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EXAMINING THE U.S. PUBLIC HEALTH RESPONSE TO THE ZIKA VIRUS

WEDNESDAY, MARCH 2, 2016

House of Representatives,

Subcommittee on Oversight and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:15 a.m., in Room 2322 Rayburn House Office Building, Hon. Tim Murphy [chairman of the subcommittee] presiding.

Members present: Representatives Murphy, Burgess, Griffith, Brooks, Mullin, Hudson, Collins, Cramer, Castor, Tonko, Clarke, Kennedy, Welch, and Pallone (ex officio).

Also present: Representative Bilirakis

Staff present: Brittany Havens, Oversight Associate,

Oversight and Investigations; Charles Ingebretson, Chief Counsel, Oversight and Investigations; Tim Pataki, Professional Staff Member; Chris Santini, Policy Coordinator, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight and Investigations; Sam Spector, Counsel, Oversight and Investigations; Dylan Vorbach, Deputy Press Secretary; Christine Brennan, Minority Press Secretary; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Professional Staff Member; Ryan Gottschall, Minority GAO Detailee; Chris Knauer, Minority Oversight Staff Director; Una Lee, Minority Chief Oversight Counsel; Elizabeth Letter, Minority Professional Staff Member; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; and Kimberlee Trzeciak, Minority Health Policy Advisor.

Mr. Murphy. Good morning. We are here for the Subcommittee on Oversight and Investigations for the Committee on Energy and Commerce for a hearing called "Examining the U.S. Public Health Response to the Zika Virus."

This morning we'll be examining this other public health crisis affecting the Western Hemisphere, that Zika Virus. This virus of mosquito-borne pathogen is currently rampaging through South and Central America, and in total has spread to more than 48 countries and territories.

While as of late February there have been no known locally-acquired mosquito-borne cases reported in the Continental U.S., over 100 travel-associated Zika Virus cases have been identified in over 20 states. Outside of the 50 states local mosquito-borne transmissions have been reported in Puerto Rico, the U.S. Virgin Islands, and American Samoa.

Public health officials in the U.S. are bracing for the time when Zika passes from a traveler with Zika in his or her blood to a local mosquito, and then to another person.

Only about one and five people with Zika infection exhibit symptoms, most of which are mild and flu-like. Of greater concern is growing evidence of a link between Zika infection and microcephaly, a congenital birth defect in infants born to infected mothers, as well as Guillain-Barre Syndrome, an immune disorder that can result in temporary paralysis. On this basis, the World Health Organization recently declared Zika a public health emergency of international concern.

The virus may also be transmitted through blood transfusions and sex leaving the Center for Disease Control to issue interim guidelines for prevention of sexual transmission, and the Food and Drug Administration to take steps to reduce the risk to the U.S. blood supply.

Thus far, there has been only one reported case in the U.S. of a child born with microcephaly to a mother with travel-associated Zika Virus. However, another pregnant American woman -- other pregnant American women have become infected with Zika. Our understanding of how the virus may impact a developing child during pregnancy is nearly non-existent. We can, however, reasonably assume that a virus affecting development of the brain on a large scale leading to microcephaly in the first trimester will also impact significant developmental functions for infants, toddlers, and

children exposed to the Zika Virus. These include my concerns for developmental disorders of difficulty with learning, primary sensory and sensory integration, memory, attention, concentration, behavior, mood, language, motor, and others.

Given all of the unknowns the importance of acting now to protect pregnant women and women of reproductive age from exposure to Zika Virus cannot be overstated. However, we must be equally concerned with protecting infants and children with developing brains and not wait five to ten years for symptoms to appear before we take action to protect, to track, and to treat.

To help prepare for and respond to Zika, the Administration recently requested Congress provide over $1.8 billion in emergency funding. The request includes support to states, U.S. territories, the International Community for Mosquito Control, virus testing, and expanding surveillance and response activities. It also supports efforts to build upon existing resources to develop a vaccine for Zika.

While the Administration's request has worthy aims, it's one-off emergency funding approach like the $6 billion for Ebola emergency funding demonstrates a reactionary posture towards public health preparedness rather than a strategic one. We want a strategic posture.

On February 12th, this subcommittee held a hearing examining the federal government's preparedness for biological threats focused on the finding of the Blue Ribbon Study Panel on Biodefense. The panel concluded that the federal government is ill prepared to handle future biological threats, an alarming conclusion because since 2002 infectious disease outbreaks, epidemics, and pandemics have emerged with increasing frequency, and Zika is just the latest example of this trend.

The Administration's response to Zika raises very serious questions. There are no commercially available diagnostic tests for Zika, nor has a vaccine been developed. In the absence of these measures, mosquito control is the nation's critical defense. However, mosquito control in the U.S. is a patchwork of 700 mosquito abatement districts depending on the state, county, and city funding and personnel with varying capabilities. This unorganized hodgepodge could leave the U.S. vulnerable to a rapid outbreak of Zika. The Administration has not explained how its emergency

request will address issues with vector control. We want to work with the Administration to solve that problem.

Public Health Departments and the CDC are using two Zika diagnostic tests only available for U.S. labs. As the Government Accountability Office testimony makes clear, these tests have serious limitations, including the ability to either detect Zika or to be able to distinguish Zika from other viruses.

In addition, the confirmatory testing for Zika detection is used only by CDC and a few labs, is cumbersome and not suitable for screening a large number of individuals. This very limited capacity for confirmatory testing is very troubling when we consider the expected surge and the demand for Zika testing as we reach the warmer months. Again, the Administration must explain its plan to address this testing capacity issue.

Once again as with Ebola, we are assured that Zika will not be a significant problem in the U.S., and while Dr. Anthony Fauci of NIH has stated that it is unlikely the U.S. will have a major Zika outbreak, other experts differ. In his written testimony to this committee, Dr. Peter Hotez of Baylor School of Medicine notes the experience of Texas showed a Dengue outbreak occurred in the poorest areas of Houston and other Gulf Coast cities vulnerable to Zika.

This morning we'll be taking testimony from a panel of federal witnesses and experts, including the Assistant Secretary for Preparedness and Response at HHS, the Director of CDC, the Director of the National Institute of Allergy and Infectious Diseases at NIH, the Acting Chief Scientists of FDA, as well as the Chief Scientist of the GAO. Welcome.

We will then hear from a second panel featuring specialists in tropical and maternal fetal medicine, mosquito control, and global health law.

I want to thank all our witnesses for joining us this morning and look forward to hearing your testimonies.

I now recognize, since Ms. DeGette is not here, we're promoting her to the Ranking Member Pro Tempe of the subcommittee, Ms. Castor of Florida, for five minutes.

[The statement of Mr. Murphy follows:]

********** COMMITTEE INSERT 1**********

Ms. Castor. Well, thank you, Mr. Chairman, for calling this important hearing, and I want to thank all of our expert witnesses who are here today for everything that you do to keep American families healthy and safe.

So many of my neighbors across the State of Florida, and the Gulf Coast, and Puerto Rico are very concerned with the impacts of the Zika Virus. We want our states and our communities to be well prepared and we want to better understand the impacts of the virus.

In Florida, we have -- CDC has confirmed the Zika case count is now up to 44 cases. All of these cases are travel-related, so there are no locally-acquired cases in Florida. Overwhelmingly, people who have traveled to Brazil and Latin America to visit family and friends, or travel on business or for pleasure have contracted the virus and have brought it back. Fortunately, the Zika symptoms are not severe but there is a great concern for emerging evidence to support the association between Zika and microcephaly in infants born to mothers who contracted the Zika Virus during pregnancy.

I'm also especially concerned with the American citizens in Puerto Rico because we now have 117 confirmed cases. It is the most affected area in the United States, and the CDC predicts a sharp rise. Again, family and friends who travel back and forth from Puerto Rico to the U.S. want to know what the impacts are and how they can be better prepared, especially as spring and summer approach. That's going to bring larger and more active mosquito populations. The U.S. must be prepared to quickly address local transmission within Puerto Rico, the Gulf Coast, and the entire United States.

I'm also particularly concerned with the weakening of our public health infrastructure across the country. After the Great Recession, I saw very significant cuts in the State of Florida, but Florida is not alone. We have those cuts and weakenings to public health departments and public health infrastructure. And I think Ebola was something of a wake-up call, but the Zika Virus and other viruses, diseases, we've got to be better prepared. I agree with Chairman Murphy, a much more robust prevention strategy would be in our best interest.

For the Zika Virus, addressing the crisis requires a multidimensional response, including accelerating the research, development, and procurement of vaccines and diagnostics, providing emergency assistance to states. Thank

you, CDC, for what you've done in responding quickly to the State of Florida's request, and we've got to enhance our surveillance capacity.

Thank you, again. I look forward to your testimony. I yield back.

[The statement of Ms. Castor follows:]

**********COMMITTEE INSERT 2**********

Mr. Murphy. Thank you. Now we'll go to -- we'll take Mr. Upton's testimony, and for the record recognize Dr. Burgess for five minutes.

Mr. Burgess. Thank you, Chairman, thank you for the recognition, thank you for having this hearing this morning, thanks to our witnesses. We always learn so much when we have a panel like this in front of us, and today I'm sure will be no exception.

This virus continues to spread through the Americas and it really has become clear that this is a direct threat to our public health and our public safety. So I'm in contact with people back in my state, and my county health officials, and one of the things that they've expressed to me is concern over the flexibility and the scalability of federal aid at the state level, so I'm actually interested in hearing from our panel about that this morning. Obviously, I share that concern. It is important that state and local agencies, as well as the local docs on the ground have the ability to fight what they need to fight and not have barriers from us at the federal level.

You know, Ebola happened in our backyard in north Texas, and many ways we thought we were prepared, but in some ways we turned out not to be prepared. So I guess I'm interested this morning; yes, I want the reassurances that we're prepared, but I really also want to hear what were the Lessons Learned when we went through the Ebola crisis in September and October of 2014, and what is the applicability of those lessons to what's going on on the ground today. A variety of other questions concerning the testing and the development of tests for this illness. And, obviously, I'm terribly interested, Dr. Fauci, in the pathogenesis of the illness as it affects pregnancies, both miscarriages and infants who are born affected, and very interested in learning the status of the vaccine development.

Thank you, Mr. Chairman. I will yield back my time.

[The statement of Mr. Burgess follows:]

**********COMMITTEE INSERT 3**********

Mr. Murphy. Anybody else on our side wish to take any time? If not, Mr. Pallone on his way but what we'll do is we will begin our testimony, or begin that process. When he comes in, we may interrupt after one of you speak.

Let me introduce the panel, start off with this. We have Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response with the Department of Health and Human Services; Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention; Dr. Anthony Fauci, Director of the National Institute of Allergies and Infectious Diseases at NIH; Doctor, is it Luciano or Luciana?

Dr. Borio. Luciana.

Mr. Murphy. Luciana Borio, Acting Chief Scientist at FDA; and Dr. Timothy Persons, Chief Scientist at the U.S. Government Accountability Office. Welcome everyone for being here.

You're aware that the committee is holding an investigative hearing and when so doing has the practice of taking testimony under oath. Do any of you have any objections to taking testimony under oath? Seeing no objections, the Chair then advises you that under the rules of the House and the rules of the committee you're entitled to be advised by counsel. Do any of you desire to be advised by counsel during your testimony today?

Dr. Borio. No.

Mr. Murphy. No one wants that, so in that case would you all please rise, raise your right hand. I'll swear you in. [Witnesses sworn.]

Mr. Murphy. Thank you. You are now all under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. We'll have you give a five-minute opening statement. Mr. Pallone, do you want to give your's now or do you want to wait until we do some of the panel? We can go right to your opening statement.

Mr. Pallone. It's up to you.

Mr. Murphy. Well, let's make a smooth transition. If you're ready, we'll do that now, and then I'll call on Dr. Lurie. We just did the swearing in so you're aware of what we did. So Mr. Pallone is recognized for five minutes.

Mr. Pallone. Thank you, Mr. Chairman, and the witnesses today for joining us to discuss the Zika Virus and what

the federal government is doing to respond to the threat.

Zika represents a serious threat to global health and security and we must address that threat decisively both at home and abroad. It's suspected of causing a multitude of devastating birth defects, most notably microcephaly, a condition which babies are born with severe brain defects. In adults, the virus has been associated with Guillain-Barre Syndrome which can result in paralysis and even death. Although scientists are not able to say definitively that Zika is the cause, evidence is mounting each day to support a causal relationship between the virus and these serious health conditions.

The Zika Virus is spreading explosively through the Americas with active local transmission in 31 countries and territories. The Pan American Health Organization predicts that the virus will eventually spread to every country in the Americas except perhaps Canada and Chile.

The crisis in Puerto Rico could become particularly severe as Zika is expected to infect one in five Puerto Ricans, and given the territory's debt crisis and inability to fund even the most basic health services robust assistance from the federal government will be absolutely crucial to contain the virus and protect as many pregnant women as possible.

As spring and summer approaches we must also be prepared to address local transmission of Zika within the Continental United States, particularly in southern states where the mosquitoes that carry the disease are common.

As Dr. Hotez on our second panel has previously noted, "Local transmission of Zika in the U.S. will likely disproportionately affect poor neighborhoods in the southern states where inadequate window screening, standing water, and imperfect waste disposal provide ideal mosquito breeding grounds, and addressing Zika will require a multidimensional public health response. It must include accelerating research, development, and procurement of vaccines and diagnostics, providing emergency assistance to states and the U.S. territories, and enhancing our surveillance capacity to track the Zika Virus in people and in mosquitoes."

The Administration has requested emergency funding to address each of these components, and I look forward to hearing more about the details of this request today. Unfortunately, the Republican chairs of the House Appropriations

Committee have declined to fund the Administration's request and have, instead, called upon the agencies to divert unobligated Ebola funds. I believe this decision is shortsighted and would increase health risks both at home and abroad.

As our witnesses will make clear today, Ebola remains and will continue to remain a threat to human health for the foreseeable future. It could reemerge at any point, and as we've seen it can cause outbreaks that decimate economies, trigger widespread panic, and result in a tragic loss of human life.

NIH is using its Ebola funds to conduct essential ongoing research including the development of an Ebola vaccine, and CDC is continuing to conduct its global efforts to combat the Ebola Virus on the ground. Shortchanging these efforts would damage our ability to effectively respond to both Zika and Ebola, as well as to any future threats. The remaining Ebola funds are largely committed to the global health security agenda, a multi-year effort to keep Americans safe by strengthening the capacity of developing countries to prevent, detect, and respond to emerging epidemics.

