that the numbers, as you say, can quickly go to tens of thousands, hundreds of thousands, if we don't get control.

Am I correct that the home health kits are primarily for the benefit of the caregivers, that it's to keep the infection from spreading? Does it make the home sort of a hospice for the infected person with Ebola?

Dr. BRANTLY. I think that's a fair way to look at it. As I said, you can't carry out complicated medical interventions in a home, but you can give people oral rehydration solution. You can give them Tylenol to help with their fever and pain. But the most important part of that kit is the part that offers protection to the caregiver, because without that we're not stopping transmission, and that's what has to happen to control this epidemic, is to stop the transmission of this disease.

Senator ALEXANDER. You took a great risk in going there and it's obvious from the testimony of you and Mr. Charles and others that we'll need hundreds, thousands of people, in addition to the soldiers who are going. What would you say to others, people like yourself? We have a tradition in this country of Doctors Without Borders, Samaritan's Purse, of which you were a part. What would you say to Americans who are seeing this and trying to decide whether to go to West Africa to help control this disease?

Dr. BRANTLY. Thank you, Senator. This is a topic very dear to my heart. I think the International President of Doctors Without Borders said it very well in a recent article. She said,

> "Comparing Ebola to a fire, this is not the time to run away; this is the time to put on our protective gear and run into the burning building."

Physicians and health care professionals, even if it's just symbolic, have taken an oath. In many institutions they still take the Hippocratic Oath, and that oath is to the service of mankind. I think if we can help people overcome the fear of facing a deadly disease and remember that this is not just a disease, these are people who need help, societies that are collapsing because of the weight of this burden, we just need people to go help.

The CHAIRMAN. Senator Burr.

Senator BURR. Thank you, Mr. Chairman.

Dr. Brantly, Mr. Charles, thank you for being here. Mr. Charles, when you go back and see your daughters, I hope you'll share with them that the purpose of this committee is to try to make sure we can process enough fact to make sure that we can provide what's needed from a standpoint of the resources. There are other parts of government that has the responsibility to get them there, to train, to equip. But we have to make sure that we have the resources. And what you've shared with us, both of you, is invaluable from a standpoint of how we look at it. As I think both Senators said, to see the human face behind the issue is absolutely crucial to those of us who sit on this committee and in this institution and ask taxpayers to in turn fund things for people that they'll never meet.

But I do have a couple of questions. Dr. Brantly, are you convinced that ZMapp played a role in your cure?

Dr. BRANTLY. Thank you, Senator Burr. My opinion——

Senator BURR. I take for granted that from a standpoint of good supportive care, since you knew them, you were getting it.

Dr. BRANTLY. I was receiving the best care that they could afford to give me in Liberia.

My own opinion is that ZMapp, I believe, had a beneficial effect in my treatment. But, as Dr. Fauci very clearly said, this is an experimental drug, that my story is an anecdote and, while a very convincing one, it's just one. And it really requires more extensive testing of an experimental drug to prove whether or not it is beneficial on a large scale. I'm very thankful for Mr. Zetland and all the people at Mapp Biopharmaceuticals because I think it was helpful to me, and I think it will be helpful in future Ebola outbreaks, because there will be more Ebola outbreaks.

Senator BURR. Let me say, Dr. Brantly, when the chairman said he was concerned this might spiral out of control, I think we've already spiraled. I think we're in that spiral now. I think had we had more time with Robin Robinson we would understand that we're probably January at the earliest for therapy, and that's without extensive clinical trials, as you can imagine. We're January, first quarter, with potentially some vaccine product, and that's with—doctor, you know, if we're talking about a 5-month clinical trial process, we have accelerated it greatly.

We're going to break every fail-safe that exists at the FDA, just like they did in the decision to administer ZMapp to you. And because that's jurisdictionally under this committee, it's important that we all understand. We're going to sort of recreate the wheel, because this is an extraordinary circumstance.

I guess I'm asking for your medical opinion and your opinion as somebody that knows the folks that are being affected. If we choose to go before we know everything with some type of therapeutic response, is that the best course for us to follow, or should we be prudent and take longer, knowing that we know a little more about the therapy or the vaccine?

Dr. BRANTLY. I think WHO came out with a statement several weeks ago saying they believe it's ethical to use experimental drugs in circumstances such as this. I would agree with them that if we know—in my case, we didn't even know if it would be harmful or not. I think if you're going to start giving it to people who don't

have the background to be able to give really understood informed consent, it's important that we know that what we're giving them is safe and potentially beneficial.

But I think those types of drugs, especially vaccines—I think the other panelists spoke to that better than I can, but I think they would have a role, especially if we don't have this thing under control by January.

Senator BURR. The numbers that we look at suggest for every infected individual that they will infect somewhere between 5 and 20 additional individuals. The multiples are huge. I think I heard both of you say that when we look at Sierra Leone, 1,620 cases, 653 in the last 21 days, Liberia 2,407, 1,383, you think those are woefully understating the size of the problem. Did I hear both of you correctly?

Mr. CHARLES. Yes, Senator.

Senator BURR. OK.

Dr. BRANTLY. Senator, may I speak just a moment on that?

Senator BURR. Sure.

Dr. BRANTLY. I think those numbers may be underestimated for sure, but I think what you're seeing is a representation of how quickly this thing is growing when you compare what the numbers were to how fast they're growing now. And those experimental drugs don't have anything to do with the transmission. That's why we need to intervene in the communities to disrupt the transmission of this disease.

Senator BURR. When CDC said act now, I sort of agree with your definition of "now." "Now" is like tomorrow. I'm not sure that we've ever had that type of turnaround out of government. So facing the reality of what's in front of us is also important.

Last question, and you've been very patient to stick with us as long as you have. What are the possibilities of using social media as our communication tool in West Africa, and can that be effective?

Mr. CHARLES. Yes, the use of social media has a lot of effects in Sierra Leone specifically, especially among young people who are literate, maybe the school-going population and those who also have access to mobile phones. But the cost of communication is tremendously expensive compared to what I can access in America on my cellphone at the cost and what I can access in Sierra Leone on a monthly basis for the same cellphone. It's very expensive. But it definitely has a very big impact because a lot of information is being—it's sometimes misleading also. That's another negative aspect. But the fact is a lot of this information, good information, is also being transmitted and communicated through WhatsApp and Facebook especially.

Senator BURR. Dr. Brantly, you agree?

Dr. BRANTLY. I agree. I think even up until this point Liberia has been using social media and radio and print media to reach the population. There's even a really catchy tune that they play on the radio about Ebola, reminding people that Ebola is real and they need to protect themselves and protect their families, and that talks about how the disease is spread. I think it's a very important means of reaching people.

Senator BURR. I want to thank both of you. I especially want to thank Samaritan's Purse. Whenever you have a tragedy somewhere in the world, they are certainly there. They're part of the story. I think a lot of the presence in North Carolina and I think a lot of Franklin and the vision and the commitment. Not to say that we don't have a lot of good NGO's around the world that respond, but they're certainly consistently there, and for that we're grateful.

I thank you both.

Dr. BRANTLY. Thank you.

Senator ALEXANDER. Thanks to both of you for coming. We're at the end and Senator Harkin will end this in a minute. But I want to make sure I understood something you said. You said you began to treat patients on June 11 and became ill on July 20, is that right?

Dr. BRANTLY. July 23d, yes.

Senator ALEXANDER. You became ill on July 23d. About how many patients did you treat?

Dr. BRANTLY. I believe during that time we had about 45 or 50 patients come through our unit. Not every one of those was positive for Ebola, but even many of them who were negative for Ebola died because of the severe illness they came to our hospital with.

Senator ALEXANDER. So of the 45 or 50, all but one died?

Dr. BRANTLY. No, sir. There were some who tested negative and we discharged them from the unit.

Senator ALEXANDER. Of those 45 or 50, some had Ebola?

Dr. BRANTLY. I can't remember the numbers exactly, but I would say of those 45 probably 20 of them had Ebola and probably 10 or 12 of them were tested negative and discharged. So that would leave another five or so who came to us with something other than Ebola, but unfortunately died because of the severity of their illness.

Senator ALEXANDER. Now, you became ill on July 23d. You were tested on July 26th. You said something about a 2-week course. Does that mean that within 2 weeks you know whether you're going to recover or die if you have Ebola? Is that right?

Dr. BRANTLY. In general. Most people with Ebola, they usually, if they die from it, they die between days four and ten. But it can be a 14 or 16-day illness. So you can't just say, oh, you're on day ten, you're out of the woods. That's not the case. It was day nine when I was the sickest and almost died.

Senator ALEXANDER. So you become infected, you don't infect others until you have symptoms, correct?

Dr. BRANTLY. Correct.

Senator ALEXANDER. So there's a period of time of about maybe 2 weeks, a week or two, when you can infect other people, plus the time after—if you die, there's that period of time.

Dr. BRANTLY. Correct. You contract the virus and you have a 2 to 21-day window before you become symptomatic. Once you become symptomatic, your illness may run from 3 days, where you die after 3 days, or you may be sick for 2 weeks. In my case, I was sick for almost 4 weeks before the CDC decided that my test was negative enough consecutive times that they could discharge me from the hospital.

So you're correct, people are infectious during their illness and usually that is less than a 2- or 3-week period.

Senator ALEXANDER. So what's really different about this epidemic is how fast it moves, is that right?

Dr. BRANTLY. The virus moves—it kills quickly. Like Dr. Fauci and Dr. Bell said, it's not so contagious like the flu virus that someone will get it by sitting near you. But it kills its victims quickly.

Senator ALEXANDER. So within that 2-week period or so of infection, to use Senator Burr's figures, one might infect 5 to 20 other people. They have an incubation period of 2 to 21 days and then they may have a 2-week period of infection during which they might infect 5 to 20 more people. So that all happens very, very rapidly if it happens.

Dr. BRANTLY. Yes, sir.

Senator ALEXANDER. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Alexander. Senator Burr, thank you.

Again, both of you, thank you very much for being here, for your patience, and for sharing with us your personal stories.

The Obama administration is moving rapidly on this. Today President Obama went to the CDC. We are ourselves working here to do everything we can to rapidly respond and to support the President in this effort. I think you're right, time is of the essence, but it has to be done correctly rather than rushing in and doing things that may even make it worse. Certainly we need to get the equipment there, the personal protection gear for home health and health care workers in these countries. We need to do a rapid series of educational programs so that the local populace begins to know what to do and how to respond and not to be afraid. That needs to be done rapidly.

I trust that there are NGO's like the one you are with, Mr. Charles, there are NGO's there that could be very helpful on this, I believe, and who have been there for some time and who have good relations with people in these countries. I'm hopeful that as we do this rapidly, we will learn from, lean on, ask the help of the NGO's that are in these countries. They can be extremely helpful. Do you concur with that? We need to really ask them for their help.

Thank you very much, and I hope and trust, Mr. Charles, that your wife and your daughters are safe, and if they hear any of this at all I want to assure them that you're going to be back home and you'll be safe.

Mr. CHARLES. Thank you very much.

The CHAIRMAN. Thank you. And thank you, Dr. Brantly, again for your great example.

The record will remain open for 10 days. Thank you very much. We'll stand adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

RESPONSE BY BETH P. BELL, M.D., MPH TO QUESTIONS OF SENATOR CASEY, SENATOR BENNET, SENATOR WHITEHOUSE, SENATOR SHAHEEN, SENATOR BALDWIN, SENATOR WARREN, SENATOR ALEXANDER, SENATORS ALEXANDER AND BURR, SENATOR MORAN, SENATOR COCHRAN, SENATOR SHELBY, SENATOR BURR, SENATOR KIRK, AND SENATOR ENZI [1]

SENATOR CASEY

Question 1. What is the CDC's plan to communicate with the public regarding the current threat posed by Ebola, and how will these communications change should Ebola reach the United States?

Answer 1. CDC educates Americans on ways to protect themselves when traveling in numerous ways, such as:

• Issuing travel health notices advising U.S. citizens to avoid nonessential travel and to take enhanced precautions if they are visiting the affected West African nations.[2] The recommendation to avoid nonessential travel is intended to help control the outbreak and prevent continued spread by:

1. Protecting U.S. residents who may be planning travel to the affected areas, and
2. Enabling the government of the affected countries to respond most effectively to contain this outbreak.

• Working closely with Customs and Border Protection (CBP) in the Department of Homeland Security (DHS) and other partners to enhance practices at U.S. ports of entry to use routine procedures to identify travelers who show signs of infectious disease. In response to the outbreak, these procedures have been enhanced through guidance and training. CDC's quarantine station staff respond as needed, for example by evaluating ill travelers identified by CBP officers.

• Providing comprehensive information to travelers at U.S. ports of entry through airport messaging to outbound and inbound travelers, CDC website, and social media. Ebola-specific travel messages have been developed for electronic monitors and posted to reach travelers from West Africa, and posters have been displayed in Transportation Security Administration (TSA) screening areas of airports to reach outbound travelers. Furthermore, CDC maintains detailed and updated actions for travelers to take before international travel on the CDC website, including Ebola-related recommendations.

• Developing interim guidance to provide public health authorities and other partners with a framework for evaluating people's level of exposure to Ebola and initiating appropriate public health actions on the basis of exposure level and clinical assessment. Specifically, CDC developed "*Interim Guidance about Ebola Virus Infection for Airline Flight Crews, Cleaning Personnel, and Cargo Personnel*," As well as "*Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure*."

• Issuing advice for colleges, universities, and students about study abroad, foreign exchange, and other education-related travel, as well as advice for students who have recently traveled from a country in which an Ebola outbreak is occurring.

• Developing guidance for humanitarian aid organizations whose employees or volunteers are working in countries where an Ebola outbreak is occurring. Humanitarian aid workers play a vital role in the Ebola outbreak response, and CDC encourages them to continue the important work being done to stop the disease's spread at its source.

CDC will continue to update its communication products and webpages with new information on the Ebola outbreak for the general public and specific audiences to share credible, factual information and to dispel misconceptions about Ebola.

Question 2. You noted in your testimony that there are three key things that we need to respond to this epidemic: resources, technical experts, and a coordinated, global unified approach. Which of these things do you feel we are currently doing well? Which of them do you feel we are currently doing poorly, and how do you suggest we improve our efforts?

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[1] Note: Content accurate as of October 15, 2014. Responses do not reflect enactment of the $1.777 billion for CDC in emergency funding to prevent, detect, and respond to the Ebola Epidemic.

[2] For more information about travel notices to the West Africa region and other countries, please visit CDC's Travelers' Health website.

Answer 2. We are continuously evaluating all three of these areas. On resources, we continue to work across the U.S. Government to determine the resource needs to ramp up the response and stop this epidemic globally while protecting the United States. The U.S. Government also is actively coordinating with other donors to support these efforts. For technical expertise, CDC has been fighting this disease for decades, and along with our partners, we have the technical expertise to stop this. We need to transfer some of that expertise to countries experiencing the epidemic and those at risk, so that our pool of experts is larger and is on the ground when outbreaks occur. Global coordination continues to improve. We are doing our best to respond to the current epidemic both by working intensively in the countries currently experiencing the epidemic as well as by preparing nearby countries to be ready to respond to imported cases. CDC has identified 11 countries at high risk for importation and potential outbreaks and is working intensively with these countries to improve their surveillance, laboratory, and other pivotal capabilities.

Question 3. Is there a sufficient supply of personal protective equipment (PPE) available (or capable of being procured) to supply the affected West African nations? Do we also have a sufficient supply of PPE available should Ebola reach the United States?

Answer 3. CDC is aware that challenges remain with the supply of PPE in West Africa. The United Nations Logistics Cluster has been activated to assist with PPE needs and supplies. WHO and MSF also communicate directly with the largest PPE manufacturers to ensure that they can produce the necessary PPE for the response. Thus far, the manufacturers have not had problems producing PPE supplies in sufficient quantities; however, procurement and distribution remain challenging.

In the United States, as of October 15, 2014, there have been no reported shortages of PPE. Hospitals have reported sufficient quantities for health care workers who might treat suspect or confirmed patients with Ebola virus disease (EVD). Moreover, as we understand it, manufacturers are aware that there may be increased demand, and they are preparing for that demand.

SENATOR BENNET

Question 1. Dr. Bell, in your testimony you say that "the technology, capacity, and resources exist to make measurable progress across member countries, but focused leadership is required to make it happen." Can you expand upon what kind of focused leadership you think is needed here?

Answer 1. The importance of having a well-functioning incident management system in an Emergency Operations Center (EOC) in each affected country cannot be overemphasized. It is critical that there be strong coordination and communication among countries, with clear delineation of responsibilities. For its part, CDC has activated its EOC to help coordinate technical assistance and control activities with partners. On August 6, 2014, CDC elevated the EOC to a Level 1 activation, its highest level, because of the significance of the outbreak. CDC supports countries in establishing their own national and sub-national EOCs. Each of the three West African countries at the center of the epidemic now have an Incident Manager, reporting to the President of the country, to lead response efforts.

Question 2. There are many charities and volunteers here that want to help end this outbreak and care deeply about the outcome. For example, in my home State, the Centennial-based Project CURE has been working with local volunteers and high schools, like Valor Christian High School in Highlands Ranch, to send medical supplies to West Africa. They have already sent four large containers of supplies for medical workers there. They want to know that their government is showing a coordinated response to this effort, and that their work will not be in vain. Can you give them and other volunteers across the country some peace of mind that their work is helping and you all are doing everything you can to coordinate an effective response to this outbreak?

Answer 2. The U.S. Government's goal is to enable the most effective and coordinated international response possible, using our governmentwide capabilities to fight the Ebola epidemic on a regional basis. In September 2014, President Obama announced a scaled-up U.S. response to the crisis, building on a whole-of-government response across the U.S. Agency for International Development (USAID), the Department of Defense (DoD), Department of State, CDC, and other Federal Departments and Agencies. The United States also is working intensively on this effort with the United Nations, the governments of the affected countries, and other donor partners.

