

**ZIKA VIRUS: ADDRESSING THE GROWING PUBLIC
HEALTH THREAT**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE ZIKA VIRUS, FOCUSING ON ADDRESSING THE
GROWING PUBLIC HEALTH THREAT

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FEBRUARY 24, 2016
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C O N T E N T S

STATEMENTS

TWEDNESDAY, FEBRUARY 24, 2016

Page

COMMITTEE MEMBERS

Alexander, Hon. Lamar, Chairman, Committee on Health, Education, Labor, and Pensions, opening statement	1
Murray, Hon. Patty, a U.S. Senator from the State of Washington	3
Collins, Hon. Susan, a U.S. Senator from the State of Maine	26
Warren, Hon. Elizabeth, a U.S. Senator from the State of Massachusetts	27
Burr, Hon. Richard, a U.S. Senator from the State of North Carolina	29
Baldwin, Hon. Tammy, a U.S. Senator from the State of Wisconsin	31
Cassidy, Hon. Bill, a U.S. Senator from the State of Louisiana	32
Murphy, Hon. Christopher, a U.S. Senator from the State of Connecticut	34
Roberts, Hon. Pat, a U.S. Senator from the State of Kansas	36
Bennet, Hon. Michael F., a U.S. Senator from the State of Colorado	38
Franken, Hon. Al, a U.S. Senator from the State of Minnesota	39
Casey, Hon. Roberts P., a U.S. Senator from the State of Pennsylvania	41
Scott, Hon. Tim, a U.S. Senator from the State of South Carolina	43

WITNESSES

Schuchat, Anne, M.D., RADM, USPHS, Principal Deputy Director, Centers For Disease Control And Prevention, Atlanta, GA	5
Prepared statement	7
Fauci, Anthony, M.D., Director, National Institute of Allergy And Infectious Diseases, Bethesda, MD	12
Prepared statement	13
Robinson, Robin, Ph.D., Director, Biomedical Advanced Research And Devel- opment Authority, Washington, DC	17
Prepared statement	19

ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.:	
Senator Casey, prepared statement	49
Statement from international and domestic groups, submitted by Senator Murray	50

ZIKA VIRUS: ADDRESSING THE GROWING PUBLIC HEALTH THREAT

WEDNESDAY, FEBRUARY 24, 2016

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m. in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander, chairman of the committee, presiding.

Present: Senators Alexander, Murray, Burr, Collins, Scott, Roberts, Cassidy, Casey, Franken, Bennet, Baldwin, Murphy, and Warren.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

For the information of Senators, the vote has been moved to noon. So we do not have an 11 a.m. vote, and I appreciate Senator McConnell doing that because there is no need to interrupt hearings that we have prepared for to have a vote unless it is necessary.

This morning, we are having a hearing about the Zika virus to help Congress and the public gain a better understanding of the virus, as well as carefully assess what we can do to prevent its appeal in South and Central America and how much of a concern this will be here in the United States.

Senator Murray and I each will have an opening statement. Then we will introduce our panel of witnesses. After our witness testimony, Senators will each have 5 minutes of questions.

Earlier this month, Senator McConnell hosted a briefing on the Zika virus with Secretary Burwell.

Two weeks ago, the Senate Appropriations Labor, Health and Human Services, and Education Committee held a hearing with Dr. Frieden and Dr. Fauci. I guess that is the committee that Senator Murray is the ranking member of.

This is the third opportunity that some of us have had to hear more about the virus. And I thank the witnesses for keeping Congress and the public informed.

I hear a lot about it when I go home, and I am going to be asking some questions today which were the questions that were asked me by family members and friends. There are a lot of questions.

Let me run through a little of what we know.

This virus was discovered in 1947. Until recently, it was only thought to cause mild symptoms, including fever, rash, joint pain, that lasts for about a week. Only one in five people infected actually experience any symptoms. This is what we have been told.

Zika is spread mostly by the bite of an infected mosquito of the *Aedes* species. This is the same mosquito that spreads dengue fever and chikungunya. The virus can be spread from a pregnant woman to her unborn child. It can also be sexually transmitted. And I want to ask more about that today because there is some new information about that I understand.

Zika has been showing up in numerous South and Central American countries, including Colombia, Mexico, Costa Rica, Puerto Rico, and the U.S. Virgin Islands.

Last year, after an outbreak of Zika, Brazil reported a sharp increase in the number of reported cases of a rare birth defect called microcephaly in areas affected by the Zika virus outbreak. Babies born with microcephaly have smaller heads and often have underdeveloped brains. It is a lifetime condition that can range from mild to severe, and treatment varies for that reason.

Today there are over 4,000 reported cases of microcephaly in Brazil. More than 500 of these have been confirmed. In 2014, 147 cases of microcephaly were reported in Brazil.

In conjunction with an outbreak of the Zika virus, an additional five countries, French Polynesia, El Salvador, Venezuela, Colombia, and Surinam have reported an increase in the incidence of cases of microcephaly and/or Guillain-Barre syndrome, a syndrome that attacks the nerves and causes temporary paralysis.

Today there are no reported cases of anyone being infected by a mosquito with Zika in the United States, or at least that is the information we have. There are 82 travel-related cases in the United States, including one in Tennessee, in which individuals become infected with Zika after traveling to an area where Zika is spreading.

The Centers for Disease Control and Prevention also announced yesterday that CDC and State public health departments are investigating 14 new reports of possible sexual transmission of Zika in the United States.

Currently there is not a vaccine or an approved treatment for Zika. We will want to talk more about that in this hearing. There is also no commercially available diagnostic to test for Zika, although the CDC and some public health laboratories can test to determine if a patient has the Zika virus. We will want to talk also about the development of diagnostic tests. CDC is working to produce and distribute over 1 million diagnostic tests.

Today I will be asking about the link between the Zika virus and microcephaly and also about how the virus affects young children. I asked Dr. Frieden at a hearing earlier this morning how long a woman who becomes sick with Zika or travels to a country where Zika is, should wait before trying to get pregnant. I would like to ask that question again today. I will be asking if there is any update on what we were told earlier.

I will also be interested in hearing about the progress on vaccines, diagnostic tests. Dr. Fauci said in previous testimony it might take 12 to 15 months to develop a vaccine.

The World Health Organization has turned its attention to controlling mosquitoes. More than 200 soldiers in Brazil are being deployed to help eliminate standing water. The WHO reports that mosquito larvae have been found in plates under potted plants, bird baths, and dog bowls. Mosquito control is generally a State and local issue. I am interested in hearing how CDC is working with these partners to support efforts to control mosquito populations in the United States.

There has also been some discussion about the use of genetically modified mosquitoes. I would like to hear how realistic that is and what the issues are with that.

I want to thank the witnesses for being here. This is an issue that has the attention of millions of Americans, and hopefully in this hearing today, we can provide some accurate information so that we take the risk of the Zika virus in the United States seriously, but that we do not overreact to it at the same time.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much, Chairman Alexander. Thank you to all of our colleagues who are joining us.

Dr. Fauci, Dr. Schuchat, and Dr. Robinson, I really appreciate all of you being here and sharing your expertise with us today.

Like the chairman, many of us are hearing from families in our home States who are deeply concerned about the spread of Zika virus, which can have such tragic consequences, especially for young families. I am glad we have the opportunity to speak with experts who are on the front lines of our response efforts and talk about ways Congress can best support this critical work.

There is still a lot we need to learn about this virus, but one thing is clear is we cannot wait to act. The scientific consensus at this stage is that four out of five of those who become infected show no symptoms. For the other 20 percent who do, the most common result is a week of mild flu-like symptoms. However, in rare instances, there are indications that some people infected with the virus have developed Guillain-Barre syndrome, which is a potentially life-threatening neurological condition. There is growing evidence that Zika can lead to microcephaly, a birth defect that usually results in abnormal brain development with possible serious long-term consequences.

The CDC has also reported that in Brazil two women miscarried after being infected with Zika and is exploring whether there may be other potential consequences for pregnant women who become infected.

The same mosquitoes that carry the virus in South America can be found in many parts of the United States. The virus has spread to Puerto Rico, putting pregnant women there at risk, and many are concerned that it will make its way to the mainland when the warm weather returns. And as of this week, there are cases being reported as far north as my home State of Washington as a result of travel. Speaking for moms and grandmothers across the country, this is deeply disconcerting.

So now is the time to prepare for that possibility and develop strategies for controlling the mosquitoes that harbor the virus. As

we work to fill in the gaps in our knowledge about the disease, we also need to expand mosquito control efforts, as well as laboratory and diagnostic capabilities, in States and cities nationwide. We should work to accelerate research and development of effective lab tests, antiviral drugs, and critically, a vaccine. And we need to educate health care providers and families about this virus and improve health care services for low-income pregnant women in areas where Zika poses a risk.

According to the CDC and the Pan-American Health Organization, women in many Zika-affected countries face barriers to reproductive health care as well as high rates of sexual violence.

I believe it is critical that in Zika-affected countries we do everything we can to ensure women have access to the full range of reproductive health care, including access to family planning services. Democrats are going to continue urging bipartisan work to ensure women everywhere have the ability to plan their pregnancies, especially in light of this virus.

The Administration has laid out an aggressive plan to fight the Zika virus and has requested supplemental funding to ensure all the appropriate resources are being put toward protecting families here at home and abroad.

Some of my Republican colleagues have suggested that additional funding is not needed to respond to Zika. They believe the Administration should simply shift funding away from Ebola response efforts, which are still ongoing. I disagree. We need to both finish the job of responding to the Ebola crisis and act to address the growing threat of the Zika virus. Families' health and safety should not be a zero sum game.

I am very hopeful that here in Congress we can put the politics aside and work together to ensure that we do provide much needed tools and support. And with the health and well-being of many families at risk, I hope we can do so quickly.

Mr. Chairman, I would like to include in the record a statement from 29 international and domestic groups supportive of women's health. This statement reiterates the need for prioritizing women's access to the full range of reproductive health care, including family planning, as we respond to this Zika virus.

Thank you again to all of our witnesses who are here today. I look forward to hearing from you.

The CHAIRMAN. Thank you, Senator Murray, and it will be included.

[The information referred to can be found in additional material.]

The CHAIRMAN. I am delighted to welcome our witnesses. Thanks for being here. Your work is integral to the government's response to Zika.

First, we will hear from Dr. Anne Schuchat. She is the Principal Deputy Director of the Centers for Disease Control and Prevention. She has worked at CDC since 1998. She has been director of the CDC's National Center for Immunization and Respiratory Diseases and Acting Director of the Center for Global Health, among other leadership positions. She has worked on vaccine trials for meningitis, pneumonia, and Ebola.

Next, we will hear from Dr. Anthony Fauci. He is the Director of the National Institute of Allergy and Infectious Diseases, which

is part of the National Institutes of Health. He leads research related to preventing, diagnosing, and treating infectious diseases. He has held this position since 1984 during which time he has led the agency's research efforts related to HIV/AIDS, influenza, malaria, Ebola, and other infectious diseases. In 2014, Dr. Fauci was involved in caring for the Ebola patients at NIH and also worked on vaccine trials for Ebola.

Last, we will hear from Dr. Robin Robinson. He is Director of the Biomedical Advanced Research and Development Authority. This is the agency Senator Burr had such a large role in helping to create. And he is the Deputy Assistant Secretary in the Office of the Assistant Secretary for Preparedness and Response. Dr. Robinson was appointed in 2008 as the first Director of BARDA and has led the efforts to build our Nation's medical countermeasure pipeline comprised of more than 160 medical countermeasures for public health threats, including pandemic influenza and emerging infectious diseases.

We look forward to your testimony and ask that you summarize it in about 5 minutes. We have a number of Senators who would like to ask questions and that would leave time for that.

Dr. Schuchat.

STATEMENT OF ANNE SCHUCHAT, M.D., RADM, USPHS, PRINCIPAL DEPUTY DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. SCHUCHAT. Thank you, Chairman Alexander, Senator Murray, and members of the committee, for the chance to speak with you this morning. I am looking forward to discussing the CDC's efforts to prepare and respond to our newest threat, which is particularly concerning for pregnant women.

CDC and partners around the world are working around the clock to find out as much as we can and share this quickly so that we can get ahead of this problem.

I want to make three key points about the Zika virus.

This is a very dynamic situation. We are learning more every single day, and what we learn we will share as quickly as possible. But there is a lot that we still do not know.

Second, nature is a difficult adversary. This is a new syndrome. It is not a new virus, but it is a new syndrome that we are managing and that can be scary. But it is important to remember that we can and we should do more to detect, respond, and prevent this and other emerging pathogens.

Third, CDC has unique decades-long experience in dealing with this kind of threat. Through our prevention, detection, and response activities, our surveillance, our laboratory capacities, we work on this kind of thing and are quite effective working with State and local public health and with countries around the world.

I want to just briefly go over what we do know, the facts. The virus was first found in 1947, the first outbreak almost 10 years ago in the small Pacific island of Yap, but what we have been seeing this past year is a large outbreak in the Americas and then these concerning increases in microcephaly, a serious birth defect, and possibly a link with Guillain-Barré syndrome, a serious neurologic problem.

The virus is spread through the mosquito *Aedes aegypti* primarily, and that is a really difficult mosquito to control. It is a daytime biter. It feeds on many different people. It can be inside and outside the home. And it has been challenging to control it in other contexts. So that is going to be difficult.

I want to mention what I think our likely future is and preface that by saying we have to be prepared for different scenarios. Most of what we think will happen is based on what we have seen happening with dengue and chikungunya that are also viruses spread by the same mosquito. Those are endemic in much of Latin America and they are endemic in Puerto Rico and other U.S. territories, but they are not endemic to the continental United States. So the trajectory we think we will see is based on what we saw with them, that there can be big outbreaks of dengue and chikungunya and possibly of—

The CHAIRMAN. Excuse me, Doctor. What do you mean by “endemic?”

Dr. SCHUCHAT. “Endemic” is native or natural to the area. In Puerto Rico, we have a dengue branch, a laboratory that is based in Puerto Rico, because they have that virus causing disease year in and year out. We are worried that the Zika virus could take hold in Puerto Rico and really be a long-term problem there.

We also know that we have risk in travelers returning from areas where the virus is spreading. We saw that with chikungunya. We see that with dengue. And we expect to see more and more of that with Zika.

We have had small-scale local spread of dengue and chikungunya in the continental United States, in Florida, Texas. We think that may happen with Zika, and that is one of the reasons we are very keenly interested in supporting State and local governments in the southern United States. And we need to be ready for things to not play out the way that we have seen with those other viruses.

CDC has had a very aggressive response so far with attention to protecting pregnant women with our special travel guidance, developing diagnostic tests so that States and locals and clinicians could figure out if a person had this virus, supporting the States and territories to be ready and to start preparing for this, and working with international partners, particularly Brazil and Colombia where we have teams on the ground trying to answer questions about this syndrome.

Last week, I was in Brazil and saw the very high-level commitment that the government there has to engaging in this and was really touched by those same images everybody has been seeing of the families who have children severely disabled from this virus.

While we are doing much already, there is so much more we need to do, and that is what the supplemental request is about. We need to prepare to respond in Puerto Rico. We need the rest of the United States to be ready because travelers will be returning from these affected areas, and we need to work with international partners on the ground to learn as much as we can so that we can protect Americans.

We are learning more every day, but there is much more to learn and much more to do. And we will use surveillance diagnostics,

mosquito control methods, and guidance focused on prevention, particularly for pregnant women.

CDC is the first line of defense for America's health, and we are building on our expertise to respond to emerging pathogens like Zika, including the essential components of disease detection.

I want to thank you for the chance to answer your questions in the future.

[The prepared statement of Dr. Schuchat follows:]

PREPARED STATEMENT OF ANNE SCHUCHAT, M.D., RADM, USPHS

INTRODUCTION

Good morning Chairman Alexander, Ranking Member Murray, and members of the committee. Thank you for the opportunity to testify before you today on Centers for Disease Control and Prevention's (CDC's) efforts to prepare for and respond to the Zika virus outbreak, which threatens the United States and the rest of the Americas. The Administration has requested approximately \$1.9 billion in emergency funding to respond to the Zika virus outbreak, including \$828 million for CDC, in support of both the domestic and international response, with particular attention to emergency assistance to the Commonwealth of Puerto Rico and other U.S. Territories and States with local transmission of Zika virus.

