

ZIKA IN THE WESTERN HEMISPHERE: RISKS AND RESPONSE

HEARING

BEFORE THE

SUBCOMMITTEE ON WESTERN
HEMISPHERE, TRANSNATIONAL CRIME,
DEMOCRACY, CIVILIAN SECURITY, HUMAN
RIGHTS, AND GLOBAL WOMEN'S ISSUES
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ZIKA IN THE WESTERN HEMISPHERE: RISKS AND RESPONSE

WEDNESDAY, July 13, 2016

U.S. SENATE,
SUBCOMMITTEE ON WESTERN HEMISPHERE,
TRANSNATIONAL CRIME, CIVILIAN SECURITY, DEMOCRACY,
HUMAN RIGHTS, AND GLOBAL WOMEN'S ISSUES,
COMMITTEE ON FOREIGN RELATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:54 p.m., in Room SD-419, Dirksen Senate Office Building, Hon. Marco Rubio, chairman of the subcommittee, presiding.

Present: Senators Rubio [presiding], Gardner, Isakson, Boxer, Kaine, Udall, and Markey.

OPENING STATEMENT OF HON. MARCO RUBIO, U.S. SENATOR FROM FLORIDA

Senator RUBIO. Thank you. Good afternoon. And today's hearing on the Subcommittee on Western Hemisphere, Transnational Crime, Civilian Security, Democracy, Human Rights, and Global Women's Issues will come to order. And I thank all of you for being here today.

The title of this hearing is Zika in the Western Hemisphere: Risks and Responses. We will have three witnesses: Ms. Judith Garber, the Acting Assistant Secretary, Bureau of Oceans and International Environmental and Scientific Affairs at the U.S. Department of State; Dr. Tom Frieden, Director of the Centers for Disease Control and Prevention; and Ms. Irene Koek, the Acting Deputy Assistant Administrator of the U.S. Agency for International Development.

We thank you all for being here today. We apologize for starting late. We—the Senate gods decided to schedule a vote right as the time we were supposed to begin. But we appreciate your time and your dedication.

And I would also like to thank all of those who worked alongside my staff to make this hearing possible.

Today, we face an issue that is already affecting many countries in our hemisphere, including our own. It is not partisan in nature. The growing threat of the Zika virus as a full-blown public-health crisis in the United States is a clear call to action.

Just look at statistics. As of July, 65 countries and territories have reported evidence of vector-borne Zika virus transmission. What is even more troubling is the fact that four countries are clas-

sified as having possible endemic transmission or have reported evidence of local vector-borne Zika infections in 2016.

As much as Zika remains a threat on the international stage, it also poses a real and timely threat to our country. That means, in these countries, a disease that has already spread rapidly and made its way into the population. We are seeing this, as well, is the island of Puerto Rico. And Puerto Ricans, as you all are well aware, are American citizens, and Puerto Rico is an American territory. According to the statistics from the World Health Organization, the United States is one of 11 countries with evidence of person-to-person transmission of the Zika virus. That means that our neighbors, our friends, our families are already at risk, even without mosquito-borne transmission, though that is likely coming, as well.

As the threat of the virus continues to grow here, I will continue to state the importance of moving quickly in response. I strongly believe that inaction on Zika is simply inexcusable, and I am optimistic that, after reviewing the facts and hearing from the experts here today, it will reinforce this fact and the fact that something needs to happen quickly. It has taken far too long already. The effects of the Zika virus are alarming, to say the least. Pregnant women or women who have become pregnant have contracted the virus and are at risk of having babies with microcephaly.

For those not familiar with microcephaly, it is a birth defect that causes severe neurological abnormalities, which can include small, deformed head. This has a permanent and severely detrimental impact on the development of the baby's neurological system and quality of life. Those born with microcephaly may experience seizures, intellectual disabilities, hearing and vision loss, as well as a number of other horrific symptoms.

It is our responsibility to the American people to take action when public health is in jeopardy. Although the mainland of the United States may not be worried about Zika right now, there are already 1,133 cases, and they are found in 45 out of 50 States. Just last week, the CDC reported that they are currently monitoring, in the United States, 320 cases of Zika in pregnant women.

The CDC Director, who joins us here today, called Zika a "silent epidemic." As of now, many predicted what would happen in the summer. The spread of the virus is now accelerating. The Friday before last, Federal health officials confirmed the largest number of new Zika infections in a single day in the State of Florida, with 10 new cases. That was a short-lived record. It was broken last Wednesday, when Florida confirmed 11 new Zika infections, that time in six counties, including Lake County, Florida, which had never had a case before. That record was broken again on Monday of this week, when 13 new infections were reported. And so, you get the idea. The problem is not—is only going to continue to accelerate.

This is not the first time I have spoken on the growing threat of Zika. In late January of this year, as I was somewhere outside of Florida, I saw a headline in the New York Times that stopped me in my tracks. It said, "Report of Zika-Linked Birth Defects Rise in Brazil." The article went on to say, "The health authorities in Brazil said, Wednesday, that reported cases of microcephaly, a rare

condition in which infants are born with abnormally small heads, had climbed to 4,180 cases since October, a 7-percent increase from the previous tally last week.” And it stopped me in my tracks, for a number of reasons. First was the staggering number and the breakneck speed with which the disease was spreading over just the course of a week. But it also made me pause because, for those of us who live in South Florida and travel through Miami International Airport, we know very well what happens in—we know very well that what happens in Brazil impacts us in the United States, especially in Florida.

A couple of days after that, I reached out to the U.S. Customs and Border Protection to express my concerns, and asked what they were doing, or could do, about this, given Miami International Airport’s standing as the Gateway to the Americas, with more flights and passengers going to and from Brazil than any other U.S. airport.

Here on the Senate floor and back home in my State, I have called for action from my colleagues. I urged support for fully funding the President’s funding request to deal with this virus. I have supported every single Zika proposal that has come before the Senate. Every single one. But nothing has gotten done. The problem is only getting worse.

It is our duty to act now, while we can still get ahead of this disease and before it is simply too late. I believe the Congress has a constitutional responsibility and a moral obligation to confront the Zika virus. It is my hope that today’s hearing will further call attention to the seriousness of this situation and what more we can do in the western hemisphere to help fight it. This challenge we face is emblematic of how interconnected we are as a country with our neighbors. In this global economy, public health crisis do not respect international borders. The negative impacts of these problems, from the economy to political instability, can easily impact us here at home.

The links between our country, especially Florida, and other nations of the western hemisphere are obvious. I have already covered Brazil, but, for example, the first baby born in Florida with Zika-related microcephaly was a mother who came from Haiti. Last month, Time reported that 12,000 pregnant Colombia women have Zika. The Zika virus is already a U.S. public health emergency. The problem is even worse in Latin America. It is only growing by the day. And the links between our nations make this a hemispheric public health crisis, where, once again, American ingenuity and innovation in the medical sciences must lead the way if we are to help save lives, including countless unborn children.

We must begin to meet the Zika virus with a sense of urgency that we have not seen up to now. Listen to the experts from around. It is time to act—it is time to enact serious solutions.

I am proud to stand as an advocate for any legislation that would provide funding to combat Zika as soon as possible. And we cannot rest until we have taken action in order to ensure the safety and health of the American public.

Thank you.

With that, I recognize our ranking member, Senator Boxer.

**STATEMENT OF HON. BARBARA BOXER,
U.S. SENATOR FROM CALIFORNIA**

Senator BOXER. Thank you so much, Mr. Chairman, for this hearing.

Thank you, to our witnesses, our guests.

Few issues pose as immediate a threat to the health of Americans as the Zika virus. The virus has caused severe birth defects in thousands of newborns. These birth defects include brain damage, blindness. They are devastating to mothers, to families, to communities. In some cases, we have seen the premature death of children.

The Zika virus has caused a rare disorder in adults in which the body attacks its own nervous system, causing paralysis. The Zika virus is also linked with another autoimmune disorder that resembles multiple sclerosis, which causes swelling in the brain and the spinal cord. We only have to listen to public health experts to get a clear sense of the virus's danger.

The World Health Organization has said that the Zika virus is, "spreading explosively." in the Americas and threatens to overwhelm almost every country in the western hemisphere. The Center for Disease Control and Prevention has said the virus is, "scarier than we originally thought."

The Zika virus is already here in the continental United States. Over 1,000 people have already contracted the virus through travel or sexual conduct. And as the disease travels northward from that Latin America and the Caribbean, up to 30 States are in danger of local outbreaks from mosquitos carrying the virus. Thirty States. This includes California and the Chairman's home State of Florida. In short, we need to act now. It is a real threat, and it is dangerous.

Now, here is the great news. The great news is, the Senate had bipartisan legislation, which is what you have when you have an outbreak like this. It was proposed by Senators Blunt and Murray. It provided the administration with less than they wanted, but, nonetheless, \$1.1 billion. When the President requested \$1.9 billion, the two Senators negotiated, and the best they could come up with was \$1.1 billion. But the compromise would have gone a long way without having poison pills and ridiculous riders that are dangerous to the American people included in the legislation. What happened to that bill, that wonderful bill that my Chairman voted for, that I voted for, that we all voted for? It disappeared down the black hole of partisanship.

The Republicans in the House had a conference, and they did not allow any Democrats into that conference. Not Senator Mikulski, a woman who we revere around here on both sides. Not Senator Murray, who has worked across the aisle on so many issues. No. They left them out. And you know what they came out with? A bill that actually restricts funding for birth control in the United States and in Puerto Rico, even though they know—they know that Zika can be transmitted sexually, and birth control should not be controversial, and it is part of the first line of defense. There is no room for politics in this.

Listen. The report also overrides the Clean Water Act. And I know about this, because I am the ranking member on the Envi-

ronment and Public Works Committee, and was Chairman of that committee. A landmark law that was passed by Republicans and Democrats. It overrides it. It allows the uncontrolled pesticide spraying near water supplies that we drink out of and our children swim in. Pesticides that could poison our people.

Now, you may say, "This is an emergency. Should we not be able to spray?" The answer is, under the Clean Water Act, you can. You do not even need to get a permit. The Clean Water Act understands this. It is a brilliant piece of legislation. And it says, "In an emergency, you do not need to get a permit. Go ahead and spray. Spray the amounts necessary off the approved list, and just notify the EPA—just notify the EPA." —Well, that was not good enough for my friends over there. They completely take away that whole section of the Clean Water Act. And that means that there is no more right to know if somebody goes next to your house and sprays some horrible pesticide that causes cancer, that is not on the approved list. You have no way of knowing that has happened. And the Clean Water Act is smart. Once the emergency is over, they sit down with the local agency, and they figure out a way to maintain it.

Here we have a circumstance where the House Republicans, without any consultation with anybody, completely eviscerate the Clean Water Act. so you may not get the Zika, but your kid could get cancer from swimming in water that is laden with a pesticide that is very harmful. Where is that sensible? You cannot just say—I am speaking for myself—I cannot say I am going to vote for any bill, because what if the bill does as much harm as it does good? We are legislators. We have to be careful what we do, what we vote for.

They took out the possibility for nonprofits to do birth control, which is the first line of defense against this Zika. They completely eviscerated the Clean Water Act, which makes it dangerous for our people. They even put something in there about the Confederate flag, which my colleague Senator Kaine understands, was explaining to me. He can do a better job of explaining it. But essentially, it overrode another bill, where we said you cannot fly the flag in veteran cemeteries. They did away with it. In the Zika bill.

It is discouraging. And I call on all of us who voted for that bipartisan bill—and it is all of us here, as—far as I know—bring back that bill, keep out the bad stuff. Let us get it done. It is bad enough they cut funding for Ebola. That thing could rise up again. That is horrible. But these things are added, if you will, insults to the no—to the American people thinking that we are doing something good, when we are doing some bad things, as well.

I just wanted to say quickly, in closing, I am so disgusted with the situation, as we all are, every one of us—we do not know how we got here. It just got here. So I am hoping we can do something different in the future, Mr. Chairman. And I have written legislation. It would create a \$3 billion emergency public-health fund, kind of like FEMA—kind of like FEMA—where it would be within the Department of HHS and allow the CDC and HHS to use those funds to address global health threats. And it would allow them to go in, they would notify Congress. We could overrule them if we did

not like it. But we would not put politics in the middle of this thing.

I am, you could see, a little worked up. And I apologize. Maybe I am a little too worked up. But I share my friend the Chairman's view on this Zika thing. We are sitting on this, and we have to get off sitting on it and do something about it.

Thank you.

Senator RUBIO. Thank you, Senator Boxer.

Let—we will begin with our testimony.

Ms. Garber—Assistant Secretary Garber.

STATEMENT OF HON. JUDITH G. GARBER, ACTING ASSISTANT SECRETARY, BUREAU OF OCEANS AND INTERNATIONAL ENVIRONMENTAL AND SCIENTIFIC AFFAIRS, U.S. DEPARTMENT OF STATE, WASHINGTON, DC

Ambassador GARBER. Thank you, Chairman Rubio, Ranking Member Boxer, and distinguished members of the subcommittee. We really appreciate the opportunity to testify today on the State Department's response to the Zika virus outbreak.

I have a longer statement that I would like to submit, with your permission.

With regard to the current situation, 40 countries and territories in the western hemisphere are experiencing active mosquito-borne transmission of the Zika virus. Several countries and territories in Africa and Asia are also experiencing outbreaks for the first time.

Since this epidemic began, science and medical experts, my colleague Dr. Frieden foremost amongst them, have discovered the truly heart-wrenching impacts that this virus can have on its victims, and particularly on developing fetuses.

As you mentioned, Mr. Chairman, this is a silent outbreak. We do not see hospitals full of ill patients or hear ambulance sirens in the street. Across the hemisphere, pregnant women and their partners are living in fear, fear that their child may be born with severe developmental defects.

In addition to the tremendous emotional and health toll of this epidemic on families and communities, the demographic and economic consequences are still emerging. The cost of lifetime support for children affected by Zika as well as adults experiencing Guillain-Barre syndrome or other neurological effects could significantly tax national health and education systems. Areas with high poverty levels and dense population are most vulnerable to Zika, but least able to manage the consequences.

The U.S. Government is committed to helping prevent, detect, and respond to the Zika virus, both at home and abroad. Countries around the world look to the United States as a leader in global health security, and we are working with countries in the Americas and beyond to provide tailored support.

Many countries in the region have governments and strong public health systems capable of mounting a response to Zika. Countries such as Brazil, Panama, and Colombia host respected research institutions with which we are partnering to learn more about the virus and develop countermeasures. Through regional institutions such as the Pan American Health Organization and the Organization of American States, the U.S. Government and our

neighbors are leveraging our collective expertise to share best practices and identify innovative tools for vector control and disease diagnosis. In countries such as Haiti, El Salvador, Guatemala, Honduras, and the Dominican Republic, the United States is providing more direct assistance to effectively respond to the Zika virus threat. Our embassies are working closely with these governments and international organizations such as the World Health Organization to identify capacity gaps and prioritize assistance.

U.S. voluntary contributions and other support to our regional and multilateral partners enable us to leverage U.S. funding and amplify the impact of our efforts. In addition, public/private-sector partners can help respond where—in areas where the U.S. Government has limited access or resources. And today at the State Department, we hosted an excellent public-private partnership event on just this topic.

The State Department is committed to protecting the safety and security of all U.S. citizens. This also means working with other governments to attack the Zika virus outbreak at its source. By cooperating with other countries on Zika public-health emergency response and planning, we help build a stronger global response to protect U.S. citizens and the international community while contributing to international stability. If we can control an infectious outbreak quickly, either at home or abroad, we help limit its impact on U.S. citizens.

So we are working with other governments to increase surveillance and diagnostic capacity, to scale up vector control, and to cut off the transmission cycle. We are pushing out across multiple platforms the information needed for our citizens and nationals to make informed travel decisions and to help to protect them from contracting Zika while overseas on the basis of CDC guidance. This is particularly true in the case of the Olympics in Brazil, where we expect over 100,000 U.S. citizens to attend. And Brazil is working very hard to protect the health and safety of all athletes and spectators attending the Olympics and Paralympics, including through its own public awareness campaigns and vector-control efforts.

Zika, like Ebola before it, has highlighted how interconnected we are as a global community. We have a window of opportunity to address the urgent needs now, before we put at—we are put at further risk, by working with our international partners and reaffirming leadership in the region. As Secretary Kerry said at the Global Health Security Agenda Summit in 2014, in an interconnected world, we invest in global health, not simply as a matter of charity or as a matter of moral responsibility, but we do it as a matter of national security.

Thank you for your consideration, and I welcome the opportunity to answer any questions you may have.

[Ambassador Garber's prepared statement follows:]

PREPARED STATEMENT OF JUDITH G. GARBER

Chairman Rubio, Ranking Member Boxer, and distinguished Members of the Subcommittee, thank you for the opportunity to testify today on the international Zika virus outbreak response and the U.S. Department of State's contribution to those efforts.

Forty countries and territories in the Western Hemisphere, including the Commonwealth of Puerto Rico and the U.S. Virgin Islands, are currently experiencing

active, mosquito-borne transmission of the Zika virus. Several countries and territories in Africa and Asia are also experiencing outbreaks for the first time, including outbreaks of the epidemic strain circulating in the Americas. It is likely only a matter of time before we experience local transmission in the continental United States and Hawaii as well.

In the short time since this epidemic began, international science and medical experts—my colleague Dr. Frieden foremost amongst them—have sought to understand the truly devastating impacts that this virus can have on its victims, and particularly on developing fetuses. It will be years before we know the full extent of what physicians are now calling “Congenital Zika Syndrome.”