We continue to appreciate the efforts of the Congress and concerned American citizens to raise awareness and get involved in the response to this crisis. USAID

is coordinating all kinds of donations and volunteers, and suggests a list of charities for the public at *http://www.usaid.gov/ebola*. These efforts make a tremendous difference.[3]

Question 3. Given the emergence of Ebola as a significant public health threat—and the level of funds understandably being allocated in response—I am concerned about our ability to respond to other emergencies, such as pandemic influenza, which are far more common threats. In particular, I'm concerned that we are jumping from crisis to crisis and failing to adequately budget for rapid response capabilities to public health pandemics, like Ebola, pandemic influenza, and MERS. Just earlier this month, for instance, a DHS OIG report highlighted that our pandemic influenza stockpiles have not been effectively managed, and I'm concerned that we may be falling behind on these other types of preparedness issues. How are you assuring that we are adequately prepared and not compromising our ability to rapidly respond to address other public health crises, like pandemic influenza, in addition to emerging threats like Ebola?

Answer 3. The emergence of a novel, pandemic strain of influenza represents a continued threat to global health. To address this threat, CDC has developed plans and capabilities to respond to pandemic influenza at any time, regardless of other ongoing response activities. Since the 2009 H1N1 pandemic, we have enhanced our capabilities with more robust domestic and international surveillance systems, improved communication with partners, and increased public health laboratory capacity at the State, local and international levels. CDC is prepared to address public health crises, but the agency would be concerned about the ability to respond effectively to multiple, large-scale, concurrent events.

With respect to the referenced report by the DHS Office of the Inspector General, CDC cannot speak to the work product of another department. However, it is important to note that this report encompasses a review of DHS preparedness to continue critical operations of DHS activities during an influenza pandemic. This report does not evaluate the nationwide preparedness to respond to such a pandemic.

SENATOR WHITEHOUSE

Question 1. Several commentators have cited distrust of health care officials by people in affected regions as one of the barriers to receiving care. What steps has CDC taken to overcome this mistrust? How are CDC and the World Health Organization partnering with trusted local leaders and communications outlets to disseminate information?

Answer 1. CDC has deployed several teams of public health experts to the West Africa region to work directly with local leaders and stakeholders who can inform on the best ways to foster trust and reach communities. 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.

Question 2. In Rhode Island, public health officials at the Department of Health and elsewhere are working with local residents from West Africa to help them communicate to their family and friends on ways to stay safe. Do you recommend outreach and education efforts of this kind? Will you be supporting and spreading this approach to other States that are part of the Liberian diaspora in the United States like Minnesota, Pennsylvania, Maryland, Georgia, and Washington, DC?

Answer 2. CDC has engaged and continues to engage in outreach directly to West African communities and organizations serving the West African diaspora across the country, including groups in Dallas/Dallas County, Rhode Island, California, Minnesota, and the Bronx. CDC's specific activities include:

- CDC is helping counter stigma during the Ebola response and encourages our public health partners to do so as well. CDC has developed messaging on avoiding stigma in West African populations in the United States and shared it with all State health departments and others. CDC has also created guidance for social service and community-based organizations in the United States serving immigrant communities, including additional guidance on preventing stigma for sharing with the population they serve.

[3] For further information on the organizations working to combat the crisis, additional ways to volunteer or contribute, or more information on the response, please visit USAID's Center for International Disaster Information website.

• CDC has hosted several calls for West African community groups to provide the most up to date information on Ebola and opportunities for these groups to support Ebola response efforts, delivery of key health messages and CDC resources, and securing CDC speakers for special events. Participants have included faith-based groups and national organizations serving Liberians, Sierra Leoneans, and Guineans in the United States. For example, two calls were held on September 30, 2014 with groups representing the West African diaspora population. One call was organized by Congressman David Cicilline's office for the diaspora in Rhode Island, and the other call was open to diaspora groups and individuals across the country. CDC is planning to continue this type of outreach on an ongoing basis.

• CDC is collaborating with a private partner, AudioNow, to deliver PSAs on their call-to-listen platform popular with West African communities in the United States. Several PSAs have been developed targeting this group, with a focus on how to inform relatives in the West African region about Ebola, and travel related issues (*e.g.*, visitors coming from and traveling to the region). These are in production now in four languages for 72 radio stations that are identified as reaching large groups of West Africans in the United States. CDC has also worked with President Jimmy Carter and the Carter Center to develop some specific messages, building on their existing relationships and portfolio of work in Liberia.

CDC will continue to take measures to ensure that geographic areas with large West African populations receive timely information and make available resources as needed. CDC has a cadre of experts who have experience reaching immigrant populations, including individuals that speak Hausa and Fulani, two of the major non-English and non-French languages in the region, to provide consultation on linguistic and cultural issues.

Question 3. What do you advise State and local health officials to do to protect their populations? What additional resources are needed at the State and local level to insure that Ebola from any imported case is not spread?

Answer 3. CDC has created plans outlining its course of action for when a laboratory-confirmed Ebola diagnosis occurs in the United States and continues to work with other Federal, State, and local health governments and private organizations to strengthen U.S. readiness for detecting and preventing Ebola cases.

Recognizing that even a single case of Ebola diagnosed in the United States is a concern, CDC is working with medical and public health professionals and health care facilities across the country to prepare and respond and to safely manage a patient with suspected Ebola Virus Disease. This includes engagement in the following activities:

• Enhancing surveillance and laboratory testing capacity to detect cases domestically;

• Developing guidance and tools, such as checklists for health departments, hospitals, emergency medical services, and health care coalitions to conduct public health investigations;

• Providing recommendations for health care infection control and other measures to prevent disease spread;

• Providing guidance for flight crews, emergency medical units at airports, and U.S. CBP officers about reporting ill travelers to CDC;

• Coordinating with maritime authorities to assess the potential risk to the United States from cargo vessels from the four affected West African countries; and

• Disseminating up-to-date information about the epidemic to the general public, international travelers, and public health partners.

Since July, CDC's Health Alert Network has issued seven notices on Ebola, reaching hundreds of thousands of clinicians and others.

CDC also is working to prepare U.S. healthcare facilities for safe management of patients with suspected Ebola virus and to educate health care professionals across the country about important precautionary measures related to Ebola. CDC communicates with health care workers on an ongoing basis through the HAN, Clinician Outreach and Communication Activities, and a variety of other existing tools and mechanisms.

In regards to what private health organizations can do to prepare for such a public health emergency, CDC recommends the following steps to assist in any potential response:

• Health care organizations can encourage U.S. hospitals to be prepared to identify and initially manage patients with Ebola;

• Health care providers can increase their understanding of Ebola, using the latest healthcare guidance; and

• Health care organizations can support health care provider requests to work in West Africa assisting those affected by the Ebola epidemic. USAID provides information on volunteer needs on its website.

Finally, CDC has issued advice for colleges, universities, and students about study abroad, foreign exchange, and other education-related travel, as well as advice for students who have recently traveled from a country in which an Ebola outbreak is occurring. CDC advises that all non-essential travel, including education-related travel, to Guinea, Liberia, and Sierra Leone be postponed until further notice. Students, faculty, and staff who have recently traveled to countries where the Ebola outbreaks are occurring should consult with school authorities on what instructions to follow, and monitor their health for 21 days after returning. CDC advises colleges and universities to identify students, faculty, and staff who, within the past 21 days, have been in countries where Ebola outbreaks are occurring and conduct a risk assessment for each person to determine his or her level of risk exposure, as well as the appropriate public health response and medical care based on CDC's *Interim Guidance for Monitoring and Movement of Persons with Ebola Virus Disease Exposure*.

SENATOR SHAHEEN

Question 1. How can we apply the lessons we are learning in the current global emergency response to better leverage our resources to support a long-term local epidemiologic infrastructure operated and staffed by local scientists and public health officials?

Answer 1. The global response to Ebola underscores the need for well-functioning and effective health and public health systems across the world. The current response shows that capacities outlined in the Global Health Security (GHS) Agenda to prevent, detect, and respond to public health emergencies are critical in a country's ability to lessen the impact of infectious disease outbreaks. Several components of the immediate response to Ebola are key areas for GHS implementation—an EOC, laboratory capacity, surveillance, and workforce development.

In this epidemic, we have seen that some countries, even with nascent detection and response capacities, were able to successfully contain and eradicate the outbreak after experiencing cases in their countries. An example is Nigeria, which used its existing EOC developed for the polio response and Field Epidemiology Training Program to monitor operations, conduct surveillance and contact tracing, showing that improvements to core public health systems are critical to responding to emerging threats.

Some of the work we are currently doing for the response, including surveillance, information systems, workforce strengthening, EOC development, and laboratory services, will serve as the foundation for longer term GHS strengthening.

Question 2. Among the various challenges that we face with this ongoing epidemic is collecting real time data in a rapidly changing situation. Further, sharing this information between corroborating agencies in an international context is challenging. How is CDC keeping pace with the data and making sure that decision-makers have the best up to date information available to inform their planning?

Answer 2. CDC has activated its EOC to help coordinate technical assistance and control activities with partners. On August 6, 2014, CDC elevated the EOC to a Level 1 activation, its highest level, because of the significance of the outbreak. CDC supports countries in establishing their own national and sub-national EOCs. Each of the three West African countries at the center of the epidemic now has an Incident Manager, reporting to the President of the country, to lead response efforts.

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 continues to send additional public health experts to the affected and neighboring countries. CDC experts have been deployed to non-affected border countries, including Cote d'Ivoire, to conduct assessments of Ebola preparedness in those countries.

Through the Disaster Assistance Response Team (DART), led by USAID with CDC staff embedded, and regular communication with on-the-ground staff, the CDC EOC maintains daily interaction to obtain the most up-to-date data from the field. This data feeds directly to each Ebola response team to shape plans and allow for nimble changes in tactics to address evolving situations in each affected country.

In the United States, CDC has data collection and tracking mechanisms in place to monitor any potential case of the disease. CDC, along with other Federal agencies, has created and implemented a response plan to manage a laboratory-confirmed case of EVD in the United States, and is providing guidance to health care facilities about how to safely manage a patient with suspected EVD. This includes engagement in the following activities:

- Enhancing surveillance and laboratory testing capacity to detect cases domestically.
- Developing guidance and tools for health departments to conduct public health investigations.
- Providing recommendations for healthcare infection control and other measures to prevent disease spread.
- Providing guidance for flight crews, emergency medical units at airports, and U.S. CBP officers about reporting ill travelers to CDC.
- Coordinating with maritime authorities to assess the potential risk to the United States from cargo vessels from the four affected West African countries.
- Disseminating up-to-date information about the outbreak to the general public, international travelers, and public health partners.

Question 3. Is CDC employing the latest mobile technologies and software to record and disseminate information?

Answer 3. CDC employs extensive surveillance and sophisticated modeling techniques to gather, analyze and act on data and information, in cooperation with global partners.

The Department of Health and Human Services (HHS), and in particular CDC, is working closely with the World Health Organization (WHO), the United Nations, the Ministries of Health in affected countries, and other international partners to respond to the current Ebola outbreak in West Africa. CDC receives regular updates of morbidity and mortality to evaluate the spread of the disease and combines this information with reports from CDC's staff deployed to the area. Hundreds of CDC staff members have provided logistics, staffing, communication, analytics, management, and other support functions for the response. CDC continues to commit significant staffing and financial resources to the international Ebola response both on the ground in West Africa and through its domestic EOC. 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. CDC is partnering with major telecommunications companies in the affected countries to disseminate messages across the 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 study and preliminary report in Sierra Leone and is using this report to inform future message strategies.

CDC continues to update its communication products and webpages with new information on the Ebola outbreak for the general public and specific audiences. CDC is using social media as a way to share credible, factual information and to dispel misconceptions about Ebola.

Question 4. Our Nation's intensive care units are at the forefront of caring for the most critically ill patients including during times of widespread medical emergencies such as pandemics. While we know that Ebola is not affecting a large number of Americans today, we do know that the next pandemic could be just around the corner and we need to ensure that our critical care system is equipped to respond. Dr. Bell and Dr. Robinson, does our hospital system currently have the necessary critical care infrastructure in place for this type of virus, such as appropriate critical care containment rooms?

Answer 4. Any U.S. hospital should be prepared to identify, assess and isolate a patient with Ebola. CDC developed guidance documents and checklists to help U.S. hospitals prepare for, test, and treat patients with Ebola, and works to keep the health care system informed of new developments. CDC uses its HAN to provide information and guidance to U.S. healthcare workers and hospitals regarding EVD. CDC distributed a HAN notice August 1, 2014, and five updates have followed. The most recent HAN notice about Ebola was distributed on October 2, 2014.

CDC created and implemented an operational plan outlining the course of action for the first 72 hours to manage a laboratory-confirmed Ebola diagnosis in a patient. Plan activities include rapid dissemination of news regarding the Ebola case(s) to key public health, healthcare system, and emergency management partner organiza-

tions; providing current and timely information to State, local, and territorial public health departments; and coordinating critical issues management regarding State and local needs for the CDC EOC incident manager and other response task force teams.

CDC has redoubled its efforts to educate American health care workers about how to isolate patients and how to protect themselves from infection, including developing and disseminating resources, hosting informational calls, and creating trainings. CDC has:

- Hosted Clinician Outreach and Community Activity calls for clinical professionals to provide information about what U.S. hospitals need to know to prepare for EVD.
- Created guidance about EVD for clinicians in U.S. health care settings.
- Posted a Medscape Expert Commentary for healthcare providers whose patients are travelers with concerns about Ebola. The commentary includes information about the Ebola outbreak in West Africa, the transmission Ebola virus, and how to talk to travelers about their risk.
- Created guidance for U.S. healthcare workers on "Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals."
- Developed a checklist for hospitals to aid in Ebola preparedness that can be found on the CDC website.
- Built a Safety Training Course for Healthcare Workers Going to West Africa in Response to the 2014 Ebola Outbreak. The primary purpose of the course is to ensure that clinicians intending to provide medical care to patients with Ebola have sufficient knowledge of the disease and its transmission routes to work safely and efficiently in a well-designed Ebola Treatment Unit (ETU).
- Collated the Top 10 Ebola Response Planning Tips: Ebola Readiness Self-Assessment for State and Local Public Health Officials to help guide planning and readiness for Ebola response at State and local levels and assist health officials in assessing their jurisdictions' level of readiness for a potential Ebola response.

SENATOR BALDWIN

Question. The President recently outlined a comprehensive response to combat this epidemic that includes the efforts of an estimated 3,000 U.S. forces and a strong partnership with the United Nations and our other international partners. The first cases of Ebola were reported in March; it is now October and the Ebola crisis is only worsening. Why did we not initiate this response in March? In hindsight, what should have been the United States' first action item when cases were first reported, and what can we learn from this to prevent the world from seeing such tragedy again?

Answer. CDC is incorporating lessons learned as the response evolves, and, as is done after all large-scale responses, the agency will conduct a comprehensive "after-action" review to learn additional lessons that will prepare the agency to better respond to future events.

CDC initiated the first stages of response in March 2014 when it activated its EOC to help coordinate technical assistance and control activities with partners. On August 6, 2014, CDC elevated the EOC to a Level 1 activation, its highest level, because of the significance of the outbreak. CDC supports countries in establishing their own national and sub-national EOCs. Each of the three West African countries at the center of the epidemic now has an Incident Manager, reporting to the President of the country, to lead response efforts.

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 continues to send additional public health experts to the affected and neighboring countries. CDC experts have been deployed to non-affected border countries, including Cote d'Ivoire, to conduct assessments of Ebola preparedness in those countries.

Through the Global Disease Detection (GDD) program, CDC develops and strengthens global capacity to rapidly detect, accurately identify, and promptly contain emerging infectious disease and bioterrorist threats that occur internationally. The GDD Operations Center, implemented in 2007, is a surveillance system that enables the ongoing, systematic collection, management, analysis, interpretation, and dissemination of health-related data.

SENATOR WARREN

Question 1. If the Global Security Agenda had been launched 5 years ago, and we already had these pieces in place, would this epidemic have been better contained?

Answer 1. The global response to Ebola underscores the need for well-functioning and effective health and public health systems across the world. The current response shows that capacities outlined in the Global Health Security Agenda (GHSA) to prevent, detect, and respond to public health emergencies are critical in a country's ability to lessen the impact of infectious disease outbreaks. Had these capacities been developed, the course of this outbreak would likely have resulted in earlier containment, fewer deaths and decreased economic ramifications.

Several components of the immediate response to Ebola are key areas for GHSA implementation—EOC, laboratory capacity, surveillance, and workforce development. In this epidemic, we have seen that some countries, even with nascent detection and response capacities, were able to successfully contain the outbreak after experiencing cases in their countries. An example is Nigeria, which used its existing EOC and Field Epidemiology Training Program to monitor operations, conduct surveillance, and conduct contact tracing, proving that even basic improvements to public health systems can be effective in responding to emerging threats.

Some of CDC's work in this response, including surveillance, information systems, workforce strengthening, EOC development, and laboratory services will serve as the foundation for longer-term, broad, global health security strengthening.

Question 2. How will the Agenda help to address the challenges of political instability, the lack of infrastructure, and the lack of basic health care resources that have all played a huge role in the continued spread of this epidemic?

Answer 2. The vision of the Global Health Security Agenda is a world safe and secure from global health threats posed by infectious diseases—where we can prevent or mitigate the impact of naturally occurring outbreaks and intentional or accidental releases of dangerous pathogens, rapidly detect and transparently report outbreaks when they occur, and employ an interconnected global network that can respond effectively to limit the spread of infectious disease outbreaks in humans and animals, mitigate human suffering and the loss of human life, and reduce economic impact.