CDC is the Nation's health protection agency, working 24-7 to save lives and protect people against unpredictable threats such as the Zika virus. Nature is a formidable adversary, and Zika is our newest threat, particularly to pregnant women. CDC has some of the world's leading experts both in diseases spread by mosquitos and in birth defects. We must act swiftly to stop the spread of the Zika virus, both domestically and globally. While we are learning more about the Zika virus every day, there are many things we do not know yet about Zika. These include our understanding of the spectrum of effects of Zika infection during pregnancy, the risk the virus may play in microcephaly, Guillain-Barré syndrome and other possible complications, the duration of Zika infectivity in semen, and determining what other factors may play a part in the consequences associated with the virus. In addition to answering these questions, we are also working to accelerate optimal mosquito control strategies, improve testing and assure preparedness for rapid detection, control, and prevention within the United States and U.S. territories.

We are making advancements in these areas and will need the additional requested funding to do so. We are figuring out more about Zika literally every day, and will share information—and adjust our guidelines and recommendations—as we learn more. That is the nature of a scientific response to an emerging health threat. The doctors, scientists, entomologists, and others at CDC are working nonstop to protect Americans from this and other health threats. We have already made significant progress identifying the Zika virus in brain tissue of affected deceased infants, developing new diagnostic tests, issuing guidance, conducting epidemiological investigations along with affected countries, and improving monitoring and surveillance in the United States including in the Commonwealth of Puerto Rico and the other U.S. territories. Much of what we know about Zika and similar viruses today is based on the work that's been done by CDC scientists. But there are still many things we do not yet know. We will continue to use the best of modern science to protect the American people. I understand that Zika virus and the emergence of serious birth defects cause concern. We are committed to providing the American people with the most accurate and timely information about Zika virus and the current outbreak.

CDC is working in collaboration with other components of the Department of Health and Human Services (HHS), including the Office of the Assistant Secretary for Preparedness and Response (ASPR) and its Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health, and the Food and Drug Administration (FDA). We are also working with partners across the U.S. Government to communicate with travelers and health care providers, update travel alerts and clinical guidance, and develop improved mosquito-control methods.

ZIKA AND ITS HISTORY

Zika is a flavivirus, which is closely related to dengue, yellow fever and West Nile viruses. Zika virus is primarily spread to people through the bite of infected *Aedes* species mosquitos, particularly *Aedes aegypti*. The *Aedes aegypti* mosquitos, which also transmit dengue and chikungunya viruses, are extremely difficult to control.

They bite during the day, indoors and outdoors, and they preferentially feed on humans. And they need only the smallest bit of water to breed—just a bottle cap is enough. The mosquitos become infected when they bite a person with Zika virus. These infected mosquitos can then spread the virus to other people through bites. Case reports of other modes of transmission include spread through sexual transmission and blood transfusion. Of great concern, Zika virus infection in a pregnant woman has been linked to issues in fetal development, and the virus has been detected in association with fatal brain malformation in newborns as well as in miscarriages.

While its adverse effects were unforeseen, Zika is not a new virus. It was first recognized in 1947 and has caused occasional illness in Africa and Asia, but the first outbreak we know of occurred in 2007 in the small Pacific island of Yap. Last May, the first local transmission of Zika in the Americas was reported in Brazil, and by the end of 2015, Brazilian authorities estimated that the outbreak there involved perhaps a million suspected cases of Zika virus. In recent months, the virus has spread rapidly throughout Latin America and the Caribbean, as well as to parts of the Pacific. As of February 18, 2016, 32 countries and territories, including the Commonwealth of Puerto Rico, a United States Territory, the U.S. Virgin Islands, and American Samoa have reported local transmission of the Zika virus.

SYMPTOMS AND ADVERSE OUTCOMES

Many people exposed to Zika virus will have only mild symptoms—such as fever, rash, joint pain, and red eyes or conjunctivitis—that will last no more than a week. In past outbreaks, about four out of five people infected with Zika appear not to have had symptoms at all, although we do not know if that is the pattern in this outbreak.

Increasing evidence suggests that Zika virus infection may be associated with more serious health outcomes. In October 2015, Brazilian authorities recognized a concerning increase in microcephaly, which has occurred in close sequence to Brazil's outbreak of Zika virus. Microcephaly is a usually rare, serious condition where a baby's head is smaller than expected based on age and sex. Microcephaly is not a diagnosis in and of itself, but a sign that the brain did not develop as it should in the womb. Babies with microcephaly can have a range of problems, including seizures, developmental delay, feeding problems and hearing loss. In some cases these problems can be fatal.

Laboratory tests at CDC strongly suggest a link between Zika virus infection during pregnancy and microcephaly. We do not fully understand the nature of this relationship, or if there are important cofactors. We also do not know what, if any, other outcomes might be associated with Zika infection during pregnancy among infants who do not have microcephaly. Microcephaly in infants can be devastating to the affected families, and this ongoing outbreak is concerning to everyone, especially for pregnant women, and their families who may travel to or live in the infected areas. The association between Zika virus and microcephaly is unexpected. A new infectious cause of fetal malformations has not been identified in decades. Zika virus spread in the Americas and its effect on pregnancy are developments that we are working with partners to better understand.

Our key priority at this point is to reduce the risk to pregnant women of Zika virus infection. Given the potential risks associated with maternal Zika infection, prevention is key for this response, with a parallel approach of acting based on what we know now and, at the same time, discovering more so that we can better prevent adverse health outcomes in the future. That's why, during the same week we identified Zika in brain tissue specimens from affected infants, we issued a warning to advise pregnant women not to travel to affected areas. That's why we are working intensively with the Commonwealth of Puerto Rico and other areas to get support to women who are or who may become pregnant and do what we can to reduce the threat of Zika there. And that's why we are also engaging in studies with international partners so that we can more fully understand the magnitude of risk and the range of outcomes associated with Zika virus infection during pregnancy.

Health authorities in Brazil and elsewhere have also reported an increase in suspected cases of Guillain-Barré syndrome, a rare neurologic disorder in which a person's own immune system damages nerve cells, leading to nerve damage or paralysis that lasts for several weeks or several months. Most people fully recover, but it can take a few months or even years to do so. Some people with Guillain-Barré syndrome have permanent damage and, in rare cases, people have died. It is difficult to determine if any particular pathogen "caused" or "triggered" Guillain-Barré syndrome. Currently, we do not know if Zika virus infection causes Guillain-Barré syndrome. However, the development of Guillain-Barré syndrome is a recognized

after-effect of a variety of different infections. CDC is currently collaborating with public health officials in Brazil to investigate whether there is any causal link between Zika infection and Guillain-Barré syndrome.

DOMESTIC ACTIVITIES

While we are working to better understand these health outcomes, transmission, diagnostics, and mosquito control, CDC is moving quickly to respond. We have moved our Emergency Operations Center to the highest alert level for Zika virus to further enhance our response activities in areas with current local transmission and to accelerate preparedness efforts in anticipation of local transmission in the continental United States.

For the Commonwealth of Puerto Rico as well as the U.S. Virgin Islands and American Samoa, a surge in resources is urgently needed. The population of *Aedes aegypti* mosquitos is widespread on these islands, protective environmental factors such as window screens are not as prominent, and the density of people puts people there at high risk for transmission. All three areas have already reported local Zika transmission, with Puerto Rico alone reporting at least 30 cases. Furthermore, recent outbreaks of dengue and chikungunya suggest that Zika virus may spread extensively and rapidly in these areas. CDC has deployed staff to the U.S. Virgin Islands, American Samoa, and Puerto Rico to support response activities and provide technical assistance to health departments there. CDC and the CDC Foundation are also partnering to create Zika prevention kits. Containing educational materials, and initial supplies of prevention tools such as insect repellent, the purpose of these kits is to help pregnant women in areas with local Zika transmission protect themselves and their pregnancies. Five thousand of these kits have been dispatched to the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and American Samoa; and CDC plans to distribute more than 45,000 kits to these areas in the future.

While we have not yet seen transmission of the Zika virus by mosquitos within the continental United States, we expect many returning travelers will have Zika infection. As a potential benchmark, we received reports of 3,270 travelers from 49 States with laboratory confirmed cases of chikungunya infection in 2014 and 2015. There are about 40 million people traveling between the continental U.S. and Zika-affected areas each year. Therefore, all U.S. jurisdictions must be prepared to evaluate, test, and manage patients with potential Zika virus infection, particularly pregnant women. Furthermore, *Aedes aegypti* is found in many areas of the United States, raising the risk of local transmission. The most recent data available suggest that *Aedes aegypti* are found in 13 States and *Aedes albopictus* are found in 31 States and the District of Columbia. Recent chikungunya and dengue clusters in the United States suggest that Zika outbreaks in the U.S. mainland may be relatively small and localized due to protective factors like window screens and less dense living conditions; however, any local outbreaks will be of deep concern to the people living there, and we must be prepared for different scenarios including more extensive transmission risk.

CDC is working with health departments across the country to ensure coordination and to expand capacity for detecting and responding to Zika virus. Surveillance is essential to monitor and quickly identify areas with local transmission. We conduct multi-faceted surveillance for arboviruses, including Zika, through ArboNET, an integrated network which funds, through our Epidemiology and Laboratory Capacity cooperative agreements, staff in 49 States, the Commonwealth of Puerto Rico, and six large municipalities to conduct human case investigations, collect and test mosquitos, and perform laboratory analysis on arboviruses including Zika. Zika virus is now a nationally notifiable disease, meaning States report the virus to CDC, which will aid Zika surveillance efforts. CDC is also working with several States and the Commonwealth of Puerto Rico to determine a baseline prevalence of microcephaly so that any increase, should it occur, can be quickly and accurately identified.

With support from the President's emergency request, CDC will build on its current efforts to provide financial and technical resources to States and territories through its cooperative agreements to strengthen their capacity to prepare for and respond to emerging insect-borne threats such as Zika virus. These resources may be used to help health departments expand their capability to manage cases of local Zika virus transmission in their areas and to implement community education and prevention programs to reduce human-mosquito contact and subsequently, the risk of Zika transmission. Resources will also be used to implement mosquito control strategies, including mosquito surveillance. Current mosquito surveillance capacity is uneven across the country, which makes our knowledge about the locations of the two mosquito vectors that transmit Zika virus potentially incomplete. To effectively

track the spread of the outbreak, it is critical that States and territories receive specimens and test for Zika virus to diagnose and report travel-related and locally acquired cases of Zika. Under the emergency request CDC will expand its efforts to assist public-health labs nationwide to test for Zika and to provide the guidance on how to interpret test results. In addition, CDC is available to provide testing of any Zika samples upon request. We are working to expand the number of health departments that have the ability to perform testing, but will need to increase the existing capacity to meet the projected demand for Zika testing. Given that, last year, it is estimated that approximately 500,000 travelers to areas of current Zika transmission were pregnant women and 36,000 pregnant women are currently living in the Commonwealth of Puerto Rico, the expansion of testing capacity in public health labs nationwide, included in the request, is urgently needed in order to ensure that every pregnant woman needing testing for Zika virus has access.

Recognizing the potential for Zika virus transmission through blood transfusions, CDC is collaborating with FDA to ensure the safety of the blood supply from Zika virus, particularly in regions experiencing local outbreaks. CDC has sent experts to the Commonwealth of Puerto Rico to assess the steps needed to assure both that Puerto Rico's blood supply needs are met and that transfusion-transmitted Zika is prevented.

CDC experts are working intensively to learn more about the outbreak and provide people with the information they need to protect themselves. We will continue to issue travel alerts for the affected areas as confirmation of the virus is reported, and we'll keep the American people informed as the situation changes. We recognize people are eager for information, and our website has exceeded half a million views in recent days.

CDC has also provided guidance for doctors and other clinicians on evaluation, treatment and followup care of pregnant women and infants with possible exposure to Zika virus, partnering with organizations from around the health care community to help distribute this information as widely as possible. Our guidance will continue to be updated as our knowledge increases. We have recently updated our guidance to provide recommendations for the clinical care and management of pregnant women living in areas where Zika transmission is widespread, with special consideration to the ongoing risk of maternal Zika virus infection throughout pregnancy. These guidance documents were prepared in consultation with the American College of Obstetricians and Gynecologists, the Society for Maternal Fetal-Medicine, and the American Academy of Pediatrics.

CDC also wants to ensure that the general public knows what it can do to protect itself. Pregnant women should postpone travel to regions with ongoing Zika virus transmission. If they must travel, or if they live in affected areas, CDC recommends pregnant women talk to their doctors or other healthcare providers first and strictly follow steps to prevent mosquito bites. Reducing exposure to mosquitos is important for anyone traveling to or residing in areas where the virus is circulating. Wearing long sleeves, long pants, using EPA-registered repellents such as DEET and permethrin-treated clothing (both of which are safe to use in pregnancy), and using other protections such as air-conditioning will reduce exposure to mosquito bites. Given the potential for Zika virus to be spread through sex, pregnant women and their male partners living in or who have been to Zika-affected areas should abstain from sex or use condoms for the duration of pregnancy. This is a rapidly changing situation and our understanding of the risks concerning Zika virus infection is incomplete and evolving. As we get new information, we will update our advice.

GLOBAL ACTIVITIES

On February 1, the World Health Organization (WHO) declared the recent cluster of microcephaly cases and other neurological disorders (such as Guillain-Barré syndrome) and their possible association with Zika virus, a public health emergency of international concern, a reflection of the seriousness of this unfolding health threat. CDC is coordinating its response with the U.S. Agency for International Development, as well as the Pan American Health Organization (PAHO), the regional arm of the World Health Organization (WHO), and other parts of WHO, and is collaborating with many international partners to learn more about this outbreak. We are working with the Brazilian Ministry of Health on investigation and research partnerships. Specifically, one partnership involves studying the link between Zika virus infection and microcephaly, while another is examining the relationship between Zika virus and Guillain-Barré syndrome. Research teams from CDC are also in other countries, including Colombia, to explore collaborations that will shed light on the risk of microcephaly in relation to Zika virus infection during pregnancy.

In addition, CDC is offering support to all countries so that they can test samples from microcephaly cases for serologic evidence of Zika virus infection, and CDC is helping countries throughout the Americas establish in-country diagnostic capacity. To that end, we are currently, and in conjunction with PAHO, providing training to laboratorians in South and Central America on diagnostic tests, including two recent workshops in Brazil and Nicaragua.

CDC's Central American office has also facilitated the verification of Zika cases in several countries throughout Latin America, including Colombia, Venezuela, and Nicaragua. At the request of the Department of State's Bureau of Medical Services, staff from CDC's Global Disease Detection Center in Guatemala has been involved in communication efforts to ensure that new information regarding Zika virus and its possible link to birth defects is communicated to U.S. Mission Health Unit staff throughout the Americas.

The Global Health Security Agenda, with critical support from Congress, is collaborating with countries around the world so that we can find, stop, and prevent health threats when and where they first emerge. Zika has been present in Africa for decades, and it's possible that it could become linked to microcephaly there as well. The sooner we detect a problem, wherever it occurs, the more rapidly we can respond to it and prevent it from spreading. It is in all of our best interests to work with others to improve public health capacity around the world.

IMPROVING THE TOOLS AND INFORMATION FOR RESPONDING TO ZIKA

We need a better understanding of the epidemiology of Zika and potential Zika-associated birth defects and other adverse health outcomes. We need better diagnostic methods that can quickly and clearly differentiate between similar viruses to detect evidence of past Zika infection. Testing for current Zika infection is only reliable in the first week of illness. A Reverse Transcription-Polymerase Chain Reaction (RT-PCR) test can provide a definitive diagnosis of Zika, but only if it is performed within about 7 days of symptom onset. The tests we have available for Zika in persons who are no longer ill may have cross-reactivity with similar flaviviruses, particularly dengue, which can lead to false-positive or inconclusive results and confirmatory testing is required. Diagnosis is particularly challenging with Zika virus since most people will not experience symptoms. We also need to determine how long a man who has been infected with Zika may continue to be able to sexually transmit the virus to a partner, and we need better tools to screen the blood supply.

We also need to advance our ability to control the mosquito population. Existing methods for mosquito control all have shortcomings, especially in areas where the population of *Aedes* mosquitos is rampant. Furthermore, in some areas like the Commonwealth of Puerto Rico, mosquitos may have developed resistance to certain insecticides, which could reduce the range of substances that can be used to effectively decrease mosquito populations. We need to implement the best tools we have today, improve current vector control strategies, and identify better options. We also need better mosquito surveillance to determine the location of mosquitos and areas with mosquito resistance to insecticides, which would inform the implementation of new mosquito control techniques.