IMPACTS ON THE WESTERN HEMISPHERE

This is a silent outbreak: We do not see hospitals full of ill patients or ambulances in the streets, but across the hemisphere, pregnant women and their partners are living in fear—fear that their child may be born with severe developmental defects, fear that they cannot do enough to protect their families, and fear that they will be unable to financially care for a child suffering from Congenital Zika Syndrome. The Brazilian government has reported a surge in children born with microcephaly or other central nervous system defects; many more could be affected across Central and South America and the Caribbean this summer.

In addition to the tremendous emotional and health toll this epidemic has had on families and communities, the demographic and economic consequences are still emerging. In the longer term, the cost of lifetime support for children affected by Zika as well as adults experiencing Guillain-Barré Syndrome or other neurological effects could significantly tax national health and educational systems. Areas with high poverty levels and dense population are most vulnerable to Zika infection, but also least able to manage the consequences. Even with government assistance, affected families, and particularly women, may face economic hardship.

MITIGATING THE CONSEQUENCES OF THE OUTBREAK

Countries around the world look to the United States as a leader in global health security, and we are working with countries in the Americas and other international partners to provide targeted, customized support to those affected or threatened by the virus.

As a result of strong development progress in the region in recent decades, countries have strong public health systems and governments capable of mounting a response to Zika. Countries such as Brazil, Panama, and Colombia host respected research institutions with which we are partnering to learn more about the virus and develop countermeasures. Yet the ubiquity of the mosquito vector and its resilience against traditional vector control methods poses a tremendous challenge to governments and international organizations seeking to contain the outbreak. Through regional institutions such as the Pan-American Health Organization (PAHO), the Organization of American States (OAS), the Caribbean Public Health Agency (CARPHA), and the Inter-American Development Bank (IDB), the U.S. government and our neighbors are leveraging our collective expertise to share best practices, define priorities, and identify innovative tools for vector control and disease diagnosis.

Other countries such as Haiti, El Salvador, Guatemala, Honduras, and the Dominican Republic will benefit from more direct assistance to effectively respond to the Zika virus threat and help prevent congenital infection. This includes capacity building and training for vector control, support for social and behavior change communication, support for family planning and maternal and child health interventions and services delivery, surveillance, disease detection, and monitoring and evaluation. Our embassies are working with these governments and international organizations to identify key capacity gaps and prioritize assistance.

U.S. voluntary contributions and cooperation with the World Health Organization and other multilateral partners also stimulates global donors and amplifies the impact of our efforts. Crucially, multilateral, non-governmental, and private sector organizations can help extend response efforts to areas where the U.S. government has limited access or resources.

PROTECTING U.S. CITIZENS

Cooperating with other countries on Zika public health emergency response and planning helps build a stronger global response to protect U.S. citizens and the international community, while contributing to international stability. If we can control an infectious disease outbreak quickly, either at home or abroad, we can help minimize the spread within the United States and limit its impact on U.S. citizens.

Millions of U.S. citizens live and travel overseas within the Western Hemisphere each year, including U.S. government employees and military personnel. The State Department is committed to ensuring the safety and security of all U.S. citizens, and utilizing all available platforms to provide the information they need to make informed travel decisions and protect themselves from mosquito bites and other forms of Zika transmission while overseas. The U.S. government must also take a pro-active approach, working with host governments to increase surveillance and diagnostic capacity, to scale up vector control, and to cut off the transmission cycle by providing information and access to voluntary family planning services, mosquito repellants, and other personal protective commodities.

With the Olympics and Paralympics coming up in Brazil, we anticipate that over 100,000 U.S. citizens will attend. All travelers to the Olympics should follow the recommendations outlined in the CDC's travel notice. Brazil is working very hard to protect the health and safety of all athletes and spectators attending the Games in Brazil, including through public awareness campaigns and vector control efforts at Olympic sites. The Brazilian Government has also emphasized that the Olympic Games will take place during Rio de Janeiro's winter, when the population of mosquitos is low. On June 14, the World Health Organization, at the third meeting of the International Health Regulations Emergency Committee on Zika, concluded that there is a very low risk of further international spread of Zika virus as a result of the Olympic and Paralympic Games. The WHO and the CDC have stated available evidence does not indicate there would be any meaningful public health impact from altering the schedule for the Games. The CDC recommends that pregnant women not attend the Olympics.

CONCLUSION

The United States is fortunate to have forewarning of the tragic outbreak that continues to spread northward. Zika, like Ebola before it, highlights how interconnected we are as a global community and shines a spotlight on the urgency with which we must fill the gaps in our collective preparedness. We have a window of opportunity to address the urgent needs now, before we are put at further risk, by working with our international partners and reaffirming our leadership role in the region. As Secretary Kerry said at the Global Health Security Agenda Summit in 2014, "in an interconnected world, we invest in global health not simply as a matter of charity or as a matter of moral responsibility, but we do it as a matter of national security."

Thank you for your time and consideration. I welcome the opportunity to answer any questions you may have.

Senator RUBIO. Thank you.

Dr. Frieden.

STATEMENT OF DR. TOM FRIEDEN, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GEORGIA

Dr. FRIEDEN. Thank you very much, Chairman Rubio, Ranking Member Boxer, members of the committee.

With your permission, I will submit the written statement for the record.

CDC works 24/7 to protect Americans from threats. We use the best of modern science. Zika is both unprecedented and tragic. Never before have we known of a situation when a single mosquito bite could result in a devastating birth defect. The top priority in the response to Zika is to protect pregnant women. We are literally learning more about Zika every day, and, in the 6 months of our response, we have learned and done a number of things to protect Americans better. We wish we had a more rapid and robust support for funding to do even more. I will go through those ten things very quickly.

First, the Zika response is extraordinarily complex. We have almost every center at CDC involved, more than 1,000 of our top scientists—this involves our Birth Defect Center, our vector-control work, our laboratory work, obstetrical work, information on sexual

transmission, mosquito control, virology, laboratory production—to identify the best methods in each community to protect pregnant women.

Second, it is now definitive that Zika causes both microcephaly and other severe birth defects, and that it does so whether or not the infected pregnant women—woman had symptoms of Zika during the infection. This led us to rapidly issue travel guidance, literally within days of first seeing the Zika virus in the brains of infants who had died from the Zika infection, and to provide guidance and education to providers and women of childbearing age and their partners. With additional resources, we would be able to better understand the mechanisms of that harm and the full range of harm. We do not know what happens to infants born with normal-sized heads to mothers who were infected with the Zika virus, and we may not know that for months or years, but we need to begin those studies now.

Third, as mentioned, asymptomatic illness in pregnancy can cause a birth defect. And that is why we have very detailed guidance for what doctors should do for testing of pregnant women who may have been exposed.

Fourth, Zika almost certainly causes the Guillain-Barre syndrome. We will know more soon. A variety of infections cause Guillain-Barre syndrome. It would not be a surprise for Zika to be associated with that. The really new and different thing about Zika is the connection to birth defects. As a result, with other parts of the Department of Health and Human Services, we are planning for an increase in the number of cases in Puerto Rico and possibly elsewhere.

Fifth, we recognize that diagnosing Zika is hard, but we have made lots of progress. CDC laboratory experts have created the tests that are being used in more than 100 laboratories around the United States and nearly 100 countries around the world. We have produced nearly 1 million test-kit materials for testing. And we have identified more about how to do that more accurately. However, testing for Zika is difficult. Viral loads tend to be low in serum, and we have learned that more is needed to do a better job testing. There is currently no test that can determine whether someone had Zika infection months or years before. We need to accelerate work on that basic question.

Fifth, sorry, sixth vector control is even harder. The mosquito that causes Zika is difficult to stop. We see that, in Puerto Rico, the mosquitoes are resistant to just about all of the most common insecticides used. It is critically important that we strengthen mosquito monitoring and control in the U.S., in the territories, and learn more about how to do a better job stopping mosquitoes from spreading. This is something which additional resources would be very helpful in.

Seventh, there are other routes of transmission. It is also the first time we have identified a mosquito-borne disease that can also be sexually transmitted. And that has implications for the sexual partners of women who are pregnant. So we have had additional guidance there. It is also clear that it can potentially be spread through blood. So we have worked carefully with the FDA, with the

blood banks of the U.S., to ensure that the blood supply is safe in this country.

Eighth, Puerto Rico is being singled out by the mosquito. Today in Puerto Rico, dozens and potentially as many as 50 additional pregnant women will become infected with the Zika virus. Puerto Rico has been dealt a difficult hand because of its environment, and it is critical that we do everything we can to protect pregnant women there now.

Ninth, globalization and urbanization are driving the spread of Zika, as well as cholera, yellow fever, and other diseases. It is the latest in a series of unpredicted and unpredictable health threats. What is predictable is that we will have new health threats, and we need a way to respond rapidly and robustly to identify problems where they first emerge, and stop them when they first come out.

Tenth, we have seen a remarkable capacity within CDC for innovation—new laboratory tests, new mosquito-control methods. Every day, we are discovering new ways, better ways to protect, detect, and respond to Zika. We are committed to ensuring that the American people have the most accurate, up-to-date information.

And I look forward to answering your questions.

[Dr. Frieden's prepared statement follows:]

PREPARED STATEMENT OF DR. TOM FRIEDEN,

INTRODUCTION

Good morning Chairman Rubio, Senator Boxer, and members of the subcommittee. 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 in support of both the domestic and international response.

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 track and respond to 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 the effects of Zika infection during pregnancy just how the virus causes microcephaly, a severe birth defect that is a sign of a problem with brain development, as well as the effects of Zika infection on the development of Guillain-Barré syndrome (GBS) and other possible complications. In addition to answering these questions, we are also working to accelerate optimal mosquito control strategies, improve laboratory testing and assure preparedness for rapid detection, control, and prevention within the United States and U.S. territories.

We are making advances in these areas and need the additional requested funding to do so. Much of what we know about Zika and similar viruses today is based on the work that's been done by CDC scientists. We are learning 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, laboratory experts, entomologists, disease control specialists, and others at CDC and other key Department of Health and Human Services (HHS) agencies are working nonstop to protect Americans from this and other health threats. We are committed to providing the American people with the most accurate and timely information about Zika virus, the current outbreak, and about what to expect here in the continental United States.

It's very important that Americans remember the core prevention message: If you're pregnant, you should not travel to a place where Zika is spreading, and if you are pregnant and in a place where Zika is spreading, do everything you can to avoid mosquito bites. In addition, if you are pregnant, you should either refrain

from sex with a partner who has been in an endemic area or use a condom every time you have sex during your pregnancy.

Most people infected with Zika virus appear to have no symptoms, and most of those with symptoms have only mild symptoms such as fever, rash, joint pain, and red eyes or conjunctivitis—that last no more than a week. Zika virus infection is, however, a cause of microcephaly and other severe fetal brain defects and is associated with serious health outcomes for babies of women infected during pregnancy, even when the woman has no symptoms. In addition, Guillain-Barré syndrome has been reported following Zika virus infection, although a causal link has not yet been definitively established. CDC is investigating the link between Zika and GBS. GBS is very likely triggered by Zika in a small proportion of those infected, much as it is after a variety of other infections.

CDC's key priority in responding to this epidemic is to reduce the risk of Zika virus infection to pregnant women. CDC is acting based on what we know and, at the same time, undertaking research to better prevent adverse health outcomes in the future. That's why, during the same week we identified Zika in brain tissue specimens, CDC advised pregnant women not to travel to affected areas.

CURRENT STATUS

While we have not yet seen transmission of the Zika virus by mosquitoes within the continental United States, many returning travelers to the US have been infected with Zika virus. As of July 6, 1,132 cases of travel associated Zika virus infections have been reported in US states and the District of Columbia. Also, as of July 6, 2,534 cases of Zika virus infections associated with mosquito-borne local transmission have been reported in the US territories, mostly in Puerto Rico. During the same timeframe, 320 cases of Zika virus infection have been reported among pregnant women in the United States and 279 infections have been reported among pregnant women in US territories. We know also, that a small number of cases can be attributed to sexual transmission.

CDC is also reporting the outcomes of pregnancies with laboratory evidence of possible Zika virus infection in the U.S. states, DC and the territories. As of June 30 there have been seven live born infants and five pregnancy losses with birth defects reported to CDC's US Zika Pregnancy Registry. As of the same date, one pregnancy loss with birth defects has been reported by the territories to either the US Zika Pregnancy Registry or to the Puerto Rico Zika Active Pregnancy Surveillance System.

CDC urgently needs a surge of resources to prevent and control the spread of Zika virus in the U.S. Commonwealth of Puerto Rico and the U.S. Virgin Islands, and other U.S. territories. The population of *Aedes aegypti* mosquitos, the primary vector for Zika virus infection, is widespread on these islands. Protective environmental factors such as window screens are not as prominent in the territories, and the density of people puts people there at high risk for transmission. All three areas have already reported local mosquito-borne Zika transmission. 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.

Furthermore, *Aedes* mosquitos are found in many areas of the continental United States, raising the risk of local transmission. Recent clusters of locally-transmitted dengue virus disease in the United States reinforce that Zika outbreaks in the continental U.S. may be relatively small and localized due to protective factors like window screens and less dense living conditions. However, any local outbreak will be of deep concern to the people living there, and we must be prepared for different scenarios including more extensive transmission risk. Local transmission of Zika will occur when a mosquito bites someone who is infected with Zika, likely someone infected during travel to a Zika-affected areas, and later bites another person, spreading the virus. There are about 40 million people travelling between the continental U.S. and Zika-affected areas each year.

WHAT CDC IS DOING

WHO has declared Zika a public health emergency and pregnant women, especially, need to be protected from its effects. To prevent and track Zika virus infection, CDC is conducting surveillance of the spread of the virus, developing and distributing better diagnostic tests, working with states and localities to improve mosquito control and tracking, assisting Puerto Rico and other territories, issuing travel guidance, and providing clinical guidance on Zika. CDC experts are also working to protect pregnant women by better understanding the link between Zika infection and adverse health outcomes.

Surveillance is essential to monitor and quickly identify areas with local transmission. Most of CDC's surveillance for arboviruses, including Zika, is captured through ArboNET, an integrated network which is used to monitor incidence of disease, conduct human case investigations, collect and test mosquitoes, and perform laboratory analysis. CDC's Epidemiology and Laboratory Capacity Cooperative Agreement supports ArboNet, including funding staff in 49 states, Puerto Rico, and six large municipalities. Zika infection is now a nationally notifiable disease, meaning states report all identified cases of Zika infection to CDC.

While we know Zika infection causes microcephaly and other fetal anomalies, we do not fully understand how, or if, there are important cofactors for these adverse outcomes. CDC is working to improve our understanding of the spectrum of effects of Zika infection during pregnancy (i.e., whether children born with normal-sized heads might have other neurological damage, which may not be apparent for months or years), just how the virus causes microcephaly, the duration of Zika infectivity in semen, and why some but not all women infected during pregnancy give birth to infants with microcephaly. A child born with microcephaly can cost up to an estimated \$10 million to care for over their lifetime, and can have devastating effects on families and communities who must care for them. In addition to surveillance for Zika cases, CDC is working with the states and territories on surveillance of pregnancies with evidence of Zika infections and pregnancy outcomes through the U.S. Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System. These are unique and unprecedented systems which can monitor pregnant women and their families and support health departments which provide care to these families. CDC is also planning a prospective cohort study in Colombia to evaluate the risk of maternal, fetal, and neonatal complications of Zika infection in pregnancy according to when during the pregnancy the infection occurred. This study will complement an ongoing multi-country study supported by the National Institutes of Health (NIH) to evaluate the magnitude of health risks that Zika virus infection poses to pregnant women and their developing fetuses and infants.

CDC, along with other HHS agencies and private sector partners, has worked around the clock to develop and ship diagnostic tests to detect Zika virus infection. CDC currently has two different Emergency Use Authorizations (EUAs) from the Food and Drug Administration (FDA), one for the MAC-ELISA test, which measures the body's immune response to the virus (issued February 26, 2016 and reissued on June 29, 2016) and the other for the Trioplex rRT-PCR assay, which identifies the acute presence of the virus (issued March 17). These tests have been distributed through the CDC Laboratory Response Network (LRN). The LRN is an integrated network of domestic and international laboratories that can respond to biological and chemical terrorism and other public health emergencies. In addition to use in the United States, many other countries were provided the CDC assays necessary to run these tests. In the United States, Zika diagnostic tests are now also available through commercial laboratories. CDC is working to increase laboratory capacity in the United States to handle the surge capacity needs posed by the Zika virus. CDC remains open to collaboration and assisting partners, including private industry, in their endeavors to bring accurate and precise Zika diagnostic assays to market.

Many states and localities have existing mosquito control programs. CDC provides technical expertise on mosquito control strategies, including the best methods to control immature and adult mosquitoes, monitor resistance to insecticides, conduct mosquito surveillance, and monitor efficacy of control efforts. Expanded capacity has also been provided to states through the Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement, Public Health Emergency Preparedness Cooperative Agreement, and federal vector control contracts to extend mosquito surveillance and control. In collaboration with the U.S. Departments of Defense, Agriculture, and Homeland Security, as well as the Environmental Protection Agency, HHS is working across its Operating Divisions to accelerate mosquito control research and to coordinate response efforts in the territories, as well as in the continental United States and Hawaii.