Ebola is the most tangible—and tragic—example so far for why the global community must work together to make the world safer from infectious disease outbreaks. The Ebola crisis in West Africa is precisely the kind of complicated disease eruption the Global Health Security Agenda is designed to address. The GHSA will help prevent, detect and respond to infectious disease outbreaks in the following ways:

- Coordination and communication among nations will be strengthened and streamlined, allowing disease outbreaks to be discovered and characterized at the earliest possible moment.
- Laboratory capacity will be increased and operating standards strengthened so that potential diseases can be accurately and precisely identified. Then treatment protocols can be established more quickly to effectively treat patients and protect health care workers.
- New disease detectives will be trained around the world and deployed to close gaps in surveillance and provide early detection.
- More countries will be equipped with networked EOCs governed by a universal set of standards and rules that will allow a unified and effective response.
- The availability of more detailed information sooner will allow a more unified response and, if needed, the ability of partner countries to surge experts to affected areas so disease outbreaks are contained at the earliest possible moment and while they are still small in scope.

Ultimately, having better information around disease detection and response enables more timely and accurate communication with the public. This can help limit unease and panic that affects commerce, travel, political stability and public health.

Question 3. How would the effectiveness of the Agenda be maximized by investments to improve the basic healthcare infrastructure of developing nations?

Answer 3. The GHSA outlines nine objectives to accelerate progress toward a world safe and secure from infectious disease threats in partnership with other nations, international organizations and public and private stakeholders. Several of these address the investments related to improve health care systems:

- Reduce the number and magnitude of infectious disease outbreaks. Establish effective programs for vaccination against epidemic-prone diseases and for nosocomial infection control.

• Train and deploy an effective disease surveillance workforce. Build capacity for trained and functioning biosurveillance workforce, with trained disease detectives and laboratory scientists.

• Improve global access to medical and non-medical countermeasures during health emergencies. Strengthen capacity to produce or procure personal protective equipment, medications, vaccines, and technical expertise, as well as the capacity to plan for and deploy non-medical countermeasures. Strengthen policies and operational frameworks to share public and animal health and medical personnel and countermeasures with partners.

Question 4. Who do you think should be ultimately responsible for the international coordination and financing of outbreak responses when local governments are unable to do so?

Answer 4. To respond adequately to a major crisis such as the Ebola Outbreak in West Africa, multiple actors are needed and, in fact, are now responding. They include U.N. agencies (such as WHO, UNICEF, World Bank), the U.S. Government, other countries, NGO's (such as MSF and the International Red Cross), as well as other entities within the private sector. Within the West Africa region affected by the Ebola outbreak, USAID continues to lead the United States' overseas response, while the Department of Defense, CDC, Department of State, and other departments and agencies are supporting the whole-of-government approach to this national security priority. USAID has deployed a DART to coordinate planning, operations, logistics and other components of the interagency effort. CDC staff is working with Ministries of Health to improve surveillance, contact tracing, laboratory capacity, emergency operations planning and other critical capabilities.

HHS, and in particular CDC, is working closely with the World Health Organization (WHO), the United Nations, the Ministries of Health in affected countries, and other international partners to respond to the current Ebola outbreak in West Africa. The Ebola epidemic reminds us that our global efforts to build the capacity to prevent, detect, and rapidly respond to infectious disease threats like EVD have never been more vital.

In February 2014, the United States came together with nations around the world to launch the Global Health Security Agenda (GHSA) as a 5-year effort to accelerate action. On September 26, 2014, President Obama met with leaders of 40 nations as well as top Administration officials to advance progress in the GHSA.

CDC receives regular updates of morbidity and mortality to evaluate the spread of the disease and combines this information with reports from CDC's staff deployed to the area. Hundreds of CDC staff members have provided logistics, staffing, communication, analytics, management, and other support functions for the response. CDC continues to commit significant staffing and financial resources to the international Ebola response both on the ground in West Africa and through its domestic EOC.

CDC has activated its EOC to help coordinate technical assistance and control activities with partners. CDC supports countries in establishing their own national and sub-national EOCs. Each of the three West African countries at the center of the epidemic now has an Incident Manager, reporting to the President of the country, to lead efforts.

CDC continues to send additional public health experts to the affected 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 the affected countries.

The below mechanisms for coordination have been developed to direct their support to the target population in West Africa. At the international level, the United Nations has established its Mission for Ebola Emergency Response (UNMEER) in Ghana, and is serving as a regional hub for logistics and coordination of the U.N. Bodies (including WHO, UNICEF, and others), while working closely with the Governments of Guinea, Liberia and Sierra Leone.

WHO-AFRO has established a Regional Outbreak Coordination Center in Conakry, Guinea.

Within countries, through their country offices, WHO is coordinating support to the national operational plans. The United States has established DARTs in each of the affected countries for coordination of U.S. Government planning, operations, logistics, administrative issues and other critical areas related to the U.S. Government interagency response. These efforts are all done in direct coordination with national governments, given that they have responsibility for coordinating their respective national response efforts.

Private sector resources also may be called upon to support lead agencies and directly impacted areas. For the private sector, this includes companies lending their

core competencies and assets on the ground as well as providing financial resources to support other priorities. The private sector also can contribute by maintaining operations in impacted countries/regions as they are an important part of local economies.

Question 5. What is the ideal design for an international response system for future outbreaks?

Answer 5. The International Health Regulations (IHR, 2005) provide the legally binding framework for the coordination of the management of events that may constitute a public health emergency of international concern. IHR aims to improve the capacity of all countries to detect, assess, notify, and respond to public health threats. While IHR was signed by the 194 member states of the World Health Organization, fewer than 20 percent of those countries reported in 2012 that they have fully achieved compliance with IHR and are fully prepared to detect and respond to disease threats. The aim of the Global Health Security Agenda is to close this gap.

The Global Health Security Agenda (GHSA) is an effort by nations, international organizations, and civil society to accelerate progress toward a world safe and secure from infectious disease threats; to promote global health security as an international priority; and to spur progress toward full implementation IHR and other relevant global health security frameworks.

Question 6. What is the ideal design for our national response system for future international outbreaks?

Answer 6. CDC is fully supportive of the National Response Framework (updated in 2013) and the National Incident Management System (NIMS) outlined within it. The guiding principles of NIMS are: engaged partnership; tiered response; scalable, flexible, and adaptable operational capabilities; unity of effort through unified command; and readiness to act.

The National Response Framework works best when State and local health departments are fully staffed and well trained and have robust surveillance and laboratory capacity. Strong clinical networks that local health departments can link into for novel or unfamiliar global infectious disease outbreaks and a stockpile of medical countermeasures are also important as scalable resources. Another scalable resource that is needed for international and domestic outbreaks is a cadre of highly trained public health workers, including disease detectives, capable and ready to respond. CDC supports these goals domestically through the Public Health Emergency Response (PHEP) and Epidemiology and Laboratory Capacity (ELC) cooperative agreements, the Strategic National Stockpile (SNS), and support for the Laboratory Response Network (LRN) as well as internationally through programs such as the Field Epidemiology Training Program (FETP), Global Disease Detection Centers, and the Global Health Security Agenda.

Question 7. How would long term investments to improve the basic healthcare infrastructure of developing nations help to improve our ability to respond to new outbreaks and epidemics?

Answer 7. Health care services are a part of every nation's public health system, and they play a crucial role. There are linkages between Global Health Security and health care services. The Global Health Security Agenda takes a public health, or systems-level approach. Through the Agenda, the United States commits to working with at least 30 partner countries (containing at least 4 billion people) to prevent, detect and effectively respond to infectious disease threats, whether naturally occurring or caused by accidental or intentional releases of dangerous pathogens. The objectives of the agenda emphasize systems-level interventions in the three areas: Prevent, Detect, and Respond. Select activities include:

- Prevent: Countries will have systems, policies and procedures in place to prevent or mitigate avoidable outbreaks.
- Detect: Countries will have real-time biosurveillance and effective modern diagnostics in place that are able to reliably conduct at least five of the 10 core tests.
- Respond: Countries will have a public health EOC functioning according to minimum common standards.

Investing in global health security means investing in public health systems, and systems such as these provide critical information needed to inform health care practice. For instance, reliable nation-wide laboratory networks are needed for the detection of priority pathogens. These same networks also are needed for the accurate diagnosis of priority pathogens in individuals. In addition, information gathered

through public health surveillance can help inform decisions about how limited healthcare resources could be targeted to be most impactful.

Question 8. How are the United States and international aid organizations helping to take care of health care needs besides Ebola in the epidemic regions?

Answer 8. The U.S. Government is making investments in the region to address multiple health issues such as HIV and AIDS, maternal and child health, nutrition, malaria, and vaccine preventable diseases, including polio. Relationships on the ground, nurtured in part by CDC's work in the region have proven to be important assets in addressing the current Ebola outbreak. CDC also continues to support priority activities in the region as well.

The United States and international organization partners continue to support the President's Malaria Initiative in the epidemic regions ensuring that planned malaria prevention activities, such as long-lasting insecticide treated bed net distributions, health indicator surveys, and healthcare working trainings are minimally disrupted. CDC is sending staff to support in-country national malaria control programs while the Resident Advisors are engaged in the Ebola response. Recently, CDC/WHO revised guidance for the diagnosis of malaria in Ebola countries to respond to the needs of the healthcare workers and partner organizations by recommending treatment options for specific populations in the Ebola affected areas to reduce the incidence of febrile illnesses.

CDC plays a critical role in helping Ministries of Health in partner countries build strong, sustainable programs that respond effectively to the HIV/AIDS epidemic. CDC provides support to more than 60 countries as a key partner in the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). CDC through PEPFAR, is working to achieve that inspiring goal through proven science, smart investments, and shared responsibility with partner countries.

CDC also is continuing immunization activities in the region. CDC is working with partners at WHO and UNICEF to maintain high levels of polio immunity there as part of the global effort to eradicate polio. CDC also supports measles vaccination and related immunization activities there. The worsening epidemic has slowed immunization activities in Ebola affected areas; however, the networks established by immunization activities are being used to provide education and information about stopping the spread of Ebola.

In addition, CDC's expertise in responding to the polio epidemic in Nigeria was leveraged to assist in establishing emergency response operations in that country to stop the spread of Ebola. The threat to Nigeria posed by the arrival in Lagos of a patient acutely ill with Ebola was potentially enormous, but the virus does not appear to have been widely spread there. The limited spread against the backdrop of the large, dense, urban environment suggests early response efforts were successful. CDC provided key guidance, and leadership, in a variety of areas, including incident management, contact tracing, public messaging and information, and port security to encourage a quick and effective response.

SENATOR ALEXANDER

Question 1. The United States has pledged support to help fight Ebola, and there are other countries stepping up to the plate as well. How are these efforts being coordinated and is it effective? Who is on the flagpole?

Answer 1. Within the West Africa region affected by the Ebola outbreak, USAID continues to lead the United States' overseas response, while CDC, the Department of Defense, Department of State, and other Federal Departments and Agencies are supporting the whole-of-government approach to this national security priority. USAID has deployed a DART to coordinate planning, operations, logistics and other components of the interagency effort. CDC staff is working with Ministries of Health to improve surveillance, contact tracing, laboratory capacity, emergency operations planning and other critical capabilities.

HHS, and in particular CDC, is working closely with the World Health Organization (WHO), the United Nations, the Ministries of Health in affected countries, and other international partners to respond to the current Ebola outbreak in West Africa. The Ebola epidemic reminds us that our global efforts to build the capacity to prevent, detect, and rapidly respond to infectious disease threats like EVD have never been more vital. In February 2014, CDC came together with nations around the world to launch the GHSA as a 5-year effort to accelerate action. On September 26, 2014, President Obama met with leaders of 40 nations as well as top Administration officials to advance progress in the GHSA.

CDC receives regular updates of morbidity and mortality to evaluate the spread of the disease and combines this information with reports from CDC's staff deployed to the area. Hundreds of CDC staff members have provided logistics, staffing, com-

munication, analytics, management, and other support functions for the response. CDC continues to commit significant staffing and financial resources to the international Ebola response both on the ground in West Africa and through its domestic EOC.

CDC has activated its EOC to help coordinate technical assistance and control activities with partners. CDC supports countries in establishing their own national and sub-national EOCs. Each of the three West African countries at the center of the epidemic now has an Incident Manager, reporting to the President of the country, to lead efforts.

CDC continues to send additional public health experts to the affected 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 the affected countries.

Question 2. Dr. Frieden cautioned that, "The window of opportunity to stop Ebola from spreading widely through Africa and becoming a global threat for years to come is closing, but it is not yet closed." Is that window still open? What do we need to be doing to keep that window open?

Answer 2. CDC continues to increase our efforts, and strongly encourage global partners, to "keep the window open." The global community still has an opportunity to reverse the course of the epidemic in the three affected countries and prevent the spread of Ebola to other countries in Africa and throughout the world, but coordinated leadership and unwavering support must be brought to bear. HHS, and in particular CDC, is working closely with the World Health Organization (WHO), the United Nations, the Ministries of Health in affected countries, and other international partners to respond to the current Ebola outbreak in West Africa.

CDC continues to commit resources at never-before seen levels to support the U.S. Government response to the Ebola outbreak. CDC has activated its EOC to help coordinate technical assistance and control activities with partners. CDC supports countries in establishing their own national and sub-national EOCs. Each of the three West African countries at the center of the epidemic now has an Incident Manager, reporting to the President of the country, to lead response efforts. CDC is also:

- Providing hundreds of CDC staff members for 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 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 the affected countries. CDC experts have also been deployed to non-affected border countries, including Cote d'Ivoire, to conduct assessments of Ebola preparedness in those countries.
- Working with airlines, airports, and ministries of health in West Africa to provide technical assistance for developing exit screening and travel restrictions in the countries where Ebola outbreaks are occurring.
- With CBP, conducting enhanced entry screening to detect possible cases of Ebola in travelers who have traveled to the United States from or through Guinea, Liberia, and Sierra Leone. Enhanced entry screening at five U.S. airports (New York-JFK, Washington-Dulles, Newark, Chicago-O'Hare, and Atlanta) will evaluate travelers from the affected countries in West Africa.
- Redoubling its efforts to educate U.S. healthcare workers on how to isolate patients and how to protect themselves from infection. Resources for U.S. healthcare workers are available on the CDC website. Over the coming days and weeks, CDC will be working with other Federal, State, and local governments and private organizations to strengthen U.S. readiness for the detecting and preventing additional cases of Ebola in this country. These efforts include the aforementioned enhanced entry screening at five U.S. ports of entry and enhanced outreach to healthcare workers and hospitals to improve their infection control practices and policies.

Question 3. How is this outbreak testing the boundaries of what we know? In what manner will we need to alter the response given the different characteristics of this epidemic?

Answer 3. The epidemic is unprecedented in size, scope, and complexity, but the fundamental risk factors and primary modes of transmission are the same as in previous Ebola outbreaks. The core public health interventions that have worked to stop previous Ebola outbreaks—surveillance, case identification and contact tracing,

isolation and treatment, safe burials—will work to stop this epidemic. CDC along with other parts of the U.S. Government and global partners are working on multiple fronts to expand capacity to meet this challenge.

Question 4. We know that there is desperate need for doctors and nurses to care for people sick with Ebola. Estimates suggest a facility treating 70 Ebola patients' needs a minimum of 250 health care staff, but Liberia didn't even have that many doctors in its country even before the outbreak. The United States Agency for International Development has created a website where health professionals can sign up to help with the Ebola response.

How are you coordinating with USAID? What are you doing to prepare these volunteers? Please describe any training provided to these volunteers.

Answer 4. Within the West Africa region affected by the Ebola outbreak, USAID continues to lead the United States' overseas response, while CDC, the Department of Defense, Department of State, and other Federal Departments and Agencies are supporting the whole-of-government approach to this national security priority. USAID deployed a DART to coordinate planning, operations, logistics and other components of the interagency effort. USAID is the lead Agency for recruiting and coordinating volunteers for the response.

Humanitarian aid workers play a vital role in the Ebola outbreak response, and CDC encourages them to continue the important work being done to stop the disease's spread at its source. CDC developed guidance for humanitarian aid organizations whose employees or volunteers are working in countries where an Ebola outbreak is occurring to help them plan for safe deployment. The recommendations include steps to take before departure, during travel, and upon return to the United States.

CDC also created a Safety Training Course for healthcare workers going to West Africa in response to the 2014 Ebola outbreak. The primary purpose of the course is to ensure that clinicians intending to provide medical care to patients with EVD have sufficient knowledge of the disease and its transmission routes to work safely and efficiently in a well-designed Ebola Treatment Unit (ETU). In addition, CDC developed an introductory training course for licensed clinicians (*e.g.*, nurses, physicians, and other healthcare providers) intending to work in an ETU in Africa to ensure that these clinicians have sufficient knowledge of the disease and its transmission routes to work safely and efficiently. The 3-day course is being given weekly and is already full for the next few months.

Question 5. Since the hearing, we have had a patient land in the United States one airplane ride away from a person who was exposed to Ebola landing in the United States and becoming ill. What is the Department of Health and Human Services doing to prepare?

There are four specialized medical isolation units in the United States that have been reported to be available to treat Ebola patients. Three of these have been used to treat the patients or exposed individuals brought back to the United States. If these fill to capacity and other individuals sick with Ebola are in need of care, how prepared are our hospitals to take care of Ebola patients?

Answer 5. CDC has created plans outlining its course of action for when a laboratory-confirmed Ebola diagnosis occurs in the United States. The operational plans include assistance to State, tribal, territorial and local officials and the domestic health care community, and leverage CDC's expertise and resources in epidemiology, surveillance, coordination of laboratory testing, health promotion and communication, healthcare and infection control, traveler health and screening.

CDC's response to a diagnosed case follows three key public health tenets: prevention, detection and response. The concept of prevention focuses on actions which can affect the spread of the disease. Detection centers on activities to find the disease through surveillance and contact tracing. CDC's response efforts include its agency-wide incident management and response capabilities in support of domestic requirements. CDC, along with other Federal agencies, has created and implemented a response plan to manage a laboratory-confirmed case of EVD in the United States and is providing guidance to health care facilities about how to safely manage a patient with suspected EVD. This includes engagement in the following activities:

- Enhancing surveillance and laboratory testing capacity to detect cases domestically.
- Developing guidance and tools for health departments to conduct public health investigations.
- Providing recommendations for healthcare infection control and other measures to prevent disease spread.
- Providing guidance for flight crews, emergency medical units at airports, and CBP officers about reporting ill travelers to CDC.