Finally, a vaccine is needed to protect people at risk of Zika virus infections, particularly preventing infection among women of childbearing age. At CDC, our scientists developed both a West Nile virus vaccine, which is currently in use for animal protection in the United States, and a dengue vaccine, which is currently in clinical trials. The President's request will increase Zika research, improve diagnostics and support advancements in vector control methods. Although availability of a licensed Zika vaccine is several years away, we do not know how long Zika will be a problem in the Americas nor whether the mosquito control efforts that must be implemented will yield durable results.

CONCLUSION

Microbes continue to be formidable adversaries. To protect Americans, the Zika emergency request invests in the laboratories, disease detectives, disease tracking systems, mosquito control, and investigations needed to continue to improve these essential tools.

The emergence and reemergence of health threats, including those spread by mosquitos and other vectors is not a unique event but something we expect to continue to see in the future. These outbreaks cannot be expected to occur in isolation of one another. The Commonwealth of Puerto Rico and Hawaii were already responding to outbreaks of dengue when Zika virus arose as an urgent health threat. We need to address the threat of mosquito-borne diseases systematically, rather than episodically. Thank you again for the opportunity to appear before you today. I appre-

ciate your attention to this concerning outbreak and I look forward to answering your questions.

The CHAIRMAN. Thank you, Dr. Schuchat.
Dr. Fauci.

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

Dr. FAUCI. Mr. Chairman, Ranking Member Murray, members of the committee, thank you for calling this committee and thank you for giving me the opportunity to discuss very briefly with you and to answer questions later on on the role of the National Institute of Allergy and Infectious Diseases and other NIH institutes in the research endeavor to address the Zika virus outbreak.

As shown on this visual, the NIAID has a dual mandate. We maintain and grow, as other institutes do, a robust basic and clinical research portfolio in the particular discipline for which we are responsible. In this case, that is microbiology, infectious diseases, and the diseases of the immune system.

However, in addition and simultaneous with that, we must be ready to respond rapidly to new and emerging disease threats as they occur, in many cases completely unpredictably. And in fact, just last month, I was asked and did write a commentary in the *New England Journal of Medicine*. And as you can see from this title, I called it “Zika Virus in the Americas: Yet Another Arbovirus Threat” because over the last 20-plus years, we have seen in the western hemisphere and the Americas diseases which we had not seen before, starting with West Nile virus back in 1999–2000, chikungunya in 2013, dengue over the past 20 years, and now most recently in 2015 the Zika virus. This is something that we always need to be prepared for because there will always be emerging diseases.

The NIH and NIAID’s response is very complementary to the CDC and other components of HHS and in fact the entire Federal Government. Our role is the development and research of countermeasures to address these outbreaks.

For example, we do the fundamental basic research, clinical research. We provide materials such as reagents not only for academia but also for industry, with the ultimate goal of developing countermeasures in the form of diagnostics, therapeutics, and vaccines.

I want to spend just a minute or 2 going over some of the things—and you have asked those questions yourself, Mr. Chairman, in your opening remarks. The questions that remain: the difference between symptomatic and asymptomatic disease, how long after infection is one vulnerable with regard to pregnancy, what are the frequency of sequelae, doing cohort studies to determine the incidence of adverse pregnancy in Zika-infected individuals and understanding just what the underlying pathogenesis of the development of microcephaly is in babies born of infected mothers.

With regard to basic research, it is very similar to what we do with many of the other viruses, going all the way back to HIV/AIDS, determine the molecular virology, the structure of the virus, does it change, and what is the relationship to clinical manifesta-

tions. What about the immune response to the virus? How does the body respond making someone clear the virus, and can that be sort of a way for us to be able to get a guiding path to develop a vaccine and importantly the establishment of animal models?

As you heard from Dr. Schuchat, the CDC is very heavily involved with their diagnostic and reference laboratory to develop diagnostics for Zika.

The NIAID and our grantees are also heavily involved in getting approved diagnostics, not only for the virus itself with what we call the RT-PCR but sensitive and specific antibody tests to determine in fact if someone has been infected. And as you well know, that is the question we are all being asked by women who have been exposed. Have I been infected or not? That is of great importance to them. And those kind of diagnostic tests will be critical.

One of the most important things we have done and are doing now with Zika is the development of vaccines. Shown on this slide are a number of candidates. The ones with the red bullets are those that are essentially what we call “shovel ready,” in other words, ready to go right into the development in clinical trials. The others are not far behind.

One of the advantages that we have with the development of vaccines—let us take the first one on that top bullet called “DNA vaccine.” And I have next to it “success with West Nile virus.” And what we did, as some of you may remember, is that we were able to take this what we call vaccine platform, which is a chunk of DNA, in which we inserted the gene for West Nile virus. And we made a successful West Nile virus vaccine many years ago. It was not used because industry was not particularly interested in it.

But what we were able to do now is very easily pull out that West Nile gene and stick in the Zika gene and do exactly the same thing. And in fact, we are doing that right now, developing product to do preclinical toxes, and we predict that we will be in phase 1 study by the end of the summer, and that should take about 3 to 4 months. If it is safe and induces the kind of response we want, we feel comfortable in being able to go to an advanced trial. Whether we will be able to show it is effective or not, that is always the big question with vaccines, but we are moving very quickly.

And then finally with the development of therapeutics, there are in vitro screening assays and we are looking at any of a number of drugs not only for Zika but for other flaviviruses.

Let me close with this slide, which is an article that I wrote some time ago, which really says it all about what our mandate is. Emerging infectious diseases have been around forever, are around now, and will always be around. And it is very important for us to address what I call this perpetual challenge.

I want to thank this committee and others for having over the years been so very supportive of us in this endeavor. Thank you very much.

[The prepared statement of Dr. Fauci follows:]

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

Mr. Chairman, Ranking Member Murray, and members of the committee, thank you for the opportunity to discuss the National Institutes of Health (NIH) research response to Zika virus, an emerging public health threat of international concern. I direct the National Institute of Allergy and Infectious Diseases (NIAID), the lead

NIH institute for conducting and supporting research on emerging and re-emerging infectious diseases, including those caused by flaviviruses such as Zika virus.

The Administration is taking appropriate action to protect the American people and, as you know, it announced a request to Congress for approximately \$1.9 billion in emergency funding to enhance ongoing efforts to prepare for and respond to outbreaks of the Zika virus, both domestically and internationally. This includes funding for work on the development of vaccines and diagnostics and to improve scientific understanding of the disease.

The overarching mission of NIAID is to conduct and support research to better understand, treat, and prevent infectious and immunologic diseases. This is accomplished through a spectrum of research, from basic studies of the mechanisms of disease to applied research focused on developing interventions such as diagnostics, therapeutics, and vaccines. As part of this mission, NIAID has a dual mandate encompassing both research on ongoing public health issues and the capability to respond rapidly to newly emerging and re-emerging infections such as Zika virus.

These emerging and re-emerging disease threats, whether man-made or naturally occurring, are perpetual challenges, in part due to the capacity of microbial pathogens to evolve rapidly and adapt to new ecological niches. To address the challenges posed by emerging infectious diseases, NIAID employs both targeted, disease-specific research as well as broad-spectrum approaches. NIAID maximizes its efforts by prioritizing the development of drugs effective against multiple bacteria or viruses, and “platform” technologies to facilitate rapid development of vaccines and diagnostics applicable to multiple infections.

NIAID is well-positioned to rapidly respond to infectious disease threats as they emerge by leveraging fundamental, basic research efforts; domestic and international research infrastructure that can be quickly mobilized; and productive partnerships with industry. NIAID provides preclinical research resources to scientists in academia and private industry worldwide to advance translational research against emerging and re-emerging infectious diseases. These resources are designed to bridge gaps in the product development pipeline and lower the scientific, technical, and financial risks incurred by industry in order to incentivize them to partner with us in the advanced development of effective countermeasures. NIAID also supports our Vaccine and Treatment Evaluation Units (VTEUs), a research network that conducts clinical trials to quickly investigate promising therapeutic and vaccine candidates when public health needs arise. NIAID collaborations with other Federal agencies, including those undertaken within the Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), help advance progress against newly emerging public health threats. In addition, partnerships with academia, the biotechnology and pharmaceutical industries, and international researchers and organizations such as the World Health Organization (WHO) and WHO’s regional office, the Pan American Health Organization (PAHO), are integral to these efforts.

OVERVIEW OF ZIKA VIRUS

Zika virus is a flavivirus. These viruses typically are transmitted by mosquitoes and often have the ability to spread quickly to new geographic locations because of the widespread prevalence of these vectors. Other well-known flaviviruses include dengue virus and yellow fever virus; like Zika virus they are transmitted by *Aedes* mosquitoes. Zika virus was discovered in monkeys in Uganda in 1947 and is now endemic to Africa and Southeast Asia. During the past decade it has emerged in other areas of the world, including Oceania, the Caribbean, and Central and South America, where countries, notably Brazil, are currently experiencing unprecedented Zika transmission.

Infections caused by Zika virus are usually asymptomatic. About 20 percent of infected individuals experience clinical symptoms such as fever, rash, joint pain, and conjunctivitis (red eyes). Symptoms of Zika virus infection in humans are typically mild and brief, with very low hospitalization and fatality rates. The recent outbreak of Zika virus disease in Brazil has coincided with a reported increase in the number of infants born with microcephaly, a birth defect characterized by an abnormally small head resulting from an underdeveloped and/or damaged brain. In addition, increases in suspected cases of Guillain-Barré syndrome (GBS), a rare, acute, immune-mediated peripheral nerve disease that leads to weakness, sometimes paralysis, and infrequently, respiratory failure and death, have been noted in Brazil and other countries in the Americas.

Further research is needed to better understand the effect of Zika virus infection on the body, particularly during pregnancy; to investigate the potential relationship between Zika infection and congenital abnormalities including microcephaly, as well

as to explore the potential relationship between Zika infection and GBS; and to develop better diagnostics, vaccines and treatments, and new methods of vector control. Currently, no vaccines or specific therapeutics are available to prevent or treat Zika virus disease. Improved diagnostic tests also are needed because Zika virus infection causes non-specific symptoms or no symptoms at all and can be difficult to distinguish by antibody screening tests from other mosquito-borne infections such as dengue, malaria, and chikungunya. Moreover, current antibody screening tests can be falsely positive or inconclusive if the individual was previously infected with related viruses such as dengue, which is prevalent in South America and the Caribbean. Therefore, a positive result with the antibody screening test requires an additional test to confirm the diagnosis.

NIH RESEARCH ON ZIKA VIRUS

NIAID has a longstanding commitment to flavivirus research, including extensive efforts to combat diseases such as dengue, West Nile virus, and yellow fever. This research has informed our understanding of the viral genetics, vector biology, and pathogenesis of flaviviruses and provides a strong foundation for our efforts to learn more about Zika virus. NIAID has responded to the newly emerging Zika virus disease outbreak by expanding our portfolio of basic research on Zika virus and other flaviviruses. NIAID also is accelerating efforts to develop improved diagnostics and candidate therapies for Zika virus as well as prioritizing the development of Zika virus vaccines. In addition, screening tests and pathogen reduction technologies are critically important to assure safety of the U.S. blood supply.

The emergency funding for NIH would support development of vaccines to prevent Zika virus infection, from the discovery phase through preclinical and eventually clinical testing. In addition, the funds would support basic research to understand the natural history, viral biology and pathogenesis, including potential links to microcephaly; establishment of animal models to test candidate countermeasures; development of rapid, sensitive, and specific diagnostic tests; and discovery and pre-clinical development of new therapeutics to treat disease caused by Zika virus. This research is necessary to better understand this emerging infection and uncover the best ways to diagnose, treat, and prevent Zika virus disease.

In January 2016, NIAID issued a notice to researchers highlighting NIH's interest in supporting research and product development to combat Zika virus. Areas of high priority include basic research to understand viral replication, pathogenesis, and transmission, as well as the biology of the mosquito vectors; potential interactions with co-infections such as dengue and yellow fever viruses; animal models of Zika virus infection; and novel vector control methods. In addition, NIH is soliciting Zika virus research to develop sensitive, specific, and rapid clinical diagnostic tests; drugs against Zika virus as well as broad spectrum therapeutics against multiple flaviviruses; and effective vaccines and vaccination strategies.

NIAID also is partnering with other NIH institutes, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute of Dental and Craniofacial Research, to accelerate Zika virus research as it relates to the mother-infant pair. The Institutes issued a notice that indicates NIH's interest in supporting research to understand transmission, optimal screening and management in pregnancy, and the mechanisms by which Zika virus affects the developing nervous system, including potential links to microcephaly and other congenital abnormalities.

DEVELOPING TOOLS TO COMBAT ZIKA VIRUS

In response to public health concerns about Zika virus, NIAID has accelerated ongoing flavivirus research efforts to speed the development of tools that could help control current and future outbreaks of Zika virus.

VECTOR CONTROL

For many years, NIAID has supported extensive research to understand the biology of mosquitoes to help develop tools to limit the spread of deadly mosquito-borne diseases such as dengue and malaria. This research aids in vector control strategies to reduce mosquito bites or limit mosquito populations. In the Americas, Zika virus is transmitted primarily by *Aedes aegypti* mosquitoes, and vector control or other methods to prevent exposure to these mosquitoes are currently the only ways to prevent Zika infection. NIAID plans to support vector competence studies to test various mosquito species for their ability to carry and transmit Zika virus and for insecticide resistance. Understanding the specific mosquito species involved in Zika out-

breaks and which insecticides may be effective against them will aid current vector control efforts and may inform novel mosquito control strategies in the future.

DIAGNOSTICS

Accurate diagnostic tests for Zika virus infection are needed to distinguish it from other flavivirus infections and to identify women who have been infected with Zika virus during pregnancy and may be at risk for developing fetal complications. Blood, organ, and tissue donor screening tests are also needed to assure the safety of transfusion and transplantation in areas of active mosquito-borne virus transmission. Currently, Zika virus itself can often be detected during the acute phase of infection and up to 7 days after the onset of symptoms using diagnostic tests for viral RNA (RT-PCR test). While prior infection can be detected by testing for the presence of antibodies against Zika virus, assays for Zika antibodies may also detect or cross-react with antibodies against other flaviviruses, particularly dengue virus. For this reason, a positive antibody test does not definitively confirm prior Zika virus infection in the setting of possible co-infection or prior infection with dengue and other related viruses, and separate confirmatory testing is required. This is a particular concern in South America where there is a high level of exposure to other flaviviruses, particularly dengue virus.

To facilitate the development of improved Zika virus diagnostic tests, NIAID grantees are working to generate antibodies that can distinguish between Zika virus and dengue virus. They also are working to identify biosignatures unique to Zika infection that could form the basis of additional rapid, specific, and sensitive diagnostic tests. In addition, NIAID is pursuing the development of a mouse model of Zika virus infection that could be used to test new diagnostic and therapeutic tools.

VACCINES

A safe and effective Zika vaccine would be a very valuable tool to help stop the spread of infection and prevent future outbreaks. NIAID is investigating multiple Zika virus vaccine candidates, including vaccines based on technologies that have shown promise in targeting other flaviviruses. The NIAID Vaccine Research Center (VRC) is pursuing a DNA-based vaccine for Zika virus that is similar to a West Nile virus vaccine previously developed by NIAID. The West Nile vaccine candidate was shown in Phase 1 testing to be safe and generated a strong immune response in humans, offering a model for Zika vaccine development. NIAID scientists also are designing a live, attenuated vaccine, using an approach similar to that used for making a vaccine against the closely related dengue virus. The dengue vaccine candidate showed an excellent safety profile and generated strong immune responses in early phase clinical trials. In January, a large Phase 3 trial assessing the dengue vaccine candidate was launched in Brazil in collaboration with the Butantan Institute. In addition, NIAID grantees are in the early stages of developing a Zika virus vaccine based on a recombinant vesicular stomatitis virus—the same animal virus used successfully to create an investigational Ebola vaccine. Plans are underway to evaluate this potential vaccine construct in tissue culture and animal models.

While these approaches are promising, it is important to realize that the development of investigational vaccines and the clinical testing to establish whether they are safe and effective takes time. Although a safe and effective, fully licensed Zika vaccine will likely not be available for a few years, we plan to begin early stage clinical testing of one or more NIAID-supported vaccine candidates in 2016.