Let's not forget how Ebola managed to spiral out of control. To build an effective global system for containing infectious disease we must make sure that the poorest and most vulnerable countries have the surveillance capacity to identify outbreaks and respond quickly, and fighting Zika will not be easy. Like Ebola, it thrives in impoverished communities and its heaviest burden falls on vulnerable populations least able to respond. The disease is difficult to track as most people infected with Zika experience no symptoms, and the research agenda is extensive given how little we know about the disease. But I'm confident that our federal agencies are up to the task as long as Congress does its part and provides the necessary resources. And I hope that all my colleagues on both sides of the aisle recognize the importance of these investments and that we'll be able to work together in a bipartisan manner to address the Zika threat in the coming weeks.

Thank you, Mr. Chairman. I yield back.

[The statement of Mr. Pallone follows:]

**********COMMITTEE INSERT 4**********

Mr. Murphy. Thank you. Now we'll go and proceed with the testimony. We'll start with you, Dr. Lurie. You know how this works; watch your lights and try and keep it at five minutes.

Thank you very much. You may proceed.

STATEMENT OF NICOLE LURIE, M.D., ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; THOMAS FRIEDEN, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH; LUCIANA BORIO, M.D., ASSISTANT COMMISSIONER, COUNTERTERRORISM POLICY, U.S. FOOD AND DRUG ADMINISTRATION; TIMOTHY PERSONS, Ph.D., CHIEF SCIENTIST, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF NICOLE LURIE

Dr. Lurie. Thanks. Good morning, Chairman Murphy, Ms. Castor, and distinguished members of the subcommittee. I'm Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response, and thank you for the opportunity to talk to you today about yet another emerging threat, the Zika Virus.

While we don't yet know everything we need to know about Zika, as a primary care physician and as a mom, I know how deeply concerning what we're all learning is. As you know, ASPR was established almost a decade ago by the Pandemic and All Hazards Preparedness Act in part to overhaul the government's approach to emergencies that threatens the public's health, whether naturally occurring or manmade. Since that time and with the support of Congress including many of you, ASPR has done just that, developing a flexible set of capabilities to quickly adapt to challenging threats, including Ebola, MURS, and now Zika Virus.

Since early reports of the potential link between Zika Virus and microcephaly, HHS has taken proactive and as scientific evidence has mounted increasingly targeted actions to protect the American people. Today I'll highlight three areas in which ASPR's work is critical.

First, our central role is to coordinate across HHS and beyond insuring that all components have the latest information and best scientific evidence to inform key decision making, and that all are driving toward the same goals.

Second, ASPR has a mandate to develop the most promising medical countermeasures through the Biomedical

Advanced Research and Development Authority or BARDA. I know this committee is aware of how successful BARDA has been producing 22 licensed products and support nearly 200 countermeasure candidates over the years.

Third, ASPR is clearing longstanding obstacles to progress in this area, such as agreements on virus sample sharing and close collaboration with regional and international partners. You should know that well before the first case of Zika in the U.S. in early January, I convened the HHS Disaster Leadership Group to coordinate our preparedness efforts. This group is made up of leaders from across HHS including CDC, NIH, and FDA, and it insures that the department's senior leaders have shared awareness and the ability to make timely, informed, and coordinated decisions during emergencies. We've convened this group for every emergency and it will continue to meet throughout this crisis.

Similarly, on December 2nd of last year I directed the Public Health and Medical Countermeasure Enterprise or PHEMCE to conduct a comprehensive review of its portfolio to identify candidate products with the potential to stop transmission of Zika.

This committee is well aware that the best ideas for medical countermeasures won't translate into the drugs, vaccines, diagnostics we need without investment. The BARDA component of ASPR is tasked with transitioning promising medical countermeasures through advanced development and across the so called valley of death toward FDA approval. In the case of Zika we've established three countermeasure priorities, vaccines, diagnostics that can detect both acute and previous infections, and insuring a blood supply that's safe by developing blood screening tests for Zika, and techniques for virus inactivation in blood.

Because access to virus samples is critical for developing diagnostics and vaccines, we've worked across government to successfully establish sample sharing and vaccine development agreements, including with Panama and Brazil, respectively. We've also established a mechanism to address international requests for assistance because we recognize that health security knows no borders.

While we move forward aggressively to prepare for the threat of Zika, many of our efforts will depend on new resources. The Emergency Supplemental Request includes funds for CDC, which is responsible for the bulk of the public

health response, for medical countermeasure development, and for contingencies that may arise over the course of the response.

For countermeasures we've been successful in moving from a reactive model of preparedness to a proactive one, building on strong day to day systems and a flexible set of capabilities to do this. The same goes for state and local health departments which is why preparedness for all hazards is so important.

A lesson from both H1N1 and Ebola was the need for flexible funding to insure that we can move quickly as other departments can so that something that starts as a crisis does not become a full-blown emergency. The contingency fund included in the President's supplemental request addresses this overarching need; enabling us, if needed, to make emergency procurements or quickly take other actions that become necessary but that we cannot currently anticipate.

In sum, HHS has mounted a proactive and coordinated response to the Zika Virus, building on Lessons Learned from previous challenges, and the domestic preparedness infrastructure we've worked so hard to establish. Congressional approval of the Administration's funding request will provide critical resources to improve our ability to prevent, detect, respond, and rapidly adjust to Zika and other emerging vector-borne infectious diseases.

Thank you again for inviting me here. I look forward to your questions.

[The statement of Dr. Lurie follows:]

**********INSERT 5**********

Mr. Murphy. Thank you, Dr. Lurie.

Now, Dr. Frieden, you're recognized for five minutes.

STATEMENT OF TOM FRIEDEN

Dr. Frieden. Thank you very much, Chairman Murphy, Representative Castor, and members of the subcommittee.

At the outset, I want to make a few key points. First, we're literally still discovering new things every day about Zika. CDC has about 600 staff currently working on this response. We're activated at Level 1, the highest level of our emergency operations center. We have staff in Brazil, Colombia, Puerto Rico, and other parts of the world looking at and learning from a developing situation.

Zika is new, and new diseases can be scary particularly when they affect the most vulnerable among us. And it's also particularly scary because in Puerto Rico today cases are doubling every week. By April we're likely to see widespread transmission in Puerto Rico, and by June, mosquito season is likely to start in parts of the U.S. where the mosquito that can spread Zika is present. There's a limited window of opportunity to take action. When we look at chikungunya which affected Puerto Rico in -- started in 2014, within two months it was all over the island, within eight months one out of four adults were infected. If that pattern is followed with Zika we could see hundreds of thousands of infections by the end of the year.

CDC is working 24/7 to respond to this, learning more about the link with microcephaly, Guillain-Barre Syndrome, improving diagnostics, looking at ways to optimize vector control with current tools. This is the latest in a series of unpredicted and unpredictable health threats. What is predictable is that there will be more health threats, and that's why it's so important that we continue to improve the ability of countries around the world to find, stop, and prevent health threats.

Now, first, what do we know about Zika? You've outlined, Mr. Chairman, other members some of the key facts here. It's been around since 1947. We didn't know it could cause outbreaks until 2007. It was thought to cause mostly mild disease. It spread primarily by the Aedes aegypti mosquito. This is the cockroach of mosquitoes. It lives indoors, it

lives in the shade, it is hard to kill, and it's very effective at spreading diseases. That's why Dengue and Chikungunya and other diseases spread by it can spread so explosively.

What is really new and unprecedented is the link to microcephaly. It's been more than 50 years since a pathogen causing microcephaly or other severe birth defects was identified that would do so on such a broad level. And as far as we know, never before has there been a mosquito-borne cause of a severe fetal malformation.

The link to Guillain-Barre Syndrome looks increasingly certain. Studies published this week, if replicated would basically prove that link, and it wouldn't be surprising. We've seen Guillain-Barre Syndrome after a wide variety of infections. But microcephaly, the complication of microcephaly is truly unanticipated, potentially catastrophic, and permanent, the very definition of the need for an emergency supplemental response.

Fundamentally, there are four different patterns of spread. First, among travelers, some of them pregnant. And we have 40 million people going to and from Zika-affected areas each year. Second, sexual partners. This is why we issued guidance to reduce the risk of sexual transmission. Third, possible cases and clusters in parts of the U.S. that have the mosquito vectors present. That's why we need to scale up our support for those entities. Fourth, areas likely to have widespread transmission around the world, and especially in parts of the U.S., including Puerto Rico, that have had large outbreaks of Dengue.

The supplemental is critically important for CDC to respond as part of a whole of government response. The request of CDC is for $828 million in three categories; urgent support for Puerto Rico, a response in the Continental U.S., and international support, as well.

There are many very concerning diseases out there whether it's Ebola, SARS, MURS, or the next HIV. We can't let down our guard. Supplemental funding is essential for us to do several things, including reducing the risk to pregnant women by finding out more and doing more especially in Puerto Rico and other areas where it may spread widely, by finding where mosquitoes are spreading in the U.S., and better controlling them, by establishing a registry for birth defects and improving the monitoring of pregnant women, by supporting states and territories directly to improve prevention and

management of cases, diagnosis of patients, increased laboratory capacity, and implement key interventions. This is a critically important and urgent need, and I look forward to answering your questions. And thank you for the invitation to appear before you today.

[The statement of Dr. Frieden follows:]

**********INSERT 6**********

Mr. Murphy. Thank you, Dr. Frieden.

Dr. Fauci, you're recognized for five minutes.

STATEMENT OF ANTHONY FAUCI

Dr. Fauci. Mr. Chairman, Ms. Castor, members of the committee, first I want to thank you for giving me the opportunity to discuss with you today the role of the National Institute of Allergy and Infectious Diseases and the NIH in general in the research endeavor to address this. As you know, the NIH is part of a multi-component aspect of the Department of Health and Human Services, and we're responsible primarily for the research for the development of countermeasures.

As I have told this committee in past hearings, the dual mandate of the Institute is somewhat unique among NIH institutes because although we, like others, have the responsibility of developing a robust basic and clinical protocol and agenda in all of the areas for which we're responsible, for us it happens to be infectious diseases, microbiology, and immunology. However, we also have the unique dual mandate of being able to respond very rapidly to emerging threats. And as a matter of fact, that's exactly what we're doing right now.

I had the opportunity and the privilege to write this perspective in the New England Journal of Medicine in January in which I said exactly what Mr. Chairman said in his opening statements, that this is yet again another threat, another arbovirus threat. If you historically over the last couple of decades we had West Nile, we have chikungunya, we have dengue, and now we have Zika. And as Tom said just a few moments ago, we're going to have others, so it's very important for us to have as part of the overall effort a research component to be able to develop the response. And as shown on this slide it's multifaceted. We do everything from basic research to fundamental clinical research and clinical trials. We do provide, not very well appreciated, the research resources for pharmaceutical companies, as well as for academics who want to get into the field of studying this disease, and we're already negotiating with a number of them.

The bottom line of it all, and the end game is to develop diagnostics, therapeutics, and vaccines. I just want to spend a minute or so going through some of the things that we are now addressing.

First, natural history. We were discussing just a couple of moments ago, it's very important to understand the

true natural history, not only of the disease, symptomatic versus asymptomatic. Can an asymptomatic person who's infected and pregnant actually have a baby who is a microcephalic baby, or a baby that has a congenital defect? We need to study that. we also need to have cohort studies to understand how this has evolved. What we call pathogenesis of disease is trying to understand how this disease evolves. We did this with Ebola, we did this with HIV, and we're planning to do that with Zika.

Another is the fundamental basic research. We know an awful lot about viruses like HIV, like chikungunya, like dengue. We need to know a lot more about Zika. Luckily, it's related to some of those diseases.

Also, the immune response. We don't understand a lot about the immune response. The immune response is generally helpful. We know with dengue that immune response can actually enhance disease. We need to know the protection against Zika, and whether or not there are any deleterious effects. And also, we need to establish animal models.

You mentioned vector control. We do have basic research collaborations with pharmaceutical companies and individual investigators looking at novel ways to have vector control. You've heard of several of these such as Wolbachia infection of mosquitoes or genetic modification of mosquitoes.

Also in diagnostics, the CDC has taken the role in developing and now distributing widely some of the diagnostics that are available, but we still need high specific, easy to perform diagnostics that can tell an important question. To tell if someone is infected is relatively easy. We do a PCR, it's highly specific. The question that is really on everyone's mind is, have I been infected and if so, how long ago? And that is something that needs specificity because the current available antibody tests tend to cross-react with diseases that are prevalent in these societies, particularly dengue.

Now the issue that we're really concentrating much of our effort on is the issue of vaccines, and we now do have a couple of candidates that we're looking at putting into a Phase 1 trial, hopefully by the end of this summer and early fall, which will take a couple of months to determine if, in fact, they're safe and do they induce an immune response that will allow us to go to the next phase of the response, which is an efficacy phase. And we have a number of candidates that I'll

be happy to talk to the group about during the question period.

One I want to bring up in particular, and that is why we have what we call vaccine platforms, things that we have experience with. An example is, we developed a vaccine for West Nile virus several years ago. It was safe, and it induced a good immune response. Unfortunately, there was no company that was particularly interested in partnering with us. I don't think we're going to have that problem now because we have a number of companies that are interested. But what we've done is we've taken that DNA platform and done a very simple thing; we've pulled out the gene of West Nile and we stuck in the gene of Zika, and we're going to be starting a Phase 1 trial, as I mentioned, hopefully. And then finally, we have our screening assays for the development of therapeutics we're going to be looking at because, obviously, therapeutics are a very important part.

So I'll close with this last slide, reiterating what Dr. Frieden, and Dr. Lurie, and I said, that these threats will continue to confront us. And I want to thank the committee for your interest and support of us during these periods. Thank you.

[The statement of Dr. Fauci follows:]

**********INSERT 7**********

Mr. Murphy. Thank you, Dr. Fauci.

Dr. Borio, you're recognized for five minutes.

STATEMENT OF LUCIANA BORIO

Dr. Borio. Good morning, Chairman Murphy, Representative Castor, and members of the subcommittee. Thank you for the opportunity to discuss the FDA's actions to respond to the Zika Virus outbreak.

FDA is working closely with our partners to help minimize the impact of yet another tragic outbreak. Last month I had the privilege of traveling to Brazil, my country of birth, with a small HHS delegation to meet with the Brazilian Minister of Health and several of his senior officials. The engagement was extremely productive. In particular, FDA and ANVISA, Brazilian's National Regulatory Agency, committed to working very closely and reach convergence in the areas of vaccine development and diagnostic tests.

FDA is working to help protect the safety of our nation's blood supply, to facilitate the development and availability of blood donor screening and clinical diagnostic tests, to support the development and investigation of vaccines and therapies, to review a proposal for the use of innovative strategy involving genetically engineered mosquitoes to enhance vector control, and to protect the public from fraudulent products. To help mitigate the risk of Zika transmission from blood transfusions, FDA issued guidance recommending important measures to keep our nation's blood supply safe. And just yesterday, FDA issued new guidance with recommendations to reduce a risk of transmission of Zika by human cellular and tissue-based products are used in medical procedures.