• Coordinating with maritime authorities to assess the potential risk to the United States from cargo vessels from the four affected West African countries.

• Disseminating up-to-date information about the outbreak to the general public, international travelers, and public health partners.

CDC has developed guidance documents and checklists to help U.S. hospitals prepare for, test, and treat patients with Ebola, and works to keep the health care system informed of new developments. CDC uses its Health Alert Network (HAN) to provide information and guidance to U.S. healthcare workers and hospitals regarding EVD. A HAN notice was distributed by CDC on August 1, 2014, and five updates have followed. The most recent HAN notice about Ebola was distributed on October 2, 2014.

CDC has redoubled its efforts to educate American health care workers about how to isolate patients and how to protect themselves from infection, including developing and disseminating resources, hosting informational calls, and creating trainings. CDC has:

• Hosted Clinician Outreach and Community Activity calls for clinical professionals to provide information about what U.S. hospitals need to know to prepare for EVD.

• Created guidance about EVD for clinicians in U.S. health care settings.

• Posted a Medscape Expert Commentary for healthcare providers whose patients are travelers with concerns about Ebola. The commentary includes information about the Ebola outbreak in West Africa, the transmission of the Ebola virus, and how to talk to travelers about their risk.

• Created guidance for U.S. healthcare workers on "Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals."

• Developed a checklist for hospitals to aid in Ebola preparedness, which can also be found on the CDC website.

• Built a Safety Training Course for Healthcare Workers Going to West Africa in Response to the 2014 Ebola Outbreak. The primary purpose of the course is to ensure that clinicians intending to provide medical care to patients with Ebola have sufficient knowledge of the disease and its transmission routes to work safely and efficiently in a well-designed ETU.

• Collated the Top 10 Ebola Response Planning Tips: Ebola Readiness Self-Assessment for State and Local Public Health Officials to help guide planning and readiness for Ebola response at State and local levels and assist health officials in assessing their jurisdictions' level of readiness for a potential Ebola response.

CDC also is working with additional hospitals to ready their facilities for additional patients with Ebola. Any U.S. hospital should be prepared to identify, assess and isolate a patient with Ebola. CDC developed guidance documents and checklists to help U.S. hospitals prepare for, test, and treat patients with Ebola, and works to keep the health care system informed of new developments. CDC uses its HAN to provide information and guidance to U.S. healthcare workers and hospitals regarding Ebola. CDC distributed a HAN notice August 1, 2014, and five updates have followed. The most recent HAN notice about Ebola was distributed on October 2, 2014.

CDC created plans outlining its course of action for when a laboratory-confirmed Ebola diagnosis occurs in the United States. The operational plans include assistance to State, tribal, territorial and local officials and the domestic health care community, and leverage CDC's expertise and resources in epidemiology, surveillance, coordination of laboratory testing, health promotion and communication, healthcare and infection control, traveler health and screening.

CDC's response to a diagnosed case follows three key public health tenets: prevention, detection and response. The concept of prevention focuses on actions which can affect the spread of the disease. Detection centers on activities to find the disease through surveillance and contact tracing. CDC's response efforts include its agency-wide incident management and response capabilities in support of domestic requirements.

SENATOR ALEXANDER AND SENATOR BURR

Question. You State in your testimony, "We do not view Ebola as a significant public health threat to the United States." Could you please reconcile this statement with the fact that in 2006 then Secretary of Homeland Security Michael Chertoff determined, pursuant to Section 319F–2 of the Public Health Service Act that the Ebola virus presents a material threat against the United States population sufficient to affect national security, and that in August of this year the Secretary used

this determination to authorize emergency use of a diagnostic for identification of Ebola virus.

Answer. The difference between the two statements is that the former deals with the natural transmission of Ebola as a public health concern, whereas the latter primarily has to do with Ebola's potential for harm if artificially disseminated in a bioterrorist attack. In the United States, while there may be secondary cases among contacts of an imported Ebola case, the public health system will stop Ebola before an outbreak occurs. From a public health perspective, we know how to contain Ebola and we have the systems to do so. A DHS Material Threat Determination is made based on the risk of a terrorist using Ebola as a bio-weapon. DHS has determined that in certain scenarios the intentional use of the Ebola virus as a weapon could affect national security, even recognizing the public health system's ability to control outbreaks. CDC is working closely with the Food and Drug Administration (FDA) to approve Emergency Use Authorizations (EUAs) that make available diagnostic and therapeutic medical devices to diagnose and respond to public health emergencies, whether of natural or deliberate origin. As a result, FDA has enacted several EUAs for laboratory tests to aid in detecting the Ebola virus.

SENATOR MORAN

Global Health Security

Question 1. Dr. Bell, the Administration requested a new Global Health Security Initiative in fiscal year 2015. This Initiative would strengthen the capacity to prevent the introduction and spread of global health threats in 12 countries: Uganda, Vietnam, India, Kenya, South Africa, Kazakhstan, Georgia, Thailand, Tanzania, Jordan, Philippines, and Ethiopia. Given the need for this kind of program in West Africa, would the list of 12 countries change given the Ebola outbreak?

Answer 1. As part of the Ebola response, CDC is working to build key components of the Global Health Security Agenda (GHSA), but the scope and impact is much greater than just stopping the Ebola outbreak. The vision of the Global Health Security Agenda is to create a world safe and secure from global health threats posed by infectious diseases—where we can prevent or mitigate the impact of naturally occurring outbreaks and intentional or accidental releases of dangerous pathogens, rapidly detect and transparently report outbreaks when they occur, and employ an interconnected global network that can respond effectively to limit the spread of infectious disease outbreaks in humans and animals, mitigate human suffering and the loss of human life, and reduce economic impact.

We want to be sure to increase country capacity throughout the world so that another Ebola-like crisis can be averted. We don't know where the next public health emergency will occur, so it is imperative to assist as many countries as possible to be able to prevent, detect and respond to emerging threats.

We are expanding our efforts in West Africa and exploring opportunities to engage with Ministries of Health on GHSA once the acute needs of the Ebola response are met.

Question 2. If so, which countries will receive funding in fiscal year 2015 if the Global Health Security Initiative is funded?

Answer 2. The requested funding will reduce risks to Americans by enhancing capacity for vulnerable countries to prevent disease outbreaks, detect them early, and swiftly respond before they become epidemics that threaten our national security. We will prioritize urgently needed investments in vulnerable nations, transport hubs, and States without the capacity to prevent global spread of Ebola or stem the tide of future threats. It is important to maintain the flexibility to make adjustments given the dynamic national and global health security environment in these countries. We also expect that other key donor partners will leverage this effort under the Global Health Security Agenda to complement our funding.

Ebola Response Plan

Question 3. Dr. Bell, what is the plan for a U.S. Government response? How do we help get the Ebola outbreak under control? Which agency is in charge of the response efforts?

Answer 3. Public health knows how to stop the spread of communicable diseases. To halt the spread of Ebola, the links of transmission between people must be interrupted. Public health does that by making sure that every person with Ebola is promptly diagnosed and promptly isolated and that their contacts are identified and actively monitored every day for 21 days. If any of the contacts develop symptoms or fever, we follow the same process again. That is how public health authorities have stopped every Ebola outbreak in history except the one currently in West Africa.

HHS, and in particular CDC, is working closely with the World Health Organization (WHO), the United Nations, the Ministries of Health in affected countries, and other international partners to respond to the current Ebola outbreak in West Africa. CDC receives regular updates of morbidity and mortality to evaluate the spread of the disease and combines this information with reports from CDC's staff deployed to the area. Hundreds of CDC staff members have provided logistics, staffing, communication, analytics, management, and other support functions for the response. CDC continues to commit significant staffing and financial resources to the international Ebola response both on the ground in West Africa and through its domestic EOC.

CDC is working closely with U.S. Agency for International Development (USAID) and its Office of Foreign Disaster Assistance (OFDA) to support the deployment to Liberia of a DART, which is overseeing 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), provided a field laboratory to Liberia to increase the number of specimens being tested for Ebola. The lab is currently operating at full capacity and is only the second site in Liberia capable of testing specimens from patients with suspected Ebola. CDC has also deployed a second laboratory in Sierra Leone.

CDC has activated its EOC to help coordinate technical assistance and control activities with partners. On August 6, 14, CDC elevated the EOC to a Level 1 activation, its highest level, because of the significance of the outbreak. CDC supports countries in establishing their own national and sub-national EOCs. Each of the three West African countries at the center of the epidemic now has an Incident Manager, reporting to the President of the country, to lead response efforts.

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 continues to send additional public health experts to the affected and neighboring countries. CDC experts have been deployed to non-affected border countries, including Cote d'Ivoire, to conduct assessments of Ebola preparedness in those countries.

Risk to Americans

Question 4. Dr. Bell, what is the risk of Ebola spreading from West Africa to the United States?

Answer 4. In response to the case of Ebola in the United States, teams from CDC are deployed to Dallas to assist with the investigation. They are supported 24/7 by CDC's EOC and Ebola experts at CDC's Atlanta headquarters. Teams work closely with State and local health departments in finding, assessing, and assisting everyone who came into contact with the Ebola patient. Although the risk spread of Ebola in the United States is very low, CDC and partners are taking precautions to isolate any cases of Ebola and prevent the spread of the disease. CDC recognizes that even a single case of Ebola diagnosed in the United States raises concerns and that when a case is imported into the United States, secondary cases resulting from transmission from that case may occur. CDC and partners are taking precautions to contain any cases of Ebola and prevent the spread of the disease.

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. CDC has enhanced its outreach with DHS and other partners at ports of entry (primarily international airports) to use routine procedures for identifying and reporting travelers who show signs of infectious disease. CDC and 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 Guinea, Liberia, or Sierra Leone. CDC provides interim guidance for monitoring people potentially exposed to Ebola and for evaluating their intended travel, including the application of movement restrictions when indicated.

The virus is not transmitted easily, does not spread from people who are asymptomatic, and the United States has effective infection control measures in place to prevent the spread of the disease in the United States. Medical and public health professionals across the country have been preparing to respond, and any U.S. hospital should be prepared to identify, assess and isolate a patient with Ebola.

SENATOR COCHRAN

Border Security and Ebola

Question 1. Dr. Bell, it is my understanding that the Centers for Disease Control and Prevention is working closely with U.S. Customs and Border Protection and other partners at our ports of entry, particularly international airports, to identify travelers who show signs of infectious disease. While this is an important step, I am hopeful that we are also paying close attention to our land border as a potential entry location. Can you specifically speak to the contingencies that are being deployed in the event Ebola arrives from our Nation's Southwest border?

Answer 1. We defer to the DHS with regard to contingencies at U.S. borders. We do note that CDC and partners are taking precautions to prevent the spread of Ebola to other countries. The U.S. Southwest border is not a major route of entry for people coming from the affected countries in West Africa. CDC has issued a Warning Level 3 (the highest level) travel notice for the three countries where the Ebola outbreak is severe. U.S. citizens should avoid all nonessential travel to Guinea, Liberia, and Sierra Leone. CDC is assisting with exit screening and communication efforts in West Africa to prevent sick travelers from boarding commercial planes, buses, trains, or ships. CDC also has issued interim guidance about Ebola virus infection for airline flight crews, cleaning personnel, and cargo personnel. This is part of a layered approach that includes exit screening and standard public health practices such as patient isolation and contact tracing in countries with Ebola outbreaks. Successful containment of the recent Ebola outbreaks in Nigeria and the Democratic Republic of Congo demonstrate the effectiveness of this approach. Increasing awareness and preparedness here in the United States to rapidly identify and isolate potential Ebola patients and ensuring ready access to diagnostic testing through the Laboratory Response Network are additional components of this approach. Ultimately, the best way to protect Americans from Ebola is to stop the outbreak in West Africa.

Response from International Community

Question 2. Thank you for coming in today to describe efforts by the U.S. Government to respond to the Ebola outbreak in West Africa. I am hopeful that the United States can play a leadership role in addressing this humanitarian crisis, but I am also curious about the contributions of international organizations and our partner nations. Will you please describe efforts by the international community to stop the Ebola epidemic?

Answer 2. Generating increased international support for the response is a top priority for the U.S. Government. As the United States expanded our response (scaling from 20 to over 100 personnel from CDC, deploying the largest DART in USAID's history and then establishing the Joint Force Command), agencies and departments have been engaged in a steady campaign to mobilize contributions of resources and personnel from other countries, including direct outreach to international counterparts by principals.

Pressing other countries to increase their responses to the Ebola epidemic has been a feature of nearly all bilateral engagements, and we have also used the announcement of the Joint Task Force deployment on September 16, 2014, the U.N. Security Council session hosted by the United States on September 18, 2014, and the U.N. Secretary General's High-Level Meeting on September 25, 2014, to mobilize increased engagement and investment from other governments. The U.N. Secretary General initiated the United Nations Mission for Ebola Emergency Response (UNMEER), and the Mission was approved unanimously by the U.N. General Assembly on September 18, 2014.

The Mission's overall aim is to reinforce government leadership and for a rapid and coherent response focused on five strategic priorities—stop the spread of the disease; treat the infected; ensure essential services; preserve stability in affected communities; and prevent the spread to neighboring countries and beyond. The immediate focus is on getting treatment units built, staffing them, and tracing contacts of those infected with Ebola to isolate and treat them if they come down with the disease.

To date, more than 35 donor countries have contributed and pledged upwards of $690 million to the response. Highlights include:

- Following the announcement of the Joint Force Command, the United Kingdom, which had previously committed to establish a hospital in Sierra Leone to care for infected health workers, announced that it will stand up 700 Ebola treatment beds in Sierra Leone and establish a military command center there.
- France has announced additional resources, and that it will provide a hospital facility in Guinea.

• Germany has pledged to build additional Ebola treatment units, will provide C–160 transport aircraft to support the air bridge in West Africa, and is mobilizing volunteers to support the response.

• The World Bank has committed $400 million, and the African Development Bank has committed $150 million.

• The European Union has committed to providing $180 million and to expanding its response effort.

• The IMF Executive Board approved $130 million expansion of zero-interest loans for the three affected West African nations.

• South Africa has committed to build and staff an Ebola treatment unit as well.

• Others, including China, Cuba, India, Japan, Canada, Sweden, Australia, Norway, Switzerland, South Korea, Thailand, Ghana, Malaysia, Denmark, Spain, Ireland and the African Union, are providing significant financial and in-kind support.

Ebola Protection and Control

Question 3. Do you believe the additional $88 million that has been requested by the President to respond to this Ebola crisis will provide you with the resources required to protect against the potential spread of Ebola in the United States and to address needs abroad?

Answer 3. The Congress appropriated $30 million for CDC through the continuing resolution. These resources will support CDC for period of the continuing resolution, allowing us to ramp up efforts to contain the spread of this virus. More than half of the funds are expected to directly support staff, travel, security and related expenses. A portion of the funds will be provided to the affected area to assist with basic public health infrastructure, such as laboratory and surveillance capacity, and improvements in outbreak management and infection control. Should outbreaks recur in this region, they will have the experience and capacity to respond without massive external influx of aid, due to this investment.

The remaining funds will be used for other aspects of strengthening the public health response such as laboratory supplies/equipment, and other urgent needs to enable a rapid and flexible response to an unprecedented global epidemic. CDC is working to identify our potential resource needs for the rest of the fiscal year, and possibly further, as we deal with this evolving public health emergency.

Capacity for Drugs or Vaccines

Question 4. Do you believe the capacity we have to approve, produce, and distribute drugs and vaccines here in the United States is sufficient to contain an infectious disease such as Ebola should it make its way here to the United States?

Answer 4. The United States has the capacity to approve, produce, and distribute drugs and vaccines in the United States for many infectious diseases for which there are commercial products (*e.g.*, pandemic influenza) to prevent or treat these diseases or there are late-stage product candidates in the pipeline (*e.g.*, H7N9 avian influenza). However, we, like other industrialized countries, must depend initially on a high quality healthcare system to provide supportive care for infectious diseases where the drug and vaccine development pipeline is comprised of very early stage product candidates like Ebola or there are no candidates at all in the pipeline like MERS-CoV; the domestic development and manufacturing infrastructure established over the past 5 years (*e.g.*, CIADMs) is engaged and rapidly responding with the advanced development and manufacturing of new experimental drugs and vaccines. This infrastructure is being utilized today in the Ebola response by transitioning early stage drug and vaccine candidates into advanced development by conducting clinical trials and scaling up manufacturing to commercial scale, leading to an accelerated availability of these product candidates from several years to less than 1 year.

SENATOR SHELBY

Auburn Canine Program

Question 1. Dr. Bell, today, canines are trained to detect explosives, drugs, chemical changes in people with diabetes and epilepsy, and even certain cancers quicker and more effectively than any mechanism available to us. Researchers at Auburn University are currently using decades of research and development in canine detection to train dogs to instantly detect viruses like Ebola in the field. While this research area is new, its foundation is based on decades of research that has proven the canine nose to be one of the greatest detection devices in the world. This would provide first responders and medical professionals in the field a much more effective method to detect a virus in a person or on materials and surfaces that could spread the deadly virus. The possibilities are limitless in diagnoses, triage, and containment. It would also establish a baseline capability that would have applications

across the spectrum of disease prevention. Are you familiar with this concept and would this type of effort fit within your purview and capability to support and fund?

Answer 1. Efforts of this kind are outside of CDC's scope of responsibility and expertise; however, CDC is open to exploring rigorously evaluated and proven innovations as they emerge from private or public partners.

Components to a Response

Question 2. Dr. Bell, you have stated that there are 4 necessary components to the Ebola response:

- Case identification and prompt isolation and treatment of patients;
- Identify contacts, monitor them for 21 days, isolate if they become sick, and identify and monitor their contacts;
- Infection control in health care facilities; and
- Safe burial practices.

How much of this has been occurring in the affected countries?