Puerto Rico has a particular challenge when it comes to vector control and mosquito-borne disease. Dengue and chikungunya, which are spread by the same mosquito, have spread rapidly throughout the island, and insecticide resistance is common. Now, dozens of pregnant women are infected every day with Zika virus, and we are very concerned about what the coming months will hold. We are working with our partners in the Puerto Rico government, private industry, and other federal agencies to reduce the risk from mosquitoes spreading Zika in the territory. Activities include using CDC-developed mosquito traps, conducting indoor and outdoor residual spraying, distributing personal protection tools to pregnant women in Zika Prevention Kits, and amplifying our public education efforts.

CDC has issued 49 travel notices related to Zika. These are Level 2 travel health notices, advising travelers to practice enhanced precautions, with additional guidance for women who are pregnant or are trying to become pregnant. 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 to prevent mosquito bites. Reducing exposure to mosquitoes is important for anyone traveling to or residing in areas where the virus is circulating. Wearing long sleeves, long pants, using EPA-approved repellents such as DEET and permethrin-treated clothing (both of which are safe to use during pregnancy), and using other protections such as air-conditioning and window screens will reduce exposure to daytime mosquitoes. 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 the pregnancy.

CDC also has provided guidance for doctors and other clinicians on evaluation, treatment, and follow-up care of pregnant women and infants with possible exposure to Zika virus, partnering with organizations from the health care community to help distribute this information as widely as possible.

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.

COORDINATION AND PARTNERSHIPS

CDC is working closely with health departments across the country and in the territories to support and coordinate its efforts and to expand capacity for detecting and responding to Zika virus. Strong collaboration with states and local partners is critical to an effective response. CDC is helping states assess and expand capacity, while engaging stakeholders including healthcare providers, blood banks, vector control organizations, medical associations, schools, employers, and others. We are continuously refining and improving our recommendations based on issues identified during the CDC-hosted Zika Action Plan Summit for state and local health officials and continued feedback from states.

I also want to acknowledge our federal partners. I have mentioned a few already. CDC is working in collaboration with other components of HHS including the Office of the Assistant Secretary for Preparedness and Response (ASPR) and its Biomedical Advanced Research and Development Authority (BARDA), the Office of the Assistant Secretary for Health, the NIH, who are working to develop a vaccine, and the FDA. We are also working with partners across the U.S. Government, including the Department of State, the Department of Homeland Security, the Department of Veterans Affairs, and the Environmental Protection Agency, to communicate with travelers and health care providers, update travel alerts and clinical guidance, and develop improved mosquito-control methods.

OLYMPIC GAMES

CDC and the United States Olympic Committee (USOC) signed a memorandum of understanding on May 27, 2016, and are working together to communicate risks and protective actions that can be taken before, during, and after travel to the 2016 Olympic Games in Brazil. The target audience for CDC's outreach efforts include Olympic and Paralympic athletes, staff, and delegation members. Our guidance for the general public for travel to the Olympics is the same guidance we have issued for travel to Brazil and other areas with Zika. While many Americans will travel to Brazil for the Olympics, travel to the Olympics is only a small fraction of overall global travel to countries that have ongoing Zika transmission. Travel to the Olympic Games represents about 0.25 percent of total aviation travel annually to Zika-affected areas.

CDC's communication actions for the Olympics include webinars to National Governing Body staff to share Zika prevention and travel health information, hosting an in-person informational booth during out-processing in Houston, co-branded print materials tailored to the U.S. delegation, a customized CDC website with content tailored to National Governing Body needs, social media messages disseminated through USOC channels, and short videos on packing clothing for prevention.

In addition to Zika prevention guidance, CDC also has posted general guidance for all travellers to the 2016 Summer Olympic and Paralympic Games in Brazil. Guidance for travel to the Olympics includes information about travel vaccines, safe food and water practices, and safety and security in crowds.

As we continue to learn more about the Zika virus, we will update our guidance and recommendations for the 2016 Olympic and Paralympic Games as appropriate.

CONCLUSION

The emergence and reemergence of health threats, including those spread by mosquitoes and other vectors, will continue for the foreseeable future. These outbreaks cannot be expected to occur in isolation. Puerto Rico and Hawaii were already responding to outbreaks of dengue when Zika virus emerged as an urgent health threat. We need to address the threat of mosquito-borne diseases systematically, rather than episodically.

While we need congressional action on the President's funding request, CDC has not waited for Congressional action to respond to the threat posed by Zika. We have made difficult decisions and redirected resources from other important public health activities to support our most critical needs. These redirected funds, however, are not enough to support a comprehensive Zika response, and they divert funding from other critically important public health activities. They only temporarily address what is needed until the Congress acts on the Administration's emergency supplemental request. Without the full amount of requested emergency supplemental funding, many activities that need to start now may have to be delayed or stopped within months, or may not occur at all. We need to start now to do the work to better understand the link between Zika disease and birth defects; track the spread of mosquitoes in the U.S. and control them before the epidemic spreads here; support states and territories to prevent and manage cases of Zika, diagnose patients, and increase lab capacity; and better understand, develop, and more fully deploy laboratory testing and for mosquito control.

We are hopeful that Congress will work quickly to fund critical response efforts to protect pregnant women against Zika.

Senator RUBIO. Thank you, Dr. Frieden.

Ms. Koek.

STATEMENT OF IRENE KOEK, ACTING DEPUTY ASSISTANT ADMINISTRATOR, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT, WASHINGTON, DC

Ms. KOEK. Thank you, Chairman Rubio, Ranking Member Boxer, and distinguished members of the subcommittee, for inviting me here today to testify on USAID's response to the Zika virus outbreak. I want to thank you for your continued leadership and commitment to this issue.

I will submit a written statement for the record, but today I would like to briefly describe USAID's work with the U.S. Government and regional international partners to address Zika.

Our aim is to minimize the negative pregnancy outcomes associated with Zika infection. Our efforts are focused on countries at risk for adverse outcomes from Zika that have relatively weaker government capacity to respond to Zika and where we expect that governments will want support from the United States. Our top-tier priorities include Haiti, Guatemala, El Salvador, Honduras, and the Dominican Republic.

Our strategy has four interconnected lines of effort: vector control, social and behavior change, service delivery related to maternal and child care and family planning, and innovation.

In vector control, our activities aim to improve and expand existing vector management efforts in Zika-affected or at-risk countries to reduce the Aedes mosquito populations. We will implement household and community-level vector control, helping those at risk learn to eliminate sources of standing water in which the Aedes mosquitos breed, scrub containers for mosquito eggs, and apply larvicide to water sources that cannot easily be eliminated.

For social and behavior change in community engagement approaches, put the community at the forefront of managing their risks, and prevention and management of the disease, and are of

critical importance. We will give people the tools and knowledge to adopt personal protection, protective behaviors, including the use of repellents, long-sleeved clothing, and condoms, seek care, and help with community response.

Our service delivery approach begins before a woman becomes pregnant by ensuring that women in Zika-affected areas who may wish to delay or limit future pregnancies can access family-planning information and services. For women who are currently pregnant, providers must be trained to counsel them and their partners on the need to prevent sexual transmission of Zika through condom use. Once a woman becomes pregnant or has a baby in a Zika-affected area, USAID is committed to ensuring that she receives cost-effective, high-quality maternal and child health services, with an emphasis on respectful care of pregnant women and infants with suspected congenital Zika syndrome.

Innovations are critically needed to mitigate the spread and impact of Zika virus and improve our ability to prevent, detect, and respond to future infectious disease outbreaks.

While we are utilizing all the tools in our toolbox to mitigate the impact and spread of Zika virus, many of those tools have limitations. As such, USAID worked quickly to launch a new Grand Challenge called Combating Zika and Future Threats. We received over 1,000 responses and believe we have some very exciting options. We expect to begin making awards by the end of this month or in early August.

So far in our programming efforts, we have completed a new interagency agreement with CDC and transferred \$78 million to enable them to start on critical surveillance and research activities. And we have obligated \$18 million to partners to work primarily in service-delivery and behavior-change areas. We are also working with UNICEF and PAHO in the region and with the World Health Organization in Geneva to address growing needs on a global level and outside of the western hemisphere. By the end of this month, we expect to begin our vector-control activities. In August and September, our community engagement activities will be rolled out.

We have designed our efforts to ensure they solidify the legacy of USAID's 50-year history of health assistance gains in the region. USAID is committed to addressing the Zika virus outbreak of today and strengthening capacities to ensure that this threat will be mitigated as much as possible.

Thank you for the opportunity to speak with you today. I am happy to answer any questions.

[Ms. Koek's prepared statement follows:]

PREPARED STATEMENT OF IRENE KOEK

Thank you Chairman Rubio, Ranking Member Boxer and distinguished members of the subcommittee for inviting me here today to testify on the U.S. Agency for International Development's (USAID) response to the Zika virus outbreak. I want to thank you for your continued leadership and commitment to global health and global development issues. We see you as partners in USAID's mission to end extreme poverty and promote resilient, democratic societies while advancing our security and prosperity.

Zika cases currently have been identified in 49 countries, 40 of them in the Americas. More than 298 million people live in Zika-suitable transmission zones within the Americas. In 2015, over 5.4 million births occurred in these environmentally suitable areas and during times of year when transmission is most likely to occur.

Additionally, summer peak travel between the United States and the countries of Central America, and the Caribbean coincides with peak seasonal mosquito abundance. We do not yet know the extent to which pregnant women or their children in much of the region have been affected. While there is still a great deal to understand about Zika, and the current set of tools we have are limited, there is still much we can do to help those at risk protect themselves and reduce the impact of Zika on pregnant women and their babies.

Today, I would like to briefly describe USAID's work at country, regional and global levels with partners in the U.S. government and with regional and international partners, I will also share with you some of the opportunities and challenges that we are all facing.

USAID has been working closely with partners across the U.S. government to implement our collective response to the Zika outbreak. This collaboration aims to minimize the number of pregnancies affected by Zika virus transmission. Together, U.S. government agencies plan to undertake surveillance efforts to identify the progression of the Zika virus, diagnose infections when they occur, provide care and support for pregnant women who have been identified as having contracted the Zika virus, and take efforts to prevent further infections. We are also working jointly to accelerate innovation and research across each of these categories of response.

Most of these international efforts are being undertaken with \$211 million that USAID reprogrammed from the planned Ebola response effort. Of that total, USAID has provided \$78 million to our colleagues at the Centers for Disease Control and Prevention (CDC) to capitalize on their expertise in surveillance, laboratory testing, public health response, and entomology to ensure accurate detection of infections and evaluation of Zika control measures. We also count on CDC to leverage key research studies and evaluations that will help us better understand this virus. While Dr. Frieden may provide more details on these efforts, I think it is important to highlight the value of learning as much as we can about the virus. Each new piece of evidence allows us to more effectively shape our responses. For example, when we initially planned our response to Zika and submitted the Administration's request for additional funding, we were unaware of the relative risk of sexual transmission. Now, armed with that information, we know that our efforts must target both pregnant women and their partners in order to be effective, and we have adjusted our plans accordingly.

With the balance of \$133 million, USAID is working through existing country systems to reduce the risk of new infections, particularly in pregnant women, and provide care to those known to be affected. USAID has a long history of supporting countries in Latin America and the Caribbean, which culminated with technical assistance to ensure that health systems could be responsive to changing circumstances. In many cases, we successfully concluded nearly 50 years of assistance through a deliberate process that was designed to ensure that countries could effectively continue to advance the health of their populations. We know that in many of these countries, inequities exist and that hard wrought gains can be easily damaged by an economic or political crisis. For example, USAID's health program in Honduras is successfully concluding this year, having been extended from its original end date as a result of instability constitutional crisis that occurred as we were just beginning our phase-out plan. Our focused efforts over the last five years of this graduation process successfully resulted in a 16 percentage point increase in women delivering their babies in healthcare facilities. Yet, the Honduran government still has more work to do; there is a 40 percentage point gap between the rate at which the richest women deliver in a facility when compared to the poorest women. Bearing this in mind, our response to Zika will seek to further support and strengthen country systems, including those responsible for ensuring pregnant women have access to quality prenatal care.

We have designed our efforts to ensure that a short-term focus on mitigating the impact of Zika does not undermine systems, but rather solidifies the legacy of USAID's impressive health assistance gains in the region. Efforts that both strengthen host country systems and impact Zika require a more narrow focus to ensure a strategic use of available resources. We want to ensure that all efforts relate directly to minimizing the negative pregnancy outcomes associated with Zika infection. We will do this by improving the quality of Zika prevention and care services through both public and private sector delivery channels and also by ensuring that communities are engaged with implementation of measures that will reduce the risk of Zika infection in pregnant women.

USAID's response is focused on four interconnected lines of effort: Innovation, Vector Control, Social and Behavior Change Communication, and Service Delivery related to: family planning, antenatal and postnatal care, as well as child develop-

ment and care for families with infants affected by Zika. I will briefly present our programs and approach in each of these areas:

Vector Control

Our activities aim to improve, expand, and focus existing vector management systems, networks, and programs in Zika-affected or at-risk countries to reduce *Aedes* mosquito populations. Preliminary findings from vector control capacity assessments in our priority countries indicate that the capacity of national vector control programs to conduct surveillance and vector control activities is weak and investments are needed to improve public health entomology and protect pregnant women. These assessments will be finalized in August 2016 and we will have concrete recommendations that will inform and direct our partners' activities in this area. However, based on the preliminary results, we plan to support regional trainings and technical assistance to bolster inclusion of quality vector control approaches into national vector control programs, while monitoring mosquito populations for resistance to insecticides and to determine the effectiveness of vector control interventions. Through our community engagement efforts, we will implement household-to-household vector control in at-risk or affected communities. Specifically, households will learn how to eliminate sources of standing water in which *Aedes* mosquitoes breed and scrub containers for mosquito eggs. Larvicides will be used in standing water sources that cannot be easily eliminated. We will purchase and distribute the required vector control commodities to public and private sector partners, and we will build country capacity to conduct GPS mapping of breeding sites, which will provide us with information to forecast areas at heightened risk of transmission in real time.

Social and Behavior Change Communication

Social and behavior change communication and community engagement approaches put the community at the forefront of managing their risks in prevention and management of the disease. We have learned from previous emerging disease outbreaks that effective risk communication and community engagement from the outset and throughout the course of public health emergencies is essential for effective disease control. As an example, we saw that in order to control the recent Ebola outbreak, strengthening clinical services alone is not enough. We expanded our work with communities to better understand their cultural practices, including traditions around burial practices. By actively engaging communities and understanding local cultural practices, we were able to encourage safer behaviors, while still respecting community traditions and long held beliefs. These social and behavioral interventions, combined with effective biomedical interventions, played a key role in effectively controlling the outbreak.

In order to tackle the worst effects of Zika, we will also need to earn the full engagement of at-risk communities so they are committed and effective partners in prevention and control activities. Our approach is aimed at enabling communities, households and individuals affected by and at risk of Zika to better understand their risks and practice key protective behaviors to minimize negative pregnancy outcomes. The overall approach will work through global, regional, national, and local levels to implement effective social and behavior change interventions designed to minimize negative pregnancy outcomes by focusing on the most at risk and vulnerable audiences: pregnant women, women of reproductive age and their partners, in households and communities in lower resource settings. With community involvement and the benefit of local perspectives, we will use the most appropriate channels to encourage behaviors for personal protection including use of repellents, long-sleeved clothing and condoms, to promote prevention, community response and care-seeking. These activities will be closely monitored for effectiveness and adjusted based on the results of that monitoring. Effective messages and approaches will be shared region-wide.

Service Delivery

In order to truly mitigate the impacts of this virus, we must improve access to healthcare services for women of reproductive age in Zika-affected or at-risk communities. These services include antenatal and postnatal care, child development, and family planning services. A key component of improving access to services is improving providers' capacity to deliver quality Zika-related healthcare and social services to women of reproductive age, particularly pregnant women, families, and children affected by Zika. Although most countries have issued Zika care guidelines, the rapid evolution of the evidence base requires constant updating of the guidelines, and the need for more specific protocols and procedures.

Our service delivery approach begins before a woman becomes pregnant by ensuring that women, adolescents, and couples in Zika-affected areas who may wish to

plan to delay or limit future pregnancies can access information, services, and methods regarding family planning. We must reach women who are considering becoming pregnant, and may wish to delay or limit pregnancies; as well as women who have unmet need for family planning, and want to prevent unintended pregnancies. For women who are currently pregnant, providers must be trained to counsel them and their partners on the need to prevent sexual transmission of Zika through condom use.

Once a woman becomes pregnant or has a baby in a Zika-affected area, USAID is committed to helping her receive cost-effective, high quality maternal and child health services, with an emphasis on respectful care of pregnant women and infants with suspected congenital Zika syndrome. Therefore, our work will focus on strengthening antenatal care services for all pregnant women including counseling on prevention (repellents, condoms, and other measures) and validating women's fears and concerns. Within this, we will have a special focus on strengthening antenatal care and delivery services for women with suspected Zika infection during pregnancy, including psycho-social support for the family and specialized newborn care at delivery. Through policy-level engagement, USAID will work with partners and with host countries to improve awareness of Zika-linked health conditions in children and ensure the engagement of all relevant ministries including education, family welfare, etc. for the care and support of Zika-affected families and children.

At the present time, we are not planning to focus our resources on care for children born with Zika congenital syndrome. However, this could become a growing area of need if we are unable to mount an effective response as soon as possible. As the need for this population becomes more evident or with additional resources, we will explore the effects of congenital Zika syndrome for infants with suspected cases, including the application of basic neurodevelopmental monitoring and therapy including early stimulation.