I'm happy to report that last week we issued the first emergency use authorization for a test developed by the CDC. We continue to work very interactively with the CDC and several diagnostic companies, several diagnostic companies to support development of additional tests.

The association between Zika, microcephaly, and other pro-pregnancy outcomes results in a very serious and challenging situation for pregnant women who test positive for Zika Virus infection. Just last week, CDC reported that among nine pregnant travelers with laboratory confirmed Zika Virus infection there were two early pregnancy losses, two elective terminations, and one infant with severe microcephaly at birth. It is not difficult to imagine the fear, uncertainty,

and anguish these women and their families likely experienced; therefore, it is essential that diagnostic tests for Zika Virus provide accurate results.

In recent weeks we have seen an increased interest by clinical laboratories to develop their own tests for Zika. We share the goal of expanding the availability of good tests, and to support these efforts FDA developed simple templates that developers can use to submit data to the FDA for expedited review, but FDA is urging developers to work with us to insure that their tests meet the standards for accuracy and precision. And I need to make clear that FDA will not hesitate to take appropriate action to prevent the use of tests that did not meet our standards.

FDA is actively engaged with NIH and BARDA to help accelerate the development of vaccines, and as we did during the Ebola epidemic we will do all we can to facilitate access to investigation of vaccines through appropriate clinical trials as quickly and safely as possible.

Finally, we are reviewing a proposal for a field trial to determine whether the release of a genetically engineered line of Aedes aegypti mosquitoes will suppress the local Aedes aegypti mosquito population in the release area of Key Haven, Florida. We are preparing to soon, very soon release for public comment a Draft Environmental Assessment regarding the potential impacts of this proposed field trial.

In closing, FDA is deeply engaged and fully committed to sustaining our aggressive response activities to mitigate the impact of Zika. Thank you.

[The statement of Dr. Borio follows:]

**********INSERT 8**********

Mr. Murphy. Thank you, Dr. Borio.

Now, Dr. Persons is recognized for five minutes.

STATEMENT OF TIMOTHY PERSONS

Mr. Persons. Thank you, Mr. Chairman, Ms. Castor, and members of the subcommittee. I'm pleased to be here today to discuss GAO's preliminary observations on Zika Virus disease. I'll summarize our findings of the four topics you asked us to examine; specifically, one, the epidemiology and transmission of Zika including what's known about its link to microcephaly and neurological diseases. Two, the current diagnostic and testing methods for Zika. Three, the methods for mosquito control. And, four, the proposed federal research agenda as it relates to Zika Virus and disease.

With regard to epidemiology and transmission, while several countries noted over here on this graphic have reported outbreaks of Zika Virus disease, unanswered questions remain regarding the epidemiology and transmission of the disease. Accurate information on the incidents of Zika is lacking. Five primary reasons for this are first, about 80 percent of persons who are infected do not show clinical symptoms resulting in potentially significant underestimation of the true incidence of infection. Second, since many of the remaining 20 percent of those who manifest clinical symptoms may not go to a physician because the symptoms are mild, the true incidence of disease is potentially significantly under-reported. Third, an accurate count of the number of cases of Zika Virus disease requires a consistent standardized international case definition; however, at the moment different countries have different definitions, thus complicating epidemiological analysis and research. Fourth, on February 1st of this year the World Health Organization acknowledged that there was no international standard surveillance case definition for microcephaly. Problems with changing case definitions, lack of sufficient information on underlying causes of brain pathology, and lack of baseline data make it difficult to accurately determine the increase of microcephaly in Brazil, and how much stems from the Zika Virus. And fifth, the lack of approved diagnostic tests complicates our understanding of the virus and may hinder our response to the current outbreak.

With regard to detection and testing, currently no commercially available test exists for Zika, as the Chairman pointed out. The FDA recently issued an emergency use authorization for an antibody-based test for the Zika Virus;

however, the main limitation is the inability to differentiate between infection with Zika and infection with other closely related flaviviruses such as dengue. Since closely related flaviviruses such as dengue may also be present in regions where Zika has broken out, the use of this test could incorrectly identify non-Zika Virus associated infections, thus risking extra burden on laboratory and health care systems, and distorting epidemiological analyses.

With regard to mosquito control, because Zika Virus disease cannot yet be prevented by drugs or vaccines, controlling the vector remains a critical factor in mitigating the spread of the virus, and hence disease. GAO identified three categories of mosquito control. First, standing water treatment. Second, insecticides. And third, emerging technologies.

The WHO determined that maintaining vector control after a disease subsides is complicated by dwindling resources. In the United States vector control methods are under state and local jurisdictions which determine the method to use by local needs and factors. Emerging control technologies include the use of biologicals, genetically modified mosquitoes, and auto dissemination traps. According to the scientific literature these technologies show some promise in studies and field trials but would need to be part of an overarching integrated mosquito control strategy.

With regard to the federal research agenda, the NIH and CDC have identified several high priority areas for research; for example, linkages between Zika and microcephaly, improving diagnostic tests and vaccine development. Efforts in these areas are necessarily ambitious but agencies may face challenges in implementing this agenda. For example, given the number of known cases in the U.S. is so few, NIH and CDC may have to rely on the cooperation of other countries to account for a sufficient number of cases to carry on the proposed research. However, data from other countries may differ because of differing definitions of Zika Virus disease and microcephaly.

Turning to vaccine development, NIH officials told us that given their experience with the development of a vaccine for dengue fever, a vaccine for Zika could be ready in three to four years. Zika Virus disease poses new challenge to vaccine development testing especially on pregnant women for whom several barriers to developing and testing vaccines exist. Overcoming these barriers may extend the time for vaccine testing and approval, and the information we

have from NIH in our prior work suggests that developing a Zika Virus vaccine may take longer than currently anticipated.

In conclusion, GAO's past work including, for example, our recent analysis on Swine Enteric Coronavirus Disease outbreaks in pigs has shown some similarities such as a lack of validated diagnostic tests, immature mechanisms for reporting the disease and no approved vaccine. These preliminary observations on the Zika Virus point to a persistent and urgent need for a proactive, agile, integrated and coordinated set of programs in research and development including epidemiological studies, mosquito control, testing capabilities, modeling and simulation, and vaccine development, especially in light of other emerging diseases such as chikungunya and dengue which spread via the same mosquito vectors as Zika, and which also pose a risk to human health.

Mr. Chairman, Ms. Castor, members of the subcommittee, this concludes my prepared remarks. I'd be happy to respond to any questions that you or other members may have at this time. Thank you.

[The statement of Mr. Persons follows:]

**********INSERT 9**********

Mr. Murphy. Thank you. I thank all the panel for your information. Now we'll begin questioning. I'll begin with five minutes myself.

Dr. Lurie, under the Pandemics and All Hazards Preparedness Act and its reauthorization, the Assistant Secretary for Preparedness response was create a lead federal official for coordinating these health emergencies. My understanding, Secretary Burwell designated you as Lead Federal Official for coordinating the response with Flint and Ebola. Am I correct? [No response.]

Mr. Murphy. Has she named you the Lead Federal Official for the Zika response?

Dr. Lurie. So in terms of the Zika response, ASPR's role as it usually is, is to coordinate for her and on her behalf policy issues and other issues related to the Zika response. ASPR is very actively fulfilling that role, as you heard in my testimony. As part of that role, the CDC has primary responsibility for the operational public health response, and Dr. Frieden has the lead for that.

Mr. Murphy. So is that how it's going to break down, the lead response -- Lead Federal Official will be Dr. Frieden, and not you, or do we -- is that --

Dr. Lurie. ASPR has coordinating responsibility on behalf of the Secretary for this. The primary response is an operational public health response and that's what CDC does day in and day out.

Mr. Murphy. We just want to make sure we have some sense of how this is working out.

Dr. Lurie. Yes, absolutely.

Mr. Murphy. Dr. Persons, what are the concerns associated with the assay recently authorized by the FDA for emergency use?

Mr. Persons. Yes, thanks, Mr. Chairman. The test is called the MAC-ELISA test. Its main concern is just its cross-reactivity with other flaviviruses, as other witnesses have pointed out. So you can tell that you have a related flavivirus but you cannot have the specificity to say you have Zika with assurance, unless or until you have the RT PCR basis to back you up and do that.

Mr. Murphy. But is all this going to put an extra burden on the labs and health care systems, and will that distort some of our analysis then if we don't -- if we can't fully do that?

Mr. Persons. That is, indeed, a risk to the system.

Mr. Murphy. Dr. Frieden, do you want to comment on that, too?

Dr. Frieden. Just to clarify, the IGM that was FBUA approved by FDA in wonderful excellent time with good collaboration, that test we believe is accurate, particularly in people less likely to have been exposed to dengue. There is a second test that we do which is a neutralization assay, a PRNT on the IGM positive, so we would in some cases, depending on the combination of the IGM and the PRNT be able to say we believe it is definitively Zika. In other cases we can say only that it's a flavivirus that may or may not --

Mr. Murphy. So we can get a false positive if they've exposed to dengue. Is that what happens, Dr. Borio?

Dr. Borio. Well, just for clarity, is that the emergency authorization is not just for the ELISA test, the one that causes the cross-activity. The authorization is for the ELISA test and a confirmatory test done at CDC. We will have very high standards for the UA.

Mr. Murphy. I'm aware of that, and you had elaborated to this point, too. I just want to find out if we have enough capacity in our public health labs and health care system to handle what the GAO is concerned about with this emergency response. If we don't, we need to know that as Congress.

Dr. Frieden. So we are concerned about the capacity in terms of the number of tests. Our laboratories have been working around the clock for the PCR. We've produced more than 370,000 of them. We think that's ample for the MAC-ELISA. We're up around 100,000 level. It could be that in some places, in some areas individuals who want to be tested will not be able to be tested until we further scale up production and roll out validation of the state labs.

Mr. Murphy. Let me make sure I understand this. So if we're also currently trying to develop a vaccine and some people who have been exposed to Zika Virus will develop their own -- they'll be immune to it. And is that the avenue? I guess, Dr. Fauci, this is your area. Is that the avenue by which will help us determine a vaccine, if some people have

developed their own immunity? Does that give us some other ideas of where to go with this? Am I down the right road there?

Dr. Fauci. Yes. I think in a vaccine trial it depends on what stage of the trial. When you're in a Phase 1 trial you're going to want to -- those are people who are completely normal. That's the thing I was mentioning that would start at the end of the summer. When you get into a trial in the field in Brazil, I mean, obviously you're going to want to know people who were pre-exposed, as well as people who were not exposed as a subgroup of the study. The fundamental study will be to determine the extended safety and some degree of efficacy in a Phase 2A2B. As a subset of that group, you'd want to know what the response would be in those who were previously exposed, perhaps asymptomatically, versus those who were never exposed.

Mr. Murphy. And so where we are now, we just -- we don't have the capacity and you're asking Congress for help because we just don't have the capacity to handle this. Right, Dr. Frieden?

Dr. Frieden. There are many things that we will not be able to do or do at scale without the emergency supplemental.

Mr. Murphy. And this will delay our responsiveness and detection in developing a vaccine until we get this level higher? We all agree with that?

Dr. Fauci. Agreed.

Mr. Murphy. Thank you. Ms. Castor, recognize you for five minutes.

Ms. Castor. Thank you. The Zika outbreak began in Brazil nearly a year ago, and it's rapidly spread across the Americas. I'm very concerned by the virus' recent arrival in Puerto Rico and its rapid spread there. News reports earlier this week said there are well over 100 confirmed cases of Zika in Puerto Rico, and that the number is almost sure to rise over the next few weeks.

Dr. Frieden, can you give us an update on the situation in Puerto Rico? What should we expect to see there in the coming weeks? And then could you go into greater detail on the current diagnostic tools in Puerto Rico, and whether

or not they differ in Brazil and across the Americas?

Dr. Frieden. Thank you very much. In Puerto Rico we have basically the 1-2 punch of Zika and similar viruses. We have the mosquito that can spread the virus, and we have a human environment without screens and air conditioning widely available that lead to explosive spread of viruses spread by this mosquito. So as I mentioned earlier, we have chikungunya which spreads by the same mosquito. One out of four adults became infected with it within eight months of the introduction of that virus to the island.

In terms of the diagnostic tests, the tests are the same but they perform differently in different places depending on what the individuals there have been exposed to. So first off, as Dr. Fauci mentioned, the test for active infection, that's straightforward and accurate, so if someone is sick, they have fever, then between the onset of symptoms or maybe a day or two before until about four to seven days after symptom onset, that test will be positive and it's definitive. But past that period it's much more challenging to determine whether someone was previously infected with Zika. That requires looking at antibodies, and the EUA that the FDA approved on Friday allows us to do that in a way that looks at the IGM or short-term antibody response which may become positive within the first week, and stay positive for some as yet undetermined period of time, it could be months. And then to confirm that with a test that actually grows the virus and sees if it is inhibited by the patient's own serum, the neutralization assay. So it's an algorithm-based testing. CDC has a dengue branch in Puerto Rico. We currently have all 50 of our people from that branch plus another 25 from the rest of CDC on the island now working hard on every aspect of the response.

Ms. Castor. Dr. Fauci, Dr. Borio, do you want to add anything on the diagnostics?

Dr. Fauci. No, but we will do better. I mean, as Dr. Frieden said, this is what we have right now, but we are all of us trying very hard to develop a much more specific test that would answer the question directly that everyone is concerned with. But for what we have now, that's what we're talking about.

Dr. Lurie. I would only add that we've been really approached by a whole array of companies who are now actively working to develop their own diagnostic tests. We're in a position to provide them support and to work closely in

collaboration with FDA to make a smooth, easy path if those diagnostics are effective.

Ms. Castor. Thank you. And, Dr. Frieden, Puerto Rico has seen recent outbreaks of other related infectious diseases in Puerto Rico. What have those outbreaks taught us about Puerto Rico's public health infrastructure and its capacity to respond?

Dr. Frieden. Well, I think it's fair to say that mosquito control, the capacity is very limited. In addition, the challenges of controlling this mosquito are very great so even though there have been efforts to reduce spread of dengue and chikungunya, they have had very little, if any, impact on the actual disease spread.

Ms. Castor. I understand that the FDA has issued guidance on blood donation calling on blood banks in areas where Zika is locally transmitted to import blood from regions without an outbreak, instead of using local donations. Dr. Borio, what does that mean for Puerto Rico? Does it affect their ability to provide medical care to their residents?

Dr. Borio. So FDA's guidance meets an important public health need, which is to keep the nation's blood supply safe. In areas with active transmission, the guidance does require whole blood and blood components to be imported from areas without active virus transmission until a diagnostic test that can be used to screen the blood supply is available. So there is a potential that our guidance could impact in theory the supply of blood to areas of active transmission.