THERAPEUTICS

NIAID has an active program to screen for antiviral drugs active against viruses in the flavivirus family, including dengue, West Nile, yellow fever, and Japanese encephalitis viruses, as well as the closely related hepatitis C virus. NIAID has enhanced these efforts with the recent development of an assay to test compounds for antiviral activity against Zika virus. NIAID will make this test available to the research community and will soon test 10 antiviral compounds with activity against other flaviviruses to determine if they are effective against Zika virus.

Promising drug candidates identified by the assay could be further tested in a small animal model of Zika virus infection developed with NIAID support. The ultimate goal of NIAID-supported flavivirus therapeutic research is to develop a broad-spectrum antiviral drug that could be used against a variety of flaviviruses, including Zika.

EMERGENCY REQUEST FOR VACCINE RESEARCH AND DIAGNOSTIC DEVELOPMENT AND
PROCUREMENT

As I noted in the introduction to my testimony, the Administration has announced an emergency-funding request of approximately \$1.9 billion to combat the Zika virus both domestically and internationally. Included in the request are resources for Zika-related vaccine research, rapid advanced development, and commercialization of new vaccines and diagnostic tests for Zika virus. The funding will allow NIH to build upon existing resources and work to develop a vaccine for Zika virus and the chikungunya virus, which is spread by the same type of mosquito. Funding will accelerate this work and improve scientific understanding of the disease to inform the development of additional tools to combat it. The request also includes resources for FDA to support Zika virus medical product development, including the next-generation diagnostic devices. We look forward to working with the Congress to implement this request.

COLLABORATIONS

Investigation of emerging and re-emerging infectious diseases requires expertise from a variety of fields. In the case of Zika virus, studies of virology, immunology, natural history, neurology, and neonatology will be required to fully understand the pathogenesis of this infection. As mentioned previously, NIAID is partnering with other NIH institutes including NICHD and NINDS to better understand the potential association between Zika virus infection and neonatal defects, particularly microcephaly.

NIAID also is employing partnerships with research institutions in South America to advance research on Zika virus infection; additional collaborations with academic, industry, and government partners are under active exploration. NIAID held a joint meeting in December 2015 with Brazilian research institute Fiocruz in which Zika was a key area of concentration. In addition, NIAID is collaborating with other HHS agencies in responding to the Zika epidemic. For example, NIAID, CDC, BARDA, ASPR, and FDA are jointly convening a Zika virus workshop on March 28–29, 2016, where the latest information on Zika virus will be discussed by experts from Federal Agencies, academia, and pharmaceutical and biotechnology companies. Topics to be addressed at the workshop include virology, epidemiology, possible links to microcephaly, and efforts to develop diagnostics, therapeutics, and vaccines.

CONCLUSION

NIH is committed to continued collaboration with HHS agencies and other partners across the U.S. Government in advancing research to address Zika virus infection, and we look forward to working with the Congress to implement the President's emergency funding request. As part of its mission to respond rapidly to emerging and re-emerging infectious diseases throughout the world, NIAID is expanding our efforts to elucidate the biology of Zika virus and employ this knowledge to develop needed tools to diagnose, treat, and prevent disease caused by this virus. In particular, NIAID will pursue the development of safe, effective vaccines to prevent disease caused by Zika and chikungunya viruses.

The CHAIRMAN. Thanks, Dr. Fauci.
Dr. Robinson.

STATEMENT OF ROBIN ROBINSON, PH.D., DIRECTOR BIO-MEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, WASHINGTON, DC

Mr. ROBINSON. Good morning, Chairman Alexander, Ranking Member Murray, and members of the committee. I want to thank you for the opportunity to testify before you again. As you recall, within HHS, I serve as the Director of BARDA and a Deputy Assistant Secretary in ASPR.

Today I will update you on our progress and plans toward the current Zika response, while the ASPR is also leading the Federal Flint response.

As we learned through the Ebola and pandemic influenza responses, one of our key public health responsibilities in infectious disease epidemics is effective communication. One of the ASPR's

first actions was to coordinate communications efforts within HHS and with our private and public stakeholders by convening the Disaster Leadership Group to respond to emergencies. Through the Disaster Leadership Group and in coordination with the Secretary's Operations Center, ASPR is collecting and sharing information on Zika across the U.S. Government and with health departments in States and territories by leveraging our combined capabilities to prepare our Nation and formulate an organized response.

ASPR is also facilitating opportunities for coordination among State and local health systems through hospital preparedness grants and health care coalitions to provide better care of Zika patients.

Globally, ASPR is playing a key leadership and coordination role in Zika affairs by sharing Zika-related information with international partners like the WHO and hosting meetings like the Global Health Securities Initiatives ministerial meeting here in Washington, DC this week and a meeting of the Global Research Collaboration for Infectious Disease Preparedness on March 14th and 15th Washington, DC.

With regard to medical countermeasures for Zika, the ASPR is leading the coordination of medical countermeasure activities in the Zika response using the Public Health Emergency Medical Countermeasures Enterprise, or PHEMCE, in this governance infrastructure, as we have done in H1N1 pandemic and the Ebola response. The ASPR has convened a senior steering group comprised of senior leaders across the PHEMCE to address and coordinate Zika-related medical countermeasure policy and operational issues and activities like sample sharing.

BARDA, which transitions medical countermeasure candidates from early development at the NIH through the "valley of death" into advanced development toward FDA approval, is doing our part in the U.S. Government Zika response with regard to vaccines, diagnostics, and the blood supply. Building on existing and new public-private partnerships and lessons learned from the H1N1 and Ebola responses, we are supporting NIH's lead in the Zika vaccine development that Dr. Fauci is head of. In collaboration with the NIH and the Department of Defense's Walter Reed Army Institute of Research, we are utilizing our centers for innovation in advanced development and manufacturing, and our field finished manufacturing network to manufacture Zika vaccine candidates for clinical studies.

We are also providing technical assistance to our industry partner in Brazil for Zika vaccine development and commercial scale manufacturing as we have done previously for pandemic influenza vaccines.

Also, we are supporting industry partners to utilize their new, innovative vaccine platform technologies to develop new Zika vaccine candidates today and vaccines for other emerging infectious diseases in the future.

With regard to diagnostics, we are collaborating with CDC, NIH, and FDA to facilitate the development of rapid point-of-care, and laboratory-based serological assays specific for Zika to determine who has been infected previously, especially pregnant women.

We are also working with the CDC to prepare and distribute reagent validation panels for industry partners to qualify Zika diagnostic assays.

With regard to the blood supply, we are collaborating very heavily with FDA to support the development and implementation of highly sensitive rapid molecular screening methods and pathogen reduction technologies to mitigate the risk of potential Zika virus in blood supplies. As we did for the Ebola response, we are assisting our Federal partners and medical countermeasure developers through our National Medical Countermeasure Response Infrastructure, comprised of six core service assistance programs that provide animal and human clinical testing services, product development and manufacturing, and regulatory and modeling capabilities.

We also continue to encourage inquiries from academic and industrial stakeholders for potential Zika and other medical countermeasures through our Tech Watch program.

In closing, our foremost concern is protecting public health from known or emerging threats. Zika is our newest threat but not our last. Thanks to our combined efforts, coupled with lessons learned from previous challenges, we are better prepared and more resilient as a nation with the flexibility to successfully address a variety of public health threats. Congressional approval of the Administration's \$1.9 billion funding request will ensure an effective and rapid response and accelerate our ability to prevent, detect, and respond to Zika and other emerging infectious disease.

Thank you for your many years on this. I look forward to answering your questions.

[The prepared statement of Robin Robinson, Ph.D. follows:]

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

Chairman Alexander, Ranking Member Murray, and members of the committee, thank you for the opportunity to testify before you again. As you may recall, within the Department of Health and Human Services (HHS), I serve as the Director of the Biomedical Advanced Research and Development Authority (BARDA) and as a Deputy Assistant Secretary for Preparedness and Response (ASPR). Through ASPR and the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), BARDA leads the advanced development of medical countermeasures to prepare for and respond to emerging infectious diseases, man-made national security threats, and other public health emergencies. In ASPR we have been working to advance a mission delineated by the Pandemic and All-Hazards Preparedness Act (PAHPA) and realize our full leadership capabilities. ASPR and BARDA have matured and flourished in many diverse ways over the past 9 years. We operate efficiently and from a position of strength with the ability to manage numerous lines of effort including the water situation in Flint, MI, the recent Ebola epidemic, and the current Zika outbreaks. With this testimony I intend to provide a progress report on our current efforts and hope to clarify our capabilities in the context of Zika.

The Administration is taking appropriate action to protect the American people and, as you know, on February 8, it announced a request to Congress for approximately \$1.9 billion in emergency funding to enhance ongoing efforts to prepare for and respond to outbreaks of the Zika virus, both domestically and internationally. This includes funding for work on the development of vaccines and diagnostics and to improve scientific understanding of the disease. While I will briefly describe some of ASPR's activities overall, as the BARDA director, I will focus my remarks on the development of vaccines and diagnostics.

The Zika virus is primarily a mosquito vector-borne viral disease threatening the United States and our neighbors in Latin America and other parts of the world. Zika is a flavivirus in the same family as dengue, West Nile virus, and Yellow Fever, diseases we have been monitoring and combating for years. On February 1, the World Health Organization (WHO) declared clusters of microcephaly and other

neurological disorders, and their possible association with Zika virus, a public health emergency of international concern. Named after the Zika Forest in Uganda, Zika includes common symptoms such as fever, skin rash, joint pain, or conjunctivitis. However, eighty-percent of people with Zika do not appear to have symptoms at all. Considering recent outbreaks in the Pacific Islands, Central America, South America, and the Caribbean, we anticipate that the number of Zika cases among travelers visiting or returning to the United States is likely to increase. We have already seen cases of travelers returning to the United States with confirmed Zika virus disease and are particularly concerned about the virus becoming endemic in the Commonwealth of Puerto Rico, the U.S. Virgin Islands, the American Samoa, with potential for local outbreaks in parts of the southern United States. Moreover, the Brazilian Ministry of Health estimates that between 440,000 and 1.3 million suspected cases of Zika occurred in Brazil in 2015.

There is still much that we do not know about Zika and its adverse health effects on a population. Evidence associating Zika with birth defects like microcephaly and other adverse health conditions such as Guillain-Barré Syndrome is growing; however, there is still much to learn including whether additional factors are involved. HHS is actively monitoring the Zika virus, investigating outbreaks, and working with domestic and international partners to update health care providers and the general public. In addition, HHS is providing laboratory and diagnostic tests both domestically and internationally.

As we learned with Ebola and pandemic influenza, one of our key responsibilities in addressing an infectious disease is effective communication. This involves delineating a leadership structure and updating information as soon as possible using principles of risk communication and using multiple avenues, including translated materials for non-English speaking communities and enhanced outreach to vulnerable populations. Clear, concise, and accurate information can reduce the level of concern among the general population and support appropriate action by health care providers. With that in mind, HHS and our Federal partners are stressing a coordinated response to this emerging threat.

ASPR is fulfilling its leadership roles both through the Disaster Leadership Group (DLG) through the PHEMCE to develop and provide medical countermeasures. Both were created to effectively improve coordination within the Department and with our external stakeholders, including nonprofits, other Federal departments, the private sector, and the international community. Specifically, the DLG is comprised of leadership from across HHS to advise and coordinate policy on critical issues related to preparedness and response. Additionally, the Secretary's Operations Center serves as the focal point for International Health Regulation, and for communication across government. The PHEMCE, chaired by the ASPR, serves as the focal point for coordinating medical countermeasure development.

I will focus the remainder of my testimony on BARDA's role. BARDA has a mandate from PAHPA to transition medical countermeasure candidates from early development across the "Valley of Death" into advanced research and development toward FDA approval. BARDA has established four strategic goals to address medical countermeasure needs for the Zika response domestically and globally. These are prevention of Zika virus infection through new vaccines; detection of acute and previous Zika virus infections through new rapid diagnostics; ensuring a safe blood supply from Zika virus through screening and virus inactivation; and activation of our National Medical Countermeasure Response Infrastructure to aid medical countermeasure developers.

Building on existing and new partnerships and lessons learned from the H1N1 and Ebola responses, we are implementing our Zika medical countermeasure strategy through the advanced development and manufacturing of new Zika-specific vaccine candidates. In collaboration with NIH, FDA, and the Walter Reed Army Institute of Research, we are working on vaccine development, pre-clinical and clinical testing, and commercial scale production, including vaccine manufacturing through our Centers for Innovation in Advanced Development and Manufacturing. We are also providing technical assistance to our global partners in Brazil for Zika vaccine development and commercial scale manufacturing. We are supporting industry partners to develop and utilize new and innovative vaccine platform technologies to address public health emergencies for multiple emerging infectious diseases including new Zika vaccine candidates. We are collaborating with CDC, FDA, and NIH to facilitate the development of rapid point-of-care and laboratory-based serological assays for Zika to determine who has been infected previously, especially pregnant women. With regard to the blood supply, we are collaborating with FDA to support the development and implementation of rapid high-throughput molecular diagnostic screening and pathogen reduction technologies. We're particularly concerned about blood supplies at risk due to recent Zika virus outbreaks in the Commonwealth of

Puerto Rico and potentially other parts of the United States. As we did for the Ebola response, we are assisting medical countermeasure developers through our National Medical Countermeasure Response Infrastructure, which is comprised of six core service assistance programs that provide animal and human clinical testing, product development and manufacturing, and regulatory and modeling needs. This infrastructure could potentially be used to develop vector protection countermeasures such as mosquito repellants.

We are also encouraging and receiving numerous inquiries from academic and industrial stakeholders for potential medical countermeasures through our Tech Watch program. Moreover, contracting for ASPR's medical countermeasure programs has been designed to be transparent and responsive to industry but also ensure that we have appropriate internal controls for the contracting process overall. We're able to efficiently move from the idea and proposal stage to acquisition. Considering a governmentwide benchmark of 180 days to award a contract, ASPR is consistently awarding major acquisition contracts within 128 days. During the height of the Ebola response we were awarding contracts within 60 days. This success is a demonstration of the mature contracting function that ASPR has implemented and one that is fulfilling its requirements to support our industry partners and the medical countermeasure enterprise.

Recognizing the domestic impact of global public health emergencies, we have strengthened our international partnerships as cited above for vaccine development with Brazil. Whether it is pandemic influenza, Ebola, or a vector-borne disease like Zika, public health emergencies have no borders. We have forged trusted networks and relationships with key international partners and continue to receive and share information with the WHO, the United Nations, the United States Agency for International Development, the U.S. Department of State, and countries around the world about best emergency preparedness practices and surveillance data on infectious diseases. We maintain regular communications and coordination with the G7 countries, Mexico, and the European Commission on public health measures, including the development and deployment of medical countermeasures. These collaborations range from discussing domestic preparedness activities of other countries to the medical evaluation and coordination of medical countermeasure development. Our weekly Americas' Call teleconference involves 18 countries from North America, Central America, South America and the Caribbean. Thanks to this mode of outreach and coordination, we learned that Panama had Zika samples they were willing to share for research, which was a big step forward in helping to identify the strain for diagnostic comparisons. The Global Health Security Initiative (GHSI) is another success story for international coordination. Established shortly after the September 11, 2001, terrorist attacks, GHSI is an assembly of Ministers, Secretaries, Health Commissioners and other senior health officials from the European Commission, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States, and the WHO to address global health security issues. GHSI played a crucial role in bringing countries together for the Ebola response and is already turning its focus to Zika. An early focus has been on sample sharing, which is critical to the development of vaccines and diagnostics. The next ministers meeting is taking place this week in the United States, and Zika will be one of the main topics of discussion.

In closing, our foremost concern is protecting public health from known or emerging threats. Zika is our newest threat, but not our last. Congressional approval of the Administration's approximately \$1.9 billion funding request will ensure an effective and rapid response to outbreaks that threaten the health of the American people and can accelerate our ability to prevent, detect, and respond to Zika and other emerging infectious diseases. Thanks to our combined efforts and with lessons learned from previous challenges, we are a better prepared and more resilient Nation with the flexibility to successfully address a variety of public health threats. Thank you again and I look forward to your questions.

The CHAIRMAN. Thank you very much.

We have a vote at noon, so there should be ample time for all Senators to have a chance to ask their questions. We will have a 5-minute round, and I will begin.