Answer 2. CDC is employing a variety of strategies in the affected countries. The success of multiple approaches to halting an outbreak has been borne out by Nigeria. Multiple partners are working in each of the three affected countries to implement each component of the response. Progress is being made, but significant challenges remain on all fronts.

Question 3. In particular, how important and difficult is it to perform adequate contact tracing in this region when many of the citizens do not have regular access to phone and Internet?

Answer 3. Contact tracing is a challenge in the affected countries. In some settings where the number of cases is very large or there are security concerns, contact tracing is incomplete, but CDC teams and partners continue to support contact tracing in most settings. CDC teams in the affected countries report that cell phones are generally not being used to reach people. Home visits are the most common method of contact tracing.

Training American Health Workers for Ebola Care in West Africa

Question 4. Dr. Bell, the U.S. Government does not provide direct care to Ebola patients in West Africa. With a significant deficit of trained health workers to provide care in these countries, how is the United States contributing to help address this issue?

Answer 4. CDC has taken several steps to provide training and guidance to health care workers to respond to cases of Ebola. CDC has a lead role in infection control training for health care workers and safe patient triage throughout the health care system, communities, and households in Liberia, Sierra Leone and Guinea. In addition, CDC created a *Safety Training Course for Healthcare Workers Going to West Africa in Response to the 2014 Ebola Outbreak*. The primary purpose of the course is to ensure that clinicians intending to provide medical care to patients with Ebola have sufficient knowledge of the disease and its transmission routes to work safely and efficiently in a well-designed Ebola Treatment Unit.

The U.S. Agency for International Development (USAID) is managing the recruitment of health care workers interested in volunteering in West Africa. More information about their efforts can be found on the USAID website.

SENATOR BURR

Question 1. What are the current mortality rates associated with the Ebola outbreak for each country in Africa with an Ebola outbreak? How have these mortality rates changed since the outset of the outbreak in each country? Have these countries experienced a change in the mortality rates since additional support has been provided by the international community? If so, how have these mortality rates changed over the course of the outbreak?

Answer 1. CDC's ability to calculate case fatality rates is limited by the available data. While CDC can calculate crude case fatality rates from the data provided in the situation reports shared by Guinea, Liberia, and Sierra Leone, these likely do not reflect the true case fatality rates in each country because of limitations in reported data. These limitations include unknown clinical outcomes as well as underreporting of both cases and deaths. Reporting differs across country, resulting in differences in crude case fatality rates that are unlikely to reflect true differences.

In Guinea, as of October 14, there are a reported 1,243 cases and 748 deaths, corresponding to a crude case fatality rate of 60.2 percent. In Liberia, as of October 4, 2014, there are a reported 3,929 cases and 2,210 deaths, corresponding to a crude case fatality rate of 56.2 percent. In Sierra Leone, as of October 6, 2014, there are

a reported 2,823 cases and 880 deaths, corresponding to a crude case fatality rate of 31.1 percent.

In a report in the New England Journal of Medicine, the World Health Organization authors reported a case fatality rate based on only a subset of cases with a known clinical outcome. They report, "This analysis shows that by September 14, 2014, a total of 70.8 percent (95 percent confidence interval [CI], 68.6 to 72.8) of case patients with definitive outcomes have died, and this rate was consistent among Guinea, Liberia, and Sierra Leone."[4] Because of the limitations of the data, we are unable to report on the change in case fatality rates over time. Observed changes over time in the crude case fatality rates—like the reported differences between countries—are likely artifacts of reporting.

Question 2. Will the United States' response to the current outbreak, including the CDC, change if Ebola becomes endemic to West Africa? If so, how will the current strategies to reduce the rate of transmission, and ultimately break the chains of Ebola transmission, change in the event the Ebola virus becomes endemic to West Africa?

Answer 2. Strategies to control Ebola and break transmission chains will not change if Ebola transmission becomes more widespread in Africa. However, the magnitude and complexity of the effort to reverse the trend will be much greater, further stretching the limited capacities of countries and the international community and making success that much harder to achieve. Further, the risk of multiple exportations of cases from affected countries will increase. It is for these reasons that it is so critical to stop the outbreak in the three currently affected countries.

Question 3. How would point of care rapid diagnostics change the current trajectory of the Ebola outbreak? How would identifying an infected individual before the onset of symptoms change the current response strategy being deployed overseas in Africa? How quickly could CDC deploy point of care rapid diagnostics in the field clinics in West Africa should such diagnostic tools become available? Could this length of time be further reduced, and if so, what steps need to be taken to ensure that the time it would take to deploy and utilize such diagnostics is as short as possible, including as part of either a domestic or international response?

Answer 3. There is not currently an approved test that can determine if a person is ill with Ebola before symptoms appear although there are products under investigation. CDC is not aware of any that have been approved by recognized governmental bodies comparable to FDA. Rapid diagnostics allow for testing for Ebola in a non-laboratory environment, such as in a health care facility. In health care facilities, patients suspected to be ill with Ebola wait, often for days, for symptoms to present; inevitably there are individuals that are ill with Ebola as well as many individuals who have other diseases with Ebola-like symptoms (*e.g.*, malaria). While waiting in these areas, the latter often become infected with Ebola from those that are actually ill with the disease. Rapid tests would allow for a quicker discernment of those very ill with Ebola in these waiting areas, thus reducing the spread of Ebola to those who are not ill with the disease. However, the current rapid tests in development require a high amount of virus to be present in a person's blood, far more than the longer, standard polymerase chain reaction tests require.

CDC is partnering with companies to review and assess experimental new tests so that these technologies can be refined and produced quickly in the United States, thereby streamlining the procurement process and speeding deployment of new products to West Africa. The deployment process from the United States to the outbreak region can be undertaken as quickly as three to 5 days. However, transportation and distribution in the affected countries remains a significant challenge.

Question 4. How will the distribution of Ebola medical countermeasures, both vaccines and therapeutics, be prioritized when they become available?

Answer 4. CDC would not be making a determination of prioritizing investigational therapeutics; however, the Department of Health and Human Services is in ongoing discussions with global partners such as WHO on this issue.

No specific therapeutics for patients with EVD are approved. Furthermore, CDC cannot influence the requests made by clinicians for investigational new drugs or therapies for emergency or compassionate use. To ensure efficacy and safety, controlled clinical trials need to be implemented.

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[4] WHO Ebola Response Team. Ebola Virus Disease in West Africa—The First 9 Months of the Epidemic and Forward Projections. N Engl J Med. 2014 Sep 22. [Epub ahead of print] PubMed PMID: 25244186.

Several investigational Ebola vaccine candidates have been developed. NIH has begun initial clinical studies to assess the safety and immune response of a candidate vaccine to prevent EVD. The Department of Defense (DoD) has also begun clinical studies for a different candidate vaccine. In addition, two companies, Tekmira and BioCryst Pharmaceuticals, received funding from the DoD to develop potential drugs to treat Ebola. BioCryst, with NIH support, is working to develop an antiviral drug to treat Ebola; the first phase of (human) safety testing is expected to begin later this year.

Question 5. Please outline in detail how CDC is partnering with USAID and DoD in the training and deployment of medical personnel for the countries impacted by the current Ebola outbreak?

Answer 5. In response to this unprecedented humanitarian crisis, CDC created a first-ever domestic Ebola Treatment Unit Safety Training Course. This course provides both didactic as well as extensive hands-on education regarding the multiple complex issues faced by care providers when working in Ebola Treatment Units (ETUs). The course was designed specifically for U.S. personnel deploying to provide care in ETUs within West Africa. We have worked closely with the Department of Defense to ensure that their personnel who require this training are enrolled in this course. We have offered technical advice regarding the Department of Defense's mission to establish an ETU safety training course in-country and have shared CDC's ETU Safety Training course curriculum materials. We have also hosted several discussions with DoD regarding additional training coordination in Liberia. USAID has established a website where persons interested in deploying to provide care in ETU's may register. Links are provided on this website to the registration page for the CDC ETU Safety Training Course.

Question 6. There have been media reports that U.S. health care facilities that have provided treatment to patients infected with Ebola in the United States have had difficulty in disposing of the medical waste associated with this treatment. Please outline in detail how CDC is working with individual health care facilities, and other Federal and State partners, to resolve the issue of proper disposal of medical waste associated with the treatment of Ebola patients in the United States.

Answer 6. CDC, in collaboration with the U.S. Department of Transportation (USDOT) and the Occupational Safety and Health Administration (OSHA), have issued guidance on the disposal of medical waste from patients with Ebola to help States and hospitals coordinate for safe management of waste. Ebola-associated waste disposal is subject to State and local regulations. Notably, Ebola-associated waste that has been appropriately inactivated or incinerated is no longer infectious.

Medical waste generated in the care of patients with known or suspected EVD is subject to procedures set forth by local, State and Federal regulations. Basic principles for spills of blood and other potentially infectious materials are outlined in the OSHA Bloodborne Pathogen standard, 29 CFR 1910.1030. Medical waste contaminated with Ebola virus is a Category A infectious substance regulated as a hazardous material under USDOT's Hazardous Materials Regulations (HMR; 49 CFR, Parts 171-180). The HMR apply to any material USDOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce. For offsite commercial transport of Ebola-associated medical waste, strict compliance with the HMR is required.

The inactivation or incineration of Ebola-associated medical waste within a hospital system may be subject to State, local and OSHA regulations.

- Onsite inactivation
  - Ebola-associated medical waste can be inactivated through the use of appropriate autoclaves. Other methods of inactivation (*e.g.*, chemical inactivation) have not been standardized and would need to consider worker safety issues, as well as the potential for triggering other Federal safety regulations.
- Onsite incineration
  - Ebola-associated medical waste can be incinerated. The products of incineration are not infectious and can be transported and disposed of in accordance with standard protocols for hospital waste disposal.

Question 7. Who at the National Security Council is responsible for coordinating the inter-agency response to the Ebola outbreak in West Africa? Is this individual responsible for coordinating the inter-agency response for domestic Ebola efforts as well? If not, who is?

Answer 7. The U.S. Government response to the Ebola epidemic in West Africa is a whole-of-government effort that draws on the capabilities and expertise of numerous government departments and agencies. Similar to other crisis response and

humanitarian emergencies around the world, USAID leads and coordinates the U.S. response in the field. Many agencies are working closely on domestic Ebola preparedness and response, including HHS, CDC, and DHS, in coordination with the Assistant to the President for Homeland Security and Counterterrorism.

SENATOR KIRK

Question 1. The CDC has determined that $30 million was needed for additional response efforts. It is estimated that this outbreak could last another 12–18 months. Will more assistance be needed or do you anticipate the $30 million covering the next year and a half?

Answer 1. Congress appropriated $30 million for CDC through the continuing resolution. These resources will support CDC for period of the continuing resolution, allowing 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 potential resource needs for the rest of the fiscal year, and possibly further, as we deal with this evolving public health emergency.

Question 2. With all the different agencies involved, which one is leading the efforts against Ebola? What coordinated efforts are happening between the agencies? What are other nations doing to contribute?

Answer 2. Within the West Africa region affected by the Ebola outbreak, USAID continues to lead the United States' overseas response, while CDC, the Department of Defense, Department of State, and other Federal Departments and Agencies are supporting the whole-of-government approach to this national security priority. USAID has deployed a DART to coordinate planning, operations, logistics and other components of the interagency effort. CDC staff is working with Ministries of Health to improve surveillance, contact tracing, laboratory capacity, emergency operations planning and other critical capabilities.

HHS, and in particular CDC, is working closely with the World Health Organization (WHO), the United Nations, the Ministries of Health in affected countries, and other international partners to respond to the current Ebola outbreak in West Africa. The Ebola epidemic reminds us that our global efforts to build the capacity to prevent, detect, and rapidly respond to infectious disease threats like EVD have never been more vital. In February 2014, CDC came together with nations around the world to launch the GHSA as a 5-year effort to accelerate action. On September 26, 2014, President Obama met with leaders of 40 nations as well as top Administration officials to advance progress in the GHSA.

CDC receives regular updates of morbidity and mortality to evaluate the spread of the disease and combines this information with reports from CDC's staff deployed to the area. Hundreds of CDC staff members have provided logistics, staffing, communication, analytics, management, and other support functions for the response. CDC continues to commit significant staffing and financial resources to the international Ebola response both on the ground in West Africa and through its domestic EOC.

CDC has activated its EOC to help coordinate technical assistance and control activities with partners. CDC supports countries in establishing their own national and sub-national EOCs. Each of the three West African countries at the center of the epidemic now has an Incident Manager, reporting to the President of the country, to lead efforts.

To date, more than 35 donor countries have contributed and pledged upwards of $690 million to the response. Highlights include:

- Following the announcement of the Joint Force Command, the United Kingdom, which had previously committed to establish a hospital in Sierra Leone to care for infected health workers, announced that it will stand up 700 Ebola treatment beds in Sierra Leone and establish a military command center there.
- France has announced additional resources and that it will provide a hospital facility in Guinea.
- Germany has pledged to build additional Ebola treatment units, will provide C–160 transport aircraft to support the air bridge in West Africa, and is mobilizing volunteers to support the response.

• The World Bank has committed $400 million and the African Development Bank has committed $150 million.
• The European Union has committed to providing $180 million and to expanding its response effort.
• The IMF Executive Board approved $130 million expansion of zero-interest loans for the three affected West African nations.
• South Africa has committed to build and staff an Ebola Treatment Unit as well.
• Others, including China, Cuba, India, Japan, Canada, Sweden, Australia, Norway, Switzerland, South Korea, Thailand, Ghana, Malaysia, Denmark, Spain, Ireland and the African Union, are providing significant financial and in-kind support.

SENATOR ENZI

Question 1. In previous communications with CDC, it was indicated that there are only a few facilities specially equipped to deal with highly contagious diseases, such as Emory University Hospital in Atlanta. What will be the policy for treatment of patients diagnosed within the United States? Will they be transported to these facilities or cared for onsite or in other designated facilities?

Answer 1. CDC is working with additional hospitals to ready their facilities for additional patients with Ebola. Any U.S. hospital should be prepared to identify, assess and isolate a patient with Ebola. CDC developed guidance documents and checklists to help U.S. hospitals prepare for, test, and treat patients with Ebola, and works to keep the health care system informed of new developments. CDC uses its Health Alert Network (HAN) to provide information and guidance to U.S. healthcare workers and hospitals regarding Ebola. CDC distributed a HAN notice August 1, 2014, and five updates have followed. The most recent HAN notice about Ebola was distributed on October 2, 2014.

CDC created plans outlining its course of action for when a laboratory-confirmed Ebola diagnosis occurs in the United States. The operational plans include assistance to State, tribal, territorial and local officials and the domestic health care community, and leverage CDC's expertise and resources in epidemiology, surveillance, coordination of laboratory testing, health promotion and communication, healthcare and infection control, traveler health and screening.

CDC's response to a diagnosed case follows three key public health tenants—prevention, detection and response. The concept of prevention focuses on actions which can affect the spread of the disease. Detection centers on activities to find the disease through surveillance and contact tracing. CDC's response efforts include its agency-wide incident management and response capabilities in support of domestic requirements.

CDC has redoubled its efforts to educate American health care workers about how to isolate patients and how to protect themselves from infection, including developing and disseminating resources, hosting informational calls, and creating trainings. CDC has:

• Hosted Clinician Outreach and Community Activity calls for clinical professionals to provide information about what U.S. hospitals need to know to prepare for Ebola.
• Created guidance about Ebola for clinicians in U.S. health care settings.
• Posted a Medscape Expert Commentary for healthcare providers whose patients are travelers with concerns about Ebola. The commentary includes information about the Ebola outbreak in West Africa, the transmission Ebola virus, and how to talk to travelers about their risk.
• Created guidance for U.S. healthcare workers on "Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals."
• Developed a checklist for hospitals to aid in Ebola preparedness, which can be found on the CDC website.
• Built a Safety Training Course for Healthcare Workers Going to West Africa in Response to the 2014 Ebola Outbreak. The primary purpose of the course is to ensure that clinicians intending to provide medical care to patients with Ebola have sufficient knowledge of the disease and its transmission routes to work safely and efficiently in a well-designed Ebola Treatment Unit (ETU).
• Collated the Top 10 Ebola Response Planning Tips: Ebola Readiness Self-Assessment for State and Local Public Health Officials to help guide planning and readiness for Ebola response at State and local levels and assist health officials in assessing their jurisdictions' level of readiness for a potential Ebola response.

Question 2. What steps are being taken by CDC to ensure adequate coordination across agencies to, identify any new cases of Ebola quickly, facilitate treatment, and

to contain any spread of the disease? Please identify all of the agencies involved, the departments that are working on them, the steps taken to ensure coordination, and the plans for updating Congress on the activities.

Question 3. Since the beginning of the Ebola outbreak in West Africa, the CDC continually indicated a low probability of a case occurring in the United States. What are the CDC screening and monitoring processes for travelers who are likely to come into contact with the Ebola virus? Please identify the specific steps involved, coordinating agencies, and the data used to make claims of the low probability of occurrence in the United States.

Answer 2 and 3. Although the risk of an Ebola outbreak in the United States is very low, HHS and its sister Departments are taking steps to protect Americans from the Ebola virus. To ensure the United States is prepared to respond to an Ebola epidemic, the CDC has detailed response plans in place for once an Ebola case is confirmed to respond to Ebola cases in the United States. The plans include: instructions to rapidly disseminate information about the Ebola case(s) to key public health, health care system, and emergency management partner organizations; providing current information to State, local, and territorial public health departments; and coordinating critical issues management regarding State and local needs for the CDC EOC incident manager and other response task force teams. CDC has also developed a web-based document, for use in State and local planning that identifies rapidly emerging CDC guidelines for public health preparedness national standards regarding Ebola.