That being said, that should not be the case in Puerto Rico because we have been working very closely with our partners, Puerto Rico health officials, CDC, and Dr. Lurie's office to mitigate the impact of our guidance. And Dr. Lurie may have more to add on that.

Ms. Castor. Well, I note that the President's emergency budget request includes $225 million for grants in technical assistance for Puerto Rico and other U.S. territories facing Zika outbreaks. Is that going to get to the heart of the matter?

Dr. Frieden. That is crucially important for us to be able to mount a robust response, and the sooner the better.

Ms. Castor. Thank you very much. Thank you, Mr. Chairman.

Mr. Murphy. Yes, just a follow-up. Would you say that Florida and Texas are probably some of our highest risk states?

Dr. Frieden. Yes, we've seen clusters of dengue and chikungunya in Florida or Texas, and because of the presence of the vector we anticipate that these could be areas where we might see clusters of local transmission.

Mr. Murphy. Okay.

Ms. Castor. In fact, Mr. Chairman, there was recently a map published in the national newspaper and it had Florida in bright red, so it's definitely gotten everyone's attention, so this is very timely. Thank you.

Mr. Murphy. I will then recognize the doctor from Texas to follow up there. Dr. Burgess, you're recognized for five minutes.

Mr. Burgess. Thank you. And again, thanks to our panel for being here today, and we always do learn so much when you come in to talk with us.

So, Dr. Frieden, let me just ask you, after talking to my folks on the ground back in Denton County yesterday, what constraints has the CDC placed on states when it comes to the expenditure of preparedness Ebola dollars to combat Zika?

Dr. Frieden. We have several different funding streams available that includes the Public Health Emergency Preparedness dollars. Those I believe but would have to confirm, we have indicated to states that they can use for the Zika response.

Mr. Burgess. Those dollars should be able to travel freely between missions?

Dr. Frieden. That's the PHEP, the Public Health Emergency Preparedness grants. For the Ebola dollars, I would have to get back to you.

Mr. Burgess. And please do, because that is important. And we're hearing stuff about funding. I get that. It always come up in this subcommittee, and I'm not immune to that. But, Dr. Frieden, let me just ask you, the travel restrictions, Tier 2 travel advisory right now for countries in the Caribbean and Central America, and South America. Is that

correct?

Dr. Frieden. Yes.

Mr. Burgess. What is the reluctance to go to Tier 3 restrictions?

Dr. Frieden. There's not really a reluctance. It's a question of what's appropriate to the circumstances. We're not saying that nobody should go; we're saying that women who are pregnant should consider not going. And similarly in other situations --

Mr. Burgess. You know, you're asking us for more money. Okay, I get that, and you're saying it's an emergency. I might believe you more that it's an emergency if you would be willing to say and we really don't want you to go down there. The State Department, when I talk to them they say oh, we rely entirely on the CDC, but they're also not assigning women of reproductive age to those outposts. So there's kind of a disconnect there.

Dr. Frieden. What we feel is we need to give people information and allow them to make the choices. We've heard of situations where someone is going back for a funeral or a very important personal event, and so we say you shouldn't go, but we also say we understand there are some circumstances in which women will go. And in those circumstances we provide the information on how they can best protect themselves with mosquito repellant and other means.

Mr. Burgess. Again, it just seems logical that nonessential travel really should be circumspect right now.

Dr. Fauci, let me just ask you a question, because going back several years to what was called the Swine Flu outbreak, and we talked on several occasions during that. I remember the conference call that occurred during March Madness of 2009, and I remember talking to you during the August recess about the availability for the vaccine was a few weeks away. It wasn't quite going to be there for the start of school, but it would be a week or two after, so the middle of September. So that's a six-month time frame if I'm doing my math correctly that you were able to identify the genetic sequence of the virus, reverse engineer a vaccine, test it, assure its safety and efficacy, and get it to school teachers on the second week of school. That's pretty impressive.

Dr. Fauci. Right.

Mr. Burgess. And why are we different with this? Is this just because it's a different virus?

Dr. Fauci. Yes. Well, what you have with influenza was a strain change and a production to have over 150 million doses available over that period of time. What we're talking about right now, as I mentioned, and if I may, let me just clarify --

Mr. Burgess. Sure.

Dr. Fauci. -- what is a feasible time frame within the context of there are always vicissitudes when you're dealing. So we have this couple of candidates, two or three that are likely going to go into a Phase 1 trial in 2016. The one I mentioned as a prototype because it seems to be temporally ahead of the others, is one that we think by the end of the summer we'll have enough, and we have our own pilot plant where we're making doses. We're working very closely with the FDA colleagues on trying to make sure we get that same smooth transition that they helped us with when we went into the Phase 1 trial with Ebola. So let's say we start at the end of the summer/the beginning of the fall, it's likely it will take a few months similar to the Ebola Phase 1 where you know if it's safe and it can induce an immune response.

In 2017, likely in the first couple of months, if the epidemic is still raging in South America, that's very important for a vaccine trial.

Mr. Burgess. Sure.

Dr. Fauci. Because we're now in a trial, not a distribution. We'll likely get an answer of its efficacy very quickly. When I say quickly, I say eight to ten months at which point then you make a decision, you look at the data and you decide what kind of regulatory decision or not you're going to make.

Remember with Ebola, by the time we were ready to go with the vaccine the cases due to the CDC and other efforts had gone all the way down, and there were very few cases to be able to prove efficacy. I don't think we're going to see that because nobody anticipates that this outbreak is going to just disappear in Brazil.

Mr. Burgess. Correct.

Mr. Murphy. Thank you.

Mr. Burgess. Well, I do appreciate that, and I've got a number of questions. And certainly after communicating with my folks back home, this is going to be an ongoing evolving difficulty, and I really would appreciate the ability to interact with all of you as things develop. Thank you, Mr. Chairman.

Mr. Murphy. Thank you. The gentleman's time has expired. Recognize Mr. Pallone for five minutes.

Mr. Pallone. Thank you, Mr. Chairman.

I'm going to talk about the money, too. The President submitted the $1.9 billion request for Zika that directs funds to areas that the agencies have identified as priorities. But, of course, the House Republicans have thus far declined to fund the Administration's request; instead, calling upon the agencies to divert unobligated Ebola funds to finance the Zika response. And I believe this decision is ill-advised, and it will force federal agencies to either compromise the critical work that they're doing in other areas, or shortchange the federal response to Zika and Ebola. So let me ask questions in this regard.

Dr. Frieden, can you explain to us what you plan to do with the agency's remaining Ebola funds?

Dr. Frieden. Ebola is not over. As of today, 84 CDC top staff are in West Africa responding to the Ebola outbreak. Last month labs in West Africa tested approximately 10,000 samples for Ebola. It was only in January that we had the most recent Ebola case in Sierra Leone, so we're still actively responding and tracking. And as you noted in your remarks, the Ebola supplemental funds also directed CDC to work over a five-year period to strengthen the systems around the world that could find, stop, and prevent other health threats such as Zika before they spread widely so that we can learn more rapidly about them and protect Americans more effectively.

Mr. Pallone. All right. Let me go to Dr. Fauci, same questions. What do you expect to do with the Agency's remaining Ebola funds, and why is it important that the Agency complete this work?

Dr. Fauci. Well, the NIH was given $238 million from the Ebola supplement. We only have less than $10 million left. We have about $9 million left, and we have ongoing studies, both the survivor study, as well as the next phase of the

vaccine study, so we actually -- quite frankly, Mr. Pallone, we don't have any Ebola money to switch over. Right now what I'm doing in anticipation of hopefully the approval of the supplement, is I'm moving money from other areas right now to get a start on the things that I just mentioned to Dr. Burgess; namely, the vaccine and other components. So we're using money that we have to shift around from other places. We don't have any really substantial money that's left on Ebola.

Mr. Pallone. So let me ask to go back to -- well, ask both of you, Dr. Frieden or Dr. Fauci, if Congress does not move quickly to fund the Zika supplemental the way the President has requested, how will the agencies meet the demands of fighting the Zika epidemic? How will this affect the -- and how this will affect the other work that you do?

Dr. Frieden. Well, first off we're already drastically scaling back the work we're doing on other diseases, such as dengue and tick-borne disease because we're devoting those staff to the Zika response, even the area of birth defects which usually considered to be an area that would respond to an emergency. We've been pulling staff to work on this who would otherwise be working on a series of other challenges in that field.

And without the supplemental we won't be able to most effectively reduce the threat against pregnant women by learning more and doing more to protect them. We won't be able to rapidly improve our awareness of where the mosquito populations are in the U.S., and to control them before mosquito season. We won't be able to establish a robust birth defects registry to further understand this, or initiate and follow-up on critical studies to understand key unknowns, such as for babies born to mothers with infection who don't have microcephaly, do they have other severe problems? That's going to be a many month and many year undertaking that has to be started now or we'll lose the opportunity to do it most effectively. And we won't be able to support states and territories in their ability to rapidly increase their effectiveness here to the extent that we would like to.

Mr. Pallone. Dr. Fauci, do you want to add to that?

Dr. Fauci. Yes, Mr. Pallone. Ditto what Dr. Frieden said about not being able to do several of the things that I showed on the slide of our research agenda. But one of the additional things that also worries me about not getting the supplement is that we are now starting to forge partnerships with the pharmaceutical companies that are getting quite

interested in, and they're linked to BARDA, and we're all working together to try and push to develop products.

If it turns out we don't get the supplement, we will be viewed as an unreliable partner, and we don't want that because we had that, you might remember, when we were doing the biodefense issues years and years ago where we would start partnering with the pharmaceutical companies, and when it looked like we weren't going to get a particular amount of partnership money, they pulled back. And that would be the worst thing in the world for us, is to have the pharmaceutical companies think we're not a reliable partner.

Mr. Pallone. Thank you, gentlemen.

Mr. Murphy. Thank you. Now recognize Mr. Griffith for five minutes.

Mr. Griffith. Thank you, Mr. Chairman.

Dr. Borio, as you mentioned in your opening the FDA is currently considering an application for a field trial with genetically engineered mosquitoes that would take place in the Florida Keys. Can you update us on where it stands today with your agency, and when you expect the Florida field trial to start? And I'm going to leap forward in an attempt to save a little bit of time because you know we're limited. Does the FDA have sufficient legal authority to expedite the review process for this product given the current Zika emergency? And if not, what additional authorities are needed?

Dr. Borio. We do have the authorities, and we are expediting the review of this. And like I said, very soon we hope to release for public comment the Environmental Assessment and associated findings.

Mr. Griffith. Do you have the ability since there's an emergency to truncate or eliminate the public comment before you do the field trials, particularly in light of the fact that the particular modification of the mosquito has been tested in a number of countries in tropical environments?

Dr. Borio. Mr. Griffith, it's very important for us to go through the process and include the period of public comment. We need to give the publican opportunity to comment on the Environmental Assessment given the significant attention that this novel technology has generated, especially in the communities for the proposed sites. So it is true that there have been many field releases done, especially in Brazil. I learned more about them when I was there last week. The

data seems to be promising in terms of reducing the mosquito populations in those small field trials, but we need to go through our process. And we are greatly expediting the process.

Mr. Griffith. In light of the concerns in the Commonwealth of Puerto Rico, is it possible to expand, do you have the authority to expand and maybe look at a field site not only in Florida, but also in Puerto Rico? And since you have not yet opened the public comment you're going to go through that process, have public comment there, as well?

Dr. Borio. So if the company and public health authorities in Puerto Rico are interested in that, we would be very supportive of the process. So the geography might be a little bit different from the field trial that is being proposed, so the company would have to submit the assessment for that -- anything that may be different for the new field trial. But we will look to create efficiencies as much as possible.

Mr. Griffith. As I understand it, it's been a multiple year, I want to say four but don't hold me to that, years in getting to this point. Would they have to go through that same process in Puerto Rico, or is there some way that we could shorten that time period up extensively so the tests could be going simultaneously?

Dr. Borio. I understand that's the case, and what I an tell you is that this is being greatly expedited now. And I believe that where we are today in the process, that it would not be a protracted process to be able to rapidly assess the request for a field trial elsewhere.

Mr. Griffith. All right, I do appreciate that.

Dr. Fauci and Dr. Frieden, you all have been involved somewhat in this with the genetically engineered mosquito. How is your agency assisting the company that's developed this novel technology? It looks like it's trials of 5,000 people, lots of mosquitoes. Looks like it's been about 90 percent effective in some of the areas it's been tried in.

Dr. Frieden. We have a number of vector control experts who have consulted with the company and others, listened to them as well as provided our input. I think one of the challenges is the issue of scalability. These particular mosquitoes don't fly very far, so you may have to release millions upon millions of them every short distance in order to get the knockdown.

The other thing that's very important to understand is, this mosquito is so tricky that even when we've seen very large knockdowns in mosquito populations, we haven't necessarily seen commensurate reductions in human infections, so it'll be important to look at both of those factors.

Mr. Griffith. And while it is -- it could just be other factors. I do know in one situation some of the disease that they carry was knocked down substantially, but there may have been some other factor involved. It's hard to eliminate all the other factors, as well. I do appreciate that, as well.

I do think it's something we ought to look at. It's pretty exciting stuff, and it's got to a whole lot easier to release millions of mosquitoes than it is to go door to door with pesticides. Did you have something you want to say, doctor?

Dr. Fauci. Yes. Actually, we've been negotiating and discussing with Oxytech, the company that involved with that.

Mr. Griffith. Yes.

Dr. Fauci. And looking at trying to make sure we correlate what Dr. Frieden was saying, the decrease in mosquitoes with actually a decrease in disease because it may be that that we don't really have that exact correlate. You really want to prove that before you start doing a massive thing, because scalability is really going to be a major problem. And you don't want to scale up unless you know it works.

Mr. Griffith. And I have a follow-up question for you that's off subject, but you U.S. Pharmacopeia is looking at allergy injections for folks and trying to change some of those rules, and they may have some right. But have they consulted with you about that?

Dr. Fauci. Nothing to do with Zika.

Mr. Griffith. Nothing to do with Zika. But since you're involved with the Institute of Allergy and Infectious Diseases, I thought I'd ask.

Dr. Fauci. I'm sorry. I was taken by surprise with that.

Mr. Griffith. But they have not consulted -- -

Dr. Fauci. Not to my knowledge. They may have consulted with my staff, but not directly with me.

Mr. Murphy. If you need to think about that, you can get back to him on a time. Thank you. Now recognize Ms. Clarke for five minutes.

Ms. Clarke. Thank you very much, Mr. Chairman. I thank our panelists today. It's good to see you again, Dr. Frieden.