Dr. Fauci, I am going to ask you a series of questions which are the questions I get most often asked especially by young women in Tennessee and in our family. And if, Dr. Schuchat or Dr. Robinson, you want to add to his answers, feel free to do it.

Dr. Fauci, what is the latest information on whether the Zika virus actually causes microcephaly?

Dr. FAUCI. The evidence is literally every week, Mr. Chairman, accumulating and getting stronger and stronger. Definitive proof will come from case control and cohort studies, which are ongoing right now. But if you look at work that has been done by Brazilians themselves, by the CDC together with Brazilians, looking at, for example, stillborn miscarriages, individuals who have delivered and amniotic fluid examinations, there have now been several instances in which whole virus has been actually demonstrated, at autopsy, in the brains of these babies, who have died, as well as in placenta and amniotic fluid. So while all of us are reluctant to say there is definitive evidence, it is really quite strong, and I believe that when we finish those cohort and case control studies, we will be able to say that it is definitive.

The CHAIRMAN. I have several questions here. How long should a woman wait to get pregnant if she has recently traveled to an affected area?

Dr. FAUCI. As you know and mentioned in your opening statement, about 80 percent of the infections are asymptomatic. So a woman may not know that she is infected.

The CHAIRMAN. So how long should she wait?

Dr. FAUCI. In general, we cannot give a definitive answer, but we can take a look at what we know about the virus. The virus stays in the system anywhere from 7 to 10 days, and then it is gone from the blood. It does stay in some organs in men for longer. For example, it sequesters in the serum, and there has been one case that it has been up to 62 days in the semen. And so we cannot say definitively that after, let us say, 30 days, but we are saying that in general, approximately a month is a reasonable time. But we do not want to say that with a degree of definitiveness until we actually get more data.

The CHAIRMAN. Thank you.

You mentioned semen. What about a husband who travels to an affected area and comes back? How long should a husband and wife wait before—a man and a woman wait before a woman becomes pregnant?

Dr. FAUCI. We do not know how long the virus can sequester in the serum. So in order to be completely cautious, the recommendation is that if a man comes to an area and might have been infected, even if they do not know, and comes back and has a pregnant wife or a pregnant sexual partner, to essentially use correct and consistent use of condoms for the duration of the pregnancy or else refrain from sex.

The CHAIRMAN. If a woman has traveled or a man has traveled to an affected area and comes back—let us say they come back to Nashville and they want to know whether they are infected, how do they go about getting a diagnostic test today?

Who do they call?

Dr. FAUCI. They call their health department.

The CHAIRMAN. Could I ask Dr. Schuchat that question perhaps?

Dr. FAUCI. Yes, sure. Go ahead, Anne.

Dr. SCHUCHAT. We have issued guidance to clinicians on how to test for the virus and how to send the specimen—

The CHAIRMAN. So I am in Nashville and I am a 25-year-old female and I have just been to Colombia and I come back and I want the test. Who do I call?

Dr. SCHUCHAT. You call your doctor, and your doctor can test you and send a specimen to the State or city health department. And they will either be able to do the test, because CDC has prepared them to do so, or they will forward the test on to CDC's labs for the testing.

The CHAIRMAN. But the test should be available today. So if you come back to Nashville or wherever you live, you call your doctor. I have been to Colombia. I would like to know if I have been infected with the Zika virus. The doctor calls the local public health?

Dr. SCHUCHAT. Let me clarify that currently the availability of testing is somewhat limited. We have recommended that pregnant women who are returning from affected areas should be tested between 2 and 12 weeks after they return. And yes, they should be able to get that test result.

For other people who have symptoms, we do recommend testing, but for someone who is not pregnant, who is returning from an area, we are not yet able to have sufficient testing material for them to be tested.

And it is also important to say that today's tests are not perfect. There is a PCR or a molecular test that can tell you if you are actively infected within about a week of the infection. And there is an antibody test that can tell you if you were recently infected. But that antibody test needs a second test to make sure it is right, and that second test takes a while and is in very limited supply.

So, unfortunately, we cannot help everyone today with perfect diagnostic tests. And that is one of the reasons we really need resources to—

The CHAIRMAN. I am running out. So the answer is call your doctor.

Dr. SCHUCHAT. Exactly.

The CHAIRMAN. And your doctor gets in touch with the local public health department and you go from there.

I am going to ask one last question, even though my time is up, to whomever knows the answer. If I travel to an affected area and become infected, are my young children affected by this. If I have a 1-year-old and a 4-year-old, are they affected by a mother who might have the Zika virus, or are they likely to catch the Zika virus?

Dr. SCHUCHAT. We do not think so. Right now we think that the principal way the virus is spread is through mosquito bites. We are concerned now about sexual transmission as a possible route, and yesterday we reported on additional episodes. But we do not think that a parent returning from an area needs to worry about infecting their young child.

The CHAIRMAN. Thank you very much.

Senator Murray.

Senator MURRAY. Thank you very much.

Dr. Schuchat, pregnant women, as we have been talking about, have been told to delay travel to Zika affected areas, and in some countries, women are even being told to delay their pregnancies until 2018. According to the CDC and Pan-American Health Orga-

nization, women in many of those countries face high rates of sexual violence, lack rights to reproductive health care, and have poor access to birth control.

The U.S. Government has been a global leader on this front and needs to continue to be because a strong public health demands that women do have access to the full range of reproductive health care. And it is really crucial that women have the tools to time their own pregnancies.

I wanted to ask you, does the Zika supplemental request that has been sent over address family planning and contraception?

Dr. SCHUCHAT. The Zika request addresses response to the outbreak both internationally and domestically. CDC does not provide direct services for contraception, but we are working with the Office of Population Affairs and with HRSA to make sure that the best materials can become available. CDC's role, though, is to provide guidance and the best scientific information.

Senator MURRAY. What steps are being taken to advocate for women's reproductive health care in these countries?

Dr. SCHUCHAT. The best information available is critical for women. We know that the decision to become pregnant is a personal one, and the issues around the Zika virus are quite scary. We are really trying to get the best information out there so that women and couples can do their planning. We are working across government, though, to make the resources available that can help.

Senator MURRAY. As you know, the Zika virus was reported in my home State of Washington this week. What steps can families in my State and nationwide take to protect themselves?

Dr. SCHUCHAT. The most important thing is if people are planning trips to areas where the virus is spreading through mosquitoes, that they be aware of that and they protect themselves from mosquito bites with repellent, with long sleeves, long pants, and so forth. But we also think if women are pregnant and considering travel, that they delay.

In terms of other things to know, we think it is very important for people to let their doctors know where they have traveled if they are having fever or rash or so forth. That is important not just for Zika but for other conditions.

And we think it is important for people to stay aware because things can change. Yesterday we reported new information. We will continue to do so.

We do not expect that Washington State will have large outbreaks of the Zika virus based on the way we understand it to be spread right now. But we know that about 40 million people travel back and forth to the affected areas, and so everyone really does need to know about this.

Senator MURRAY. In every State, yes.

What best practices are you recommending for hospitals and public health experts?

Dr. SCHUCHAT. Of course, it is important to take a travel history when people are ill. We think it is important for docs talking with pregnant women to make sure that they know about the travel issues and also about the sexual risk. We were surprised that there were additional episodes of sexual transmission already evident to us.

We also think that it is very important for States to be able to diagnose this, and so our effort to train and equip the laboratories around the country with the diagnostic tests so that that information would be available for clinicians—

Senator MURRAY. Are you providing those resources to local communities?

Dr. SCHUCHAT. That is what we have been doing so far, but we are going to need help to be able to scale the way it is necessary.

Senator MURRAY. Which is part of the request.

Dr. SCHUCHAT. Absolutely.

Senator MURRAY. Dr. Fauci and Dr. Robinson, as we have been talking about, Zika has been linked to some pretty serious health outcomes, but there is no treatment that exists today for pregnant women who have been infected. Correct?

Dr. FAUCI. Correct.

Senator MURRAY. I understand that in my home State of Washington, the University of Washington is partnering with the University of Texas in Kineta and are in the process of developing an antiviral treatment option to use in people who are infected. But I know we have got to do more both in response to this particular public health crisis and more broadly to ensure we know whether treatments are safe and effective.

Are NIH and BARDA working on developing antiviral treatment options that could be used with pregnant women who are infected with Zika?

Dr. FAUCI. Let me answer first, and then Robin can followup.

The answer is yes. As I mentioned on that next-to-last slide, we have screening technologies to looking at compounds that already are known to have anti-flavivirus activity and determining if in the in vitro or preclinical testing that they have activity against Zika. The next step would be going into an animal model, which is what we are trying very, very quickly to develop because one of the ways to do massive screening is to develop a small animal model like a mouse or a guinea pig for Zika and to then do that kind of preclinical testing. If something looks good there, then we will be funding the same sort of early phase 1 trials that we have done.

The important issue that I think you are aware of, Senator, is that we have a double challenge here, not only to develop an antiviral against Zika, but to have to test it in pregnant women. And whenever you have to test a drug in a pregnant woman, there is always the added safety issue that you have to be concerned about.

Senator MURRAY. Right.

Dr. Robinson.

Mr. ROBINSON. Yes, thank you.

We are actually looking at a number of drugs that were developed for other diseases—say, Ebola—with the NIH and being able to repurpose those and to see if they have activity against Zika virus and other flaviviruses. And we will move forward as the animal models are developed that Dr. Fauci talked about.

Senator MURRAY. Thank you very much.

The CHAIRMAN. Thank you, Senator Murray.

Following Senator Collins, I have Senator Warren, Senator Cassidy, Senator Baldwin, Senator Burr, Senator Murphy.

Senator Collins.

STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Schuchat, I heard today Dr. Fauci talk about the perpetual challenge that we are always going to be facing from these emerging, very troubling, and serious health threats. The last time you testified before me, I was chairman of Homeland Security, and you testified about the pandemic flu. Last year, our Nation was focused like a laser on the Ebola outbreak.

We seem to have a system where we are constantly scrambling to put together plans and emergency funding in order to counter these emerging threats. And yet, as Dr. Fauci so correctly said, they are perpetual. They are always going to be coming at us.

How can we better plan for emerging health threats so that we are not constantly scrambling to put together emergency funding packages?

Dr. SCHUCHAT. Thank you. Nature has been a worthy adversary. And influenza, of course, is the most unpredictable of all. But CDC is committed to strengthen efforts to detect, respond, and prevent emerging infections and pandemics.

The Global Health Security agenda is all about strengthening every countries' ability to do that, to be early, to find things early and prevent them spreading. We know with the Ebola epidemic, things got extremely out of control in West Africa. Had they been able to detect that earlier, it would have been a much simpler situation.

We cannot predict every single pathogen or what nature will do, but we can prepare. And the pandemic work is a great example of that where, since the mid-2000s, investments were able to help us get ready for a pandemic, and when one happened, of course, there were extra needs to produce vaccine and so forth. But the Nation was much better prepared.

But no one was expecting a birth defect to be linked to a new virus spread by mosquitoes. So we really need to look at this systematically for the long haul because we will have more threats, and we will have them at the same time. We will not be lucky enough to have one at a time.

Senator COLLINS. That is, indeed, the challenge that we all face.

Dr. Fauci, as Dr. Schuchat indicated in her testimony, the mosquito that carries the Zika virus also is a vector for diseases like dengue fever and chikungunya, if I have said it correctly. Does NIH's research into mosquito-borne viruses like dengue fever have any applicability to our finding a vaccine for Zika?

Dr. FAUCI. There are two arms of that approach about mosquitoes and vaccine. We do have a program of vector control of doing research, of being able to have innovative and novel ways to control mosquitoes. You have heard about some of these in the press about genetically modified mosquitoes infecting mosquitoes with the wolbachia bacteria, which would inhibit their ability to develop within them the virus to the point of being able to transmit it. So we do that.

With regard to vaccines, the fact that we have these flaviviruses that you have just mentioned—chikungunya is an alpha virus, a

little bit different than dengue and West Nile and Zika. But the fact that we have been studying those for a while have really given us very much of a head start in being able to use a vaccine platform that we know actually works with one which likely—no guarantee, but likely—will work with the other, which allowed me, Senator Collins, to say in my opening statement that I think we really do have a good head start on a vaccine here.

Senator COLLINS. Would any of this research translate to other vector-borne diseases like Lyme disease, which I realize is carried by ticks, not mosquitoes, but is a major problem in my State?

Dr. FAUCI. Anytime you study one particular disease, one microbe, there almost always are spin-offs of being able to use that information for the next type of a disease that you get exposed to or that you have an outbreak with. So you are absolutely right. What we do now with one vector-borne disease gives us insight not only into the transmissibility by that vector but also, if it is even slightly related to the previous one, it helps us with therapeutics and vaccines. You heard Dr. Robinson mention that when we screen for drugs, we screen for drugs that may have had activity against other viruses that we think might also have activity against Zika. So there is that crossover that you are alluding to.

Senator COLLINS. Thank you.

The CHAIRMAN. Thank you.

When you say “vector,” that means mosquito.

Dr. FAUCI. Correct.

The CHAIRMAN. Thank you.

Senator Warren.

STATEMENT OF SENATOR WARREN

Senator WARREN. Thank you, Mr. Chairman.

Each time a new disease threat appears, whether it is SARS, it is pandemic flu, MERS, Ebola, or Zika, Congress gets very interested and it holds hearings like this. But Congress does not show the same interest in taking steps before these crises occur to make sure that our country is actually prepared when disasters strike.

Dr. Fauci, your agency is the NIH's front line for studying infectious diseases. You were here not too long ago at a hearing about Ebola, and we talked about the importance of basic research.

What is your agency's budget today compared with a decade ago?

Dr. FAUCI. The budget of the NIH in general, or do you want to take NIAID?

Senator WARREN. Your agency. What is the difference in your budget?

Dr. FAUCI. The NIH budget is really not very different. We have had a flat budget over about the past 10 years. In 2016, we had the first real increase that we have had in essentially a decade. We had an over 6 percent increase. But prior to that, from the time the NIH doubling from 1998 to 2003, ended in 2003, from then until the present time, with the exception of 2016 when we got a 6 percent increase, our budget was essentially flat, which with inflation means it has gone down.

Senator WARREN. It has gone down. And as I understand it, if we did an adjustment, kind of back of the envelope, for biomedical

inflation, it has gone down by about 20 percent over that time period.

Is private industry picking up the slack doing the same kind of work that your agency does to help us better understand these emerging diseases?

Dr. FAUCI. We synergize very well with private industry, but there are things that they do not do, that will not get done unless the NIH does it. If you look at the spectrum from the development of a concept to the development of a product, what we do at NIH is the early development of a concept, early development of a product, preclinical testing, phase 1 testing, and usually the industry will then come and pick up the advanced development with the help of BARDA, which is very much that intermediate between the two.

Senator WARREN. OK, but the roles are different. Private industry does not pick this up.

Dr. FAUCI. They will never substitute for us.

Senator WARREN. The way I see this, Congress is strangling medical research. Even with the small bump in funding last year that you referred to, our investment in basic biomedical research is billions below where it would be if we just kept up with inflation, much less if we decided to increase it.

So let me ask you, Dr. Robinson. Your agency oversees Project BioShield, which was created by Congress in 2004 with 10 years of guaranteed money to make sure that this country stockpiles countermeasures against biological threats in case we need them. Do you still have guaranteed funding today?

Mr. ROBINSON. We have the annual funding that is provided, and we thank you for that very much. And we have been able to capitalize—

Senator WARREN. So you are appropriated now.

Mr. ROBINSON. Yes.

Senator WARREN. Can you explain to me what the difference is between being appropriated and how that affects your ability to plan and develop the stockpiles that we need?

Mr. ROBINSON. We actually have multiyear budgets that go 5 years into the future. And last year, you received our multiyear budget and our expert opinions as to what we needed to actually provide under Project BioShield, under the countermeasures that were ready to be bought and to be put into the stockpile. And we thank you very much for your fiscal year 2016 appropriation because that made a lot of those dreams actually come true and we acted on those in fact.

Senator WARREN. But let me make sure I understand. The consequences of being appropriated now are that you have both less money and less certainty than we gave you more than a decade ago.

Mr. ROBINSON. It is a very different paradigm, and if more funding were provided, we certainly would work with you to make more of those medical countermeasure dreams come true.

Senator WARREN. Thank you.

Dr. Schuchat, you are Deputy Director for the Center for Disease Control, which is the front line agency responsible for tracking out-

breaks and keeping us safe when they occur. Has the CDC's budget kept up with inflation over the last decade?