Innovations

While we are utilizing all the tools in our toolbox to mitigate the impact and spread of the Zika virus, many of these tools have limitations to their effectiveness and scalability. Aedes mosquitoes, for example, are less susceptible to standard vector control approaches like indoor residual spraying, as they tend not to rest on the walls where insecticides would be typically sprayed. They also can breed in the smallest of containers—even a plastic water bottle cap—rendering large-scale larvicide approaches impractical. Available products to protect individuals from being bitten require frequent replenishment or reapplication and often are unappealing to end users, due to factors like smell, skin or eye irritation, and comfort. And, few homes, schools, or other buildings have screens on their windows. As a result, USAID has partnered with colleagues from across the U.S. Government—from BARDA, CDC and NIH to the Departments of Defense and Homeland Security—to identify promising innovations under development within each agency and figure out how to bring cutting-edge technological advances to the developing country context. Within USAID we worked quickly to launch a new Grand Challenge, called “Combating Zika and Future Threats,” to enhance our capabilities in both the short and long term by sourcing innovations that mitigate the spread and impact of the Zika virus and improve our ability to prevent, detect, and respond to future infectious disease outbreaks, like Zika. We sought solutions—from new ways to reduce mosquito populations, to new options for preventing mosquitoes from biting or transmitting Zika to humans, to entirely new ways to detect and respond to Zika infections. We sought creative ways to educate and mobilize entire communities—from entrepreneurs, scientists, engineers, students, and others around the world. We received an overwhelming response, with nearly 1,000 ideas from over 60 countries, and we are moving rapidly to identify those ideas with the most promise for curbing the current Zika outbreak and preventing such outbreaks in the future.

Unfortunately, current resources do not allow USAID to implement these response efforts region-wide. We cannot even implement them in all areas most at-risk for Zika. We have chosen to focus our efforts on countries at risk for adverse outcomes from Zika due to predicted number of cases (based on experience with dengue and chikungunya), with relatively weaker government capacity to respond to those cases, and where we expect that local governments will want robust support from the United States. These countries include Haiti, Guatemala, El Salvador, Honduras, and the Dominican Republic. Within these countries we believe that we can rapidly scale up to full implementation of our strategic set of anticipated activities and maintain these programs for several months. However, without additional resources, we would be forced to choose between cutting off programming before it can have lasting impact in our priority countries or eliminating any impact beyond the priority countries. For example, in the next set of countries USAID would work

with, which includes Nicaragua, Jamaica, Paraguay, and Peru, we planned to fund technical assistance and support at the national level across the range of intervention areas. Without additional funds, these plans would need to be reconsidered against the consequences of stopping programs too soon in the first set of countries. Our ability to truly have an impact on the spread of Zika is limited if we cannot cover more at-risk areas.

We were appreciative of receiving Congressional support to move forward with the reprogramming of funds on April 26. In the month of May alone, we completed a new Interagency agreement with the Centers for Disease Control and Prevention and were able to transfer the full \$78 million to enable them to get started on critical surveillance and research activities. We were also able to obligate an additional \$14 million to partners to work primarily in the service delivery and behavior change areas. Those partners quickly began meeting with Ministries of Health in the five target countries; coordinating with the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA), and the Pan American Health Organization (PAHO) on national level communication strategies; conducting rapid assessments of existing tools and resources available to service delivery providers; assessing the capacity of countries in behavior change communication, service delivery, and vector control; as well as creating a Zika resource web platform, the Zika Communication Network (<http://zikacommunicationnetwork.org/>)—a source for global Zika prevention and preparedness materials as well as for research and development updates. In mid-June, along with partners, we kicked off a Zika-related discussion on the Springboard virtual platform, titled “Communicating About Zika: Messaging for Pregnant Women and Women of Reproductive Age,” that drew a record 700 people to the discussion, while tweets related to the discussion have reached over 60,000. Additionally, in our priority countries, USAID-supported private not-for-profit health organizations are developing provider training materials and behavior change messages at Ministries of Health request that will be applied in their networks and shared with the public sector. Both the private and public sectors are working together to align messages under the leadership of governments.

Soon activities will be conducted to determine gaps in care processes around the availability and quality of family planning, antenatal and immediate newborn care in our focus countries. These activities will be conducted in collaboration with in-country universities, allowing us to better understand where needs are greatest and ensure that our response efforts are well aligned. At the same time, we are preparing to roll out online and in-person training courses to reach large numbers of health professionals as quickly as possible. We are also beginning partnership activities with UNICEF and PAHO in the region and with the World Health Organization in Geneva to address growing needs on a global level and outside of the Western Hemisphere. By the end of this month, we expect to be able to begin our vector control and entomological activities and then through August and September our community engagement and innovations activities will be rolled out.

A four-month time period to initiate such a broad range of activities in countries and areas where USAID does not have ongoing health projects is a very fast rate of start up. In this time period, we will have completed the required analyses to ensure that our efforts comply with environmental safeguards and standards, we will have established new awards through full-and-open competition and made necessary modifications to other awards in order to accommodate the Zika response efforts. The current timeline means that we will not achieve full implementation until the end of the typical rainy season in Central America and the Caribbean. However, we are still confident that these resources and additional resources made available in the near future will allow us to be prepared with programs in place in order to have an immediate impact on next year's rainy season and the upcoming rainy season in South America. And finally, the efforts I have described will serve to strengthen country health systems and allow us to leverage this strength for improved impact.

CONCLUSION

USAID is committed to addressing the Zika virus outbreak of today and strengthening capacities to ensure that this threat will be mitigated as much as possible. Thank you for the opportunity to speak with you today and to share the contributions we are making. I am happy to answer any questions.

Senator RUBIO. Thank you all for being here.

I want to begin with Secretary Garber. The—Brazil's new Health Minister has said that there is a almost-zero risk of athletes or spectators contracting Zika during the Olympics. Is this threat—is

the threat in Brazil truly almost zero? And what advice do you feel—let me ask this. Should our athletes or spectators feel fully safe in traveling to Brazil for the Olympics, given what we know about the situation there?

Ambassador GARBER. Thank you very much, Mr. Chairman.

We are putting out the guidance based on the CDC guidance, and pushing that out through all available platforms to make sure that travelers and the over 100,000 Americans that are planning on attending the Olympics can make informed decisions. We know the Government of Brazil is working very hard to address this outbreak through its own very aggressive public information campaigns and vector-control efforts, including through many in the Army, hundreds of thousands, as well as public health officials to work on vector control. But I would defer to Dr. Frieden, specifically, on the assessment of the risk.

Senator RUBIO. Well, Dr. Frieden, is the chance of contracting Zika in Brazil almost zero for athletes and spectators?

Dr. FRIEDEN. We recommend, for any travel, that pregnant women not go to areas where Zika may be spreading. We would recommend, for the Olympics, as we would for any other travel, that pregnant women not travel. For others, there are reasonable steps people can take to protect themselves. Historical data does suggest that viruses spread by this mosquito are less common in the period of the Olympics, but we think the key issue is not why people travel, but who is traveling. And the key message to get out there is that pregnant women should not be traveling to areas where Zika is spreading, and, if they are present in those areas, should take steps to protect themselves.

Senator RUBIO. Well, let me ask it another way. Should athletes or spectators traveling to Brazil at least think about it before they go, given what we have known about how rapidly it has spread there?

Dr. FRIEDEN. All travel involves risk. It may be from a motor vehicle crash, it may be from infectious diarrhea, it may be from dengue or other diseases. We do not think the risk will outweigh the travel benefits for most people, except for the group of pregnant women. And that is why immediately after identifying Zika in the brains of affected infants, we advise that pregnant women not travel to Zika-affected areas. Also important for men who have sexual partners who are pregnant to use condoms if they come back from an area with Zika.

Senator RUBIO. Dr. Frieden, what is a reasonable timetable to expect a vaccine for Zika?

Dr. FRIEDEN. We are told by the National Institutes of Health that they hope to be in clinical trials in September. That would mean that, in the next couple of years, we could have an approved vaccine that is both safe and effective. But only time will tell whether that happens. It is very promising. The immune response to Zika is robust, so it is certainly theoretically quite possible, but these things do take time.

Senator RUBIO. You touched upon it in your statement earlier. And a lot of the focus on Zika, and rightfully so, has been through the impact that it has on microcephaly. But let me ask you—I know that there is a study ongoing with the Colombian government

to study the link between Zika and Guillain-Barre. Is there anything you can share with us about the preliminary findings? I saw, in your statement, you said that you most certainly believe that it will prove that there is a direct link.

Dr. FRIEDEN. We have seen several studies published—one from French Polynesia. We have work going from Brazil. We expect, by the end of the summer, to finalize that work. I expect that that link will be proven, given the epidemiological patterns, but we do not yet have two really strong, independent studies determining it. That takes some time. But we have had excellent collaboration, both in Brazil and especially in Colombia, where we are really working side by side with long-term collaborators there.

Senator RUBIO. And again, just to be clear, just so anyone who might be watching this now or later would understand, the Guillain-Barre link is on everyone. Anyone infected by Zika runs that risk, beyond what we are talking about now with pregnancy, correct?

Dr. FRIEDEN. That is correct. It tends to increase with age, but anyone can be affected, and it can cause paralysis that can be severe, is usually temporary, can last from weeks to months.

Senator RUBIO. And, Ms. Koek, you—generally speaking, the health systems in Latin America and the Caribbean are stronger than those of many sub-Saharan African nations and Southeast Asian nations. And this phenomenon has prompted USAID to graduate several countries from any global health programs. But there are some groups that have come to us that are concerned that Haiti and countries in the Caribbean and in the northern triangle of Central America may be ill-equipped to handle Zika cases as well as possible related complications. What direct support, if any, are you planning to provide these countries?

Ms. KOEK. Thank you very much for that question, Senator.

USAID has a long history of supporting countries in the region, and, as you noted, we did graduate our assistance from many countries. And that was a—following a very deliberate effort and working very closely with the governments and local partners to move away. And, as you noted, it was probably because of the progress that had been made in many of those countries, and the capacity had been developed.

Haiti is still a country where we have a robust health program in all areas. And so we believe Haiti needs additional support. But as part of our program, they have already been able to move some of the resources they have through the USAID program to get a little bit ahead and start to respond to Zika.

Similarly, one of the things we are doing, particularly in Central America, which is home to a number of our priority areas, is identifying where some of those gaps are. Zika was completely unexpected, and it does present a threat that has been discussed here today, figuring out where we can fill those gaps and provide the support needed.

Senator RUBIO. Well, are there any countries that we—that have graduated from the USAID health programs, have been graduated in their levels, that have, nonetheless, appeared to need additional support as a result of Zika?

Ms. KOEK. Yes. Some of the countries that we have prioritized, including Honduras, El Salvador, and the Dominican Republic, are all countries that we have graduated assistance from, or the robust assistance. Those are countries we believe do need some additional targeted support.

Senator RUBIO. Senator Boxer.

Senator BOXER. Thank you, Mr. Chairman.

Earlier this year, El Salvador issued a nationwide call for women to avoid pregnancy for 2 full years. Now, one can debate how real that could be, given what we know. But setting that aside, other governments in Latin America also called on women—not on men, on women—to avoid pregnancy. In other words, they did not tell the men that they should work with the women. Very typical. Other governments in Latin America and the Caribbean issued similar directives, including Colombia, Ecuador, and Jamaica. Those countries said, “Women, do not get pregnant for 2 years.”

My question to any of you on the panel, do you believe these countries have the health infrastructure to give women in these countries, who have been told not to get pregnant for 2 years, access to free contraception?

Ms. KOEK. Thank you very much, Senator Boxer. It is an excellent question, and we very much share the concerns you raised in asking this question.

We are very committed to ensuring that women do have access to all the information and support and access to services. And there certainly are gaps.

Senator BOXER. That is not my question.

Ms. KOEK. Yes.

Senator BOXER. I asked you if those countries who have told their women not to get pregnant for 2 years have the infrastructure to get free contraception to these women of childbearing age?

Ms. KOEK. Yes.

Senator BOXER. They are the ones who are in charge of their own countries. They are the ones who issued this directive to their women. Do they have the infrastructure?

Ms. KOEK. I think it is a mix. Part of our graduation strategies in many of these countries was to make sure there was a strong family planning program in place, including a supply of contraceptives.

Senator BOXER. Do all these countries have the ability to get free birth control to women of childbearing age? Do they have the ability to do that?

Ms. KOEK. I think, in most cases, they have supply; but the issue of making sure that you are not telling women that you must use family planning or, as you put, putting the onus on the women, is certainly part of what we want to make sure happens.

Senator BOXER. I am not asking about that. I am asking you if they have the infrastructure and the ability to get contraception to the women that they have told that they should not get pregnant for 2 years. Or do they need our help getting that birth control to them?

Ms. KOEK. We believe the issues are mostly around the delivery. And that is where they do need some help. They do not need help

on supply of contraceptives. It is the delivery that presents a problem, making sure that those who are most in need have access.

That is where the gaps are.

Senator BOXER. How are they doing it, the ones that you say are doing a good job? How are they getting this contraception to the people who need it?

Ambassador GARBER. If I could just provide two examples, Senator Boxer, and then I will defer back to Irene for anything additional. I am aware that, in Ecuador, for example, the government, through its public hospital system, does provide universal access to birth control. There is a delivery system in place to allow for that.

And I was just in El Salvador last week and met with the Minister of Health there and talked a little bit with Irene's colleagues from USAID about how they want to prioritize the assistance that we are going to be giving them. And one of the things that the Minister of Health really emphasized tremendously was trying to be able to provide access to birth control.

Senator BOXER. What assistance are we going to give those countries who have told their women not to get pregnant for 2 years? What are we doing to provide them with free birth control?

Ms. KOEK. We are doing a couple of things. One is to make sure that the supplies that are in place are actually getting to the people that need them, and that there is full access, and that information is available to the women so they can make the choices themselves. There is some policy work also to make sure the statements that you described are—it is not necessarily going to help give access, and that is one of the concerns we have.

Senator BOXER. Okay. How many cases are there in El Salvador?

Dr. FRIEDEN. We would have to get back to you with the exact number.

Senator BOXER. Would you do that?

Dr. FRIEDEN. We do know that it is only a small number of the total cases that have been diagnosed.

[The information requested had not been received at the time this document went to press.]

Senator BOXER. Good. And what about Colombia, Ecuador, and Jamaica? Do you have those stats?

Dr. FRIEDEN. Offhand, no, but the reported numbers are, in most countries, only a small fraction of the total cases, since 80 percent of people have no symptoms at all and testing is not widely available in many of these countries.

Senator BOXER. Well, how many babies have been born with anomalies in those countries? Do you have that data?

Dr. FRIEDEN. In Brazil, where the epidemic started, you have had the largest number of pregnant women with infections in the first trimester, which appears to be the highest-risk period to come to term. And we have seen between hundreds and thousands of babies with microcephaly. Those are still under investigation, in terms of confirmation of the diagnosis. We have an investigation collaboratively with Colombia, where we are following a group or cohort of women who appear to have had Zika infection. And over the coming months, we will be able to determine with more certainty what the prognosis is.

Senator BOXER. Could you get back to me on the numbers of those countries where the countries have stated they have given this directive to the women and girls not to get pregnant for 2 years, those countries I mentioned, how many cases of anomalies they have had?

[The information requested had not been received at the time this document went to press.]

Senator BOXER. I was telling the Chairman that I heard a report on one of the radio news shows that—and I just do not know if this is anything you are involved in or we are involved in—that, for the young men and women who are going to Brazil, that they are going to be tracked afterward and followed to see what happens with their health. Could—do you know anything about that?

Dr. FRIEDEN. We have a memorandum of understanding with the U.S. Olympics Committee. We work collaboratively providing technical assistance, outreach, and education. They are also working with a university in the U.S. to do a study voluntarily for athletes and members of the Olympics and Paralympics who want to know, both before and after, whether they might have been infected. That might have been what that was referring to.

Senator BOXER. Okay.

Well, let me just say, if we know this is dangerous, so dangerous that we are asking these people to volunteer, we better talk to these people, one by one by one by one by one by one, and let them know how serious this is. I feel very strongly about that. I do not want our people being used as guinea pigs, “Oh, you come home, we will follow you, we are going to see whether you got this or not, and how—if you had any babies who have microcephaly.” This is not right.

I would just close my frustrating comments here today by saying that we cannot have one hand tied behind our back by saying, as the House said in a completely partisan way, none of this money could be used for nongovernmental entities to help provide birth control, which is so critical. And it is wrong—a country thinks they solved the problem, when they just tell the women in the country they should not become pregnant. There is something wrong about that on so many levels. And I hope we will let them know more about this.

And lastly, for our young people who are going to go to Brazil, where there are all these problems. I understand that they are spraying; they are doing everything, and I am very glad about that. There is a whole other issue of whether it is even morally responsible to have the Olympics. That is not our job to discuss, but it is happening. And we are now going to track our people voluntarily to see whether they get this disease, whether there is something amiss. I would just encourage us to reach out to these athletes very clearly. If the risk is so great that you are going to spend money following them, maybe they ought to know it.

Senator RUBIO. Before I turn it over to Senator Isakson, are we providing our Olympic athletes a basic kit of repellent and whatever they need to take with them in order to prevent the disease, the contraceptives, whatever it is? What are we providing them? Are we working with the Olympic Committee to do so?