This question is for Dr. Frieden, Dr. Lurie, and Dr. Fauci. Just as a bit of background, it's my understanding that the majority of people infected with the Zika Virus will remain asymptomatic. However, 20 percent of those infected will experience symptoms which range from fever to GBS, which can leave persons paralyzed.

Though so far there have been no local transmission of the virus in the Continental U.S., does CDC expect to see local transmission in the U.S. as the mosquito population increases this summer? While the mosquitoes that carry Zika are common in southern states, they can range as far north as my home district of Brooklyn, New York. Your location, as well as lack of access to air conditioning increases one's chance of coming in contact with the virus, as was pointed out by Dr. Frieden in discussing the situation in Puerto Rico.

Many of my constituents living in the Brownsville section of my district in Brooklyn are very low income, and likewise the low income communities of the south has some of the highest concentrations of poverty in the United States, and tend to lack access to air conditioning. In the south not only do these communities lack access to air conditioning, but they also lack access to health insurance as many southern governors have chosen not to expand Medicaid coverage under the ACA. If they do get sick with the Zika virus, having access to care may become problematic. The bottom line is that economically distressed Americans will likely be the ones most impacted by the spread of Zika were that to manifest.

With that in mind here's my question. What are we going to do to assist low income and disadvantaged communities to prevent being infected in the first place, as well as spread the word of the virus in their communities especially since Zika can be sexually transmitted?

Dr. Frieden. Thank you very much. Our primary concern or most urgent concern is places like Puerto Rico which

are likely to see widespread transmission. In addition, we're advising pregnant women and their sexual partners to use condoms if the sexual partner has come from an area where there has been Zika transmission.

Furthermore, there are parts of the U.S. that have a secondary vector, the albopictus mosquito, the tiger mosquito is much more widely distributed, but it appears to be much less effective at spreading Zika. So unlike aegypti, which bites multiple people, bites only humans, lives indoors, albopictus is less of a threat. It appears that it can spread Zika, and dengue, and other viruses but much less efficiently than the other virus. So our goal with the supplemental funding would be to provide resources for states and local communities to both reduce the risk of mosquito-borne transmission where that is at higher risk, and also to respond to cases so that people who come back with Zika minimize their chances of being bitten by a mosquito, and thereby initiating a chain of transmission.

Ms. Clarke. And my hope is that there will be a lot of public information, education, particularly as the summer hits, especially in a place like New York where you have that international mix and blend of individuals.

Dr. Fauci and Dr. Frieden, the CDC expects to see local transmissions of the Zika Virus at some point in the Continental U.S. Currently, the south has the highest number of people living with HIV in the United States, over 40 percent of those living in the south are HIV positive. I'd like to know how the Zika Virus impacts with those living with HIV? Do we expect to see some more serious symptoms in HIV positive individuals who are infected with Zika? Do we have a sense of that yet?

Dr. Frieden. I'll let Dr. Fauci continue, but I would say the primary issue we see at this point is to pregnant women regardless of HIV status with the risk of birth defects.

Dr. Fauci. Yes. If you look at the historical analogies with other flaviviruses, we have not seen a serious difference at all in an HIV infected versus non-HIV infected person with that kind of -- however, I'm glad you brought that point up, Ms. Clarke, because that's part of natural history studies. When you do natural history studies of cohorts you will be able to get subgroups of that who are HIV positive or not, and actually definitively answer your question, as opposed to saying our impression is that there really is not. But just to reiterate what Dr. Frieden said, we really focus on the pregnant

women. That's the real target issue here.

Ms. Clarke. Very well. Mr. Chairman, I yield back.

Mr. Murphy. The gentlewoman yields back. Now recognize Mr. Hudson for five minutes.

Mr. Hudson. Thank you, Mr. Chairman, and thank you to the panel for this very informative discussion.

One of the -- it was mentioned that there are clusters of dengue in Florida and Texas. It got me thinking, just in terms of folks coming across our southern border. You know, there's been a lot of discussion about different diseases and other public health concerns.

Dr. Frieden, is this also a concern that folks coming across the border could be bringing Zika with them? Is that something we're looking at?

Dr. Frieden. Well, on the one hand we know that Zika and other diseases do spread largely because of human migration. But, in fact, there are 40 million Americans or 40 million people from the U.S. who travel to Zika-affected areas each year and then travel back, and so the number on the border crossing will be a very minute proportion of that.

What we have seen is in some communities that are essentially across the border, for example, Brownsville and Matamoros in Texas, when dengue spread it spread in both parts, but it spread eight times more in Matamoros because it was more crowded and had less access to air conditioning.

Mr. Hudson. I understand. Dr. Lurie, what role will mosquito or vector control play in our response to Zika?

Dr. Lurie. Well a we talk about this paradigm of prevent, detect, respond, prevention is key, so mosquito vector control has got to underpin our efforts for the foreseeable future for Zika, and also for other vector-borne diseases.

Mr. Hudson. Well, there are currently 700 mosquito control districts across the United States at the state and local level. What role should the federal government play in mosquito control?

Dr. Frieden. One of the areas that we would like to enhance and for which we need supplemental funding is to better understand the capacity of mosquito control districts, and to support improvement of that capacity, and better linkage of the mosquito control districts with the health departments and environmental departments, whatever is most

effective within that state or county. They often bridge multiple counties and they may not always be well integrated, but in effective vector control programs for vector-borne disease you may need an integration of the public health staff and the mosquito control staff to identify the places or even the houses to target. And that's really important, and one of the areas that we want to urgently improve.

Mr. Hudson. When you talk about houses to target are you talking about spraying insecticide?

Dr. Frieden. Yes.

Mr. Hudson. Is that the effective way to --

Dr. Frieden. Both insecticide and what's called larvicide that kills the developing mosquito.

Mr. Hudson. Okay. Well because the mosquito that carries Zika breeds in small pools of water often indoors near houses, aggressive trash cleanup and removal is something that's been talked about as one of the most effective ways. Do you envision a federal role in terms of trash cleanup and those sort of things, or is it more information -- -

Dr. Frieden. No. I mean, we really want to support state and local entities with technical guidance. We also recognize that reduction in breeding sites, cleanups is important, it's high profile, but it's very difficult, as you pointed out with mosquitoes that can breed in the amount of water of a bottle cap. It can be extremely difficult to be effective, so it is a component of integrated vector control strategies. We do think that is a state and local responsibility, but we have, I believe, a responsibility to provide technical guidance, best practices, and catalytic funding to try to improve that, especially when something as unanticipated and potentially devastating as Zika is upon us.

Mr. Hudson. So the funding request doesn't cover any of those type activities. It's more just the coordination and information?

Dr. Frieden. We would have some support for local vector control, mostly along the lines of rapidly surging in if there's an area that's not able to do it, and for a particular cluster by establishing rapid response teams, sharing best practices, identifying resources that can be shared among jurisdictions.

At CDC more than 60 percent of our funding or thereabouts goes out to state and local entities. We exist to

support the front lines at the state and local government, but what we do at CDC is to develop the tools, the science, the things like the test kits for Zika that we then distribute to and support local entities to use.

Mr. Hudson. Makes sense. Is it possible to predict or anticipate using surveillance or other means what the next emerging infectious disease would be?

Dr. Frieden. There are many people who would tell you yes. My own belief is probably not, because there are so many possibilities. Just to give you a sense, I just returned from a trip to Africa looking at some of our programs there. I've recently spoken with our teams in India. They've identified two tick-borne viral hemorrhagic fevers, this is Congo Crimean Hemorrhagic Fever and Kyasanur Forest Disease that are much more widely distributed than anyone knew before. So whether we're going to have now a tick that could bite you and you could have a bleeding disease that kills you, I don't know if that's going to come next. But no one, I think, would have predicted that H1N1 would have come from Mexico, or MURS from the Middle East, or Ebola widely distributed in West Africa, or Zika causing birth defects.

Mr. Hudson. Thank you. Mr. Chairman, I'm out of time. I yield back.

Mr. Murphy. Thank you. Now recognize Mr. Tonko for five minutes.

Mr. Tonko. Thank you, Mr. Chairman. Thank you to our witnesses for providing very valuable information.

I'm encouraged by our government's rapid response to the Zika Virus, and the assistance we have provided and are continuing to provide in the areas most affected by the outbreak. This in my opinion underscores one of the most important messages we hear every time we have a hearing on disease outbreak, and that is that we have to be prepared for what we can't predict.

So with that in mind, Dr. Frieden, how is our response on Zika, and our continued response on Ebola preparing us for the next emerging threats?

Dr. Frieden. We use the framework of prevention, detection, response. Those are three core areas of what we need to do both in this country and around the world. Prevention may be things like better vaccines or reduced risk of spread of Ebola and other diseases in hospitals. Detection is about laboratory networks, as well as disease detectives or

epidemiologists, and tracking systems so we know how common certain conditions are and can quickly detect an increase, whether it's in microcephaly or other conditions. And response, the ability to have rapid response teams that can be on the ground within hours or days and have the tools needed to assess the situation and mitigate to the greatest extent science allows.

Mr. Tonko. Thank you. And how are we assisting our state and local health departments in their preparedness, and certainly their response efforts? What can we do to coordinate the response across all levels of government?

Dr. Frieden. There are many aspects of the response which are critically important to be coordinated. For example, we provide diagnostic tests, we work with health care providers, we inform of the latest scientific evidence about it. And with the supplemental request we would be able to be much more robust and involving many parts of state government around the U.S., and within states strengthening the hands of state and local health departments in their ability to provide services, education, information, and interventions to address the spread of Zika, and to reduce the risk.

Dr. Lurie. If I might, I must just also -- -

Mr. Tonko. Sure, Dr. Lurie.

Dr. Lurie. -- add that one of the most important components of this is being sure that our day to day public health system is strong so that it can do this detection. If you start from, you know, a low level each time and we build and then let it decay it doesn't really make any sense. Our country has a pretty good history of national attention deficit disorder when it comes to preparedness and maintaining a strong public health infrastructure, and a strong preparedness system is going to be key both for this outbreak and for all the questions about how we are going to deal with the next outbreak. Those day to day systems are critical.

Mr. Tonko. Thank you. And it seems as though keeping each one of those independent bodies strong and functioning then provides for a better sense of coordination. And infectious diseases that are threats out there need to be addressed in a way that addresses individual states and individual nations. I mean, no one can escape some of those impacts, so I think coordination is important. And the key to containing those infectious diseases is to contain them at

their source, I would think. So the coordination here, I agree, is very important.

Dr. Lurie. Yes. No, thank you for that, and that's the job of my office, is really to do that coordination.

One of the things that we also do is think about Lessons Learned from other outbreaks. And as I said earlier, one of the things that is characterized challenges in our response whether it was to H1 or to Ebola is that Congress was, you know, very generous in providing supplemental funds, but we can't move out quickly and prevent a crisis before become an emergency unless we have some kind of a contingency fund to be able to get going at the beginning.

We've shortened the time dramatically between when Congress is able to approve funding and when we can get it out the door, but each one of those things still creates a lag. I work with FEMA all the time, and you know that when a Presidential emergency is declared and the Stafford Act is activated, money moves right away. At HHS, we don't have that kind of a response fund to respond to public health emergencies, and that's something that I think we're very focused on.

Mr. Tonko. Okay. That's good information to have. And finally, Dr. Frieden, how does our assistance in Latin American countries as they grapple with Zika help keep America safer, Americans safer?

Dr. Frieden. The more quickly we can understand Zika from our work in Latin America and the Caribbean the better for those countries and the better for Americans. This is where it's spreading now, this is where the evidence is. That's why we have teams on the ground in Brazil and Colombia, and we're working side by side in partnership with those countries and others. We disseminated our diagnostic test to countries around the world, and we learn together so we're safer together.

Mr. Tonko. Thank you very much. Mr. Chair, I yield back.

Mr. Murphy. Thank you. Now recognize Mr. Collins for five minutes.

Mr. Collins. Thank you, Mr. Chairman. I want to thank the panel.

I've just got a couple of questions. I mean, certainly, in the past whether it was dengue fever or West Nile, the threat was there, but nothing like what we potentially have here with Zika and the link to the microcephaly. So if a

woman is tested and she tests positive, I'm trying to -- is there a treatment today? I mean, is there -- there isn't, so this -- for a pregnant woman to be diagnosed with Zika is a very bad, stunningly bad day for her, her family, and the potential of which -- -

Dr. Frieden. That's why we've worked very closely with the American College of Obstetricians and Gynecologists. We've provided detailed guidance in conjunction with ACOG. They've sent that out to their members, as well, and we provided information so that as soon as we know more information we provide that to clinicians, as well as women.

Mr. Collins. So here's a question. We do know, I mean, there's been some studies done that there's some women that have a history of breast cancer in their families, and some women will decide to forego the test for fear of what the test will show, especially if there may not be a treatment. So if you're a pregnant woman and there is no treatment if you test positive, is there some worry -- there are women who just for their own sanity would opt to not be tested.

Dr. Frieden. We leave that up to the pregnant woman and her --

Mr. Collins. Well, I know, but -- -

Dr. Frieden. -- clinician, but we do find that there's a great desire on the part of pregnant women to be tested. And it's not that there's nothing that can be done. For example, we would want to insure that that infant were delivered in a facility that has advanced care capacity to provide the intensive support that it might need. Dr. Fauci?

Dr. Fauci. Actually, just to confirm that what we're seeing, the anxiety associated with people who are traveling there, there is a great need to know. We're not seeing denial. There are people who really want to know as much information as we can give them. And as Dr. Frieden said, we leave the individual response to that information up to the individual and their physician, but they are really very much in desire of information, which is what we're trying to get them. This relates to the answer to the question about ultimately getting a highly specific and sensitive test to tell you if, in fact, you were infected.

Mr. Collins. So to lead to that, now I'm assuming the rapid tests that people are looking at are all antibody tests

pretty much.

Dr. Fauci. Well, as we said you have to ask are you looking -- are you infected now? That's not an antibody test, that's a molecular PCR test. The test that people are more in desire of, they go and come back and say I know that 80 percent are likely asymptomatic, so I don't know if I were infected or not.

Mr. Collins. What was your --

Dr. Fauci. They want to know an antibody test. Right?

Mr. Collins. That's correct. So I'm assuming the industry is looking at the rapid tests, are in fact antibody tests. They're not going to pick it up pre-antibody but -- -

Dr. Fauci. Right.

Mr. Collins. I'm assuming that's what's being done.

Dr. Fauci. A lot of activity is trying to develop an antibody test that's highly specific for Zika and doesn't cross-react with other similar viruses.

Mr. Collins. All right. So like in HIV where you've got some false positives, there's the Western Blot that will look for P24 protein or something like that.

Dr. Fauci. Right.

Mr. Collins. Is there such a protein in Zika?