Additional CDC efforts include:

• Preparing providers, hospitals, State and local health departments and others involved in public health preparedness and response for the possibility of an Ebola case in the United States, including guidance documents on the identification and treatment of an Ebola patient, infection control guidelines, laboratory testing and other recommendations necessary to protect U.S. health care workers and the general public. Over the coming days and weeks, CDC will be working with other Federal, State, and local governments and private organizations to strengthen U.S. readiness for detecting and preventing additional cases of Ebola in this country. These efforts include the entry screening at U.S. ports of entry and enhanced outreach to healthcare workers and hospitals to improve their infection control practices and policies.

• Providing funding and assistance to State and local health departments for all-hazards preparedness, including an infectious disease outbreak. This funding and assistance helps public health departments develop capabilities that are applicable to responding to many public health threats.

• Developing guidance for laboratory technicians and other health care personnel who collect or handle specimens in the United States.

• Working closely with DHS's CBP and other partners at U.S. ports of entry to conduct enhanced entry screening to identify travelers who show signs of infectious disease. CBP is conducting entry screening at five U.S. airports (New York-JFK, Washington-Dulles, Newark, Chicago-O'Hare, and Atlanta), that receive 94 percent of travelers from the Ebola-affected nations of Guinea, Liberia, and Sierra Leone, as of October 11, 2014. If a potentially sick traveler is identified during or after a flight, the traveler will be immediately isolated, and CDC will conduct an investigation and work with the airline, Federal partners, and State and local health departments to notify them and take any necessary public health action. Entry screening is part of a layered process that includes exit screening and standard public health practices, such as patient isolation and contact tracing in countries with Ebola outbreaks. Successful containment of the recent Ebola outbreaks in Nigeria and the Democratic Republic of Congo demonstrate the effectiveness of this approach.

• Assisting with exit screening and communication efforts in West Africa to prevent sick travelers from boarding commercial planes, buses, trains, or ships. CDC also has issued interim guidance about Ebola virus infection for airline flight crews, cleaning personnel, and cargo personnel.

In addition to CDC's efforts relating to prevention, detection, and response, FDA is investigating what types of medical products could be used to address the Ebola epidemic in West Africa and in the United States. Currently, there are no treatments or vaccines that have been shown to be safe or effective against the Ebola virus, and products currently under development are in the very early stages of investigation. FDA is using its regulatory mechanisms to enable access to investigational medical products to facilitate appropriate access to investigational Ebola medical products under an appropriate regulatory mechanism to support preparedness and response efforts to help protect people of the United States from the Ebola virus.

Additionally, under the FDA's Emergency Use Authorization (EUA) authority, FDA can allow the use of an unapproved medical product—or an unapproved use of an approved medical product—for a larger population during certain types of emergencies, when, in addition to other factors, there is no adequate, approved, and available alternative. FDA has authorized the use of an Ebola diagnostic test, developed by DoD, under an EUA to detect the Ebola virus in laboratories designated by DoD. This test has been made available to 14 laboratories within the United States to support the rapid diagnosis of any suspected cases of Ebola infection and to monitor patients already infected with the Ebola virus. These sites are located close to ports-of-entry where travelers from West Africa frequently arrive in the United States or in locations where infected U.S. patients are currently being treated. In addition, FDA has issued EUAs authorizing the use of Ebola diagnostic tests developed by CDC and is working with U.S. and non-U.S. commercial diagnostic test developers to clarify EUA regulatory requirements and provide support in order to increase the supply of available diagnostic tests for Ebola infection in the United States and West Africa.

NIH and Biomedical Advanced Research and Development Authority (BARDA), along with DoD, are supporting the development and manufacturing of early stage Ebola vaccine and therapeutic candidates. Key animal challenge efficacy studies and human safety and immunogenicity studies are or will be underway in the United States and other countries for several of these candidates. The results of these initial human safety studies will inform expanded clinical studies in affected African countries early next year. Scaled up manufacturing of several of these product candidates has started as well to achieve commercial scale manufacturing capacity next year.

RESPONSE BY ANTHONY S. FAUCI, M.D. AND ROBIN A. ROBINSON, PH.D. TO QUESTIONS OF SENATOR CASEY, SENATOR BENNET, SENATOR WHITEHOUSE, SENATOR BALDWIN, SENATOR WARREN, SENATOR ALEXANDER, SENATOR MORAN, SENATOR SHELBY, SENATOR COCHRAN, SENATOR BURR, AND SENATOR KIRK [1]

SENATOR CASEY

Question. In addition to vaccines and treatments that are specific to Ebola, are there any broad antiviral products being considered for development, that could be used against either Ebola or other known novel viruses?

Answer. Guided by our Strategic Plan and priorities, the National Institute of Allergy and Infectious Diseases (NIAID) supports the fundamental research needed to better understand infectious agents in order to develop broad-spectrum antibiotics and antivirals—drugs that can prevent or treat diseases caused by multiple types of bacteria or viruses. In addition, NIAID has intensified its efforts to develop new technologies that can be broadly applied to more efficiently develop diagnostics and vaccines against a wide variety of infectious agents, including pandemic influenza viruses, methicillin-resistant *Staphylococcus aureus* (MRSA), extensively drug-resistant *Mycobacterium tuberculosis*, dengue, chikungunya, and filoviruses such as Ebola.

NIAID is funding BioCryst Pharmaceuticals to develop and test BCX4430, a novel drug with broad-spectrum antiviral activity including against Ebola viruses. To date, BCX4430 has shown some activity in animal infection models for Ebola and Marburg viruses. A Phase I trial is expected to begin in late 2014 or early 2015. NIAID is also funding *in vivo* studies of brincidofovir, a broad-spectrum antiviral developed by Chimerix, Inc., for use against other viral diseases, including smallpox. In addition, NIAID offers *in vitro* testing as part of its suite of preclinical research services available to the scientific community and private industry to test products for antiviral activity against Ebola viruses. NIAID is using this screening program to assist investigators who have antiviral candidates that may be effective against Ebola viruses.

Intramural scientists at NIAID's Rocky Mountain Laboratories (RML) in Hamilton, MT, are working on therapeutics that might be effective against all hemorrhagic fever viruses including the filoviruses Ebola and Marburg and the arenavirus Lassa. Ribavirin, a drug currently used to treat hemorrhagic fever viruses such as Lassa virus, is being examined for its potential use in combination therapy to treat Ebola virus infection. NIAID intramural scientists are investigating broad antiviral therapies that target host cell proteins essential to viral replication. One such

[1] Note: Content accurate as of October 15, 2014. Responses do not reflect enactment of the $238 million for NIH in emergency funding to support clinical trials in response to the Ebola Epidemic.

antiviral currently being evaluated for hepatitis C treatment has shown activity against Ebola virus *in vitro* and will be further assessed. NIAID scientists also have screened a small collection of broad-spectrum antivirals that are in development against influenza and other RNA viruses; this screening has generated two potential lead compounds for further evaluation.

NIAID's pursuit of broad-spectrum therapies effective against entire classes of pathogens aims to maximize the investment in research on emerging and re-emerging infectious diseases. NIAID will continue to pursue broad-spectrum antiviral drugs for use against a variety of viruses including Ebola virus.

SENATOR BENNET

Question 1. There are many charities and volunteers here that want to help end this outbreak and care deeply about the outcome. For example, in my home State, the Centennial-based Project CURE has been working with local volunteers and high schools, like Valor Christian High School in Highlands Ranch, to send medical supplies to West Africa. They have already sent 4 large containers of supplies for medical workers there. They want to know that their government is showing a coordinated response to this effort, and that their work will not be in vain. Can you give them and other volunteers across the country some peace of mind that their work is helping and you all are doing everything you can to coordinate an effective response to this outbreak?

Answer 1. NIAID defers to other witnesses.

Question 2. Given the emergence of Ebola as a significant public health threat—and the level of funds understandably being allocated in response—I am concerned about our ability to respond to other emergencies, such as pandemic influenza, which are far more common threats. In particular, I'm concerned that we are jumping from crisis to crisis and failing to adequately budget for rapid response capabilities to public health pandemics, like Ebola, pandemic influenza, and MERS. Just earlier this month, for instance, a DHS OIG report highlighted that our pandemic influenza stockpiles have not been effectively managed, and I'm concerned that we may be falling behind on these other types of preparedness issues. How are you assuring that we are adequately prepared and not compromising our ability to rapidly respond to address other public health crises, like pandemic influenza, in addition to emerging threats like Ebola?

Answer 2. NIAID has a dual mandate that balances research on current biomedical challenges with the capacity to respond quickly to emerging and re-emerging infectious threats. Since the 2001 anthrax attacks, with the support of the Congress, NIAID has vastly expanded its research portfolio in biodefense and naturally emerging and re-emerging infectious diseases, focusing its efforts on pathogens that pose high risks to public health and national security, including pandemic influenza, MRSA, *Mycobacterium tuberculosis*, dengue, chikungunya, and filoviruses such as Ebola.

To improve our preparedness for numerous infectious threats, whether naturally occurring or deliberately introduced, NIAID has adopted a flexible strategy to encourage the development of broad spectrum therapeutics effective against whole classes of pathogens. To encourage this process, NIAID "de-risks" the development of new and improved therapeutics by providing early stage research resources to academia, biotechnology firms, and industry. For example, NIAID offers *in vitro* and *in vivo* screening and evaluation of candidate countermeasures against a broad array of infectious pathogens including bacteria, fungi, viruses, and parasites. These preclinical research services, coupled with NIAID's strong support for basic and applied research, have enhanced our ability to ultimately address a variety of global infectious disease threats.

NIAID research includes the development of new and improved vaccines against a variety of infectious disease threats to global public health. As part of this effort, the NIAID Vaccine Research Center (VRC) is pursuing design strategies to facilitate the development of vaccines for emerging public health threats such as Middle East Respiratory Syndrome (MERS), chikungunya, pandemic influenza, and Ebola viruses. The VRC is currently applying the results of its longstanding preclinical vaccine research program to accelerate clinical studies of a chimpanzee adenovirus-based Ebola vaccine candidate developed in collaboration with GlaxoSmithKline. Phase I clinical studies of this vaccine are ongoing at the National Institutes of Health Clinical Center, and additional studies are planned for sites around the world.

In response to the public health threats posed by seasonal and pandemic influenza, NIAID VRC and extramural researchers are engaged in a broad range of basic

and applied research on influenza virus. NIAID is supporting research and development of new therapies, diagnostics, and vaccines for both seasonal and pandemic influenza strains. For example, during the 2009 H1N1 influenza pandemic, VRC researchers utilized advanced genetic sequencing and gene-based vaccine technology platforms to develop and test an experimental 2009 pandemic H1N1 influenza vaccine within 4 months. In addition, NIAID-supported clinical research units quickly determined the safe and effective doses of the 2009 H1N1 influenza vaccine for the elderly, children with asthma, and individuals with compromised immune systems.

The development of a "universal" influenza vaccine is a key goal of the NIAID infectious diseases research program. A "universal" influenza vaccine would induce a potent immune response to the common elements of the influenza virus that undergo few changes from season to season and from strain to strain. Such a vaccine could protect against multiple strains of the virus over several years and help provide protection in the event of an influenza pandemic. NIAID VRC and extramural researchers are working with the conserved stem region of influenza proteins to stimulate broader, more universal protection against multiple influenza strains and to develop nanoparticle vaccine platforms to improve the potency and breadth of influenza protection.

NIAID remains committed to fulfilling its dual mandate to balance research on infectious and immune-related diseases with the capability to mobilize a rapid response to newly emerging and re-emerging infectious diseases.

SENATOR WHITEHOUSE

Question. The severity of the current Ebola outbreak has led to the use of still-experimental treatments, such as ZMapp—which Dr. Brantly received. How can we encourage the development of treatments and vaccines that treat incredibly deadly, but rare diseases, like Ebola? How have our Federal health care agencies, including NIH, CDC, and FDA, coordinated to help expand access to experimental treatments in a safe and ethical way?

Answer. The 2001 anthrax attacks underscored the importance of a national strategy for the development of medical countermeasures to combat deadly infectious disease threats, whether man-made or naturally occurring. Since that time, NIAID has greatly accelerated its biodefense research program to rapidly respond to known and possible future threats. NIAID supports basic research, identification of drug and vaccine targets, preclinical testing, and clinical trials in order to move candidate medical countermeasures along the product development pipeline. Critical to this effort are NIAID's public-private partnerships with organizations including non-profits, academic institutions, and biotechnology and pharmaceutical companies.

Equally important to the development of medical countermeasures for deadly diseases such as anthrax, smallpox, and Ebola virus disease, is NIAID's collaboration with Federal agencies such as 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). For example, NIAID coordinates with its partners through the Public Health Emergency Medical Countermeasures Enterprise to ensure that the results of NIAID-supported research can be translated rapidly into safe and effective medical countermeasures. In particular, NIAID transitions the advanced research and development of high-priority medical countermeasures to BARDA, with the goal of FDA approval, licensure, clearance, or emergency use authorization and, if appropriate, possible inclusion in the Strategic National Stockpile.

Efforts to date have included early stage development of a smallpox vaccine candidate and two smallpox drug candidates to complement the vaccines that currently exist, as well as anthrax vaccine and therapeutic candidates.

In response to the current Ebola outbreak in West Africa, the NIAID Vaccine Research Center (VRC) worked closely with FDA colleagues to expeditiously move CAd3, an Ebola candidate vaccine developed by the NIAID VRC and GlaxoSmithKline, into clinical studies while still maintaining rigorous safety, ethical, and regulatory standards. Proactive communication and partnership enabled FDA to review VRC's Investigational New Drug (IND) application in less than 1 week, leading to acceleration of the clinical study start date. Ongoing discussions among NIAID VRC, BARDA, and industry partner GlaxoSmithKline will accelerate development of CAd3 through additional vaccine manufacturing and clinical trials to further determine safety and immune response. In addition, the NIAID VRC is collaborating with the DoD Walter Reed Army Institute of Research on plans to evaluate safety and immunogenicity of the candidate vaccine in healthy adults in Uganda.

NIAID will continue its longstanding investment in research to develop tools to prevent, diagnose, treat, and control deadly diseases such as Ebola. To effectively bring a concept from the earliest stages of basic research to a finished product requires that we rigorously evaluate safety and efficacy along the product development pipeline and leverage public-private partnerships between academia, non-profit organizations, private industry, and government agencies around the world.

SENATOR BALDWIN

Question 1. Dr. Fauci, one of your NIH colleagues and an Ebola expert recently argued that scientists must share data, like diagnosis and detection data, with their colleagues in real-time to improve the public health response to the Ebola outbreak. Can you please explain why this is so critical, what is NIH's role in this data exchange, and how similar information sharing has helped address prior outbreaks like influenza and SARS?

Answer 1. The National Institutes of Health (NIH) has a longstanding commitment to make scientific data publicly available in a timely manner. This was exemplified by the Human Genome Project, an international research project that required rapid and comprehensive data release during its mapping and sequencing of the full human genome. Recently, NIH has expanded this commitment to sharing important genomic data by implementing a policy requiring NIH-funded large scale genome projects to include data sharing plans. For the past 10 years, NIAID has endorsed this commitment, and contributes to several publicly accessible and searchable international data bases, such as NIH's GenBank, a collection of all publicly available DNA sequences.

Publicly released data, including datasets generated and released by NIAID, serve as critical resources for scientists around the world, and are essential to enable the advancement of research and surveillance of infectious diseases. For example, in early April 2009, a novel influenza virus was isolated from a patient in California; by the end of April 2009, the genome of the H1N1 influenza virus was sequenced and the data released into the public domain. The genetic characterization of this virus revealed that it was a novel strain, gave clues to its drug sensitivity and resistance, and was instrumental in production of effective diagnostics and vaccines used in the subsequent 2009 H1N1 influenza pandemic. Ongoing NIAID sequencing efforts and resources seek to provide additional information about the Ebola virus strain currently circulating in West Africa. This information, shared in real-time, can help researchers to understand how the virus is transmitted and causes disease, as well as guide strategies for developing new therapeutics, vaccines, and diagnostics.

Although there is no rapid, point-of-care diagnostic test for Ebola virus currently available, real-time data sharing is an increasingly important aspect of collaborative research and could critically influence both patient care and epidemic management of the current Ebola virus outbreak. The ability to rapidly and accurately detect and report the presence of Ebola virus in blood samples would allow healthcare providers to more quickly isolate and care for patients with Ebola virus disease. Importantly, rapid diagnosis and reporting would also help to identify patients who have symptoms consistent with Ebola virus disease but actually have a disease caused by another pathogen. Upon testing negative for Ebola, these patients could minimize their contact with Ebola patients and be given appropriate treatment for their disease. In addition, real-time data sharing is critical to guiding the public health response because it allows for a more accurate understanding of sources of infection, new outbreak locations, and the scope and rate of transmission. Rapid data sharing is also important for assessing the utility of diagnostic tests and the significance of viral gene mutations. Established diagnostic assays that detect specific gene sequences of a virus may not be as effective in detecting viruses with genetic variants. Real-time generation and sharing of genetic sequence data, including mutations, is crucial to ensuring these molecular diagnostic tests remain valid.

Question 2. Dr. Fauci, in the absence of an approved therapeutic treatment for Ebola, can you please discuss the importance of highly effective and efficient diagnostics in controlling this outbreak, and what steps we are taking to develop and implement such tools? In August, the FDA authorized the emergency use of a diagnostic test developed by the Department of Defense in the affected region. Can you provide an update on how this test is working and being used on the ground?

Answer 2. Accurate and accessible diagnostics for Ebola virus infection are needed for the rapid identification 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 onsite, Ebola virus diagnostics are particularly valuable as they allow caregivers to quickly identify in-

fected patients in order to isolate them and minimize additional exposures to the virus.

NIAID provides resources for investigators developing Ebola 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. 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. In addition, intramural scientists from NIAID's Rocky Mountain Laboratories in Hamilton, MT, and NIAID's Integrated Research Facility in Frederick, MD, have responded to the ongoing epidemic in West Africa by providing technical diagnostic support on the ground in Liberia.

NIAID defers to CDC regarding the emergency use of diagnostics in West Africa.