Dr. SCHUCHAT. Our annual appropriations have not. And I think the key for the public health agency is that we are as strong as the weakest local or State health department and the weakest international country. And so much of what we need to prepare for emerging threats is a strong front line.

Senator WARREN. Thank you.

The most effective work for keeping Americans safe does not happen when the cameras are rolling and the world is focused on the latest outbreak. The real work happens every day, the long, hard efforts to lay the scientific groundwork to prepare for the next threat. And that work requires real money. It requires new mandatory funding for the NIH. It requires more support for the development and acquisition of countermeasures by BARDA and BioShield, and it requires adequate funding for the CDC.

Hearings may be good PR, but it is time to step up and fund more medical research and more preparedness efforts. Until then, our response to the latest crisis will always be too little too late.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cassidy has deferred to Senator Burr. Thank you for that, Senator Cassidy.

Senator Burr.

STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Senator Cassidy. Thank you, Mr. Chairman.

I have a number of questions that I am not going to ask the witnesses today, but I would ask unanimous consent that I be able to submit them and they be made part of the record.

The CHAIRMAN. They will be.

[The information referred to was not available at time of print.]

Senator BURR. Thank you to all three of you.

It seems like this is becoming a more regular process where we have something unexpected. And it is really at the root of why I created BARDA, wrote the legislation, and it was enacted in 2006 so that we would be ahead of this. And Senator Warren is partially right that over time, the Congress has not funded the mechanisms that were embraced so enthusiastically in a bipartisan way at the time. And we tried to get by on the cheap with a lot of the tools that were needed to supply interest by the private sector to be a partner. So I will not ask you what failed because I think we all know the answer.

Dr. Fauci, if this virus, if Zika did not affect unborn babies and did not potentially—did not or does not protect unborn babies or paralysis, how seriously would we take the virus?

Dr. FAUCI. I think it would be honest to say, Senator, that if in fact there were no deleterious effects on pregnancy and Zika was what it is—namely a disease that is relatively mild, that is self-limiting, that has almost no mortality—I do not think there would be anywhere near the concern and attention to it that we are seeing now. It is the issue of the potential catastrophic effects on the fetuses of pregnant women who get infected. There would be a big difference in our response.

Senator BURR. And how long do you anticipate it will take to make the epidemiological conclusion that there is a direct cause and effect?

Dr. FAUCI. I think we are almost there. I think it will be a matter of months not years. I think if you look at the case control and cohort studies that are being done, more and more information is accumulating, in fact, some that is even already accumulated that is not published yet. I think over the next couple of months, you are going to be seeing much more definitive proof of that association.

Senator BURR. Let me share with you my disconnect in the process to date. Last year, we funded the special reserve fund, which is the BioShield component—or this year. Excuse me. Fiscal year 2016 at \$510 million. But the request from the Administration for next year is a \$160 million cut in the special reserve fund. We are down to \$350 million. And at a time where we have had H1N1, Ebola, and now Zika—and I might put some other things in there that, Dr. Robinson, you and I have talked about that have not materialized but we were concerned—we have reduced our capacity in funding even from the request of the Administration while I read in the supplemental request that we have expanded your role of what to look at to now include those things that may pose a threat where the original legislation said does pose a threat. Am I right, Dr. Robinson? And do you see this as an expansion of the mission that we are asking BARDA to do?

Mr. ROBINSON. I would say we are being asked to act on the emerging infectious disease portion of this and the ones that actually are known. And we have been able to develop tools that actually are able to respond, as I talked about with the National Medical Countermeasure Response Infrastructure that came directly out of the BARDA funding. We need to have more of that, that capacity to be able to respond to threats that we know about and new threats that come about. That there are threats that we have known about under Project BioShield, again as I answered to Senator Warren, if we have more funding there, there are medical countermeasures that are going to be ready to be procured.

Senator BURR. Let me just switch quickly to Dr. Fauci because I am intrigued with the West Nile platform. I consider that to be a platform that you have created, insertion of an infectious disease into a DNA. And I think most of us would agree that platform technologies are emerging at a rapid pace.

And here is my question. I think it is refreshing for members to understand that there is absolutely a need of a public-private partnership, that we cannot develop, as the Federal Government, all this, we can take it from basic research to commercialization decisions. And BARDA is, in the absence of a commercial partner for things that are crucial to our future—they are that venture capital over the “valley of death.”

In the case of where we got to with the West Nile potential countermeasure, would we be ahead and by how much had we initiated the clinical trials so that maybe we went to approval of the West Nile, then confirming the platform technology, and now we insert Zika—how would that have shortcut our process?

Dr. FAUCI. I would take it even further. I would have loved to have seen a pharmaceutical partner step forward a decade ago when we did the DNA platform for West Nile. We know that platform works. We did it in a preclinical and then a phase 1 trial. It has been very, very helpful for us now with Zika.

The other thing, when you talk about platforms, Senator Burr, is that you know the other platform is the vesicular stomatitis virus, or the VSV. We actually used that successfully with Ebola. That was one of the two vaccines that we tested with Ebola, and exactly what we are doing now is the same thing. We are taking that same vector, that same platform and sticking the Zika virus gene in there. Now we do have a pharmaceutical partner for that. We are in pretty good shape with that.

So the answer is it would have been nice if we took it to fruition, but I think the platform works. And that is the reason why I am pretty confident that we are going to be able to push this through.

The difference now and West Nile is we have several pharmaceutical partners that are now calling us up as opposed to what we were trying to do hat in hand trying to get them to partner with us.

Senator BURR. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Burr.

Senator Baldwin.

STATEMENT OF SENATOR BALDWIN

Senator BALDWIN. Thank you.

I wanted to start by sharing some of the groundbreaking research on the Zika virus that scientists are conducting at the University of Wisconsin, Madison, which I think highlights some of the public health impact of basic research. A UW research team, who were initially in South America studying drug-resistant strains of HIV, were the first to identify the Zika virus circulating in Colombia in October. And as a result, now the University of Wisconsin is conducting several NIH-supported studies to help identify immune responses to the virus, as well as the exact impact of the virus on pregnancy.

But clearly, according to what we have been talking about here this morning, there is still a lot that we do not know about this virus, even though it was discovered 50 years ago. So that continued focus on basic research and information sharing is vital. And I wanted to start on that.

The first question just relates to whether—as we first identified the Zika virus predominantly in Africa and Asia, did we see evidence there of the same links to microcephaly and perhaps also links to Guillain-Barré syndrome there? Or is that something that is different about the introduction of the Zika virus in South America?

Dr. SCHUCHAT. What we know about disease in Africa over the decade since 1947 when it was first recognized is limited, individual cases, what we call sporadic or one-at-a-time cases. And then in 2007, this outbreak in Yap happened, which was an island-wide—75 percent of people were apparently infected. But it is a very small population. So a birth defect like this might not have

been visible. People now have looked back at French Polynesia and their outbreak and realized they did have an increase in Guillain-Barre syndrome, so that that was a particular issue that had not really been recognized.

Second, the surveillance in much of Africa and the other terrible conditions that occur to babies and the high maternal and infant mortality are such that you might have had a pretty big problem and not recognized it.

We are lucky that Brazil had a strong detection system. They recognized this outbreak of Zika last spring, which was difficult because it was at the same time that they usually have dengue virus. But then many months later, they recognized this increase in microcephaly.

I do feel in the next few months we may start to see increases in microcephaly in some of these other countries, in Colombia where they are having thousands of Zika cases now, and women may be in early phases of pregnancy.

I think the ability to find this in Africa may have been limited.

Senator BALDWIN. I do have some further information sort of defining where the research agenda needs to be, the basic research agenda. But I want to leap ahead to try to get a couple of other questions on the record.

One issue is scientific data sharing. I am encouraged that both NIH and CDC have joined the more than 2 dozen government organizations worldwide in pledging to share scientific and research data related to Zika to speed up our response to the virus.

What have NIH and CDC learned from the Ebola crisis to improve that sort of scientific exchange, and what challenges do you see remaining to sharing emerging research with other research partners related to Zika?

Dr. FAUCI. We are seeing a trend now, Senator, that is in my mind a very positive trend of open access to essentially everything. In fact, some researchers are actually putting their data online even before they submit it for publication. The good news about that is that you get it right away. You have to be careful because it is not necessarily peer-reviewed. But I think the positive aspect of that, if you look now compared to, let us say, 10 years ago, the accessibility to data is infinitely better than it used to be.

I see the trend. And the signing of all of those organizations that you mentioned correctly I think is a good step to formalize and codify that pledge by everyone to have open access to data.

Senator BALDWIN. Thank you.

I see I am out of time. I will submit additional questions for the record.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Cassidy.

STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you, all three, for the good work you all are doing.

A couple things. Dr. Schuchat, the Pan-American Health Organization, the World Health Organization were kind of speaking about this as if it is a U.S. issue, which Dr. Fauci with his great work is always going to be looked to internationally. On the other hand,

frankly, Pan-American and World Health should be point on this. I do not know if you can feel honest or not, but are they being point? How has their response been?

Dr. SCHUCHAT. I think the World Health Organization has really taken to heart the critiques of the Ebola response and is being much more visible and trying to get ahead of this.

The Pan-American Health Organization is quite strong in terms of regional coordination and scientific capacity, and they have been working very intensively. We have worked together with them on laboratory workshops so that all of the countries of the Americas can be trained and ready to diagnose this virus. So I think the world is trying to be more prompt and coordinated at this point.

Senator CASSIDY. Let me ask. You mentioned in response to Senator Collins regarding the influenza, and you mentioned models of predicting flow. We all know that it starts over in Australia, China, and then sweeps. Dr. Fauci in a publication has this kind of hot spot of all these diseases that are popping up. What I am unclear about is—we know that people move from Africa, Asia, to the Pacific Islands. Anecdotally Pacific Islanders were traveling to Brazil. As sure as the sun rises in the east and sets in the west, we were going to have Zika in Brazil. It seems as if this would have been predictive with big data, with cell phone data. Where are cell phones being used from one country to the next? I have no doubt that there is a Federal agency that tracks this if only for security purposes.

Where are we coupling the kind of new movement of Fauci's chart with somebody's understanding of where people are moving in order to anticipate these as opposed to finding out about them after we start hearing terrible reports?

Dr. SCHUCHAT. Thank you.

The prediction capacities are much greater than they had been in—for example, chikungunya, another one of these mosquito-borne viruses, was not in the Americas till recently. But we predicted it was coming, and we prepared for it with diagnostic tests and outreach efforts.

The different thing with Zika is—I think we expected to get it in the Americas. We never expected the birth defect issue. The good thing, though, about our preparedness is when we went to Yap in 2007 to respond to that outbreak, our laboratory developed a diagnostic test. So when the problem emerged in South America, we already had a diagnostic test sitting on the shelf—

Senator CASSIDY. But you mentioned earlier that the dengue—I think it is dengue—and Zika actually cross-react.

Dr. SCHUCHAT. That is right.

Senator CASSIDY. So it is a test but it is a poor test if you have a broad background of dengue prevalence. Correct?

Dr. SCHUCHAT. There are two different kinds of tests. The polymerase chain reaction test is specific.

Senator CASSIDY. But more expensive and less accessible.

Dr. SCHUCHAT. No. The problem is it is only positive when you have symptoms during that 1 week.

We are working on a more specific antibody test that will help differentiate, but right now that is a problem.

Senator CASSIDY. Because one of the things that is clearly quite likely, since there is a similarity of symptoms between these different viruses, that we are overstating the intensity of the Zika relative to its actual—if we have a cross-reaction of tests, then we have a background of all these other illnesses, it is hard to imagine that we are not overstating the intensity of Zika because we are aware of it, and our tests are less specific. Fair statement?

Dr. SCHUCHAT. In the Americas, they are actually testing for all three. We know that in Colombia, for instance, there are a thousand cases of dengue right now—of chikungunya—excuse me. But then they are also seeing this big emergence of Zika. So where they have been looking, they can differentiate with the PCR right now.

Senator CASSIDY. Dr. Fauci, the NIH obviously is going to be funding this. Has NIH set up a rapid funding mechanism where, as opposed to the normal kind of several week/several month process of review, boom, the dollars are going up more quickly?

Dr. FAUCI. Thank you, Senator. That is a very good question. And what we have done is that fortunately we have a portfolio of a considerable amount of grantees and resources on flaviviruses in general. We had a number of grantees both in the United States and in Brazil and other South American countries who were grantees for dengue, other types of flaviviruses. So we supplemented their grants like that. We were able to not go through the months-long review process. We were able to do a truncated process to give them a supplement to their grants at the same time that we are putting funding opportunity announcements out to go through the normal grant process. That is the reason why we were able to jump on this very quickly.

The other thing that we did is that it so happened that our intramural research program, the Vaccine Research Center who developed the Ebola vaccine, are there intramurally. We just told them to turn around on a dime and start working on Zika, which is what they did. We had two mechanisms going that were much, much more quick than the usual grant months and months process.

Senator CASSIDY. Thank you. I will yield back.

The CHAIRMAN. Thank you, Senator Cassidy.
Senator Murphy.

STATEMENT OF SENATOR MURPHY

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

Thank you all for your work. We are lucky to have you. I think a lot of people in this country take for granted the public health infrastructure that exists nationally and at the local level. And it is often not until these crises hit and we see how other countries have a complete, often, inability to respond we understand the importance of the investments that we have made and the capabilities that we have. So let me just say thank you for your continued work.

We are coincidentally, having a hearing later today in the Appropriations Committee on the proposed foreign aid and foreign operations budget. Yesterday Secretary Kerry was before the Foreign Relations Committee, on which I sit as well, talking about the same subject.

Senator Warren was making a very persuasive and passionate case for the need for robust domestic funding to try to get ahead of these crises. But I want to have you help me make the case for why we need to have a robust international presence.

I will put the sort of very broad question to you, Dr. Schuchat. Given your experience globally in encountering systems that just do not have the capability to get out ahead of these epidemics or handle them once they arrive, what is the role of the United States and the funding that we provide to a variety of different agencies in trying to help some of these places, whether it be West Africa, whether it be South America, get to the point where we are not chasing our tail on these epidemics once they hit?

Dr. SCHUCHAT. Americans' protection relies on the capacities abroad. We know that diseases are an airplane ride away. The Ebola outbreak raised awareness, but of course, measles comes in. We have so many infections that can threaten our population without strong local capacities elsewhere.

The ability for us to respond to the Ebola outbreak in the three affected countries was challenging, a huge, huge international effort to get that under control. But it could have been so much worse had it been not contained in Nigeria. And our investments in Nigeria in polio eradication, in strengthening an emergency operations center meant that when the virus was imported into Lagos, a quick response tracking 19,000 home visits of contacts and so forth was able to put that—

Senator MURPHY. These were investments that were made prior—

Dr. SCHUCHAT. Prior investments, absolutely. So the issue of the weakest country's capacity threatens America and our ability to strengthen capacities so these countries can prevent, detect, and respond promptly keeps us all safer.

Senator MURPHY. The takeaway from the massive infusion of money that we put into Ebola is not that that is a failsafe way to attack these epidemics, that you can wait until it hits, put in a bunch of money, and you will be guaranteed to have the same success we did there, which was remarkable that in a relatively short period of time, we were able to contain that virus, in part because of a lot of money that we put up at the last minute. That is not a guarantee that that is the model that will continue to repeat itself.

Dr. SCHUCHAT. It is much better to detect, prevent, and respond early than to come in when you have a multiple-country collapse. The economic and other health consequences of Ebola were enormous. And so we already know diseases like SARS had huge economic hits on Asia. We believe the Zika virus is going to be challenging in the Americas.

Senator MURPHY. Dr. Fauci.

Dr. FAUCI. To complement what Dr. Schuchat said, is that we had been invested in flavivirus research particularly dengue and West Nile and others over a period of decades. So when we now, as I mentioned in my opening statement, jump started the work on vaccines, we never would have been able to do that had we not had what you are referring to, Senator Murphy, the decades of investment in research globally and domestically that allowed us to

move. If we were really starting from scratch now, I would never be able to come before this committee and say that I think we are going to go into phase 1 trial by the end of the summer. That would be impossible for us to do that. It was that continual support that we had over a period of decades.