Dr. Fauci. You could actually -- in fact, Dr. Frieden will just explain it, so why don't you go ahead about the --

Dr. Frieden. There are several proteins in Zika that are specific to Zika. However, they're not that dissimilar from similar proteins with dengue and Yellow Fever, so there can be cross-reactivity. But we can give as of today a definitive diagnostic result to a person with prior infection in some circumstances. In other circumstances where there's more cross-reactivity in the serum it's more difficult.

Mr. Collins. But I was hearing from GAO or others that some of these confirmatory tests, they are not widely available.

Dr. Frieden. Right.

Dr. Fauci. What you can do to make it specific is that you can actually -- and this is what our grantees are working on right now, is that if you look at the molecule for dengue, which is the most likely bad actor of cross-reactivity, and you look at the molecule of Zika, you could mutate out of Zika those components that are common between Zika and dengue and still have a protein that's left that the only thing it has is things that are highly specific to Zika. That's what we're working on right now. We don't have that, but that's --

Mr. Collins. So now one last question in the last few seconds. If somebody has antibody, they progress to that state, they do a PCR test. Wouldn't the PCR test still identify the --

Dr. Lurie. No.

Dr. Fauci. No. The virus is gone within days of infection, within seven to ten days it's gone. So once the virus is cleared you could do PCR all you want, you won't get anything.

Mr. Collins. Interesting. All right. Well, thank you for that update, especially on what we ultimately need is -- I mean, if there's possibly some treatment if someone tests positive. Appreciate the information.

Mr. Murphy. Thank you. The gentleman's time has expired. Now recognize Mrs. Brooks of Indiana for five minutes.

Mrs. Brooks. Thank you, Mr. Chairman, and thank you so much for holding this important hearing.

I think what you were just talking about, Dr. Fauci and Dr. Lurie, I'm curious about what is BARDA, and HHS, and NIH doing to support and facilitate these platform-based technologies that you're referring to against the known and emerging threats? You've kind of talked about it a little bit, but what are you actually doing to support platform technologies? Dr. Lurie, you want to start?

Dr. Lurie. Sure, great question. So, you know, back in 2010 when we took a look at the countermeasure industry and decided to pivot, we decided to move away from one bug/one drug to these platform technologies, so we are actually now engaged with a host of vaccine development companies, we have open solicitations to work with them. We are

providing technical assistance on the use of platforms specifically. The same thing with diagnostics and tests in that regard. You know, we built these Centers for Advanced Development and Manufacturing. One of them is in your home state, and they also are positioned to use various platform technologies to make vaccines so that when a candidate is ready they would be the kind of place that you could actually do the scale up, development, the pilot lot manufacturing, and potentially even with technology transfer be able to, when they're ready, manufacture large volumes of vaccines. So Dr. Fauci's group and mine are working extremely actively, talk every day to be sure these hand-off are ready and the platforms are ready.

Mrs. Brooks. Thank you. Dr. Fauci, anything else you want to add to that?

Dr. Fauci. Yes. Actually some examples, just for your information. You have the DNA platform which we've worked with BARDA on. We have the vector platform, the VSV vector where you insert the gene of a particular virus. We did it with Ebola, we're doing it right now with Zika. You have nanoparticles, ferrite nanoparticles so there are all things that can be transferred across all infections, and that's what we mean by a platform, something that you could say this is the way we're going to go, and we're going to stick in the appropriate infection. Once you have those and you have a good solid group of platforms you're going to cut down very, very significantly the amount of time it takes to go after a particular infection.

Mrs. Brooks. And is there anything we need to be doing to encourage this so it does go faster?

Dr. Fauci. Yes. I think that we need some money.

Mrs. Brooks. Let me ask Dr. Lurie about money. Speaking of money.

Dr. Lurie. Yes.

Mrs. Brooks. I'm confused because the President requested just $350 million for the special reserve fund for FY 2017, and the language that was included in the President's request would expand the allowable use for the SRF. So do you believe -- this was a reduction in funds, if I'm not mistaken. It was a reduction in funds for the SRF, and so how is it that the President can put that in his budget, reduce those funds, and yet we're still needing to do all of these things we

need to do with respect to other threats like Anthrax or Smallpox?

Dr. Lurie. So there's no question at all that the funding is critically important. You know, BARDA gets -- -

Mrs. Brooks. But, Dr. Lurie, why did the President request a reduced amount of funding?

Dr. Lurie. Because it provided additional flexibility for advanced research and development funds so that we could move forward with those platforms. Right now the Special Reserve Funds are limited to being able to purchase things that are material threats on the material threat determination, and our pretty profound need right now is in the advanced research and development area.

Mrs. Brooks. And so you're not concerned about the level of funding with respect to material threats.

Dr. Lurie. Oh, we -- -

Mrs. Brooks. You believe it's sufficient?

Dr. Lurie. No, we are always concerned that we can do the job we need to do for the American people and having enough money to be able to procure for bio threats. As you know, in the multi-year budget we've got a five-year projection of what it is that we need. We believe that for Fiscal Year '16 or '17, sorry, that we have sufficient funds to procure the countermeasures that will be ready.

Mrs. Brooks. Thank you. Dr. Frieden, I'm very concerned about the stockpiling, the strategic national stockpile, and could you talk to me about things that BARDA, CDC can do to improve the effectiveness, the coordination of the strategic national stockpile because I don't think we're ready.

Dr. Frieden. Well, we've been optimizing the stockpile for some time. We're able to deliver -- -

Mrs. Brooks. What does that mean?

Dr. Frieden. We're able to now deliver products to more places more quickly. We're also looking at how to get as much protection for our dollar as possible in terms of the mix of products in the stockpile. And we're also looking at the different threats that we may face to make sure that we have a balanced portfolio to be able to address those that might be the greatest risk to Americans.

Mrs. Brooks. Based on the hospitals and the folks I talked to back home we seem to lurch from crisis to crisis and I'm very concerned that we are still not ready. Thank you, I yield back.

Mr. Murphy. Gentlewoman yields back. Now recognize Mr. Bilirakis of Florida for five minutes.

Mr. Bilirakis. Thank you very much, Mr. Chairman. Thanks for allowing me to participate in this subcommittee. Appreciate it and thanks for holding the hearing.

The Zika outbreak like global issues especially pressing in Florida and other Gulf States given that these locations are vulnerable to the spread of Zika. In Florida we already have two cases in Hillsborough County, one of the counties that I represent.

A question for Dr. Borio. You mentioned innovation strategies being proposed to help suppress virus-carrying mosquitoes. It is my understanding that FDA is currently considering an application for a field trial with genetically engineered mosquitoes in Florida. The question is, could you update us on where the field trial application stands today, and when the earliest starting date could be?

Dr. Borio. Thank you. So we are working to soon release for public comment the Draft Environmental Assessment that the company developed. We work closely with EPA and CDC in reviewing the materials, so hopefully very soon it will be released. Once we have an opportunity to review the comments we receive from the public, then we'll make a final decision regarding the application. We're expediting the process. It's part of our Emerging Infectious Disease Task Force in response to Zika, so our -- the reviewers involved in this technology are part of our Emergency Response Task Force, so we're doing everything we can to move this as expeditiously as we can.

Mr. Bilirakis. Well, give me an estimate.

Dr. Borio. Yes. I'm unable to give an estimate at this time because it really will depend a little bit on the volume and interest from the public. We are working those -- -

Mr. Bilirakis. Well, I'm sure there's a great deal of interest based on what my constituents tell me.

Dr. Borio. Yes, it has been an area of tremendous interest, and including some opposition. I think, you know,

what we don't right now is where the public stands in the setting of Zika and the new developments associated with Zika. So we're doing everything we can to move this very quickly. We're collaborating across government with CDC and EPA. We'll learn a great deal about this technology also during my visit to Brazil last week, last month, so what I can tell you right now is that we are prepared to move very quickly on this.

Mr. Bilirakis. Thank you. Next question. You mention FDA's emergency use of authorization referencing diagnostic tests. Would FDA be able to use an emergency use authorization to advance the use of this technology should the Secretary declare a public health emergency? So if you can answer that question.

Dr. Borio. Our EUA authority is currently limited to human products, not to animal products. And this technology is regulated under our animal drug regulations, so it's separate, so we do not have currently authorities on emergency authorization for animal drugs.

Mr. Bilirakis. Okay, next question. Are there other innovative products or strategies being proposed that you're aware of, and able to discuss at this time?

Dr. Borio. I would like to defer those answers to my colleagues from CDC.

Mr. Bilirakis. Please, please, please.

Dr. Frieden. There are a variety of other mosquito control approaches that are being considered. One is simply to optimize our currently available products. And we think there's considerable progress that we could make by doing that, different ways of applying different combinations of products, different ways of assessing mosquito populations after the application of these products. That's very important and needs to be done.

In addition, there are new tools that are exciting. One of them is the genetically modified mosquitoes that you mentioned. Another is Wolbachia, a bacteria that infects mosquitoes and then can reduce their life expectancy and their ability to spread disease. This has been done on a pilot basis. But, again, the question about all of them are are they scalable, will they reduce human disease, are they practically implemented? And NIH is doing work in this area, as well.

Mr. Bilirakis. Anyone else wish to comment on this? Thank you.

Right now there are three tests I understand for detecting Zika during different stages of infection. It is my understanding that Florida and a few other jurisdictions are able to utilize the RT PCR test to detect infection. However, given that those who are infected often don't show symptoms, it seems crucial that we are able to disseminate diagnostic capabilities such as the antibody testing to state and local authorities. So what hurdles do we face in increasing access to these diagnostic tests nationwide?

Dr. Frieden. We're working around the clock to do that.

Mr. Bilirakis. Yes, go ahead.

Dr. Frieden. Excuse me. We've already produced 375,000 of the realtime PCR. We've got roughly 15 to 20 states already approved for use of that. Now with the IGM EUA just last Friday, we expect to have another 15 or 20 states approved for that. That's where most of the returning travelers live and we'll continue to produce them. We've been able to accelerate our production capacity at CDC so that we can increase the proportion of the need that's met, but we recognize that there may be a period of weeks or a month or two where people who want the test can't get it. We're in active discussions as is BARDA and other parts to encourage the private sector to do more in this area. But right now, the CDC developed a test which scientists at CDC spent years working on, is the best thing out there in terms of what's available. And we're working around the clock to make it more widely available.

Mr. Bilirakis. All right. Well, thank you very much, Mr. Chairman. I appreciate it. I yield back.

Mr. Murphy. I know we're done with this. I know Ms. Clarke has one minute. She'd like to ask one more question for one minute.

Ms. Clarke. Thank you, Mr. Chairman. Thank you for your indulgence.

Clearly, there's still a lot more to learn about the Zika Virus. No doubt the public health response to Zika Virus will be complex and require coordination at the global, regional, and national level. While the response to Zika may evolve, one thing is clear; governments and international organizations must commit to funding and providing access to comprehensive reproductive health services to meet the needs of communities during this public health emergency and

far beyond.

Preventing pregnancy and the spread of the disease is desired by women in their childbearing age as has been suggested already in Brazil during this outbreak. As a follow-up to Congressman Collins' line of questioning, what more can the CDC be doing, or what else can Congress do to support the CDC to help women prevent unintended pregnancies, if so desired, and prevent continued spread of this disease through possible sexual transmission?

Dr. Frieden. Thank you. As you noted, most of the -- about half of the pregnancies in the U.S., and about two-thirds of pregnancies in Puerto Rico are unintended. We do not issue advice to women on whether or not to get pregnant. We don't think that's our role. We do provide information so that women, their families, and their providers can make a decision about whether to use effective contraception. We provide guidelines for which methods of contraception are most effective, and how those might be used. This is basically the approach that we're taking, is providing information.

Mr. Murphy. Thank you. Dr. Burgess would like one minute.

Mr. Burgess. And, Dr. Frieden, if we can just talk one second about the spraying issue. You and I have talked about this a lot in the past, straight spraying, aerial spraying. Obviously for this mosquito it is a little bit different, and it's -- as I understand it, it's backpacks and going into yards and gardens. So is the CDC developing any guidance for our local public health offices as to what they can and cannot do, or can and cannot expect? As far as local spraying, is it always going to require consent to go on property? Do people need to identify when they have an ill person at home so that those areas can be perhaps on heightened surveillance?

Dr. Frieden. We've looked at all of these issues and compared experiences across jurisdictions. We have a public health law project which provides information and advice to jurisdictions on models and what's possible in different places. I do think that there are ways to optimize current mosquito control practices, and that's one of the things that we need to rapidly accelerate, and for which the supplemental request would be used.

Mr. Burgess. Do people have the ability to actually get the insecticide themselves and use it in their homes if they don't want the CDC coming in with backpacks?

Dr. Frieden. The CDC wouldn't go in with backpacks, but this a thing that we're looking at quite actively. It depends on mosquito resistance. We're currently doing studies in Puerto Rico to see which products the mosquitos are resistant to, and we found that for some there's 100 percent resistance, for others they're largely susceptible. And it'll depend on what those results are for whether that could be done in exactly what you mentioned, showing people here's where you need to spray. Here are the products that work, is one approach that we're considering.

Mr. Burgess. Thank you. Thank you, Chairman.

Mr. Murphy. I want to thank this panel for your work. We have a second panel coming up here. As you know, other members may have questions for you, so I ask members to submit the questions and then please respond in a prompt manner. I'm sure we'll be following up with all of you by phone, by visits, by other hearings. This is critically important for our nation's health, so thank you so much for attending today.

And while this panel is stepping away and we're preparing the next panel to come to the table, I'll begin the introductions of Panel Two.

We have with us today Dr. Peter Hotez, the Dean of the National School of Tropical Medicine at Baylor. He's also President of the Sabin Vaccine Institute and Endowed Chair in Tropical Pediatrics at Texas Children's Hospital. Second we have Lawrence Gostin, Linda D. and Timothy J. O'Neill Professor of Global Health Law at Georgetown University Law Center. Next we have Joseph Conlon, Technical Advisor to the American Mosquito Control Association, and Dr. Jeanne Sheffield, Director of the Division of Maternal-Fetal Medicine at the Johns Hopkins School of Medicine. And as soon as we have our panel seated; again, it'll be Dr. Hotez, Lawrence Gostin, Joseph Conlon, and Dr. Jeanne Sheffield, I'll begin with some of the parts here.

Let me just say to the panelists, you are aware that the committee is holding an investigative hearing. When doing so it has the practice of taking testimony under oath, so if you could all please be seated, I'll swear you in. Do any of you have any objections to testifying under oath? Seeing no objections, the Chair then advises you that under the rules of the House and the rules of the committee you are entitled to be advised by counsel. Do any of you desire to be advised by

counsel during testimony today? No, say no then.

In that case if you would please rise and raise your right hand, I'll swear you in.

[Panel sworn.]

Mr. Murphy. Thank you. All the panelists have affirmed that, so now you're under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code.