Question 3. The President recently outlined a comprehensive response to combat this epidemic that includes the efforts of an estimated 3,000 U.S. forces and a strong partnership with the United Nations and our other international partners. The first cases of Ebola were reported in March; it is now October and the Ebola crisis is only worsening. Why did we not initiate this response in March? In hindsight, what should have been the United States' first action item when cases were first reported, and what can we learn from this to prevent the world from seeing such tragedy again?

Answer 3. NIAID defers to other witnesses.

SENATOR WARREN

Question 1. Fighting epidemics in developing countries presents unique challenges. Despite all the attention that's being paid to the Ebola outbreak, serious health problems have gripped these countries for years. In Liberia, for example, 17 percent of deaths are due to Malaria, and Sierra Leone has one of highest rates of infant and maternal mortality in the world. Countries currently dealing with Ebola have a poor healthcare infrastructure and very few healthcare workers—and are barely able to provide basic care, much less handle an epidemic.

How would long-term investments to improve the basic healthcare infrastructure of developing nations help to improve our ability to respond to new outbreaks and epidemics?

How are the United States and international aid organizations helping to take care of health care needs besides Ebola in the epidemic regions?

Answer 1. NIAID defers to other witnesses regarding investments to improve basic healthcare infrastructure of developing nations, and regarding how United States and international organizations are helping to take care of health care needs besides Ebola in the epidemic regions.

Question 2. Each time a new disease or disease threat appears, we see a spike in public attention and an avalanche of government support to address the immediate crisis. Congress has no problem spending billions of dollars combating SARS, pandemic flus, MERS, and now Ebola, one outbreak at a time. When there is a crisis, of course we should act. But over the same time period, Congress has slashed the purchasing power of America's flagship research agencies—the agencies that do the work to make sure that we are ready for these crises *before* they occur.

The National Institutes of Health has nearly 25 percent less purchasing power today than it did a decade ago. When asked last week about Ebola vaccine development, Francis Collins said, "If we had just been able to have basically equivalent purchasing power over these 10 years, we would have been at least a year ahead of where we are now." After years of stable reserve fund support, the budget for BARDA is now subject to the tumultuous appropriations process. A company in Cambridge, MA, received a Department of Defense grant in 2010 to develop an Ebola treatment, and the company developed a drug with promising trials. We still don't know if that treatment might be effective because the funding was cut in 2012 *because* of shrinking Federal support.

How can investments in basic research and in development help to prepare our Nation to deal with known and unknown contagious disease threats?

Answer 2. NIAID is the lead institute at NIH for conducting and supporting basic research on biodefense, including chemical, biological, radiological, and nuclear threats as well as emerging and re-emerging infectious diseases. Basic research supported by NIAID contributes to a comprehensive understanding of the scientific and

medical aspects of these potential threat agents and informs the development of medical countermeasures.

The NIAID research portfolio includes basic research to understand the biology, immune response, and pathogenesis of potential bioterror agents and emerging and re-emerging infectious diseases, including plague, smallpox, Ebola virus disease, and influenza. This research provides insight into how these agents cause disease and reveals potential targets for the development of medical countermeasures to diagnose, treat, and prevent disease. NIAID also supports translational-research and product-development efforts to capitalize on basic research discoveries and to advance candidate medical countermeasures through the product development pipeline. These efforts help to ensure our Nation's preparedness to respond to public health threats posed by emerging and re-emerging diseases.

NIAID's basic research investment helps inform development of products that can gain Food and Drug Administration (FDA) approval, licensure, clearance, or emergency use authorization and, if appropriate, be considered for inclusion in the Strategic National Stockpile. If candidate countermeasures show *promise* in proof-of-concept animal studies or early human testing, NIAID transitions these candidates to the Biomedical Advanced Research and Development Authority (BARDA) for advanced development. Examples of recent successful transitions from NIAID to BARDA include vaccines and therapies for anthrax and pandemic influenza—a next-generation treatment for chemical exposure; two smallpox antiviral drugs; and, in partnership with DoD, the candidate Ebola therapeutic ZMapp. NIAID also supported clinical trials, advanced development, and manufacturing services leading up to the BARDA's procurement of Bavarian Nordic's smallpox vaccine, IMVAMUNE®, which has been accepted into the Strategic National Stockpile. Results from recent NIAID studies have supported the procurement of NEUPOGEN® and Leukine® for the Strategic National Stockpile to treat Acute Radiation Syndrome. The progress of these successful products into advanced development and procurement to ensure the Nation's preparedness would not have been possible without NIH/NIAID's important investments in basic and applied research on biodefense and emerging and re-emerging diseases.

SENATOR ALEXANDER

Question 1. You mentioned that you have an arrangement with the Broad Institute in Boston, MA to track the genetic changes of the virus. Please describe this arrangement and how it allows you to track the genetic changes of the virus as the outbreak continues, including changes that could result in increased transmissibility or other changes with respect to the virus. Are there plans for additional arrangements to facilitate further study of the Ebola virus circulating in the current outbreak in West Africa in order to inform research on vaccines, treatments, diagnostics, including point-of-care, as well as any characteristics of the virus that could improve our public health response?

Answer 1. For the last 10 years, NIAID has supported the Genomic Center for Infectious Diseases at the Broad Institute to genetically characterize viruses that cause infectious diseases such as dengue fever and Lassa fever. Their work has expanded to include the genomic sequencing and analysis of Ebola viruses isolated from patients in West Africa. One project, the results of which were recently published in *Science* magazine, characterized nearly 100 Ebola virus genomes from patients in Sierra Leone, allowing researchers a clearer view of how the virus can change over the course of an epidemic. The researchers at the Broad Institute currently are leveraging existing partnerships in Sierra Leone and Nigeria to obtain additional samples for genomic sequencing and analysis.

Findings from these studies will inform investigations into the species of Ebola virus causing the current outbreak. The goal of these investigations is to identify and track genetic variations over time and at multiple locations and to monitor potential genetic signals of transmissibility or other changes in the biology of the virus. The research team at the Broad Institute also has allowed the scientific community immediate access to its findings by releasing the full-length genome sequences on the National Institute of Health's National Center for Biotechnology Information (NCBI) genome sequence data bank. This data sharing encourages collaboration among the global scientific and public health communities to accelerate discoveries about Ebola virus transmissibility and adaptation. NIAID will continue to support the efforts of the Broad Institute in enhancing and guiding strategies for Ebola therapeutics, vaccines, and diagnostics.

Question 2. NIAID and BARDA are funding studies and clinical trials for several candidates for Ebola therapies and vaccines. How are you coordinating together to ensure the smooth transition of promising candidates from the earlier phase re-

search supported by NIH to some of the later advanced research and development supported by BARDA? How are you coordinating with the Department of Defense on the research supported by them? Please also describe your coordination with the Food and Drug Administration with respect to these drug and vaccine candidates.

Answer 2. A core component of NIAID's mission is to conduct and support basic and applied research on potential biothreat agents, including newly emerging and re-emerging infectious agents such as Ebola virus. NIAID aims for our basic research investment to inform development of products that can gain Food and Drug Administration (FDA) approval, licensure, clearance, or emergency use authorization and, if appropriate, be considered for inclusion in the Strategic National Stockpile. If candidate medical countermeasures against biothreats show promise in proof-of-concept animal studies or early human testing, NIAID transitions these candidates to BARDA for advanced development. NIAID's longstanding and successful collaborations with BARDA, FDA, CDC, and the Department of Defense (DoD) are critical to accelerating efforts to develop treatments and vaccines for Ebola virus disease.

In partnership with BARDA, DoD, and FDA, and others, NIAID is working to accelerate the development of medical countermeasures for Ebola virus. NIAID has worked closely with FDA to advance testing of the CAd3 Ebola vaccine candidate developed by NIAID in partnership with GlaxoSmithKline. This candidate uses a chimpanzee virus as a carrier to introduce Ebola virus genes into the body in order to stimulate an immune response. NIAID is currently conducting Phase I clinical trials of the CAd3 candidate vaccine at the National Institutes of Health Clinical Center in Bethesda, MD and additional testing at the University of Maryland and Emory University. Proactive communication and partnership enabled FDA to review NIAID's Vaccine Research Center's Investigational New Drug (IND) application in less than 1 week, leading to acceleration of the clinical study start date. CAd3 will also be evaluated in the United Kingdom and the West African country of Mali, and further clinical trials are under consideration should the vaccine prove safe and indicate an ability to generate an immune response.

NIAID and DoD are currently coordinating efforts to accelerate the production of two Ebola vaccine candidates. NIAID and DoD are collaborating with NewLink Genetics on an investigational recombinant vesicular stomatitis virus (VSV)-based vaccine candidate developed and licensed by the Public Health Agency of Canada. NIAID has worked with FDA to enable this candidate to begin Phase I safety studies in the fall of 2014 at Walter Reed Army Institute of Research in Silver Spring, MD, and at the NIH Clinical Center in Bethesda, MD. 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 addition, 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 monoclonal antibodies that can protect monkeys from death due to Ebola virus when administered up to 5 days after infection. NIAID is working closely with partners at DoD, BARDA, and FDA to help determine whether ZMapp is safe and effective. BARDA currently is working with Mapp Biopharmaceuticals to accelerate the manufacturing of more ZMapp for additional testing.

NIAID is an active participant in the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), an interagency effort led by the Department of Health and Human Service's Office of the Assistant Secretary for Preparedness and Response that coordinates Federal activities to increase preparedness against chemical, biological, radiological, and nuclear threats, including Ebola viruses. As an active member of the PHEMCE, 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 the White House Office of Science and Technology Policy. 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.

NIAID will continue to play an active role in the PHEMCE and work with BARDA, DoD, FDA, and other partners to advance the development of diagnostics, therapeutics, and vaccines for Ebola virus.

SENATOR MORAN

Blood Transfusions

Question 1. Dr. Fauci, the World Health Organization has endorsed the use of blood transfusions from recovered Ebola patients into sick patients; however there doesn't appear to be much scientific information showing that this works. What is your professional judgment on this form of treatment?

Answer 1. The ability to safely and effectively prevent and treat Ebola virus infection is a longstanding priority of the National Institute of Allergy and Infectious Diseases (NIAID). However, 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 safety, determine the efficacy of candidate therapeutics, and avoid inadvertent harm. NIAID will do this with careful attention to safety, established scientific principles, ethical considerations, and the urgent, pressing needs of the affected populations.

Some patients infected with Ebola and hospitalized in facilities across the United States and affected countries in West Africa received so-called "convalescent serum" in addition to other medical care. The rationale behind use of convalescent serum is that it contains antibodies generated by the immune system of an Ebola survivor during the course of infection. These antibodies may help newly infected patients to fight Ebola virus. However, more must be known about the safety and effectiveness of plasma ("convalescent serum") transfusions from those who have recovered from Ebola virus infection.

Blood and plasma transfusions have been used as treatment against many infectious diseases, and the scientific rationale behind "convalescent serum" therapy suggests that it could be a potential treatment for Ebola virus infection. However, there are limited data from patients who have undergone this procedure, and further research is required before a determination is made that this therapy is a safe and effective treatment for Ebola virus infection.

Note that an alternative mechanism to deliver antibodies that may help to treat the Ebola virus would be to artificially manufacture these antibodies and deliver them as a drug. This is the principle on which the therapeutic candidate ZMapp, a combination of three monoclonal antibodies, is based. A drug like ZMapp contains only the most potent neutralizing antibodies and its manufacture is standardized and regulated. The Department of Health and Human Services is vigorously supporting manufacturing and further evaluation of ZMapp.

Question 2. Is there the necessary infrastructure in-country to make sure this technique is done safely? I am particularly concerned that Liberia, Guinea, and Sierra Leone do not have the proper blood screening procedures in place to ensure that they will not be spreading other diseases, like HIV.

Answer 2. Proper blood screening from donors and blood typing of donors and recipients are essential for safe transfusions and to avoid dangerous transfusion reactions. In order to safely implement blood transfusions to treat Ebola in West Africa, there must be an infrastructure capable of identifying survivors, collecting their blood, identifying blood type of donor and recipient, and processing the blood to screen it for other infectious agents common to the region, such as malaria and hepatitis C. The limited health care infrastructures in the nations seriously affected by Ebola would make it challenging to ensure that blood transfusions were consistently administered safely and to collect data appropriate for clinical research on this intervention.

Trial Infrastructure

Question 3. Dr. Fauci, the World Health Organization announced that it would accelerate the use of experimental therapies and vaccines to contain the expanding Ebola epidemic. In addition, it has endorsed the controversial treatment of blood transfusions. As these treatments are deployed, how do we tell whether they are effective? Is there infrastructure in place to track effectiveness?

Answer 3. NIAID is committed to working with partners to evaluate candidate drugs and vaccines for safety and efficacy. The U.S. 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.

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 Ebola thera-

peutics. Blood transfusions, other Ebola-specific, blood-related products such as plasma from convalescent patients or processed serum from either convalescent patients or hyperimmune serum from vaccinated individuals, and other candidate interventions will be considered as potential experimental Ebola therapeutics. These potential therapies will undergo the same rigorous testing and evaluation with regards to safety and efficacy as other candidate Ebola treatments. As these treatments are deployed for emergency use and clinical evaluation, NIAID will continue to work with its partners, including non-profit organizations, biotechnology and pharmaceutical companies, Federal agencies such as the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, and the Food and Drug Administration, to support the clinical trials infrastructure necessary to determine the safety and effectiveness of medical countermeasures for Ebola.

SENATOR SHELBY

Ebola Drug Candidate

Question 1. A university in my State is pioneering a drug, with your support at NIAID, that would reactivate the body's immune system after Ebola or other viruses deactivate it. What promise do you see in this line of drug discovery?

Answer 1. NIAID supports a broad portfolio of basic research to better understand Ebola viruses and applied research to develop diagnostics, therapeutics, and vaccines against Ebola viruses. This research includes efforts to design and develop drugs to treat Ebola virus disease that would inhibit viral replication and its deleterious effects on the human immune system. One promising approach is the development of nucleoside derivative drugs. These drugs interfere with the reproductive process of the virus and may have activity against a broad spectrum of viruses. NIAID currently is supporting preclinical studies on promising drugs for the treatment of Ebola, and nucleoside derivatives are among the candidates that may enter clinical testing to evaluate their safety and markers of efficacy in the near future.

In complement to NIAID's ongoing development of drugs that directly target Ebola viruses, NIAID is supporting research that may provide significant insights into the mechanisms that govern the immune response to viruses. These insights could be used to design highly effective and long-lasting vaccines and inform studies on the development of novel therapeutic interventions that would enhance human responses to viral infections. NIAID will continue to support promising approaches to the development of drugs to treat Ebola virus disease and enhance the immune response to combat Ebola virus infection.

NIH Research on Ebola

Question 2. Dr. Fauci, NIH has several Ebola vaccines and therapies in development. Could you talk about the prospects for these treatments and give your professional judgment on which is the most promising approach?

Answer 2. NIAID supports and conducts basic, translational, and clinical research on novel therapeutics and vaccines targeting emerging and re-emerging infectious diseases, including Ebola viruses. 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, including evaluating the use of drugs licensed or approved to treat non-Ebola diseases as a potential treatment for patients infected with Ebola. This approach has led to the generation of multiple therapeutic and vaccine candidates across the different stages of the product development pipeline.

While NIAID is an active participant in the global effort to address the public health emergency 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. The most promising therapeutic and vaccine approaches will be identified through further research, including evaluation of candidates at the preclinical and clinical stages.

Some of the candidate vaccines and therapeutics currently in development with NIAID support are described below.

Vaccines. The NIAID Vaccine Research Center collaborated with the pharmaceutical company GlaxoSmithKline to develop an experimental vaccine based on Chimpanzee Adenovirus 3. The vaccine candidate has shown promising results in animal models against two Ebola virus species, including the Zaire Ebola species responsible for the current outbreak. A small Phase I study to examine the safety and ability of this candidate vaccine to induce an immune response in humans began on September 2, 2014, at the NIH Clinical Center in Bethesda, MD, with results anticipated by the end of the calendar year. Additionally, NIH is collaborating with

DoD and NewLink Genetics on Phase I safety studies of another vaccine candidate based on a recombinant vesicular stomatitis virus.

An additional vaccine candidate being developed by a team of NIAID intramural scientists and Thomas Jefferson University investigators is based on an existing licensed rabies vaccine and aims to protect against Ebola and rabies viruses. The vaccine is currently undergoing preclinical testing and NIAID is partnering with DoD to produce sufficient quantities of the vaccine candidate to begin clinical testing in 2015.

Therapeutics. A combination of three antibodies known as ZMapp has been shown to protect monkeys from death due to Ebola virus when administered up to 5 days after infection. ZMapp was developed by Mapp Biopharmaceutical, Inc., with support from NIAID and DoD. NIAID's preclinical services are now being used to provide preliminary safety data to support the use of ZMapp for clinical trials in humans.

NIAID also has funded BioCryst Pharmaceuticals to develop and test BCX4430, a novel drug that interferes with the reproductive process of the virus. BCX4430 has activity against a broad spectrum of viruses and has shown some activity in animals against infection by Ebola virus and the related Marburg virus. Additionally, NIAID scientists are working on therapeutics that may be effective against multiple hemorrhagic fever viruses including Ebola and Marburg filoviruses and the arenavirus Lassa. Ribavirin, a drug currently used to treat viral hemorrhagic fevers such as Lassa fever, is being examined for its potential use in combination therapy to treat Ebola virus infection.

Candidate therapeutics are being considered for future clinical trials to evaluate their safety and efficacy. NIAID will continue to work with biopharmaceutical companies and public health agencies around the world to advance development of promising candidates and increase access to safe and effective medical countermeasures for Ebola virus disease as quickly as possible.

SENATOR COCHRAN

Response from International Community

Question 1. Thank you for coming in today to describe efforts by the U.S. Government to respond to the Ebola outbreak in West Africa. I am hopeful that the United States can play a leadership role in addressing this humanitarian crisis, but I am also curious about the contributions of international organizations and our partner nations. Will you please describe efforts by the international community to stop the Ebola epidemic?