Dr. FRIEDEN. Yes. We are working with the Olympic Committee to provide both information and materials for the athletes for each of the different sports that are participating, each of the different associations.

Senator RUBIO. Okay.

Senator Isakson.

Senator ISAKSON. Thank you, Senator Rubio. And thanks, to you and Senator Boxer, for calling this very important hearing.

I want to issue an invitation to the four members that are here. In recent weeks, I have had the chance, with Dr. Frieden's courtesy, to host two members of the United States Senate at CDC in Atlanta. And I would urge you to come down and spend an afternoon, and I will spend it with you, to see the research that is done and the reach that CDC has, particularly with regard to Zika.

I want to underline, CDC is always referred to as the Center for Disease Control, but it is a five-word title, not a three-word title. It is Center for Disease Control and Prevention. And we are at a critical point on Zika, where we are—the prevention needs to be what we focus on, because controlling it does not do you any good once these cases start multiplying.

I will give you some numbers for us to be aware of. The urgency of this matter is this: that, as of July the 6th, there are 1,133 Zika cases in the continental United States of America, and 320 are pregnant women, as of June the 30th. Is that about correct, Dr. Frieden?

Dr. FRIEDEN. Yes.

Senator ISAKSON. In the U.S. territories, there are 2,534 cases, and 279 are pregnant women. This is a crisis of major proportion, and we—time is of the essence.

I have made two or three speeches on the floor, talking about the need for us to pass this. And it will be professional malpractice on our part if we leave here for 7 weeks and have not dealt with this, because Dr. Frieden and the Center for Disease Control and Prevention need the funds now to prevent what could be a major worldwide crisis, in terms of the Zika pregnancy.

As a Georgian, just as an anecdotal piece of evidence, an employee of mine attended the briefing with Senator Collins that Dr. Frieden gave us on Zika a few months ago. His wife was in an early pregnancy. After the briefing, he moved his wife to Colorado, where these mosquitoes do not exist, just to be sure she is in a safer environment than Georgia during the term of her pregnancy. In our State, the two mosquitoes that are carrying the Zika both are indigenous to Georgia.

So, this is something that is priority one, as far as I am concerned. And I think it is critical that we get it done now.

I walked my dear friend Senator Boxer, whose passion I have seen illustrated on thousands of issues as we work together as co-chairs of the Ethics Committee, but when you came in, you mentioned the Confederate flag. I want you to know that, as Chairman of the Veterans Committee, I saw to it that the Senate took out the House provisions, and there is nothing in the conference report at all that deals with the Confederate flag. Correct, Tim?

Senator BOXER. That is not our understanding.

Senator ISAKSON. I see Tim nodding his head. I can tell you, I have the jurisdiction. I took care of that.

Senator BOXER. Okay. Because I was just informed that it is in there, so let us go look at it.

Senator ISAKSON. Well, as Chairman, I am telling you it is—if it is in there, somebody went over my head, because I am the one that made sure that Senate provision provided—prevailed, which was: No provision at all.

Senator BOXER. In the military bill.

Senator ISAKSON. Well, I am talking about the Zika bill we are talking about. It is not in there.

Senator BOXER. Okay. I will double check.

Senator ISAKSON. I appreciate it.

Senator BOXER. I was just briefed today on that.

Senator ISAKSON. But I want to underline the fact that this is about prevention. And we can have our differences on a lot of things, but we have got to do everything we can to get the resources in the hands of the CDC to develop a program of prevention.

They demonstrated it on Ebola. The thing about Ebola that they get so much credit for, and should, is the Ebola outbreak took place, people developed Ebola, and they got out there and they treated people with Ebola. The number of deaths was minimized, but what people forget about is, the educational reach of CDC around the world to teach people best practices actually stopped the epidemic within a pretty unbelievable period of time. I think, about 13 to 16 weeks, if I am not mistaken. And that is what we want to see with Zika. We do not want to just deal with those that have it. We want to deal with those that do not have it, and make sure they do not get it. And this funding is absolutely critical for us to see to it that that happens.

So, Senator Rubio, calling this hearing today and focusing on the need to do it is very important. And I hope, before we leave tomorrow, we can have an agreement in the Senate to ratify the conference report.

And I want to thank all of you in healthcare for what you do to help protect the pregnant moms of America and the citizens of my State against what is a real threat. And the problem is, it is a delayed reaction. You find out today that they are pregnant; 9 months from now, you find out if there is a problem. And 9 months from now is too late. We need to prevent every terrible pregnancy we can today, and that is why I want to focus on the need to pass this as quickly as possible in the United States Senate.

I yield back. That was not a question. That was a speech, and I apologize. [Laughter.]

Senator BOXER. It was a good one.

Senator RUBIO. Senator Kaine.

Senator KAINE. Thank you, Mr. Chair. And I am going to do some speeches and some questions.

You know, this is such a serious problem, but this is also an illustration why a lot of people hate Congress. They hate Congress. And this is nothing bad on my Senate colleagues. We had some differences of opinion about this Zika, how to deal with it. And so, we voted on three different Zika provisions. There was a Democratic

provision to deal with Zika that did not get enough votes. There was a Republican provision about how to deal with Zika that did not get enough votes. And then there was a bipartisan provision about how to deal with Zika that did get enough votes. And there were some things in it that probably one side did not like, and some things that the other side did not like, but we got 68 votes. And it was a billion-one, not the number we might have liked, but we got it, and it was a clean bill. It was a bill about one thing: fighting Zika. That is what it was about.

When it comes back to us, the bill is not about fighting Zika. Frankly, it is about fighting Planning Parenthood and paying for it by taking money out of the Affordable Care Act. So, we have got this massive public health challenge, and the American public is worried about it. And we are supposed to fight Zika. And that is what the Senate did. We fought Zika. But the bill comes back to us, and it is, "Let us fight Planned Parenthood. That is more important than fighting Zika. Let us take money out of the Affordable Care Act. That is more important than fighting Zika." This is why people hate Congress. This is why people hate Washington.

And again, this is no slight on us, because I think we actually reached the right compromise, but then the "fighting Zika bill" becomes the "fight Planned Parenthood bill" or the "fight the Affordable Care Act bill." And it is my hope that we will get this thing straightened out. I know everybody here on this dais wants to. And I would second a point that Senator Boxer made in her comments. The right way to deal with this, probably down the road, is budgetarily to treat infectious diseases like we treat FEMA. We have a funding mechanism for FEMA. We do not know where a hurricane will hit. We do not know where there will be a forest fire, where there will be a flood. But we do know from experience that there will be these items, and so we budget for them and then we deal with them.

We do not do that with respect to infectious diseases, and then that gives people the ability to play games and hold people hostage to try to ride their pet hobbyhorse instead of doing the thing that we are supposed to do.

Couple of questions: I am curious, on the transmission. If you can be infected and asymptomatic, if you come back into the United States and you have been in an area where there is a lot of Zika, with respect to sexual transmission, you are telling males, for example, to use condoms. How long are you doing this? Is it for months? Is it for weeks? What is the advice that you are giving people when they return from Zika-infected areas?

Dr. FRIEDEN. Our current advice, based on the best-available information, which we continue to accrue every day, is that, for men whose partners are pregnant, use a condom for the duration of pregnancy. Because we do not know how long that man may remain infectious. There are studies that are underway, but they will take 6, 12 months to finalize.

Senator KAINE. What advice are you giving, if any, to men whose partners are not pregnant?

Dr. FRIEDEN. For couples who are trying to conceive, our current advice is that, if they had no symptoms of Zika infection, they should wait at least 2 months after leaving the Zika area. And if

they did have symptoms, because they might have more virus with that, then it would be 6 months.

Senator Kaine. Right.

And then, here is another kind of transmission I was not aware of it until recently. If you are in a Zika-infected area and you come back to the United States, and you have been bitten by a mosquito there, and you may not have symptoms, your blood could have Zika infection. And so, if you are bitten by a mosquito in the United States, that could be a blood transmission to mosquitoes here. What are you—what advice are you giving people about needing to try to avoid mosquito bites in the United States after they return from a country that has a Zika problem?

Dr. Frieden. We encourage people to avoid mosquito bites by using DEET, staying indoors, staying in screened or air-conditioned spaces. But the scenario that you outlined is exactly the scenario that we think is most likely to spread Zika in parts of the U.S., where diseases like dengue have spread in the past, where we have seen clusters in parts of Florida and Texas through mosquito-borne transmission, although we have now shown that there is sexual transmission, and we know blood-transfusion transmission is possible if the blood is not screened, which is currently being screened in Puerto Rico and other places.

The more likely way that it would spread in this country is the way it is spreading around the world, primarily, which is by mosquito bites.

Senator Kaine. And so, if somebody returns to the United States from an area with a heavy Zika challenge, how long are you suggesting that it is important for that person to avoid getting bitten by a mosquito in the United States?

Dr. Frieden. Three weeks.

Senator Kaine. Okay, thank you.

I want to ask about the vector-control piece. And I know the FDA has a portion of that, as well. And so, I am assuming that, you know, you are all working together. The vaccine is going to take some time to develop. So, as I understand vector control, it is a number of different kinds of solutions. It is spraying and figuring out how to do spraying. I am—I understand that there is various proposals on the table for different—you know, mosquitoes that will not reproduce. And so, hopefully that could reduce the density of mosquitoes in certain areas. Talk about the range and kind of vector-control solutions that you are looking at. Recognizing that the vaccine is down the road, what can we do right now to reduce the density of mosquitoes that would be carrying this disease?

Dr. Frieden. So, these are very tough mosquitoes to control. They are referred to as “the cockroach of mosquitoes.” They live indoors and outdoors. They bite in the daytime and the evening. They readily develop resistance to insecticides. They have co-evolved with people in urban areas, so they are an urban pest.

The control measures, I would put into two large categories. One is proven safe and effective methods, but they have not been put together in a way that is effective to stop the mosquito. And we need to figure out how to use our existing tools better. And then new tools, experimental things like sterile male technology, where you release sterile males and try to crash the mosquito population.

Both of these things require more effort. We need to try the different methods out there and see how rapidly, how persistently we can reduce the mosquitoes. The recommended approach is an integrated vector-management approach, where you reduce standing water, you reduce larvae, and you use judiciously adulticides or pesticides to kill the adult mosquitoes. On a longer timeframe, more like the vaccine, or even longer than that, is the new tools. We need new insecticides, we need new ways to control mosquito populations. But we have to move forward rapidly in both of these areas.

Senator KAINE. And could I just—my time is up, but one last question—or maybe two quick ones.

On the—both of these—developing the vaccine takes a tremendous investment, but also the vector-control solutions, both to research to determine which are best, and then to deploy them broadly, that is also not cheap. That takes a significant investment, correct?

Dr. FRIEDEN. That is correct.

Senator KAINE. Those are all the questions I have. Thank you. Thanks, Mr. Chair.

Senator RUBIO. Thank you.

Senator Gardner.

Senator GARDNER. Thank you, Mr. Chairman.

And I apologize, I am not going to be able to use my full time here. That might not need an apology, but I am not going to be able to use it all. I have to go preside over—on the floor, here, soon.

Dr. Frieden, I wanted to talk to you a little bit about the CDC work. Of course, Fort Collins, Colorado, is home to the Division for Vector-Borne Diseases and has done a tremendous amount of work at this location on vector-borne illnesses, such as Chikungunya, dengue, and Zika virus. And I was fortunate enough to have the opportunity to visit the work concerning Zika virus there at the laboratory in February of this year, including going in to look at the live mosquitoes, the larvae, and what was happening, and how the whole process worked.

I learned, at this time, about a chemical called nootkatone that the CDC was working to reclassify as a biochemical pesticide active ingredient. Nootkatone is a—according to this tour, was a natural ingredient, I think, found in citrus, like grapefruit oil. It might be in some cedar trees, as well, but it has a natural grounding. Many may recognize this from their shampoos. I think this product is in many shampoos, as well. The EPA has to evaluate natural tick repellents and pesticides for registration before they may be sold for use by the public, to validate safety and efficacy. Has your agency—how have you coordinated with other agencies to expedite the approval of various products, nootkatone or others, to ensure they become available?

Dr. FRIEDEN. Thank you very much, Senator. And we are delighted to—that you had the chance to visit our unit out in Fort Collins, Colorado. It is the lead unit for Zika and for this work. They do phenomenal work. Their innovation has been terrific. They have come up with the new and now increasingly available laboratory tests to diagnose Zika. They have also overseen the work in

our dengue branch, which has come up with some new means of capturing mosquitoes and tracking populations.

The chemical you refer to, nootkatone, has been under evaluation for years at Fort Collins, and we have recently licensed it to several companies. We are working very closely with the EPA so that it could be brought to market as quickly as possible. It is food grade, generally recognized as safe, nontoxic, appears to be as effective as DEET against both mosquitoes and ticks. We are running out of different classes of insecticides. This appears to work in a totally new manner. So, we do not know, in the end, whether it will work out, but it is certainly very promising. We have had a good reaction from EPA that is willing to work with us and with the companies to get it to market as rapidly as possible.

Similarly, with the diagnostic tests, we have had excellent collaboration with the Food and Drug Administration, which has, within days, approved for emergency use the diagnostic tests that we have developed.

Senator GARDNER. Thank you.

And I am going to have to go to the floor now. But are you familiar with the legislation that the Senate is considering from the House on the Zika funding? Are you familiar with the details of that legislation at all from the—the House-passed version of Zika funding?

Dr. FRIEDEN. Yes.

Senator GARDNER. Okay. And I would—because I hear people talk about the funding of Planned Parenthood. And I just want to make—I have a question for you on this funding. Does the House bill take money away from Planned Parenthood?

Dr. FRIEDEN. I am not familiar with the exact funding allocations in that bill.

Senator GARDNER. I believe the answer is no. And I would just—would love to—if you could get back to me on that.

[The information requested had not been received at the time this document went to press.]

Senator GARDNER. Thank you.

Thank you.

Senator RUBIO. Senator Kaine, you had a followup?

Senator KAINE. Just one brief followup. Advice for all of us. Tell me if this is right. I understand that the mosquito that carries Zika breeds in containers, so not necessarily in standing water on the ground, necessarily, but more swimming pools or, you know, like the depression in the cover of my grill that ends up with rainwater on it, or a dog bowl in the backyard, a wheelbarrow. I have got one of those. I have got a canoe that gets water in it. So, one of the things that we can all do in our neighborhoods if we want to try to reduce the population density of this mosquito is to make sure that there is not water standing in containers in our yards and neighborhoods. Am I generally right about that?

Dr. FRIEDEN. Yes, you are, Senator. And one of the challenges of controlling this mosquito is that it can breed in tiny amounts of water, the amount in a bottlecap. So, to eliminate standing water really means eliminating all standing water. And that is why it has been difficult to do it to an extent that you will actually see a large enough impact on the number of mosquitoes to make a difference.

But different communities are different. In one community, bird-baths were found to be one of the important sources of mosquito-breeding water. So, that is one reason why it is so important that communities in this country and around the world have the tools to track the numbers of mosquitoes and see if their mosquito-control activities are succeeding.

Senator KAINE. Thank you.

Senator RUBIO. The bigger question is, Why do you have a canoe?
[Laughter.]

Senator RUBIO. But we will get into that.

Senator Markey.

Senator MARKEY. Thank you, Mr. Chairman.

Can I go to the pesticide issue and what breakthroughs we might be making in pesticides? Are there new pesticides that might be effective, that can supersede the need to use DEET or other pesticides? Can any of you talk about that?

Dr. FRIEDEN. Thank you so much, Senator.

First off, let us divide the different types of repellents in pesticides. So, DEET is a product that we would put on our skin. There are several FDA-approved products that are effective. I mentioned that there are some more products down the road which may be available in the future, that may be more pleasant to use, and just as safe and effective. There are also products that can be used in an area, what are referred to as spatial repellents, so things that you might burn in your household or spray in your household. There, we are trying to get better products available. And then third are materials that we would use to control mosquitoes in a community, so insecticides or pesticides.

One of the really interesting things that has happened in recent years is the refinement of ultra-low-volume spraying, or ULV spraying. It uses tiny amounts of the pesticide, and a very different particle size, to penetrate more deeply, waft down more slowly, kill mosquitoes more effectively at a lower dose. And what we are seeing with those ultra-low-volume applications is the ability to control mosquitoes with less pesticide but more efficacy.

So, one of the areas, again, is using our current tools more effectively, or tweaking them, if you will. The second is developing new tools, like new classes of insecticide. It has been decades since we have had a new class of insecticide available. That is why funding to develop new types of insecticides, ensure that they are safe and effective is so important. That is why we are so excited about the chemical that Senator Gardner mentioned, nootkatone, because it is nontoxic, food grade. And there are also new experimental methods, sterile male or gene drive, that are truly experimental, where we might be able to crash mosquito populations. We will have to see whether those are scalable, effective, and safe. But we will not know unless we study it.

Senator MARKEY. Now, this ultra-low-volume insecticide, have you used it in Puerto Rico?

Dr. FRIEDEN. That is currently under consideration.

Senator MARKEY. And what would be the question that you would have to answer before its use?

Dr. FRIEDEN. The spread of Zika is so rapid and so extensive in Puerto Rico that it is likely that, to have an impact, it would have

to be applied by fixed-wing aircraft or aerial spraying. That creates a lot of concern in Puerto Rico. And there has been very vocal concern about that raised. We think there is a gap of information, and we are working hard to get valid information out and to confront some myths about this.