We will now ask each of you to give a five-minute summary of your opening statement. Dr. Hotez, you are recognized first. Please make sure you're turned on, bring the mic close to you, and watch for the red light. Thank you.

STATEMENT OF PETER HOTEZ, M.D., Ph.D., DEAN, NATIONAL SCHOOL OF TROPICAL MEDICINE, BAYLOR COLLEGE OF MEDICINE, PRESIDENT, SABIN VACCINE INSTITUTE, AND TEXAS CHILDREN'S HOSPITAL ENDOWED CHAIR IN TROPICAL PEDIATRICS; LAWRENCE O. GOSTIN, J.D., LINDA D. AND TIMOTHY J. O'NEILL PROFESSOR OF GLOBAL HEALTH LAW, GEORGETOWN UNIVERSITY LAW CENTER; JOSEPH CONLON, M.S., TECHNICAL ADVISOR, AMERICAN MOSQUITO CONTROL ASSOCIATION; JEANNE SHEFFIELD, M.D., DIRECTOR, DIVISION OF MATERNAL-FETAL MEDICINE, JOHNS HOPKINS SCHOOL OF MEDICINE

STATEMENT OF PETER HOTEZ

Dr. Hotez. Mr. Chairman, Representative Castor, and members of the subcommittee, I thank you for giving me the opportunity to speak today. I'm Dean of the National School of Tropical Medicine at Baylor College of Medicine. I also head a product development partnership that makes neglected tropical disease vaccines that the big pharmaceutical companies won't make because they're vaccines for the diseases of the poorest people.

For my remarks about Zika today, I want to focus on my perspective living and working in the Gulf Coast of the United States, and our unique vulnerability to Zika epidemics, and why I believe that this spring or summer Zika could begin affecting pregnant women living in economically distressed areas of Texas, Louisiana, Mississippi, Alabama, and Florida. And why I worry that by the end of this year we could see microcephaly cases appearing on the Gulf Coast. I also want to talk a little bit about some of the hurdles in vaccine development if there's time.

The reason I'm concerned particularly about the Gulf Coast is because the Gulf Coast is unique in that it's the only part of the United States with the possible exception of Tucson, Arizona that has the Aedes aegypti mosquito. That's the mosquito that's now mostly responsible for transmission all over Latin America and the Caribbean, so it's Aedes aegypti that we mostly have to be concerned about. But my other reason I'm concerned about the Gulf Coast, and one not really being talked about enough is extreme poverty. I mean, the reason why we're seeing Zika in Pernambuco State and Recife in Brazil is because that's the poorest area, one of the poorest areas of Brazil. It is the epicenter, not just of Zika, but

all of Brazil's neglected tropical diseases. It's where we see lymphatic filariasis, that's where we see schistosomiasis. And the reason there's so much Zika there is when you -- and it doesn't take much to understand it. You an just view one of the poor communities, you see no window screens, holes in the window screens, but it's also the environmental degradation around the area. You see discarded tires, you see plastic containers filled with water, and all of those factors combine to make the perfect storm, and why Pernambuco is such a deadly place in terms of microcephaly cases and Zika.

It's the same reason why I'm very worried about Haiti. I know we're mostly focusing on the United States, but I'd just like to make the point that I think Haiti is going to be decimated by Zika. UNICEF estimates there's 264,000 pregnant women every year in Haiti, so we could be looking at more than 100,000, maybe 200,000 pregnant women with Zika in their first or second trimester. We could be looking at tens of thousands of cases of microcephaly in Haiti, in a country that basically has no health system. So this is a humanitarian catastrophe that's unfolding in front of our eyes, and I really don't see any significant global action right now happening in Haiti.

And the reason I'm particularly worried about the U.S. Gulf Coast, dengue actually caused outbreaks in Houston in 2003,2004, and 2005. That was worked on by our National School of Tropical Medicine. The reasons are clear, we have Aedes aegypti, but where this is most happening are in the poor areas of Houston, so the historic African American wards like the Fifth Ward in Houston where I can take you there just a minute off the highway. This is not hard to find, and what I'll show you are dilapidated housings with no window screens, holes in the window screens. You'll see discarded tires all along the side of the road filled with organic debris and water, and the Aedes aegypti mosquito likes nothing more than discarded tires along the side of the road.

Right now our Harris County Mosquito Control Division is finding Aedes aegypti mosquitoes. Those numbers are going to start to climb beginning April and into May, and I'm quite worried that we won't learn that there's going to be a Zika outbreak until we start seeing microcephaly cases towards the end of the year. So what do we need to do about this?

First of all, I think the U.S. Government needs a more active role in coordinating what's going on in Haiti, or

what's not going on in Haiti, working with the Organization of American States and WHO. Remember this is a disease can we fight. Between 1947 and 1962 we eradicated the Aedes aegypti mosquito from the Western Hemisphere for most of Latin America. We did it by old-fashioned mosquito control programs and being aggressive by draining water sources. The Aedes aegypti mosquito was eradicated in 18 Latin American countries and resulted in dramatic reductions in dengue and yellow fever.

Equally important, we need a coordinated response to combat the threat of Zika on the Gulf Coast. This means surveillance of mosquitos and Zika detection. Beyond mosquito control we need to collect the garbage, we need to get rid of the discarded tires and standing water in poor neighborhoods, provide pregnant women living in poverty with adequate screens for their homes. This approach goes beyond the health sector and beyond the remits of the CDC. It could require involvement of Housing and Urban Development, EPA, even Homeland Security. Remember, even if a few babies are born with microcephaly on the Gulf Coast it will be talked about in the same context as Katrina, it will be talked about in the same context as the BP Oil spills; so, therefore, I urge this committee to aggressively pursue policies to protect that region. Thank you.

[The statement of Dr. Hotez follows:]

**********INSERT 10**********

Mr. Murphy. Thank you, doctor. Your time has expired. We'll come back to you.

Professor Gostin, you're recognized next for five minutes.

STATEMENT OF LAWRENCE GOSTIN

Mr. Gostin. Thank you, Mr. Chairman Murphy, Representative Castor, and the House subcommittee. I'm going to discuss four is very briefly. First is the President's supplemental appropriation. Secondly, how we continually under-invest and the financing of these kinds of ongoing threats. Third, our public health measures like travel isolation, quarantine. And fourth is child, maternal, and reproductive services.

First in terms of the President's appropriation which I strongly support. So why act now? Well first, as you've heard from the first panel, there's a clear and present danger to the United States and our hemisphere. The United States is the global health leader, humanitarian leader, and we are the major leader in our own hemisphere in the Americas and the Caribbean. We also have our own domestic homeland to protect.

We remember when Ebola arose here in Dallas and other places, how ill-prepared we were, and the public would not accept that. Ebola taught us a vital lesson to act quickly, act decisively, mobilize funding, and attack the hazard as its source. There have been four global commissions since Ebola. I was a member of two of them, and they have strongly urged us to act and act now.

I remember during the Ebola appropriations and when the President sent military forces and the Department of Defense into West Africa. I was on PBS News Hour and they asked me what I thought, and I said I was very proud of America, and I think we need to be proud of America now in our response to Zika.

Should we take Ebola funding for Zika? I think we should not. We would be robbing Peter to pay Paul. This is still a major threat in West Africa. We promised to rebuild and strengthen the decimated health system in West Africa, and America's word is its bond, and its leadership should never be placed in doubt. And that should be on a bipartisan basis, in my opinion.

Zika, moreover, has a deep moral as well as a health dimension. I'm a public health ethicist, and if you had a hearing, for example, nine months from now and there was a mother with a microcephalic child here and we failed to act

decisively now, I think the American public would find that unacceptable.

From financing, we have continually underestimated our financing needs. I was a member of the National Academy of Science's Global Health Risk Framework Commission. They said that in Ebola epidemic, a SARS epidemic, an influenza epidemic, and now Zika could affect up to 10 percent of global GDP in the affected areas, and we have -- and the commission suggested that there was an estimated $60 billion loss to GDP every year expected with $6 trillion in the 20th century, in the 21st century. With that the President's $1.8 billion supplemental appropriation to me looks modest and would reap great benefits. I would also support a contingency fund so that we don't have to mobilize funds in the midst of an epidemic.

Third are public health measures. I believe that the CDC was absolutely right in its travel advisory for pregnant women. In fact, the CDC went further than the World Health Organization. I think it was right to do that. I think any of us if we had a daughter who asked us if she were pregnant should she go to a Zika-affected country, we would tell her what the CDC is telling her, that she should consider postponing that travel. But I would not go further and have travel restrictions or bars, isolations, quarantines, or border controls, some of which were used during Ebola, some successfully, but many not. I think there would also be Constitutional challenges appropriately to many of those measures.

And then, finally, I believe that we need to be very attentive to child, maternal, and reproductive services. Pope Francis supported the use of contraception particularly in relation to Zika. We have women in the United States and in Puerto Rico that need reproductive services and health care services for them and their children, and we shouldn't let them down if they're under-insured or uninsured.

So I thank you, Mr. Chairman and the committee for your clear recognition of this health threat facing the United States and the Americas, and for your leadership in this regard.

[The statement of Mr. Gostin follows:]

**********INSERT 11**********

Mr. Murphy. Thank you, Professor.

Now we're going to turn to Mr. Conlon, who I also understand was an entomologist in the United States Navy for a couple of decades.

Mr. Conlon. Indeed.

Mr. Murphy. So thank you.

STATEMENT OF JOSEPH CONLON

Mr. Conlon. Thank you. Good morning, Mr. Chairman and members of the subcommittee, Representative Castor. My name is Joseph Conlon. I'm a retired U.S. Navy Medical Entomologist and I serve as the Technical Advisor for the American Mosquito Control Association, and I welcome this opportunity to provide a mosquito control perspective to the deliberations of this committee.

The recent introduction and spread of Zika virus in the Western Hemisphere has reawakened in the United States an appreciation of mosquitoes as not just nuisances, but transmitters of devastating diseases. And I use the term "reawakened" advisedly for mosquito-borne diseases such as malaria, dengue, yellow fever were once quite common in the United States and, indeed, played a major part in shaping our nation's destiny. These diseases no longer claim victims in the United States as a matter of course largely due to the exemplary efforts of organized mosquito control agencies in conjunction with an enlightened and effective public health infrastructure. But even more mosquito-borne diseases are a mere seven-hour flight from our shores, and our public health agencies must be prepared to meet these challenges that they will eventually present.

Zika virus is thought to be primarily transmitted from human to human by the bite of an infected Aedes aegypti and possibly Aedes albopictus species of mosquitoes. Of these, Aedes aegypti has been primarily responsible for transmitting the disease due, in part, to its preference by humans both day and night and its predilection for biting the lower extremities out of sight. Moreover, females frequently take multiple partial blood meals often from different individual humans, not only increasing the likelihood of feeding on an infectious human, but also leading to single infectious females potentially feeding on and infecting multiple humans within a relatively short time period. This is unique.

Both Aedes aegypti and Aedes albopictus, the Asian Tiger mosquito are notoriously difficult to kill and/or prevent. They live inside our houses under furniture, beds, in closets. Their eggs can withstand months of drying and their

young can develop in water containers as small as a discarded soda bottle cap. Virtually any collection of stagnant water in containers, tree holes, leaf axles, et cetera can serve as an egg-laying habitat for these species. Thus, draining wet areas does not prevent their development around our homes and yards.

Aedes aegypti has been found in isolated areas of California and along the southern tier of states up into Georgia and South Carolina. Aedes albopictus is a bit more cold-hardy and its range includes those states but extends northward to Illinois and New York. States within this range have excellent integrated mosquito control programs in some areas, but mosquito control outside of their jurisdictions is spotty. Indeed, many potential ports of entry throughout the United States have limited or no mosquito control available and there is a pressing need for funding to establish sustainable mosquito control programs in these areas if outbreaks are to be contained.

Successful mosquito control is based first and foremost on a comprehensive knowledge of the vector in order to exploit its vulnerabilities. All prevention and control strategies are based on this knowledge; however, the cryptic nature of Aedes aegypti makes normal surveillance and control strategies problematic. This demands that mosquito control in the 734 established districts and over 1,100 municipal programs be improved in the following seven areas. Improved mosquito surveillance tools for adult Aedes aegypti, availability of pesticide resistance testing kits and accurate rapid diagnostic tests for arboviral agents and trapped mosquitoes, faster communications about protocols between public health laboratories and mosquito control programs, funding to underwrite new data call-ins that might influence a pesticide registrant's decision to keep proven products on the market, funding for field validation of new control modalities such as lethal overtraps, intracellular controls using Wolbachia, genetically modified mosquitoes, new active ingredients such as dopamine receptor agonists to name a few. We also need a national strategy to elicit sustained public participation in removing and draining containers used by Aedes aegypti as position sites. Also identifying areas at risk of Zika transmission, assisting to the extent possible any federal programs, underwriting the startup of new vector control programs in impoverished areas at risk.

The federal government has several mechanisms available to help these needs if funds already authorized were

to be appropriated. Three in particular come to mind; first, the expanded laboratory capacity program of CDC for funding increases in arboviral testing capacities.

Second, the Mosquito Abatement for Safety and Health Act by which local governments could receive matching federal funds up to $100,000 for the establishment and/or enhancement of mosquito abatement programs, and $100 million total for building sustainable programs where they do not exist. The funding for this was authorized but never appropriated.

Third, the Food Quality Protection Act which authorizes the use of federal funds when the cost of new data for public health pesticides was more than their producers could afford putting their registration at risk. The national capacity to control mosquito-borne disease at present and in the future will largely depend to the extent to which these support programs or their functional equivalent in the President's February 22nd Emergency Supplemental Fund Request are implemented. Increased tourism, travel, and trade make continual introductions of exotic diseases carried by mosquitoes virtually inevitable. Resources for prevention and control programs must be made available and employed so that future cases of exotic diseases can be contained and eliminated before their establishment and spread.

The President's recent request for emergency supplemental funding for Zika prevention and control tangibly addresses our acknowledgment of current shortfalls in mosquito-borne disease control capability and seeks avenues to remedy them towards our shared goal of protecting the American people from exotic diseases. The American Mosquito Control Association agrees. Our citizenry deserves no less. Thank you.

[The statement of Mr. Conlon follows:]

**********INSERT 12**********

Mr. Murphy. Thank you, Mr. Conlon.

Dr. Sheffield, you're recognized for five minutes.

STATEMENT OF JEANNE SHEFFIELD

Dr. Sheffield. Thank you. Chairman Murphy, Ms. Castor and representatives, I'd like to thank you for the opportunity today to testify before you on the effects of Zika virus in pregnant women and how clinicians are responding to this virus threatening the United States and the rest of the Americas.