Senator MURPHY. Contrary to popular opinion, we are spending less than 1 percent of our Federal budget on foreign aid, including health programs. One of my good friends on the Foreign Relations Committee yesterday made an analogy to foreign aid to charitable contributions that you may make in your town to local organizations. And of course, none of this is simply charitable. Right? We are doing it in part because we want to help people in far off lands, but we are really doing it as part and parcel of our national security strategy, which you are an integral part of. And I thank you for it.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy.
Senator Roberts.

STATEMENT OF SENATOR ROBERTS

Senator ROBERTS. Thank you, Mr. Chairman, and thanks to the panel.

Stephen Higgs, who is a doctor out at Kansas State University at the Biosecurity Research Institute out there, home of the ever-optimistic Wildcats—I was speaking with him earlier this week. He is an expert on Japanese encephalitis, which is a mosquito-borne virus, very similar to Zika. And he really made the point that Senator Burr made about the need for more basic research. How we do that with limited funds, I am not too sure, but he underscored that.

One in five people apparently develop symptoms. We cannot ignore those that do not have symptoms, however, and can still be carriers and possibly transfer the disease to others. That was sort of a stunning thing to me that somebody could be a carrier and they would not even know it.

Do we know how long individuals can serve as carriers? One study cited by CDC recently said it could be up to a week in blood and saliva. I am curious on your thoughts on how we try to manage the rather impossible problem of the virus in the population that is not exhibiting the symptoms.

Dr. SCHUCHAT. Thank you.

The information about one in five people having symptoms comes from our investigation in Yap, and it may not hold out. We are still looking at that right now.

What we know right now is that the blood contains the virus for about a week and then is cleared. But as Dr. Fauci said, some other body sites might have the virus for a longer period, and we are actually quite concerned about semen. There is a possibility of sexual transmission and we do not know yet how long the virus might be present in semen. For most people, the infection is all done after a week with or without symptoms, but that question of whether sexual transmission might occur later is what we are really concerned about right now.

Senator ROBERTS. A different subject. I understand that we have engaged with the World Health Organization to ensure availability of insect repellants, i.e., pesticides, insecticides, ET cetera, ET cetera, to address mosquitoes carrying the Zika virus. I.e., you get control hopefully first before you get into a massive amount of mosquitoes carrying this disease.

How is the CDC working with the EPA and others to ensure—and I would add in the USDA—that pesticide products are registered and available for use as tools in addressing this public health situation?

Dr. SCHUCHAT. We are working really closely with the EPA. I can say there was just a joint delegation to Puerto Rico of the CDC, HHS, and EPA to look into the issues of mosquito control there and to understand about currently registered and potential future tools. I think the EPA is quite open to work expeditiously to make sure there are products available.

Senator ROBERTS. Are we ensuring a variety of tools are available to States, towns, and even counties looking at vector control, outreach to local public health agencies, and mosquito control districts with this kind of registered pesticide—

Dr. SCHUCHAT. One of the reasons for the emergency request is that the mosquito control capacity is so variable, local area to local area, State to State. And we know that in many areas there are big holes. We do hope to be able to support local and State mosquito control groups in the kind of tracking that is needed, the evaluation, and the control efforts. It can be quite difficult to control *Aedes aegypti*, and it is even possible this virus can be spread through *Aedes albopictus*, which is in even more States than the *Aedes aegypti*. This is going to be a long-term effort, but we think that insect control is going to be very important.

Senator ROBERTS. The interesting tool that has been discussed a lot and tested in Brazil, the genetically engineered mosquito—how are we doing on that?

Dr. SCHUCHAT. There is very interesting information from very small-scale studies of the genetically modified mosquito. I was just in Brazil and there was active discussion about that. I think continued evaluation is important, and I understand that FDA is looking at proposals for pilot studies, as is the authority in Brazil.

Senator ROBERTS. Say a father was just informed by his daughter that she is pregnant, 3 months. Say they are from South Carolina now, and they enjoy going to the beach. I have been in South Carolina quite a bit. You can take the girl out of the South, but not the South out of the girl. This is my wife. My daughter has just told me she is 3 months pregnant. I would just like to ask you what advice I should give her with regard to going to the beach this summer.

Dr. SCHUCHAT. Congratulations to your daughter.

We would advise her not to travel to South America, countries where the virus is circulating and to stay aware of where we are reporting concerns. We are not expecting to need to issue travel guidance for the continental U.S. right now. If we have importation and local circulation, we are not expecting it to be large-scale. We do think that sun block is important at the beach, and of course, insect repellent at the right times of year is important. But we are

not expecting to caution your daughter about traveling to South Carolina.

Senator ROBERTS. Thank you.

The CHAIRMAN. Thank you, Senator Roberts.

Senator Bennet.

STATEMENT OF SENATOR BENNET

Senator BENNET. Thank you, Mr. Chairman.

I would like to pick up where Senator Roberts left off, which is if you could talk a little bit, Dr. Schuchat or Dr. Fauci, whomever, about what people ought to be doing to protect themselves, who should be worried, what actions can they take. And maybe for Dr. Fauci, in the absence of a vaccine—and I heard you say you are optimistic about that, which is good—what are the range of possibilities of how this disease is going to evolve in the United States?

Dr. SCHUCHAT. For the average person, the key message is to protect yourself against mosquitoes, and that involves repellent, clothing, screens, air conditioning, and travel guidance. Of course, it is the pregnant women that we have urged to avoid traveling to Zika-affected areas.

In terms of what we expect to happen, if the other two mosquito-borne viruses, dengue and chikungunya, are a guide, then what we would expect is big outbreaks in Latin America where this mosquito is quite prevalent, importation through travelers but hardly any local spread. Particularly we would be focusing on the Southern States where the *Aedes aegypti* occurs and have seen some local spread, but very small scale in the past.

But we would like to get ahead of that with good mosquito surveillance and understanding where there are hotspots and before there is a big outbreak, making sure we have mosquito populations under as good control as possible.

Senator BENNET. That is very helpful.

Dr. Fauci.

Dr. FAUCI. Just to add to that because I can almost guarantee that the first time that we do have local transmission in the continental United States, we will be sitting here in front of this committee and we will be talking about it. So on the one hand, you do not want to panic when that happens. You do not, on the other hand, want to be cavalier about it.

Our experience, as Dr. Schuchat had mentioned, with dengue and with other diseases like chikungunya is that you have a lot of travel cases because we are so proximal to the Caribbean and South America. We are already seeing that. We are going to see more of that. There will almost certainly—I would say likely—be along the Gulf coast, as we have seen with chikungunya and with dengue, small, mini local transmission outbreaks of clusters of cases. That is a high likelihood that that would happen.

How we respond to that will be very important because historically when we saw that with dengue in Texas and Florida, there was an accelerated mosquito control effort on the part of the local authorities which did not allow that mini, little cluster of local transmission to become a nationwide outbreak. The same thing happened with chikungunya in Florida. That does not mean that we are going to be very complacent and say, well, do not worry

about it, we have done it before, it is going to be OK. But we know that under the proper circumstances, you can take a mini, little cluster outbreak and not allow it to expand if you jump all over it right away. And that is exactly what Anne was talking about that the CDC and the State of Florida and the State of Texas are very well aware of what they need to do if in fact you wind up with this mini outbreak.

Senator BENNET. I want to thank you for your leadership.

My next question was about the CDC. As you know, the CDC's Division of Vector-Borne Diseases is in Fort Collins, CO. Senator Gardner and I went there last week to see what they are doing there. We appreciated very much the opportunity to visit with the people there. I wonder, Dr. Schuchat, if you could provide details about how the Division of Vector-Borne Diseases in Fort Collins is working on this and how you expect to involve them going forward.

Dr. SCHUCHAT. The division has been absolutely central. Fort Collins really houses our Zika gurus, and the leader of the entire response, Lyle Petersen, is the director of that division. They have the laboratory that developed the PCR test. They developed the antibody test. They are working on a next generation antibody test. And they have the mosquito experts who we have deployed to Puerto Rico and elsewhere to help get the best advice possible on the ground. We are really fortunate that we have people who have spent decades studying these kinds of mosquitoes and these kinds of viruses and are able to advise the Nation.

Senator BENNET. Mr. Chairman, when Senator Gardner and I were there, we were standing next to each other, and there was a mosquito that started to fly next to us. And I said "Is that a mosquito?" and the word did not even come out of my mouth before the head of the place just went—and that was it for the mosquito. So we are proud to have it in Fort Collins.

[Laughter.]

Senator FRANKEN. Did he have any blood on his hands?

[Laughter.]

Senator BENNET. I do not think so.

The CHAIRMAN. That was a vivid demonstration.

[Laughter.]

The CHAIRMAN. Thank you, Senator Bennet.

Senator Franken.

STATEMENT OF SENATOR FRANKEN

Senator FRANKEN. How did the first mosquito that had Zika—this is a theoretical question for Dr. Fauci. It is an actual question that has a theoretical idea behind it, which is how did the first mosquito get the Zika virus.

Dr. FAUCI. That is a very good question.

Senator FRANKEN. Thank you.

[Laughter.]

Dr. FAUCI. I am validating you, Senator Franken.

Actually what likely happened is that there is a reservoir, probably likely non-human primate that is the low-level animal reservoir, and that is how the first mosquito got infected because the mosquito has to get infected from some animal. It just does not primarily infect the mosquito. The mosquito is a vector. Senator Alex-

ander asked what a vector is. The mosquito is the vector of the virus. So the virus has to be somewhere for that mosquito to carry it.

Senator FRANKEN. There was an actual purpose to this theoretical question. Over three-quarters of the emerging diseases we have faced in the last century have come from an animal source. Ebola. We believe the pandemic—am I right in this—began when a young boy was infected from a bat. Is that correct? Is that what we believe?

Dr. FAUCI. We believe that.

Senator FRANKEN. The reason I was asking about where the first mosquito got the Zika virus, you are saying from a primate.

Dr. FAUCI. Likely from an animal reservoir, likely a primate.

Senator FRANKEN. While animals can be the source of an outbreak, they can also provide us with an early warning that a disease is present. Dr. Schuchat, you have experience dealing with outbreaks ranging from influenza to Ebola. In what ways can we strengthen the collaboration between scientific disciplines such as veterinarian medicine, environmental health, and human health to improve our ability to predict and respond to these infectious diseases?

Dr. SCHUCHAT. Working across disciplines, the human health and animal health, ecology, insect experts, is vital, and that is one of the ways that the CDC works, as you were just hearing about the Fort Collins group which has virologists, but also insect specialists and veterinarians, as well as epidemiologists. To respond to something like influenza, you really need expertise at that human/animal interface, and one of the things we know about our modern world is there are so many factors that put humans and animals and our ecosystems in closer proximity. So with the Zika virus, we think that humans are the principal reservoir for the mosquito bites, but with West Nile virus, they were birds and horses. And so we did have some early warning in terms of fatalities in birds. Similarly with influenza, looking at ill bird populations can be a signal that there is a new virus out there.

I think in public health and merging infectious diseases, we really recognize what is called “one health” where we try to put together the different components and work as a team.

Senator FRANKEN. That is what I wanted to get to is this emphasis on one health. Thank you for that answer.

The NIH has invested nearly \$100 million in research to understand viruses similar to Zika. This is good news because NIH can leverage existing projects to work on Zika. Yet the cost to complete product development and approval is a barrier to translating research investment into an approved product. This is especially true when the product’s profit potential is low because a disease affects a small number of patients in low-income countries.

For this reason, I have introduced a bill to add the Zika virus to list of diseases eligible to receive a priority review voucher to encourage private investment in neglected tropical diseases.

The question is for Dr. Fauci or Dr. Robinson. What are the NIH and BARDA doing to engage industry partners in the development of a vaccine or treatment for Zika, and what more can we as policy-makers do to support these efforts?

Dr. FAUCI. Thank you for that question, Senator Franken.

We are very actively involved in interacting with industry right now as we speak in the development of a Zika vaccine. In fact, as I mentioned in my opening statement, unlike what we have seen with West Nile where we had to push it to phase 1, and as it turned out, we could not find anybody to go into the next stage of advanced development, we have at least a handful of companies already who have come to us and actually asked about partnering, companies that we have dealt with in the past and some new companies that we have not.

The bridge between what we are doing and the ultimate development of the company is a very important role for BARDA. So I would ask Dr. Robinson to maybe give his perspective on that because it really is a continuum from us at the concept level, the product with the company, and then the intermediate with BARDA.

Mr. ROBINSON. Thank you, Tony.

The clinical studies actually show that it is well tolerated and it may be immunogenic for these vaccines. You still have to be able to make it and you have to be able to make it more than just on a laboratory scale. You have to be able to make it on a commercial scale. And that is where we have really focused our attentions over the past 8 years to make sure that domestically companies can be able to do that, certainly for big diseases like pandemic influenza, and for other diseases in which we are now doing the same thing for Zika. And as I mentioned in my statement, we are going to be helping a company down in Brazil, which we worked with them on pandemic influenza. Those investments actually made that facility actually be able to make a commercial scale.

So then we will have the clinical evidence that it may be efficacious. We will have the commercial manufacturing capability, and then have a real partner in industry that can go forward with it.

Senator FRANKEN. And that was the platform on the West Nile that you spoke of.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Franken. And thanks for mentioning your bill that you and Senator Isakson have introduced on adding the Zika virus to the FDA priority review voucher program. That bill will be taken up by this committee on March 9th and hopefully will be approved and a part of the Senate's companion legislation to the House's 21st Century Cures legislation, which includes the President's precision medicine initiative, hopefully support for the cancer moonshot, and other funding for NIH. So that is a timely bill.

Senator Casey.

STATEMENT OF SENATOR CASEY

Senator CASEY. Mr. Chairman, thank you.

I would ask consent to submit a statement for the record.

The CHAIRMAN. Yes, it will be accepted.

[The prepared statement of Senator Casey can be found in additional material.]

Senator CASEY. Thank you very much.

And thank you to our witnesses for your testimony and your public service and for taking our questions.

I guess one thing that I would hope would happen—this committee on a whole range of issues but maybe especially on health—or I should say preparedness and response to outbreaks like the one we are talking about—has always done that in a bipartisan way, and I hope that we can support the President’s supplemental in a bipartisan way.

I wanted to start with Dr. Schuchat and Dr. Fauci going back to the mosquito issue. I am told that there are some 20,000 pest control companies in the country. Kind of a two-part question. One is have you engaged with them or is there a way to engage them if you have not, in terms of their expertise or involvement in these mosquito control efforts? And No. 2, what is the public education part of this in terms of just informing the public?

Dr. SCHUCHAT. Yes, we have been working with the mosquito control groups out there. There is something called the American Mosquito Control Association, and they just had their annual meeting and passed through Atlanta on their way home, some of the top gurus working together with our response. We are really keen for that expertise, the 20,000-some entities out there, to be available to local and State health departments for the communities that need to get ready. We also want to make sure we are sharing the best practices of what is actually effective against the *Aedes aegypti* that carries this Zika virus.

And then we also think that there is a public role because individuals can protect themselves with behavioral change, with repellent, with screens, and air conditioning, long sleeves and so forth and with changing their travel behavior if it is necessary.

Senator CASEY. Dr. Fauci, anything on this just in terms of either engagement or public education?

Dr. FAUCI. We do not engage directly with the companies. That is predominantly what the CDC does. We interact with companies through our research on novel ways to do vector control.

Senator CASEY. I wanted to ask Dr. Robinson a question about children and in particular the challenge of developing medical countermeasures and the impact on children. We are told that the American Academy of Pediatrics published a statement on medical countermeasures for children in which they found that despite recent progress by the Federal Government, major gaps still remain related to medical countermeasures for children. And as you know and as the panel knows, children are much more vulnerable to the effects of exposure to some of the threats we have been talking about because many of the vaccines and pharmaceuticals approved for use by adults for medical countermeasures do not have the same—or do not yet, I should say, have pediatric formulations or dosing information or safety information.

I guess from the perspective of BARDA, how do you ensure that the needs of children are factored into the BARDA contracts, for example?

Mr. ROBINSON. The Pandemic Preparedness Act charged BARDA with actually special populations, including children. So as we develop vaccines and therapeutics, those formulations actually have to be part of what we do. And there are a number of examples. I

will give you one of a drug for radiation which we have called Prussian blue, and there is a huge blue pill that adults would take, but children cannot take that. So we have actually supported development of a much more children-friendly formulation for that and have been successful in doing that. Across the board, with certain vaccines, with pandemic influenza and seasonal influenza, we have supported development of those vaccines for children and had those tested.