Senator MARKEY. So, your—the contention of the CDC or the U.S. Government is that this ultra-low-volume spraying can be done without any danger to human beings, but yet play a good role in helping to control the Zika fly?

Dr. FRIEDEN. We believe it can rapidly reduce mosquitoes, and both CDC and the EPA have indicated that it can be done without risk to people, animals, or the environment.

Senator MARKEY. Down in Puerto Rico right now, you are saying that is being resisted because of kind of a generalized fear that something can be done that harms other children, I suppose—

Dr. FRIEDEN. There are—

Senator MARKEY [continuing]. With those kinds of insecticides being put into the air.

Dr. FRIEDEN. There are a number of concerns, a number of historical factors, current events, that make it a big challenge to do this there. But from a technical standpoint, we think this is the most likely way you could reduce the number of mosquitoes substantially and quickly.

Senator MARKEY. Now, if an outbreak occurred within the continental United States, would this be one of the methods that you would recommend be used, let us say, in the first community that had an outbreak in order to try to isolate it quickly?

Dr. FRIEDEN. It very much depends on the conditions in the community. But this is something that is done routinely in the U.S. In fact the State of Florida, each year, uses ULV aerial application in about 6 million acres. It is done routinely in Tampa, Miami, and other places. It is unfamiliar in Puerto Rico, and therefore, there are some concerns there.

Senator MARKEY. Yeah.

And can I take a—just a little bit of time just to talk about the cost of now treating children who have contracted microcephaly or other diseases related to this epidemic? The United States is now going to have long-term responsibility for the care of these children. And it is going to add millions, if not billions, of dollars over time to the budget of our country. And so, this is, to me, a classic example of where working smarter, putting the preventative tools in place up front will then protect us against huge, balloon costs that could last 30, 40, 50, 60 years with something that we could have prevented from exploding into huge numbers. So, even the children in Puerto Rico are Americans, and we have responsibility for them for years to come. So, not spending the money there now is something that ultimately we are going to pay a price that is hundreds of times higher in the long term, in terms of providing medical care for them. Could you talk a little bit about that?

Dr. FRIEDEN. Our Birth Defect Center has documented that the care of one child with a severe birth defect can be up to \$10 million, or more, in their lifetime. So, there is a personal tragedy, a family tragedy, but also an economic cost for not preventing preventable cases of birth defects. It is very rare to have birth defects

that can be prevented in the dozens, hundreds, or thousands. Our staff from our Birth Defect Center tell us that, in the 30 years they have been working on birth defects, this is the most urgent situation they have faced.

Senator MARKEY. Yeah. So, you know, the old saying is “A stitch in time saves nine.” But here a billion dollars now could save \$10 billion later, because of all the children who would not ultimately be born with this disease, that we would have a moral responsibility, a legal responsibility, to take care of.

So, I think that is something that we should all think about, in terms of Puerto Rico or any of the other places that could ultimately be affected by this disease, even if it is not something that happened inside the continental United States.

Thank you, Mr. Chairman.

Senator RUBIO. Thank you.

I—as you know, I have supported the President’s request at 1.9 billion. I thought we should err on the side of caution and do it as quickly as possible. I supported the 1.1, even if it was less, but it was something. I have been trying to urgently get us to do something to move funds so we can begin to address it.

I was wondering if you could discuss—and perhaps this applies beyond simply the CDC—but what happens if, tomorrow, Congress adjourns for 6 weeks for the conventions and the summer and no funding is forthcoming? Where are the shortfalls? What will not be happening as a result of the inability to do something about this?

Dr. FRIEDEN. Well, I will start, and my colleagues may want to say more.

We will do the best we can, but this is no way to fight epidemics. It means we cannot begin the long-term projects to figure out how to protect women more effectively, to come up with better ways to diagnose Zika, to accelerate mosquito control strategies, because we have not been able to invest in those things. We also will not be able to repay the money we borrowed. We borrowed emergency money from States throughout the U.S. so that we could allocate it for Zika, not because that money was not important or needed, because that was the only money we had access to that we could use rapidly. And we have a gap in resources to fight Ebola in West Africa, because we had dollars that we had planned to use, starting October 1, to continue to keep Ebola in control in West Africa. We are continuing to see flares of the embers that are burning from the epidemic that is over there.

And all of those resources are at risk. That is why passage of a supplemental is so important, and it shows us again why having some sort of an infectious disease rapid-response fund is critically important so that we do not have to go through this the next time there is a global public health emergency. Because, without a doubt, there will be a next time.

Ms. KOEK. Yes, if I could—thank you very much, Senator—if I could just add to that and would certainly echo Dr. Frieden that we will do the best we can, but with the resources we have, we will be able to support the countries that I noted for a period of time, for several months during the next year, but we certainly will not be able to do very much to expand to other countries or really deepen the impact of our programs. It is enough to pay for activities

running through several months, but we cannot expand. And we do believe we need to expand. It cannot just be the five countries.

Ambassador GARBER. Thank you very much, Mr. Chairman, for that question.

It has impact for the State Department activities, as well. We hope to use the money from the supplemental for targeted support for U.S. citizens, such as repatriation loans for those that may be—U.S. citizens that may be affected, living overseas. As a former Ambassador, I can tell you, one thing that gives me great concern is that, if current trends of our medical evacuation of pregnant women as employees or their spouses in our posts overseas continue as—at the current rates, we do not have sufficient money for those medical evacuations throughout the year. This was part of the targeted money for that. And I think we have to take care of our own people. That is extremely important. And we are asking them to sacrifice by going overseas. We also hope to use some of that money for improving on communications plans in many countries and out to U.S. citizens.

As we have heard in so much of the testimony today, getting the information out is so critical, and whether that is to U.S. citizens or help our embassies being able to help other governments get the information out—can do so much in the area of prevention.

And also, last but certainly not least, it enables us to make contributions to international organizations, such as the World Health Organization. Countries look to the U.S. for leadership. If we are able to make those contributions, we know that it will stimulate other countries to do the same.

Senator RUBIO. So, just to summarize, if this money does not happen tomorrow, then we are—we face a situation where all of the innovative work going into getting ahead of this will not be able to move forward. In addition to the risk of an Ebola or other outbreak happening somewhere in the world and the depletion of the emergency funds at the individual State level, we face the inability to fund the work we are doing with partner nations in the region who, if they are dramatically impacted, ultimately will impact us, because some of those cases will migrate here in search of medical care and so forth and on a humanitarian basis.

And what I have heard from you, Secretary Garber, you are saying we may not even be—have—we will run out of funds to actually bring our people back home from being—who are deployed abroad, serving in our embassies and consulates around the world.

Dr. Frieden, you talked about the screening of blood in Puerto Rico. Are we screening blood now in the mainland, as well?

Dr. FRIEDEN. The Food and Drug Administration oversees blood screening in the U.S. There are parts of the U.S. that have undertaken screening. Other parts are waiting until they have local transmission or possible local transmission. Already, parts of Texas and elsewhere, where they have had dengue before, have screened. The screening tests are highly accurate in blood, so we want to ensure that we keep the risk as close to zero as possible.

Senator RUBIO. Well, I ask—from the case of Florida, obviously Central Florida—all of Florida, in general, but Central Florida, in particular, has a very strong link with Puerto Rico, with the island. Do you know if Central Florida is screening its blood supply?

Dr. FRIEDEN. I would have to get back to you.

[The information requested had not been received at the time this document went to press.]

Dr. FRIEDEN. Also, already, the blood banks had, as of several months ago, begun a policy that people who have traveled to a place with Zika should defer donation. So, by deferring donors, that is an added layer of safety. So, people who have come from Puerto Rico, for example, would be told not to donate blood and would be asked specifically about that during that time.

Senator RUBIO. Here is the last question, Dr. Frieden. If someone contracts Zika, in most of these cases they are not even symptomatic, in essence. There are people who are carrying it today in the United States that do not even know it, either because you are not symptomatic or, if you are symptomatic, you are largely going to present at an urgent care, emergency room, or a doctor's office with what looks like the flu, in some cases, right? So, let us just use as an example if I were to contract Zika, the way I would manifest, if I had any symptoms at all, would very much mimic that of a viral infection or a flu, correct?

Dr. FRIEDEN. Correct.

Senator RUBIO. And the likelihood, even if I have traveled abroad, unless I reported it, or if I even showed up—because often-times I know these symptoms now, at 45 years of age. I have had the flu a number of times; I get the shot every year now, though, I have had the flu a number of times, and colds and what have you. And so, you would basically say, “I know what I have. I will just go through it.” The chances are that I may not even go to a doctor, much less be tested, because the—as I understand it, the screening for Zika is still not widely commercially available. It would require a referral to a Department of Health to look at it specifically. It is not the kind of thing you see in a panel written up in a doctor's office. Is that correct?

Dr. FRIEDEN. Yes, that is correct.

Senator RUBIO. And so, the reality is that it is very much—it is quite possible, and perhaps, I would dare say, even probable, that there is already a mosquito infection that has occurred in the United States, and we just do not know it, because that person has not yet been tested. What we do not—what we know is, no one who has not traveled abroad and has not contracted it sexually has not tested positive yet. But we do not know if, somewhere in the United States right now, there is someone who contracted it from a mosquito bite in the United States, but because they are not pregnant or because they are not symptomatic or because they were not tested, because they just thought they had the flu, we do not know that it was transmitted by a mosquito.

Dr. FRIEDEN. So, yes, it is certainly possible. Let me also say, on your blood donation question, I want to validate the answers I gave you before, and we will get you more information on that. But on testing, because, as you point out, 80 percent of people have no symptoms, those with symptoms have symptoms that are relatively mild, there is the possibility that transmission could occur without our recognizing it. That is why we are encouraging health departments throughout the U.S. to follow up on all known cases of Zika, and to encourage doctors in those areas where Zika might spread

through the local mosquito to be alert to the possibility, and also to test contact or family members who have illness to see if they have Zika. We have also been working hard to transfer our test methods to the private sector. They are not there yet, though we have made progress toward that.

So, I think the scenario you outlined is certainly plausible. We anticipate that it will be very difficult to identify the first locally transmitted case of Zika. This is why we need better diagnostics. This is why we need better mosquito-control programs throughout the U.S.

Senator RUBIO. Obviously, you cannot speculate entirely about the future, but do you have—personally, based on your expertise, do you have any doubt that we will see a mosquito transmission at the U.S.—in the mainland United States at some point?

Dr. FRIEDEN. I think it is likely we will see mosquito-borne transmission. We do not have a crystal ball, but the best predictor is what has happened with dengue. And with dengue, we have seen clusters and isolated cases in various parts of the country, particularly Florida and also Texas. So, if—since Zika is spread by the same mosquito, we anticipate that the same type of pattern may occur, in addition to the unexpected sexual and, potentially, other means of transmission.

Senator RUBIO. And my last question with regards to this is, Does it make any sense at any point in time, from a medical perspective, to add a test for Zika to the normal screening or the panel that would be administered to someone the way you would put some other infections or other diseases or other viral infections on a normal panel for a blood test?

Dr. FRIEDEN. At this point, probably not, for a variety of reasons. If, in the future, we were to have a test for prior infection with Zika, that might give us some useful information. But we know that, if you have a test applied where the positivity rate is low, you will have a large number of false positives, even if the test is a good test.

Senator RUBIO. There—I am sorry to—there is no—the only way to confirm a Zika diagnosis is through a blood test?

Dr. FRIEDEN. Blood and urine.

Senator RUBIO. So, it is—also appears in other fluids—

Dr. FRIEDEN. Yeah, there are two—broadly speaking, there are two types of tests for Zika, one that looks for the actual virus, the RNA of the virus. And that can be found in blood or urine for about the first 2 weeks, currently, after infection, or a test that checks for the body's reaction to the virus, the antibodies, and that becomes positive within the first week or two, and generally stays positive only for about 8 to 12 weeks.

Senator RUBIO. Yeah. And the reason why I ask only is because I was just wondering if, at some point, as part of the research that is being done, it is possible to create some sort of quick—painless, I suppose, if—ideally—a point-of-entry test that could be applied to travelers coming into the United States. But obviously, if it is your blood, you are asking them to submit to having blood drawn, which is—and having someone undergo a urinalysis at an airport is not the best way to welcome them to the United States. But—[Laughter.]

Dr. FRIEDEN. We have about 40 million trips to and from the U.S. to Zika-endemic areas, and perhaps 200 million—

Senator RUBIO. That is a lot of tests.

Dr. FRIEDEN.—over land or other trips. The—theoretically speaking, if, a few years from now, we have a good test for prior infection, and a vaccine, you could imagine a situation in which travelers leaving the U.S. would want to find out if they had immunity, and, if not and potentially would become pregnant, get a vaccine. That is very theoretical.

Senator RUBIO. We have run long, so my last question—I promise this is the last question.

If someone has traveled abroad to one of these countries where Zika is present, and they have either had relations or have been bitten by a mosquito, or think they might have been, what—how can they—how would they get tested? Could their doctor order a test?

Dr. FRIEDEN. Any doctor in the U.S. can contact their local health department. We have already distributed our test, and trained and supervised labs around the country, so that most State health labs already can do this test. And those that do not can send it to CDC labs to have done. So, again, in the first 2 weeks, there is one type of test; from 2 to 12 weeks, another type of test. If people, particularly pregnant women, are concerned that they may have an infection, they should be tested. And people with symptoms of Zika who have traveled should also be tested. And those tests are available.

As you indicate, if we could get them into the private sector, they would be more widely available. And we are doing that as rapidly as possible. We actually got Food and Drug Administration approval to do that, within the past week. We have already shipped the materials to private labs, and they are now undergoing the validation so that they can be comfortable in doing this and providing the results.

Senator RUBIO. Well, I want to thank all three of you for your time and for being here. And, from the attendance today, obviously, on the subcommittee there is clearly an interest, both among our members and the general public.

Before we conclude, I would like to include a study conducted by the University of Florida, the finest learning institution in the Southeast United States—[Laughter.]

Senator RUBIO.—from Dr. Glen Morris, as part of the hearing record. That was a point of personal privilege.

[The information referred to can be found in the “Additional Material Submitted for the Record” section at the end of this document.]

Senator RUBIO. And the record for this hearing was going to remain open until the close of business on Friday.

And, with that, the meeting is adjourned.

[Whereupon, at 4:15 p.m., the hearing was adjourned.]

Additional Material Submitted for the Record

ZIKA VIRUS EXPLAINED

February 19, 2016

EMERGING PATHOGENS INSTITUTE
UNIVERSITY OF FLORIDA



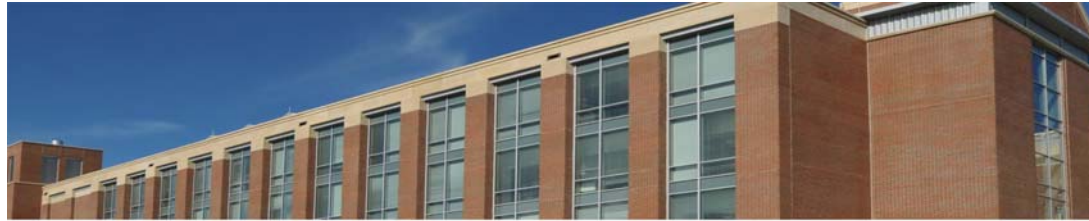
Zika Virus Explained

February 19, 2016



Agenda

- Dr. Amy Vittor, MD, Infectious Diseases specialist, UF College of Medicine and UF Health
- Dr. Michael Weiss, MD, Neonatologist, UF College of Medicine and UF Health
- Dr. John Lednicky, PhD, virologist, UF College of Public Health and Health Professions
- Dr. Jorge Rey, PhD, Interim Director, UF Florida Medical Entomology Laboratory
- Dr. Danielle Stanek, DVM, Zoonotic and Vector-borne Disease Program Manager, Florida Department of Health Division of Disease Control and Health Protection
- Dr. Glenn Morris, MD, Infectious Diseases specialist and Director, UF Emerging Pathogens Institute



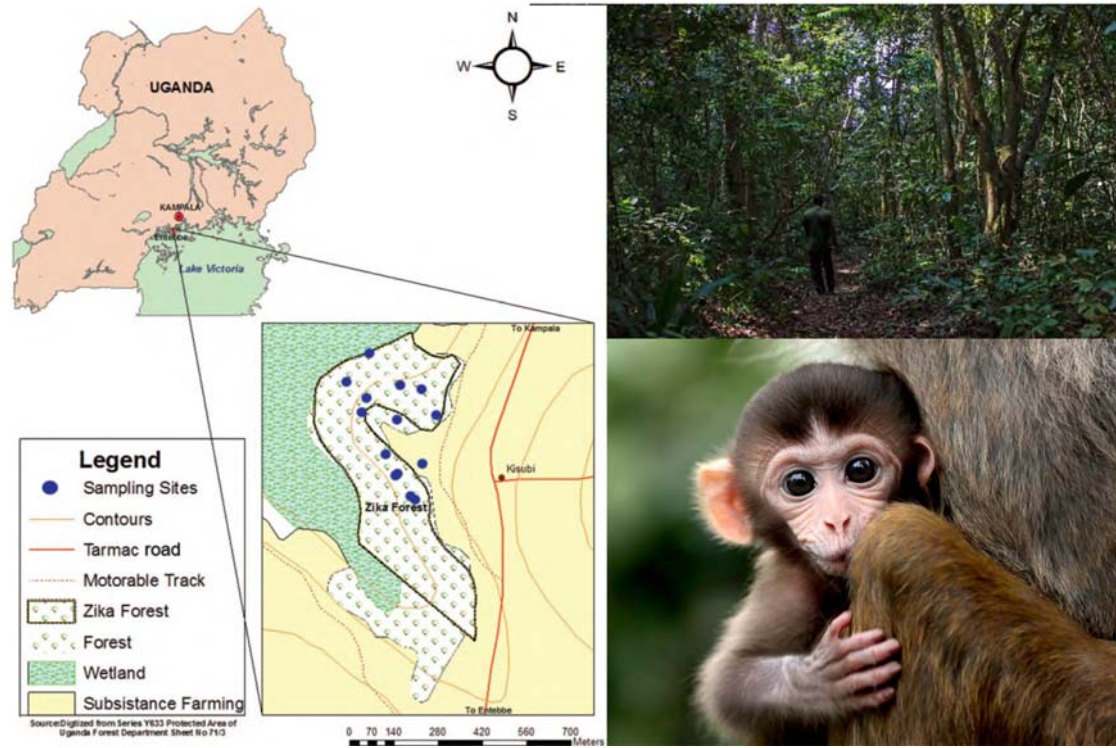
Amy Vittor, MD, PhD

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Assistant Professor of Medicine
College of Medicine
University of Florida