Answer 1. NIAID defers to colleagues coordinating the Ebola outbreak response.

Ebola Protection and Control

Question 2. Do you believe the additional $88 million that has been requested by the President to respond to this Ebola crisis will provide you with the resources required to protect against the potential spread of Ebola in the United States and to address needs abroad?

Answer 2. NIAID defers to recipients of supplemental funding.

Capacity for Drugs or Vaccines

Question 3. Do you believe the capacity we have to approve, produce, and distribute drugs and vaccines here in the United States is sufficient to contain an infectious disease such as Ebola should it make its way here to the United States?

Answer 3. NIAID defers to other witnesses.

Prioritization of Funding

Question 4. Dr. Robinson and Dr. Fauci, NIH receives approximately $1.7 billion per year for biodefense and emerging infectious diseases and BARDA receives $415 million. How does HHS prioritize the utilization of this funding to address known and emerging threats?

Answer 4. NIAID is the lead institute at NIH for conducting and supporting basic and applied research on biodefense, including chemical, biological, and radiological/nuclear threats, and emerging and re-emerging infectious diseases. This research provides the foundation for developing medical products and strategies to diagnose, treat, and prevent a wide range of biodefense threats and infectious diseases, whether those diseases emerge naturally or are deliberately introduced as an act of bioterrorism.

Since the 2001 anthrax attacks, with the support of the U.S. Congress, NIAID has vastly expanded its research portfolio in biodefense and emerging and re-emerging infectious diseases. NIAID's biodefense research is guided by its Strategic Plan for Biodefense Research, which has been developed and updated in consultation with

biodefense research experts. NIAID's research also aligns with the priorities of the interagency Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). NIAID's pathogen priority list is periodically reviewed and is subject to revision in conjunction with our Federal partners, including the Department of Homeland Security, which determines threat assessments, the Centers for Disease Control and Prevention, which prepares for and responds to emerging pathogen threats in the United States, and the Biomedical Advanced Research and Development Authority, with which we collaborate to transition promising medical countermeasures for advanced development.

Guided by our Strategic Plan and priorities, NIAID supports the fundamental research needed to better understand infectious agents in order to develop broad-spectrum antibiotics and antivirals—drugs that can prevent or treat diseases caused by multiple types of bacteria or viruses. In addition, NIAID has intensified its efforts to develop new technologies that can be broadly applied to more efficiently develop diagnostics and vaccines against a wide variety of infectious agents, including pandemic influenza viruses, MRSA, extensively drug-resistant *Mycobacterium tuberculosis*, dengue, chikungunya, and filoviruses such as Ebola.

NIAID's biodefense research portfolio includes investigator-initiated research as well as targeted research initiatives to capitalize on new scientific opportunities, provide critical research resources, and stimulate research in high-priority areas. All NIAID research, whether investigator-initiated or solicited, undergoes peer review. Scientific experts evaluate the scientific and technical merit of proposed research, and funding decisions are based on scientific and technical merit of proposed projects, availability of funds, and relevance to program priorities. NIAID's research funding process provides the flexibility needed to respond rapidly to address known and emerging disease threats.

SENATOR BURR

Question 1. How is NIAID structuring the clinical trials with respect to both Ebola vaccine and therapeutic candidates, including with respect to enrolling clinical trial participants in West Africa? Are there aspects of the current Ebola clinical trials that are unique given the state of the outbreak overseas?

Answer 1. NIAID is consulting with experts around the world to plan clinical trials of Ebola medical countermeasures that will enroll participants in West Africa. An important part of these ongoing discussions is an evaluation of whether candidate vaccines and therapeutics are available in sufficient quantities for testing and whether early clinical testing has indicated they are safe and can generate the desired response.

With respect to vaccines, the NIAID Vaccine Research Center (VRC) plays a leading role in the evaluation of safety and immunogenicity of candidate Ebola vaccines. Currently, the VRC is conducting and supporting Phase I clinical trials of CAd3, an experimental vaccine developed by NIAID and GlaxoSmithKline which has shown promising results in animal models against two Ebola virus species, including the Zaire Ebola species responsible for the current outbreak in West Africa. NIAID and GlaxoSmithKline plan to share doses of the vaccine candidate with an international consortium comprising Oxford University, the Wellcome Trust, and the World Health Organization in order to enable other planned clinical trials. With respect to therapeutics, only limited clinical use of Ebola therapeutic candidates under expanded access mechanisms has occurred so far. Plans for systematic clinical testing are under active discussion at this time.

Aspects of the planned Ebola clinical trials unique to this outbreak include the rapid establishment of complex technology transfer arrangements, the facilitation of expedited regulatory reviews, and the extraordinary deployment of NIAID resources and infrastructure to safely provide clinical materials to international partners. NIAID is committed to advancing candidate Ebola vaccines and therapeutics while ensuring the maximal safety of clinical trial participants.

Question 2. Are there vaccine and therapeutic candidates that we should be pursuing that are not already in the pipeline?

Answer 2. There are a number of promising vaccine and therapeutic candidates for Ebola virus currently in the development pipeline, and additional approaches are constantly being investigated and considered for further development. NIAID employs multiple approaches to identify and develop potential Ebola virus medical countermeasures. NIAID supports a strong foundation of basic research to better understand Ebola virus and to identify biological targets to inform the development of diagnostics, therapeutics, and vaccines. NIAID is actively examining these targets to assess scientific concepts and to advance promising approaches along the development pipeline.

NIAID employs a multifaceted and interdisciplinary approach to ensure a robust pipeline of candidate medical countermeasures for Ebola virus. In collaboration with our partners in government and industry, we will continue to evaluate novel ideas and pursue promising candidates. Currently NIAID is actively engaging scientists around the world who have come forward to discuss their candidate Ebola diagnostics, therapeutics, and vaccines. NIAID also makes resources available to academic and industry researchers, such as *in vitro* and *in vivo* screening, to help evaluate potential medical countermeasures and advance promising candidates. For example, since 2011, over 30 different vaccines, formulations, or dosing schedules against filoviruses, the virus family that includes Ebola viruses, have been evaluated using NIAID's preclinical services. Seven qualified for further testing and five are currently in the product development pipeline. NIAID is fully committed to engaging its resources to identify and evaluate promising vaccines and therapeutics.

SENATOR KIRK

Question 1. Dr. Fauci and Dr. Robinson, are there medical countermeasures in development to support the current Ebola outbreaks? I believe that Ebola was identified as "threat sufficient" to affect national security in 2006. How does HHS prioritize investments to address known and emerging threats?

Answer 1. NIAID defers to other witnesses on HHS prioritization of investments.

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 currently in development. As described below, medical countermeasures for Ebola virus disease currently in advanced development include therapeutic candidates ZMapp, CMX001 (brincidofovir), BCX4430, T–705 (favipiravir), TKM-Ebola, and vaccine candidates CAd3 and VSV-EBOV. It is important to note that these products are still in development and have not been shown to be safe and effective in Ebola patients. So far, only limited clinical use of these products under expanded access mechanisms has occurred in patients with documented or suspected Ebola virus infection.

Vaccines

CAd3. The NIAID Vaccine Research Center and pharmaceutical company GlaxoSmithKline have developed an experimental vaccine that uses the chimpanzee adenovirus 3 (CAd3) as a vector to introduce Ebola virus genes into the body, stimulating an immune response. This vaccine candidate has shown promising results in animal models against two Ebola virus species, including the Zaire Ebola species responsible for the current outbreak in West Africa. A small Phase I study to examine the safety and ability of this candidate to generate an immune response began on September 2, 2014, at the National Institutes of Health (NIH) Clinical Center in Bethesda, MD. Results from the study are anticipated by the end of 2014, and will help inform future development of the vaccine.

VSV-EBOV. The Public Health Agency of Canada has developed VSV-EBOV, an investigational recombinant vesicular stomatitis virus Ebola vaccine subsequently licensed to NewLink Genetics. NIAID is collaborating with DoD in support of efforts by NewLink Genetics to conduct Phase I safety studies for VSV-EBOV. These studies are planned for the fall of 2014 at Walter Reed Army Institute of Research in Silver Spring, MD, and the NIH Clinical Center in Bethesda, MD.

Therapeutics

ZMapp. NIAID supported Mapp Biopharmaceutical, Inc., to develop MB–003, a combination of three antibodies that provides some protection from Ebola virus disease in monkeys when administered within 48 hours of exposure. An optimized product derived from MB–003, known as ZMapp, has protected monkeys from death due to Ebola virus up to 5 days after infection. NIAID's preclinical services are now being used to gather safety data for the use of ZMapp in clinical trials. ZMapp was recently administered to several patients with Ebola virus disease as an experimental treatment, although it is not possible at this time to determine whether ZMapp benefited these patients. BARDA is implementing plans to optimize and accelerate the manufacturing of ZMapp so that clinical safety and efficacy testing can proceed as soon as possible. NIAID will continue to work closely with partners at BARDA, DoD, and FDA to advance development and testing of this therapeutic candidate.

CMX001 (*brincidofovir*). NIAID is evaluating therapeutics in development or licensed for the treatment of other diseases for activity against Ebola virus. One of these investigational agents is brincidofovir, an antiviral originally targeting smallpox that has had NIAID support for parts of the development program conducted

by Chimerix, Inc. Currently, brincidofovir is in advanced clinical testing for use against cytomegalovirus and adenovirus infections. *In vitro* screening suggested some activity against Ebola virus and the candidate is now undergoing NIAID-funded *in vivo* testing against Ebola virus disease.

BCX4430. NIAID 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. In preclinical testing, BCX4430 has shown some activity in animals against infection by Ebola virus and the related Marburg virus. A Phase I clinical trial of this drug is expected to begin in late 2014 or early 2015.

T–705 (*favipiravir*). NIAID funded early screening of T–705, or favipiravir, a broad-spectrum antiviral against RNA viruses. T–705 is owned by Toyama Chemical of Japan and licensed by MediVector for development in the United States. This drug is licensed in Japan for pandemic influenza; in the United States, it is undergoing DoD-supported Phase III clinical trials for use against influenza. Pilot studies funded by DoD are underway to test the effectiveness of favipiravir against Ebola virus in nonhuman primates.

TKM-Ebola. DoD has supported development of TKM-Ebola by Tekmira Pharmaceuticals. TKM-Ebola is a small, inhibitory RNA molecule that interferes with Ebola virus replication. Tekmira Pharmaceuticals began Phase I trials of TKM-Ebola in January 2014. The trial in healthy uninfected volunteers is currently on a partial clinical hold; however, the FDA has allowed use of TKM-Ebola under an expanded access mechanism in individuals with suspected or confirmed Ebola virus infection.

Question 2. Dr. Bell and Dr. Fauci, with all the different agencies involved, which one is leading the efforts against Ebola? What coordinated efforts are happening between the agencies? What are other nations doing to contribute?

Answer 2. NIH supports foundational research and facilitates interagency partnerships that lead to the development of new and improved medical countermeasures for biodefense and emerging and re-emerging infectious diseases. NIAID is the lead component of the NIH for research and development of medical countermeasures against Ebola virus. Basic and applied research supported by NIAID contributes to a comprehensive understanding of the scientific and medical aspects of Ebola virus and aims to advance development of diagnostics, therapeutics, and vaccines against this deadly disease. Critical to these efforts are NIAID's collaborations with other Federal entities, particularly CDC, FDA, BARDA, and DoD.

NIAID has responded to the current Ebola virus outbreak in West Africa by leveraging longstanding and productive partnerships to accelerate ongoing research efforts. For example, NIAID is working closely with partners at DoD, BARDA, and FDA, along with the product developer, Mapp Biopharmaceutical, Inc., to advance development and testing of this Ebola therapeutic candidate ZMapp to determine whether it is safe and effective. ZMapp is a combination of three antibodies developed with support from NIAID and DoD. ZMapp has shown promising results in studies with monkeys, and NIAID is partnering with BARDA and FDA to accelerate manufacturing and additional testing of ZMapp. NIAID will continue to work closely with BARDA to transition additional therapeutic candidates for advanced development as appropriate. NIAID's ongoing coordination with FDA will help to advance promising therapeutics into clinical testing to determine their safety and efficacy.

In addition, NIAID and DoD are coordinating efforts to accelerate the production of Ebola vaccine candidates. One project aims to generate immunity to Ebola and rabies viruses using a vaccine candidate based on an existing rabies vaccine. NIAID and DoD are currently partnering with researchers at Thomas Jefferson University to produce sufficient quantities of the candidate to begin clinical testing in early 2015. NIAID and DoD also are collaborating with 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. This candidate has begun Phase I safety studies in fall 2014 at Walter Reed Army Institute of Research in Silver Spring, MD, and at the NIH Clinical Center in Bethesda, MD.

NIAID will work closely with FDA to evaluate the safety and immunogenicity data from this trial as well as from NIAID's ongoing Phase I clinical trial of the chimpanzee adenovirus-based Ebola vaccine (CAd3), developed in collaboration with GlaxoSmithKline.

NIH also participates in the Ebola Medical Countermeasures Senior Steering Group, led by the White House Office of Science and Technology Policy and comprising senior staff from all Federal agencies participating in Ebola response activities. Through this and other mechanisms, NIAID will continue its efforts to accelerate the development of safe and effective countermeasures against Ebola virus by

leveraging existing partnerships with industry and other Federal agencies including CDC, FDA, BARDA, and DoD.

NIAID defers to other witnesses regarding which Agency is leading efforts against Ebola and other nations' contributions against Ebola.

RESPONSE TO QUESTIONS OF SENATOR CASEY AND SENATOR WARREN BY ISHMAEL ALFRED CHARLES

SENATOR CASEY

Question 1. You stated that stigma surrounding Ebola is a problem for combating the current outbreak. What message do you think needs to be articulated to help fight that stigma?

Answer 1. Well over the period with the current outbreak we have practically seen how stigmas and discrimination have torn apart more people almost as much as the outbreak. At community level, it is important to use our religious leaders and community volunteers to preach about acceptance and the fact that those who have survived Ebola cannot transfer the virus or cannot get anyone sick. Also at the regional and international level people need to get more education on how Ebola spreads, for example in the United States, institutions like CDC and NIH need to engage the wider society that Ebola is not an African outbreak. It can take place anywhere. It is more serious in Africa because of the bad leadership and poor health infrastructures and system. Also that Ebola does not spread by merely seeing someone but only through bodily contact, as the lack of sufficient information is also creating more confusion.

Stigma is degrading attitude of the society that brings not only shame and disgrace, but also discredits a person or a group because of an attribute to an outbreak like Ebola.

Stigma leads to people not being treated with dignity and respect and promotes hate and disunity which is socially unacceptable.

Question 1a. Which people in local communities do you feel would be best able to communicate that message?

Answer 1a. There are community stakeholders who also are the opinion leaders of the community.

The following are examples: Religious leader (*e.g.*, Imam, Pastors and Rev. Fr.), Traditional Heads, popular sports/soccer players, musicians/comedians and influential personalities.

Question 2. In your testimony, you stated that schools in Sierra Leone are closed indefinitely, while the illiteracy rate is 70 percent. How can the international community help affected countries fill in this education gap for their children and improve literacy?

Answer 2. Prior to the Ebola outbreak, the basic survival of the ordinary citizen was difficult. The outbreak has undoubtedly compounded the already worse situations.

The cost of the basic school or learning materials increased just before the outbreak and the outbreak has stopped all economic activities such as trading and movement. Schools are closed to avoid contact among pupils and students.

The following interventions may help:

(1) Take care of the education of the orphans of Ebola victims.

(2) Help the government to provide affordable education at all levels for the citizens (*e.g.*, Free tuition for secondary schools and reduction in college and university fees.)

(3) Reintroduce school feeding programs in primary schools to augment the post Ebola recovery.

(4) Support the universities directly with their needs including subsidies.

Clearly we realized that in a post conflict country only recovering from the aftermath of the war has not helped the situation at all. Schooling was badly disrupted and it has only further damaged the educational development of the country, a country with 70 percent illiteracy. Schools have closed indefinitely, and this is exposing many young girls to teenage pregnancy and further increasing the burden. My suggestion is for us to ensure that these children who will be pregnant after Ebola will need to be enrolled in a special school to ensure that they don't become drop outs.

Also there is a need for a recap type of school. Post war era, we had a schooling program called Remedial term, which was an accelerated learning and teaching pro-

gram. We will need a similar program in the post Ebola era, so that the school pupils will be able to recap and catch up with what they have lost.

SENATOR WARREN

Question 1. Fighting epidemics in developing countries presents unique challenges. Despite all the attention that's being paid to the Ebola outbreak, serious health problems have gripped these countries for years. In Liberia, for example, 17 percent of deaths are due to Malaria, and Sierra Leone has one of highest rates of infant and maternal mortality in the world. Countries currently dealing with Ebola have a poor healthcare infrastructure and very few healthcare workers—and are barely able to provide basic care, much less handle an epidemic.

How would long term investments to improve the basic healthcare infrastructure of developing nations help to improve our ability to respond to new outbreaks and epidemics?

Answer 1. Any attempt to address the health care problems in developing countries, like Sierra Leone should focus on sustainable infrastructure and a strong system that is in rhythm with international best practice(s).

Our current health care facilities including the Infrastructure do not address the needs/demands of most of the recent outbreaks and epidemics.

In addition to the substandard provisions, there are no improving systems that will implement and monitor the effective and efficient use of the health care facilities.

The following are recommended:

1. Establishment of a Centre for Diseases Control (CDC) in every country, especially those that were badly affected by Ebola.
2. Strengthening of health care systems.
3. Ensure a vibrant disease surveillance network within West Africa.

Question 2. How are the United States and international aid organizations helping to take care of health care needs besides Ebola in the epidemic regions?

Answer 2. The international aid organizations and U.S. organizations are helping in diverse ways which include provision of food and nonfood items to people as hunger and starvation is on the increase. This support is not enough, hence there is a huge need for more support to the community people across the country, especially in the badly hit areas of the country.

[Whereupon, at 5:45 p.m., the hearing was adjourned.]

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