Senator CASEY. I guess as a followup to that, what are the standards that you use to determine whether to require pediatric testing and labeling for medical countermeasures that would be used in children?

Mr. ROBINSON. The FDA really is our arbiter there and provides the guidance that we need to know what we need to do with children, if there are special studies that need to be—and we certainly work with NIH to make sure that there are models there that may simulate what would happen in pediatric animals to what you would see in pediatric populations in humans.

Senator CASEY. Thank you very much.

Thanks, Mr. Chairman.

The CHAIRMAN. Thanks, Senator Casey.

I mentioned that Senator Franken's bill and Senator Isakson's will be in our agenda for March 9. Your bill will be as well. You have a measure with Senator Burr, the Medical Countermeasure Innovation Act, which again we hope the committee will consider, approve, and make part of our 21st Century Cures legislation, which will become law this year. And I thank you for your work on that.

I apologize to Senator Scott. I got so enthusiastic talking about our March 9 markup that I forgot to call on him in order. But he will get the last word for the Senators. Senator Scott, welcome.

STATEMENT OF SENATOR SCOTT

Senator SCOTT. Thank you, Mr. Chairman, and no problems there.

Dr. Schuchat, I certainly am pleased that your answer to Senator Roberts about the safety of his daughter hanging out at the beaches in South Carolina was an affirmative. There is no issue whatsoever. So to the 25 million or so tourists who are looking to descend upon the beaches of South Carolina, please feel free to call it your home.

Thank you all for taking the time to be here this morning as well.

One of the things that we know about South Carolina is that it is in fact the home to the *Aedes* mosquito. The real question that I have—at least the first one—is what can we expect in terms of local transmission in the Southeast, and what is the CDC doing to ensure that States and communities are prepared for the possibility of a local outbreak. What does that coordination look like?

Dr. SCHUCHAT. Yes. Thirteen States have the *Aedes aegypti* present, and 31 have the *Aedes albopictus*, and both of those mosquitoes can—

Senator SCOTT. Who makes these mosquitoes, by the way.

Dr. SCHUCHAT. Good question.

Senator SCOTT. I wish they would stop.

[Laughter.]

Dr. SCHUCHAT. One of the aspects of the supplemental request is to really reinforce what needs to be done in those States to support State and local government to work across the spectrum with mosquito control, with surveillance, and lab detection, and with communication and outreach, particularly to protect pregnant women.

Senator SCOTT. One of the questions, as we think about the, hopefully, very remote possibility of anything that looks like an outbreak in the Southeast and specifically in South Carolina is that when I talk to my South Carolina officials, they specifically tell me and tell us that the mosquito in question is located in one county, whereas looking at the CDC map, it appears that perhaps it is in multiple counties. Can you talk to me about what I can share with my constituents back at home?

Dr. SCHUCHAT. Yes. This raises a key point that our maps are incomplete. And one of the key ways to control mosquitoes is to understand where they are. So part of the resources would be to really map out where the particular mosquito vector is resident. Even within a community, there can be hotspots. And we are particularly interested in—for instance, in Puerto Rico, we are interested in hotspots where pregnant women may be frequently visiting, not just their homes but the places they go.

Senator SCOTT. Thank you, ma'am.

And for anyone on the panel, are you looking into potential mitigating factors regarding the severity of the microcephaly? In the absence of therapeutics, is there any evidence that prenatal care, nutrition, vitamins could have any effect on the severity of the microcephaly and babies born to women that contract Zika? That is the first question.

The followup question is, is there any hypothesis as to why some babies develop microcephaly and others do not, once infected?

Dr. SCHUCHAT. Those are really important questions, and the focus of the study that we are doing right now in Brazil looking at women whose babies developed microcephaly and other women who were pregnant around the same time from the same communities whose babies were OK. We also do not know yet the full spectrum. It may be that microcephaly is one of the factors that this virus can cause, but that there are other parts of the spectrum. There may be milder disease or eye disease or other congenital defects. And we do not know about cofactors, as you mentioned, nutrition. People wonder about a number of things. So we are asking those questions, together with our Brazilian counterparts, to try to understand that.

I think the most critical thing we would like to be able to learn is what the risk is, that if you do have Zika virus during pregnancy at different stages, what are the chances you will have a normal baby, what are the chances your baby will have one, two, or three other problems, and whether early detection can do anything to improve the health of the child.

Dr. FAUCI. This creates a very good segue into one of the questions that we just asked, Senator Scott, about research that you do ahead of time as opposed to just in an emergency response. The

National Institute of Child Health and Human Development for years has partnered with Brazilian colleagues in prenatal centers doing research on ante-natal issues, not necessarily microcephaly because that had not been the target. But your question is highly relevant because there are so many issues that we still do not understand, as Dr. Schuchat said.

It would be really unusual for a virus that causes congenital abnormalities to have only one specific effect, namely microcephaly. We are anticipating that as we study more, we are going to see other things that maybe microcephaly is the predominant one. We are already seeing a considerable amount of eye involvement that has already recently been reported. We expect that we will continue to learn as time goes on.

Senator SCOTT. Anything to add, Dr. Robinson?

Mr. ROBINSON. No. I think they have captured it very well. Thank you.

Senator SCOTT. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Scott.

And thanks to the three of you. As I listened to all of this—see if this is right. It sounds to me like a vaccine—that we will be able to create a vaccine for this virus. Is that right, Dr. Fauci?

Dr. FAUCI. You never guarantee, but I feel pretty confident that we will only on the basis of the fact that we have done it for related viruses like dengue.

The CHAIRMAN. So your level of confidence is high.

Dr. FAUCI. It is high, yes.

The CHAIRMAN. It is high that you will be able to create a vaccine.

And it sounds like the level of confidence is high that you will be able to create the vaccine sometime in 2017.

Dr. FAUCI. That is going to depend, Senator—and that is a very important question because if you look at the standard way of dotting all the I's and crossing all the T's, vaccine like this would generally take 3 to 5 years.

The CHAIRMAN. Right.

Dr. FAUCI. The reason I said 2017 is if we start the phase 1 trial in the summer of 2016, it ends at the end of 2016. If the epidemic is still raging in South America, we could go into an advanced phase 2A/2B trial, and if in fact you have a lot of cases, you may be able to prove efficacy in 6 to 8 months, which would bring you right through 2017.

The CHAIRMAN. So it depends on there being a lot of cases so that you can prove that it is effective.

Dr. FAUCI. Precisely. And that is the reason we were stymied somewhat with Ebola in West Africa because we had a promising vaccine, and as the trial was getting going, the cases, because of good public health activities, started to come down. But if in 2017 we are in the middle of a massive outbreak, that is unfortunate for the countries, but that would be the perfect scenario to be able to prove or not the efficacy of a vaccine.

The CHAIRMAN. Well, the same for safety.

Dr. FAUCI. Safety, same thing, the same exact thing.

The CHAIRMAN. The same amount of time.

But do you not already have an epidemic in Puerto Rico, for example? Do you not have a lot of cases in Puerto Rico?

Dr. FAUCI. I know, but we are not ready for phase 2A/2B. That is the point.

The CHAIRMAN. If you were. I mean, if we get to January—

Dr. FAUCI. If the situation in the beginning of 2017 is the way it is now in South America and in Puerto Rico, we will have enough cases to pretty expeditiously prove the safety, efficacy or not.

The CHAIRMAN. Then we are talking 6 to 8 months.

Dr. FAUCI. Following the beginning of a phase 2B trial into 2017.

The CHAIRMAN. Into 2017. And if there is this number of cases, you have, I believe you said, manufacturers knocking on your door?

Dr. FAUCI. Right.

The CHAIRMAN. There should be a private sector interest to produce enough vaccine.

Dr. FAUCI. There will be.

The CHAIRMAN. Under those circumstances, by the end of 2017, the chances are—and I will use my words—sounds like they are good that we may have—that we could have a vaccine if those circumstances—

Dr. FAUCI. If those circumstances play out the way we have just described them, there is that possibility and likelihood that we would.

The CHAIRMAN. Would you also not say that given the uncertainty about this disease and the dramatic nature of the birth defect associated with it, that if we have such a vaccine by the end of 2017, that most young women who may become pregnant will want to take the vaccine?

Dr. FAUCI. I believe it depends on where you live. I believe that it would be a situation similar to what we saw with rubella. In the early 1960s, we averaged about 20,000 cases of congenital rubella syndrome in women who were infected during pregnancy. When we developed the rubella vaccine back in the 1960s, although it was for everyone—and it is one of the required vaccines—it was fundamentally developed for women of child-bearing age. So I would think that if you have an endemic or, as you said, essentially baseline level of Zika that indeed is causing congenital abnormalities in countries like Brazil, I believe that that would be a vaccine that would be highly desirable for women of child-bearing age.

The CHAIRMAN. And based upon your continued monitoring of sexual transmission, it may be a vaccine that men of those women who are partners—

Dr. FAUCI. Quite possibly, yes.

The CHAIRMAN [continuing]. Would want to take. There may be women and men in the southern most part of the United States who want to take that vaccine as well. I mean, we have areas—

Dr. FAUCI. I think that would depend on whether we have local outbreak. I would not foresee in the United States, if we do not have endemic Zika infection, that this would be something for the United States. But I would ask Dr. Schuchat to comment.

The CHAIRMAN. Dr. Schuchat, any comment?

Dr. SCHUCHAT. I think the issue of travelers is important, and so we do have many vaccines that are recommended for travelers.

And this might end up being one of them. If we do not end up with a big Zika problem here in the continental United States, folks who are planning trips might want to—

The CHAIRMAN. In the way that if we go to Africa, we take a malaria—

Dr. FAUCI. Or a yellow fever vaccine. When we all went to West Africa during the Ebola outbreak, we all had to show that we had been vaccinated for yellow fever.

The CHAIRMAN. So this would fall into a category that we are really familiar with, which is that we look for travelers. We identify parts of the world where there may be outbreaks of certain diseases and you recommend certain vaccines. So that is nothing new. We have done that for years.

Dr. FAUCI. Indeed. That is correct.

The CHAIRMAN. And travelers have safely gone to other places and come back. I mean, tens of millions of people have done that.

Dr. FAUCI. Yes, exactly.

The CHAIRMAN. This has been a very helpful hearing. There is a great amount of interest in it. I thank all three of you for the contributions that your agencies play to this. And I know that the CDC website is probably—Dr. Schuchat, if one has questions, the place to go is probably the CDC website. Is that right?

Dr. SCHUCHAT. Yes, CDC.gov.

The CHAIRMAN. CDC.gov.

Dr. Fauci, would you agree with that or is there another place to go?

Dr. FAUCI. I use it every day.

The CHAIRMAN. So if you want to know what to do, if you want to find out about diagnostic tests, if you want to know where you might travel, if you have other questions, the CDC website is the place to go.

The hearing record will remain open for 10 days. Members may submit additional information for the record within that time, if they would like.

The HELP Committee will continue its step-by-step innovation process on Wednesday, March 9, when we will consider bipartisan legislation, including two bills directly related to today's discussion on the Zika virus—I just mentioned it earlier—the Adding Zika Virus to the FDA Priority Review Voucher Program act, sponsored by Senators Franken and Isakson, and the Medical Countermeasures Innovation Act, sponsored by Senators Burr and Casey. As I mentioned earlier, these are part of what we hope to become the Senate's companion legislation to the House-passed 21st Century Cures. We will have a final markup for those measures in the first week of April, and hopefully they all add up to a substantial package.

Then we will have to have a discussion about funding, on which there is not bipartisan agreement in the committee right now. But I think we can get there when we go to the floor. So my expectation is that we will have bipartisan agreement on a package that may include as many as 45 or 50 measures ready by the first week of April, including the two I mentioned that are related to Zika, and that we will have a separate bipartisan agreement on funding that will be bipartisan. We cannot work that out in committee, but we

can work it out on the floor. And if we take both those pieces of legislation to Senator McConnell, say the House has already passed their version, and that the President support precision medicine and cancer moonshot parts especially, I think we have a very good chance of turning that legislation into law.

Thank you very much for your time today.

The committee will stand adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR CASEY

Thank you, Chairman Alexander and Ranking Member Murray, for calling this important hearing today. Senator Burr and I have worked together on public health preparedness issues for several years now, and I am grateful for his work and for the committee's tradition of bipartisan work on issues relating to public health preparedness.

As we have seen in the last several years, we face a continually evolving public health situation. From novel flu strains to Ebola, dengue to chikungunya, MERS and beyond, we have seen emerging infectious diseases affect communities across the globe. These emerging infections highlight the interconnectedness of the global economy in which we live, and the fact that many of these infectious diseases are only a plane ride away.

In some respects, we have made great progress in building our capacity to respond to these new threats; in other ways, we have much further to go to achieve the optimal level of preparedness. Ebola was a wake-up call: a disease that we had known about for decades suddenly reemerged and began spreading rapidly. Thousands of people died, and our partners in West Africa are in their (hopefully) final few weeks of monitoring to confirm that local transmission of the disease has ceased and the outbreak is over. This effort has taken over 2 years.

With Zika, we face an unusual and disturbing threat that is distinct from Ebola. While the Zika virus itself appears to cause no illness in the majority of people infected, and only moderate illness in the remainder, it has been linked to severe complications such as Guillain-Barré Syndrome in some individuals. Of greatest concern, however, is the increasing evidence that Zika can be devastating to the unborn children of pregnant women who are infected, causing microcephaly. Thus, while we are still dealing with a global response to the threat, the nature of the threat and the necessary response is quite different.

As we continue to learn more about this virus and its potential consequences, I will reiterate what I said in the early days of the Ebola virus: we should listen to medical experts, such as the ones we have here today, and be sure that we are making policy decisions based on sound science and the best medical evidence available.

I look forward to hearing from our witnesses here today about the current state of our response to the Zika virus, and what steps we need to take moving forward, including moving forward on the President's emergency supplemental funding request, which I believe we should pass so that the Federal Government has the resources it needs to respond to the threat posed by Zika.

But looking beyond Zika, we must also think about what the next virus will be, and the next, and the one after that. Are we prepared? What more do we need to do so that our public health workers are prepared for each new threat before it emerges?

STATEMENT SUBMITTED BY SENATOR MURRAY

OPEN STATEMENT ON ZIKA VIRUS

As organizations supportive of a robust and comprehensive public health response to the rapid spread of Zika virus in the Latin America and Caribbean region, we write to express our support for efforts by the U.S. Government to provide resources to aid in the global response to this international public health emergency. The spread of Zika virus, and the particular health risks it may pose to women who are pregnant or may become pregnant, highlights significant gaps in access to reproductive health care in the Latin America and Caribbean region.

We call on the U.S. Government response to Zika virus to include comprehensive reproductive, maternal, and child health services through bilateral programs as well as through contributions to UNFPA. In order to support women in making and carrying out decisions about their health, this must specifically include access to family planning information, education, services, and contraceptive commodities including emergency contraception. It must also provide maternal and child health services to support healthy pregnancy outcomes and families with children who have microcephaly. In particular, UNFPA, with a presence in over 40 countries in the region, is best equipped to provide these services immediately to the communities most in need with additional support from the U.S. Government and in coordination with the World Health Organization and Pan-American Health Organization.

We know there is still much to learn about Zika virus and the response will be complex and require coordination at the global, regional, and national levels. While the response to Zika virus may evolve, one thing is clear: the U.S. Government must prioritize access to comprehensive reproductive and maternal health care services in its response to meet the needs of women and families during this health emergency and beyond.

Advocates for Youth; American College of Obstetricians and Gynecologists; Better World Campaign; Center for Health and Gender Equity (CHANGE); Center for Reproductive Rights; Institute for Science and Human Values; International Center for Research on Women; International Women's Convocation; International Women's Health Coalition; Ipas; NARAL Pro-Choice America; National Abortion Federation; National Council of Jewish Women; National Latina Institute for Reproductive Health; National Network of Abortion Funds; National Organization for Women; National Women's Health Network; PAI; Pathfinder International; Physicians for Reproductive Health; Planned Parenthood Federation of America; Population Connection Action Fund; Population Institute; Religious Institute; Reproductive Health Technologies Project; Sexuality Information and Education Council of the U.S. (SIECUS); Sierra Club; Universal Access Project; National Women's Law Center.

[Editor's Note: UNFPA—United Nations Population Fund, formerly the United Nations Fund for Population Activities.]

[Whereupon, at 11:56 a.m., the hearing was adjourned.]