UF | Emerging Pathogens Institute
UNIVERSITY of FLORIDA

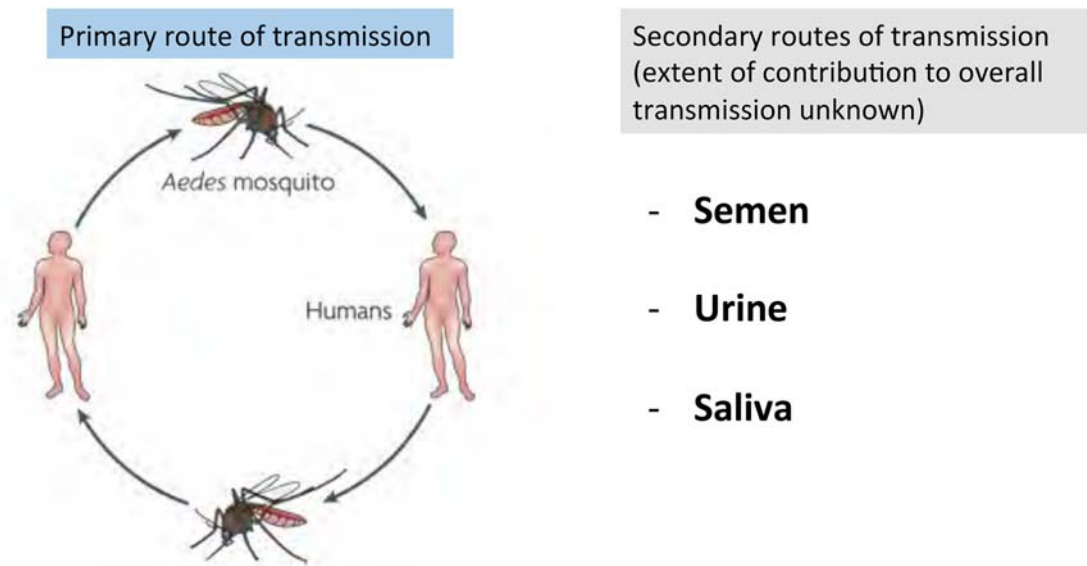
Where did Zika virus come from?



How the Zika virus spread around the world



How is Zika virus spread?



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Prospects for a dengue virus vaccine. *Nature Reviews Microbiology* 5,
518–528 (2007). All rights reserved.

Zika Symptoms

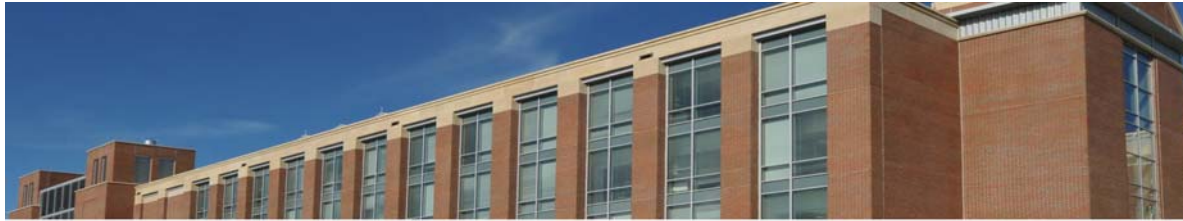
- 80% of people who are infected do not have any symptoms at all
- 20% who have symptoms are sick for 2-7 days, and have fever, rash, joint pains, red eyes, muscle pain and/or head ache
- No specific therapies exist
- No vaccine available, but development underway by Sanofi Pasteur, Inovio, Bharat Biotech (at least 18 months away from large scale trials)

Guillain-Barré Syndrome

- Neurological condition causing muscle weakness and possibly paralysis
- In severe cases, patients need ICU care to support breathing
- Guillain-Barré syndrome is seen following numerous types of infections, and is due to our own immune response that damages neurons
- Spikes in cases of Guillain-Barré have been seen in Polynesia, Brazil, El Salvador and Colombia following the arrival of Zika virus
- Whether Zika virus causes Guillain-Barré syndrome is not yet known

Microcephaly

- A condition in which an infant's head is smaller than expected, caused by infection, toxins, or genetic disorders
- 20-fold increase seen in microcephaly in Brazil late 2015
- Zika virus has been found in the brain tissue of some deceased infants and in amniotic fluid
- Babies with microcephaly in Brazil have additional brain damage that is consistent with an infectious cause
- Greatest risk appears to be associated with infection during first trimester
- Insecticide exposure is not likely to have caused the increase in microcephaly. Pyriproxyfen, the larvicide in question, has not been associated with fetal abnormalities in animals.
- Rigorous epidemiological and laboratory studies are needed to establish causation



Michael Weiss, MD

Associate Professor in the Department of
Pediatrics –Neonatology Division
College of Medicine
University of Florida

UF | Emerging Pathogens Institute
UNIVERSITY of FLORIDA



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MICROCEPHALY

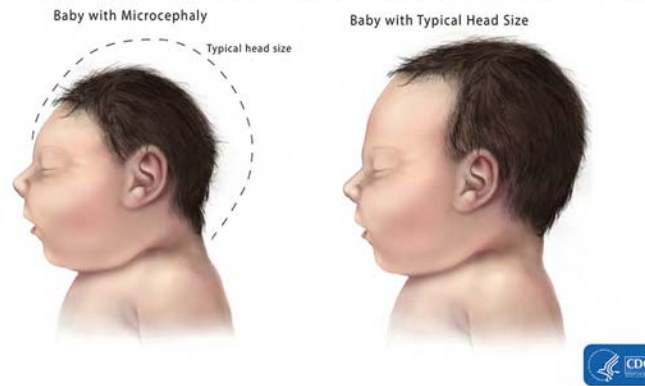
•Michael D. Weiss, MD | Associate Professor, Department of Pediatrics

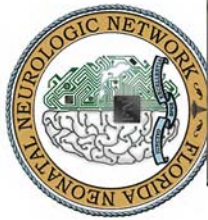




What is Microcephaly?

- Clinical finding of a small head when compared to infants of same sex and age.
- Usually less than the 3 Percentile.
 - Not a diagnosis
- When present at birth called congenital microcephaly.





What is Microcephaly?

Microcephaly

Normal Head Size



Microcephaly





Causes of Microcephaly

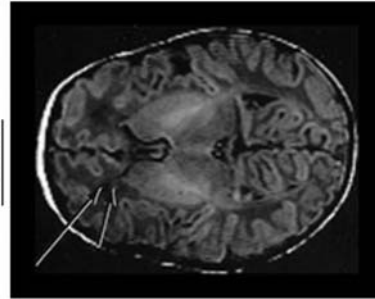
- Primary due to abnormal development
 - Genetic Etiology
- Secondary due to arrest or destruction of normally formed or forming brain.
 - Vascular
 - Teratogenic
 - Infection
 - Cytomegalovirus (CMV)
 - Toxoplasmosis Gondii
 - Rubella (German Measles)
 - Zika



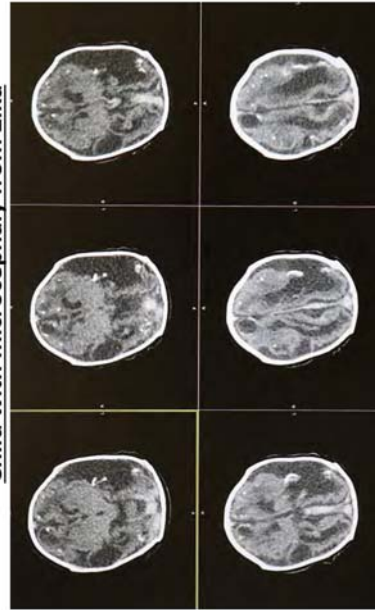
Microcephaly



Normal



Child with microcephaly from Zika





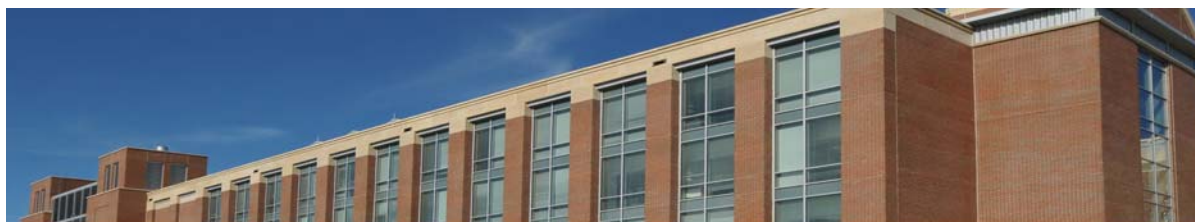
Zika and Microcephaly

What we know

- Small number of positive test results for Zika virus .
- Microcephaly pattern consistent with disruption sequence.

What we don't know

- Causal relationship between Zika and microcephaly.
- Impact of timing of infection.
- Impact of severity of maternal infection.



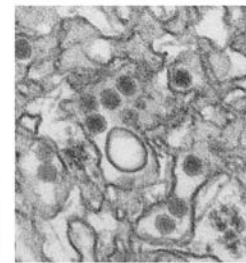
John Lednicky, PhD

Associate Professor and Co-Chair
Environmental and Global Health College
of Public Health and Health Professions
University of Florida

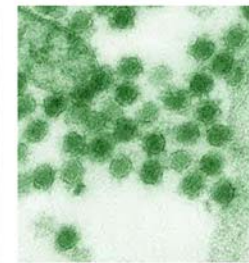
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Zika virus: Some basic information

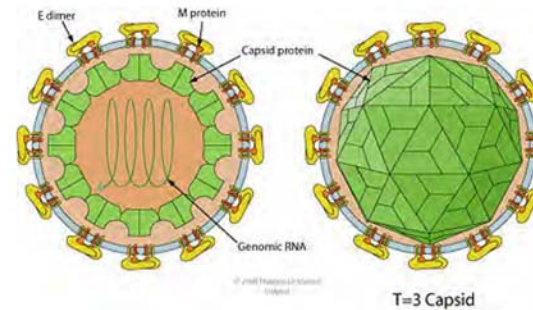
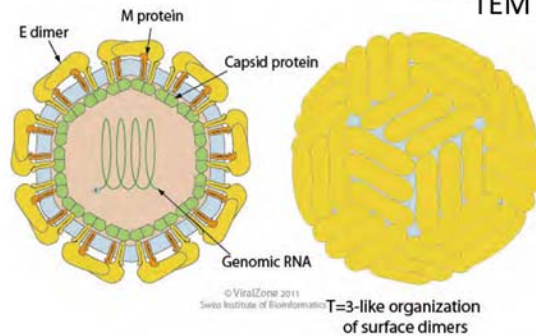
- *Zika virus (ZIKV)* is a type of flavivirus that is mosquito-borne.
- ZIKV is highly related to *Yellow Fever, Dengue* and *West Nile viruses*.
- ZIKV particles are about 40 nm in diameter and thus cannot be seen using a regular microscope (a transmission electron microscope [TEM] is usually used to visualize them).



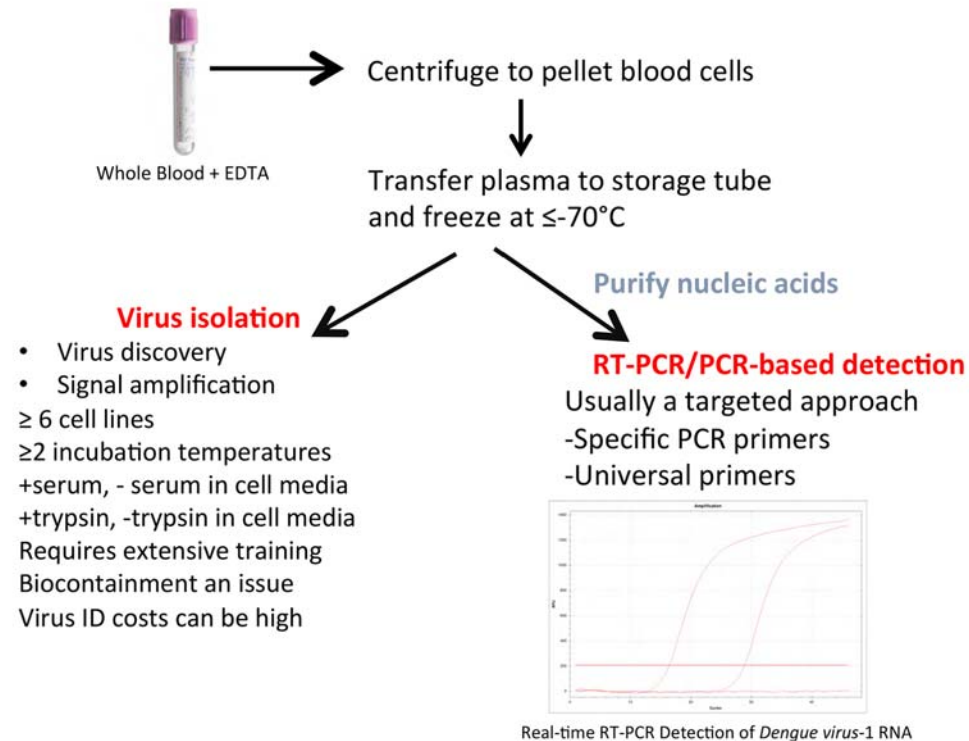
Zika virus



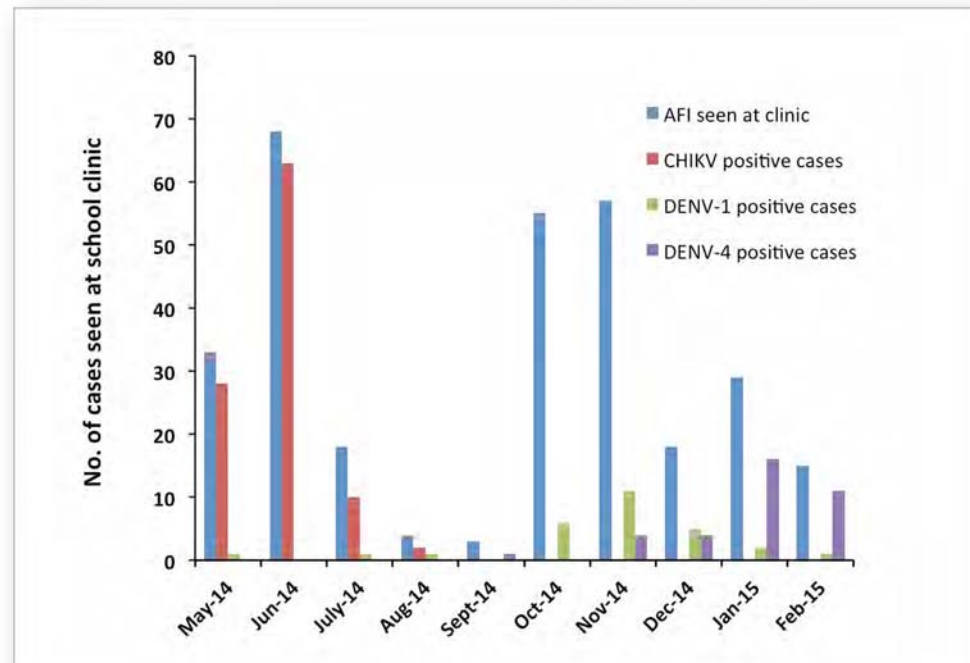
West Nile virus



Virus Detection

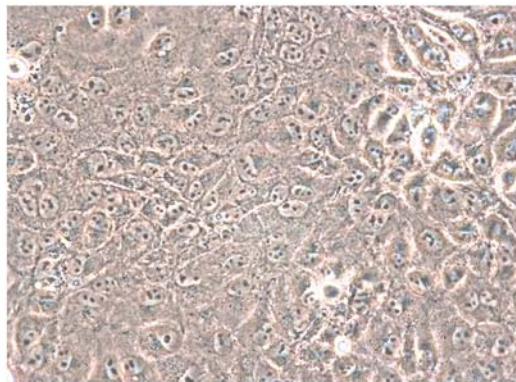


Chikungunya and Dengue Fevers Occurred in Haiti in 2014 - 2015

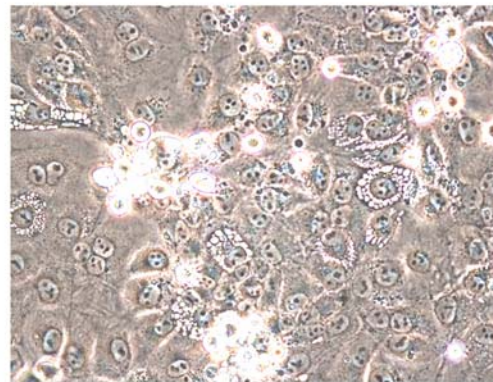


Timelines

- The EPI detected ZIKV in **May 2015** from Haitian blood **collected in Dec. 2014**.
- March 26, 2015 – ZIKV infections confirmed in Brazilians with dengue-like illnesses. http://wwwnc.cdc.gov/eid/article/21/10/15-0847_article
- Jan. 14, 2016 – News media report outbreak of Zika Fever in Haiti.
- Jan. 23, 2016 – Dominican Republic reports cases of ZIKV infections.

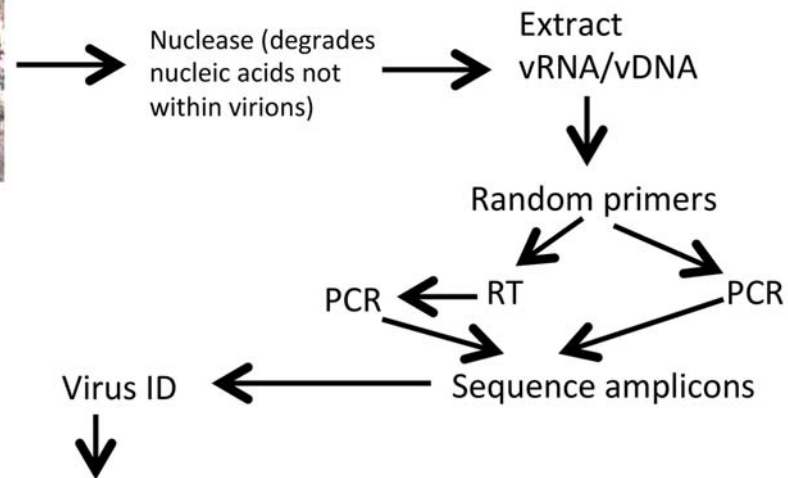
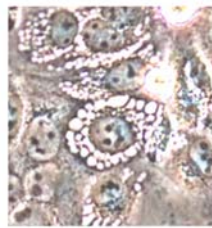


LLC-MK2 cells (Negative)



LLC-MK2 cells + ZIKV

Identification of *Zika virus*

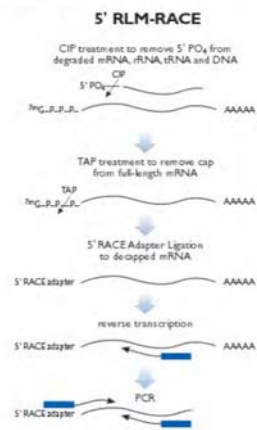


- Primer walking approach
- 5' and 3' RACE (Rapid amplification of 5' and 3' complementary ends)

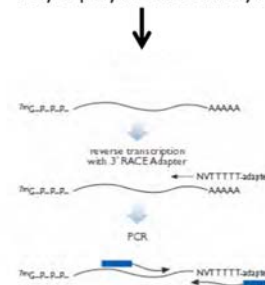
RACE



- 5' is capped by a 5'-type 1 structure (m⁷G5'ppp5'A) and that must be removed
- 3' is not polyadenylated
- RNA ligase-mediated RACE is used

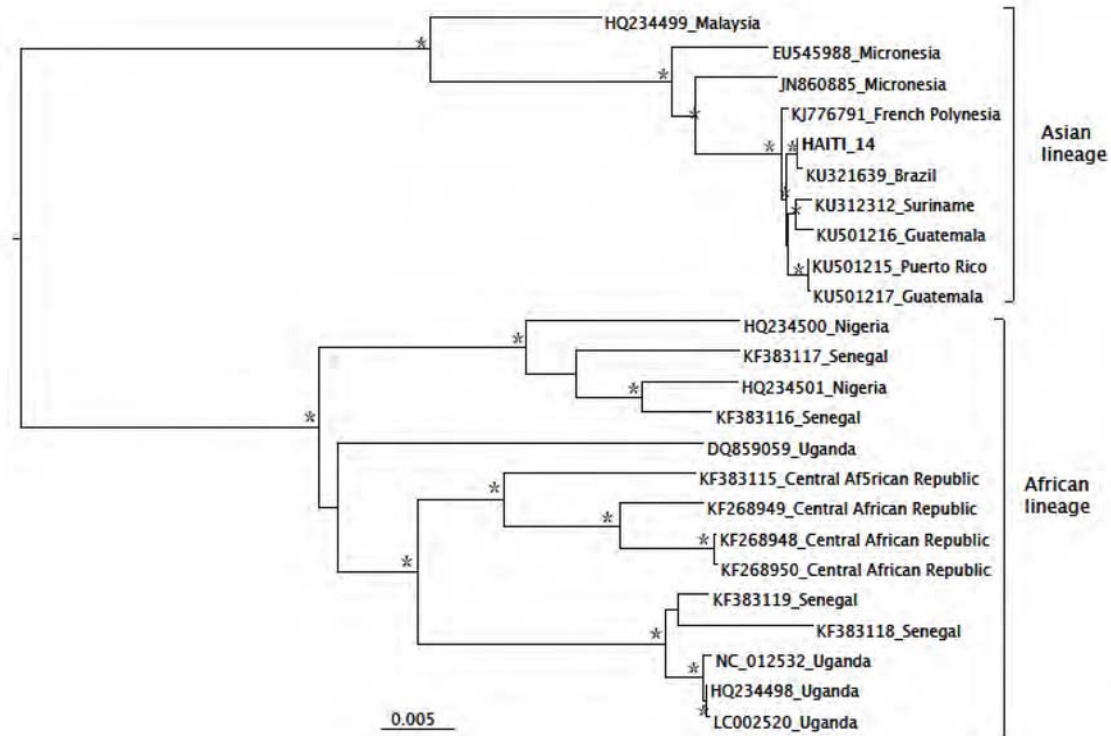


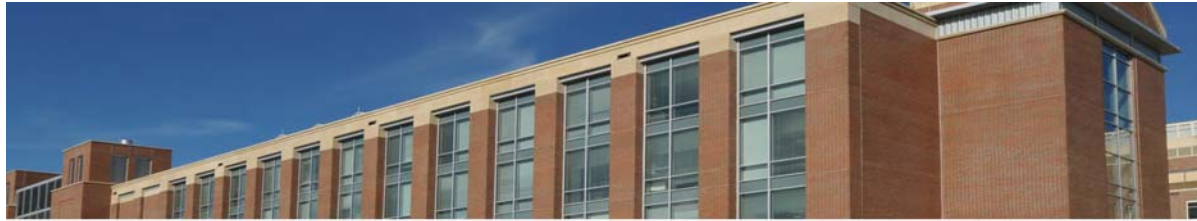
3' RLM-RACE
vRNA + Poly U polymerase or Poly A polymerase



N = A, C, G, or U
V = A, C, or G

Genetic analyses indicate that ZIKV Haiti predates 2015 Brazil strains



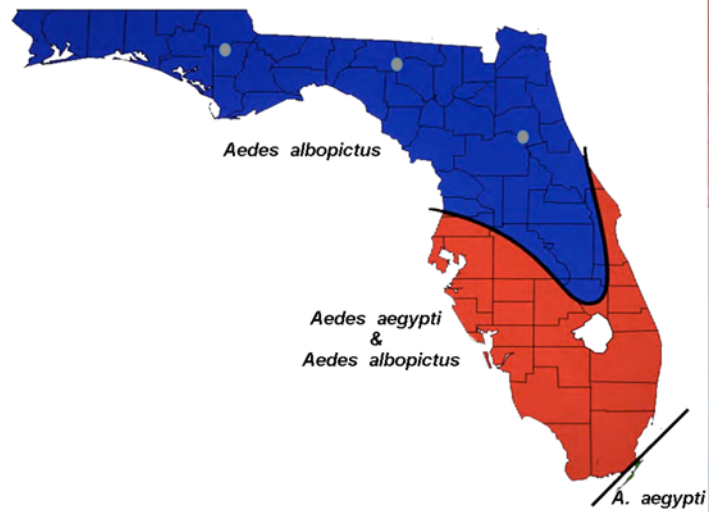


Jorge Rey, PhD

Interim Director of the Florida
Medical Entomology Laboratory
University of Florida – IFAS

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Mosquito Vectors in Florida



Yellow fever mosquito
African origin
Invaded 13-14th Century

Asian Tiger Mosquito
Asian origin
Invaded 1980s

1



Eggs

The Mosquito Life Cycle

2

Larvae



1st – 4th Instar

3

Pupa



4

Adult





Container mosquito management



- Chemical (adulticiding)
 - pyrethroids
 - malathion
 - naled
- Biological
 - Sterile males
 - Gm mosquitoes
 - Wolbachia



Source reduction
Insect growth regulators (methoprene)
Bti
Predators

PREVENTION

Remove, cover, or flush water-holding containers from around the home.

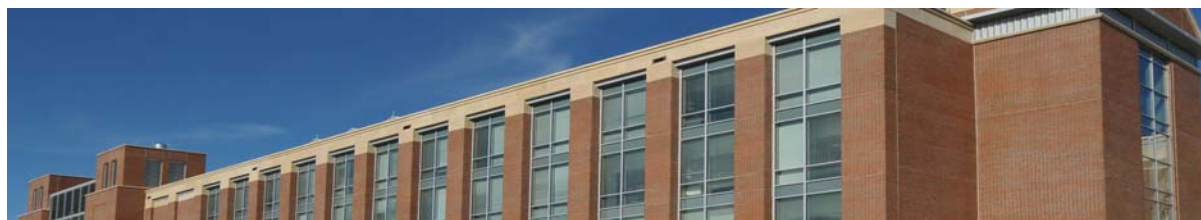


Wear protective clothing when exposed to mosquitoes



Apply an EPA-approved repellent according to label instructions.





Danielle Stanek, DVM

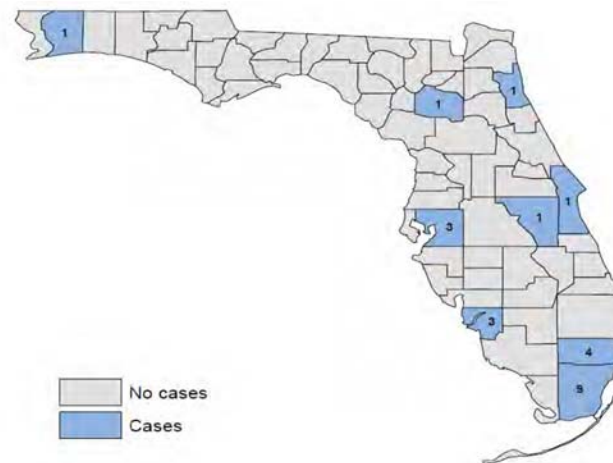
Zoonotic and Vector-borne Disease
Program Manager

Florida Department of Health – Division of
Disease Control and Health Protection

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Current Status (2/18/2016)

- To date no cases of locally acquired Zika fever have been reported
- 24 Zika fever cases (travel-associated) acquired outside the US
- 9 counties with imported cases: Alachua (1), Brevard (1), Broward (4), Hillsborough (3), Lee (3), Miami-Dade (9), Osceola (1), Saint Johns (1) and Santa Rosa (1)



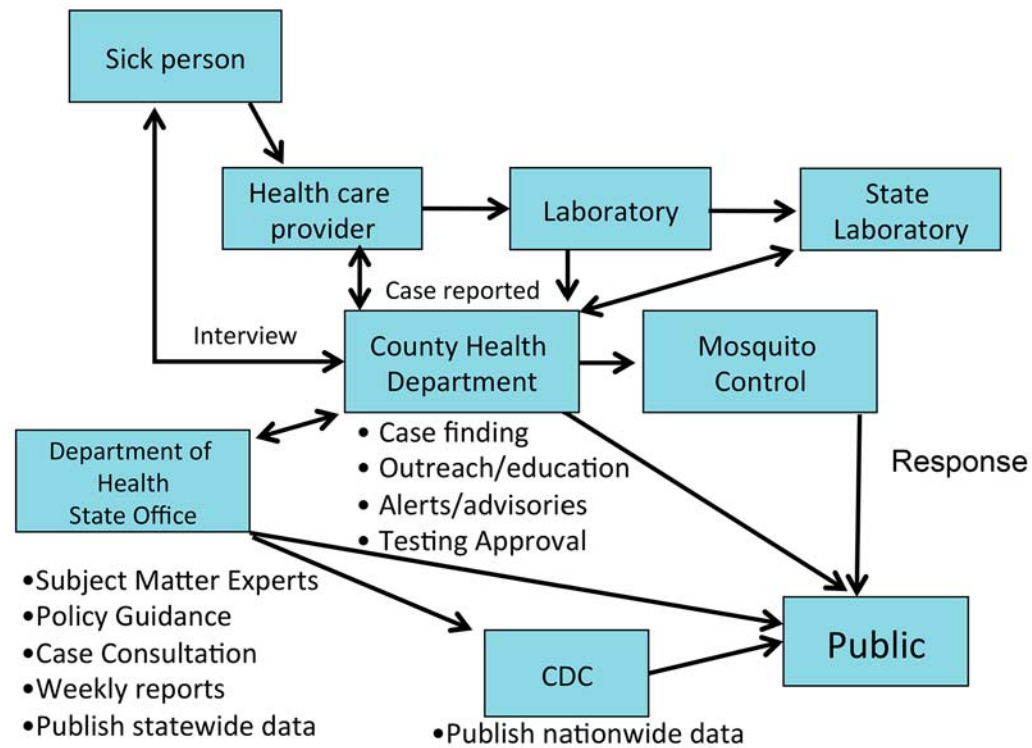
DOH Response Partners

- State Arbovirus Task Force
 - Mosquito control representatives
 - State agencies
 - Universities
- Targeted messaging to health care providers
 - Hospitals
 - American Congress of Obstetricians and Gynecologists
 - Midwives/nurses
- Working with internal partners
 - Birth Defects Registry
 - Maternal and Child Health
 - Public Health Tracking

DOH Response Activities

- Response similar to dengue/chikungunya
- During interview
 - Complete travel history
 - Avoid mosquito bites while ill
 - Highlight prevention methods
- Inform local mosquito control officials of suspect cases
- Provide testing for health care providers
- Provide public information on disease, transmission, prevention, protective actions
- Updated information on public web page

Suspected Zika Fever Case Investigation



DOH Successful Response Model

- Key partnership with local mosquito control districts
- DOH notifies mosquito control upon suspicion of mosquito-borne illness
- Appropriate mosquito control measures are implemented
- Successful partnership demonstrated previously
 - Chikungunya 2014
 - 510 imported cases identified
 - 12 sporadic local cases
 - Coordinated DOH – Local mosquito control activities
 - No sustained local transmission



STATEMENT SUBMITTED BY THE CENTER FOR VACCINES AND
IMMUNOLOGY AT THE UNIVERSITY OF GEORGIA

During the last week of June, 2016, the first person in the continental United States died in Utah from Zika virus infection. Zika is almost never fatal, however, an elderly Puerto Rican man also died in April from Zika virus complications. Urgent action is needed to stem the spread of Zika virus in the United States and throughout the Americas. Before 2007, very few human cases of ZIKV infection were reported, but now there is a full-blown epidemic and the beginnings of a ZIKV pandemic. On February 1, 2016, the World Health Organization declared the virulent Zika virus an international health emergency. Zika virus is spreading explosively and could affect millions people in the United States in the next year. This mosquito-transmitted virus is linked with birth defects in thousands of babies in the Americas, as well as Guillain-Barre syndrome, a disorder in which the immune system attacks the nervous system. Pregnant women are a high risk of complications following Zika infection.

Currently, there is no approved vaccine against the Zika virus (ZIKV). However, several organizations, including the University of Georgia (UGA), are actively developing vaccines using various platforms and technologies. While many of these are in the early stages, several are based upon previously approved platforms and designs against dengue virus and other infectious disease agents. To address this challenge, the University of Georgia and metro Atlanta-based GeoVax have entered into a partnership to develop and test a potential Zika virus vaccine. Dr. Ted M. Ross, director of UGA's Center for Vaccines and Immunology and Georgia Research Alliance Eminent Scholar, is leading a team of UGA researchers to develop this novel Zika virus vaccine. GeoVax's novel vaccine platform technology takes a different approach with virus-like particle (VLPs) by using recombinant DNA or viruses to produce VLPs in the person being vaccinated so they more closely resemble the virus generated in a body during a natural infection. GeoVax's platform is focused on vaccines against HIV and hemorrhagic fever viruses, including Ebola. It is also being evaluated for use in cancer vaccines. The UGA research team focuses on designing, developing and testing vaccines, including those for VLPs, which mimic a live virus but don't contain genetic material and cannot replicate or cause infection. VLPs give immune systems a "head start" in fighting infection, Dr. Ross said in a statement.

We strongly encourage the U.S. Congress to pass comprehensive Zika legislation for research.

TED M. ROSS, PH.D.

Director, UGA Center for Vaccines and Immunology