The Zika virus epidemic is a unique situation. It is a mild disease in adults in most cases, of little consequence to date other than the uncommon but potentially devastating complication of Guillain-Barre Syndrome. However, maternal Zika infection during pregnancy can have enormous consequences to the developing fetus. Zika has received international attention predominantly because of its effect on the developing fetus, specifically the association with microcephaly, significant effects on brain growth and development, and ocular abnormalities. Thus, much of the focus so far of current efforts has been on the management of the at-risk patients.

You've heard extensive testimony about the origin of this virus and its spread over the last six decades, so I won't repeat myself or repeat that information for the sake of time. While the Continental United States has not identified a case of local transmission of Zika, there is a growing number of confirmed travel-related cases, several of these in pregnant women as we've heard about. While transmission of Zika virus is primarily through the infected mosquito, transmission may also rarely occur through infected blood in laboratory accidents, vertical transmission from a pregnant mother to the fetus has been confirmed, and finally cases of sexual transmission of Zika from an infected person to an uninfected sexual partner is increasingly being documented.

Data regarding Zika virus infection in pregnancy are limited, and it is imperative that resources are directed to elucidating the pathophysiology of the infection on pregnancy, rate of fetal transmission, influence of timing in infection and relation to pregnancy on fetal manifestations of the disease, and long-term consequences of fetal infection. While it is unknown at this time if pregnant women are more susceptible to Zika virus, the disease itself does not appear any worse in pregnant women compared to non-pregnant women. Zika infects pregnant women in any trimester, and the virus has

been found in multiple different tissues from fetal losses, amniotic fluid, the placenta, and the brain of infected neonates.

The Brazilian outbreak of virus was associated with a significant rise in microcephaly. Microcephaly itself is diagnosed when the head is significantly smaller than what would be expected for the sex and gestational age of the infant. There are many causes of microcephaly, average rate is about 2 to 12 per 10,000 live births in the United States. There are multiple etiologies or multiple causes, chromosomal abnormalities, genetic abnormalities, toxin exposures such as mercury, alcohol exposure during pregnancy, and in the case of Zika, also other infections such as cytomegalovirus and rubella.

The reason microcephaly develops in association with Zika is currently under investigation. Infants with microcephaly can have multiple long-term complications depending on the severity of the microcephaly and the associated abnormalities; seizures, developmental delay, including speech and motor abnormalities are just a few of these complications. There is no known cure, and treatments are very limited depending on what the etiology is of the microcephaly. Significant resources are going to have to be focused on the long-term care of these affected infants.

Since the microcephaly association was first noted several months ago, we now know that there's multiple other abnormalities, and I've detailed these in my written testimony. Soon after the association of Zika virus infection and fetal microcephaly was identified, the Centers for Disease Control and Prevention set up a health alert and brought together subject matter experts including arbovirus virologists, public health personnel, and obstetrics and gynecologists with expertise in infectious disease and pregnancy. While data were very limited at that time, interim guidelines were rapidly developed to inform physicians caring for pregnant women, management strategies were disseminated, and educational materials describing preventative measures were made widely available not just to physicians but to the general public. These guidelines have been updated several times as new information has been elucidated. As was mentioned, the American College of OBGYN and also the Society for Maternal-Fetal Medicine have played a very integral part in the development and dissemination of this information, and I will be glad to answer any questions related to the management of these patients.

Zika virus infection is now a notifiable disease allowing for better surveillance of disease burden. The CDC has developed a pregnancy registry with confirmed Zika infection in the United States. They actually released a report on Friday that was briefly mentioned earlier detailing the initial results of 257 Zika tests performed for pregnant women in the report, 3 percent were positive. The nine women that were positive, two electively terminated, two had a miscarriage or first trimester loss, one delivered an infant with severe microcephaly, and two pregnancies are ongoing, two pregnancies have delivered and so far there are no known effects to the infant. One woman was infected in a third trimester and delivered a healthy infant. So while this initial report is an important first step, much more is needed for the physician to be able to effectively counsel pregnant women at risk for infection. Support for both national and international research targeting key populations such as pregnant women is imperative. Until effective treatments and/or a vaccine are developed, prevention of maternal infection is necessary to prevent the devastating consequences of fetal infection. Thank you.

[The statement of Dr. Sheffield follows:]

**********INSERT 13**********

Mr. Murphy. Thank you, doctor. I'll now recognize myself for five minutes of questions.

First, Dr. Sheffield, has any of the medical academies or the AMA come out with any recommendations with regard to asking mothers and keep putting the record if they have traveled to any areas where Zika virus is known?

Dr. Sheffield. I think that's actually a superb question, and we talked about it quite extensively. My hospital, Johns Hopkins, we have developed a very comprehensive screening tool with a list of the countries and territories that are currently affected, and we are trying to spread this information out to multiple other centers. When I talk to other colleagues from around the country they are doing the same thing. So very similar to Ebola, we're working on a screening questionnaire.

Mr. Murphy. So would you say at this point, should it be a standard that OBGYNs and pediatricians ask that question of mothers, if they have traveled to during pregnancy?

Dr. Sheffield. Absolutely.

Mr. Murphy. And with regard to that, and this is whether or not they had symptoms, just if they traveled there or nearby.

Dr. Sheffield. Whether they traveled. The pregnant women regardless of symptoms require testing.

Mr. Murphy. Even if in second or third trimester, a travel.

Dr. Sheffield. Yes, sir.

Mr. Murphy. I mean, I know myself as a psychologist, worked with many years with developmentally delayed children that there's a lot of long-term intellectual motor and sensory complications. I must admit, I'm also concerned that regardless, because we don't know yet all the route of what happened to this virus with the developing brain, that I wonder even if an infant or a young child is also infected with the Zika virus, the outcome on the brain, we simply don't know that. Am I correct?

Dr. Sheffield. I think that is actually one of the big concerns, is that even if you're infected in the third trimester, have no evidence at delivery of microcephaly or neurologic abnormalities, the long-term follow-up of these babies is

imperative because we don't know what the long-term consequences are going to be.

Mr. Murphy. That's correct. I agree with you there.

Dr. Hotez, you've been critical what you call the narrative. We've been mostly hearing from the U.S. Government that the Continental U.S. is a wealthy place with few of the risk factors contributing to the rapid spread of the arbovirus infection such as Zika, dengue, and chikungunya in Latin America and the Caribbean. But as a specialist in tropical disease based in a major Gulf Coast urban center, why do you disagree with that narrative that we shouldn't worry as much?

Dr. Hotez. Thank you for that question. The reason is we have poor people in this country, we have 20 million Americans that live at half the U.S. poverty level. We now have 1.65 million families that live on less than $2 a day according to the University of Michigan Center for Poverty. And what we're finding is something very interesting about the world's neglected diseases, that currently most of the world's neglected diseases, which include Zika, are actually found in wealthy G20 countries, but it's the poor living among the wealthy that account to it for this. So the G20 countries account for most of the world's worm infections, and dengue, and chagas disease, and leishmaniasis. We have 12 million Americans now living with a neglected tropical disease in the United States, most of them in the American south, most living along the Gulf Coast. For all the reasons that I mentioned in my previous testimony that we know that poor areas are particularly vulnerable. I have pictures

here --

Mr. Murphy. But even with that, I only have a minute, 50 seconds. I want to ask, and then we can look at those later. But even so, the mosquito -- I mean, I don't know how far these mosquitoes may travel in their lifetime, get a wind. Do we have any idea? Mr. Conlon, is it miles?

Mr. Conlon. Not in the case of Aedes aegypti and Aedes albopictus. Their ranges are about 100 to 200 meters from where they actually breed.

Mr. Murphy. I see. And along these lines, too, does anyone know if the virus can live in the water in which they

breed, and can the virus be transmitted for an adult to offspring? Just to help the American public understand this. Does anybody know? If not, we'll -- -

Mr. Conlon. To my knowledge -- -

Mr. Murphy. Your microphone needs to be on.

Mr. Conlon. Oh, I'm sorry. To my knowledge, it can't reside in water. However, it is vertically transmitted from the mosquito, the adult mosquito to their offspring, so they're born with it.

Mr. Murphy. That's disturbing, too. In your testimony, Mr. Conlon, you also observed that malaria and yellow fever, both mosquito-borne diseases were once quite prevalent, but that today they no longer claim victims due to the efforts of the Organized Mosquito Control Agencies. How is this accomplished? And the infrastructure given is pretty disjointed. How can we improve that?

Mr. Conlon. Well, as Dr. Hotez mentioned, there are many places in the United States that do have socioeconomic conditions that are conducive to the spread of these types of diseases. They -- again, those conditions were quite evident back in the past in places like Norfolk, places like Louisiana, all throughout Louisiana. There were a number of different areas that these got transmitted. Dengue fever was first discovered in Philadelphia, Pennsylvania, so we should not rely upon the south to be the potential breeding ground for these things, but anywhere that poverty occurs where you've got difficulties in trash removal, you've got certain socioeconomic conditions conducive to keeping water containers inside. Those can really hurt.

I want to emphasize, though, that mosquito control is conducted on an integrated basis and we should not think that there is any silver bullet for this. We've got to utilize all the tools that are at our disposal in order to contract the -- what we need to do in order to keep these diseases from establishing. We need a number of different modalities.

Mr. Murphy. Thank you. I'm out of time. Now turn to Ms. Castor for five minutes.

Ms. Castor. Thank you. Well, thank you all very much. In addition to the previous panel, you all have really given everyone a wake-up call about what has to be done. And I'm more convinced than ever that we've got to move this

supplemental appropriation, and it can't get bogged down in the typical Congressional budget battles. We need to move it as quickly as possible.

And, Dr. Gostin, I wanted to thank you for emphasizing the moral imperative for the Congress to act quickly. And Dr. Hotez, I think you're absolutely right to raise the issue of Haiti right now and the consequences because there hasn't been much discussion about Haiti. And I think they are particularly at risk. I think we can do better in mobilizing the international aid community and religious community that have so many initiatives there.

I want to focus back on pregnant women because it appears that the impact and the connection to microcephaly came as something of an unwelcomed surprise. Dr. Sheffield, you've been very involved in drafting the guidelines for the CDC, the Society of Maternal-Fetal Medicine, and ACOG. Can you go into greater detail on the science and what we know?

Dr. Sheffield. So when the guidelines were first drafted back right -- very soon after the reports initially came out about the microcephaly, they called a group of people together, and we freely admitted -- you know, I was not a Zika expert at the time. I knew very little actually about the Zika virus infection. However, the group of us had done a lot of work over the years with other infections and how it affects pregnancy, such as cytomegalovirus, and so the group of us that came together at the request of the CDC kind of looked at what data was available to us with the understanding of what happens with other viruses, and drafted just the original, you know, the initial guidelines, which have subsequently been updated every time new data comes out. But the guidelines initially, if you look back a couple of months ago when they first came out, they were essentially screen everybody that traveled, and we talked a little bit about how to screen, the diagnostic tools that we've already talked about earlier today, and then ultrasound looking for actual fetal abnormalities, particularly in the head.

Ms. Castor. What's going on here? Why -- with other infectious diseases in maternal health, what -- are there any other diseases where we've seen similar impacts to the fetus or child that would develop microcephaly?

Dr. Sheffield. This virus is fascinating because this virus is very neurotropic. It likes the brain, it likes the fetal

brain and nervous tissue obviously in adults since we're talking about Guillain-Barre Syndrome, but it is very neurotropic. There aren't a lot of other viruses that affect the developing fetus that is so specific to the nervous system, or to the brain. There are other viruses such as rubella, one of the most devastating viruses out there that cause multiple fetal abnormalities, but it causes abnormalities in multiple different systems. Same with some of the other viruses and parasites that will affect a pregnant woman. This one so far has been very, very focused on brain and neurologic abnormalities.

Ms. Castor. Okay. So we're going to need extensive research on all that, and that is just starting. Is that right?

Dr. Sheffield. Absolutely.

Ms. Castor. Is that how you would characterize it? So let's drill down on the recommendations for maternal health. Because in the Western Hemisphere, as Dr. Hotez says, we are so interconnected, Florida to Brazil, and Latin America and Colombia, and Puerto Rico, to Mexico, to Haiti. It's just millions and millions of families, travelers where you're just not going to be able to talk about travel bans of things like that, so you've got to give folks the most constructive recommendations. So talk about citizens of the U.S. and Puerto Rico, what you're advising them right now if they are of childbearing age and intend to get pregnant?

Dr. Sheffield. So right now myself as I'm sitting across the table from one of my pregnant women that is considering traveling and my colleagues across the country are all pretty much following the ACOG, SMFM, and CDC guidelines, which is if you have a pregnant woman that is interested in traveling to a Zika affected area currently we, one, recommend against it. If they do have to travel there is excellent education out there about prevention of mosquito bites because if they do travel, it all becomes prevention because, again, there is no treatment, and there's no vaccine currently available. So for right now it is prevention. So we spend a lot of time if they do have to travel talking about preventative measures, and there again is a lot of information on the CDC website for that.

We also, if they come back from travel -- and this is where a lot of my patients are coming in, as two months ago they never heard of Zika virus. They've all traveled down to an affected area and they're coming back suddenly in a panic after seeing everything that's happened. And those are the ones where we have testing available. Again, not perfect as

we've heard, but it's what we have available, and then ultrasound or evaluation.

Ms. Castor. Could you name those specific areas so that we have that?

Dr. Sheffield. The specific areas for the evaluation?

Ms. Castor. The travel to.

Dr. Sheffield. Oh, travel to. So the CDC has a linked website of travel notice, and they keep updating it. Every time a new country or a new territory comes up, they update that list. It's about -- last I saw it was about 30 or so countries and territories, and it's on line. It's very easily accessible, and actually we update it, you know, for our clinicians. We have the link right there in clinic. They click on it, they pull it up, and they're able to say okay, where did you travel? All right, you're on the list.

Ms. Castor. But Brazil.

Dr. Sheffield. Brazil, Colombia, Puerto Rico, though Cuba is not on it, we actually have tested one patient that's traveled from Cuba, so we're talking about the Caribbean.

Ms. Castor. And it's not going to be a static list. That list is going to change.

Dr. Sheffield. No, it is frequently. It's actually frequently updated as new countries are reporting.

Ms. Castor. Thank you.

Mr. Murphy. Thank you. Yes, that list is available on CDC's website. It's quite extensive, throughout the Caribbean, Central America, South America, Mexico. Other issues coming up, too, for the summer Olympics, as well.

Mr. Collins, you're recognized for five minutes.

Mr. Collins. Thank you, Mr. Chairman. I want to thank the panel, as well. Maybe following up on Ms. Castor's comments.

I think what a lot of us are worried about is there is no vaccine, and if somebody does test positive there's no treatment, and it's somewhat disturbing but Dr. Sheffield, that some women would even choose to terminate the pregnancy. But picking up on that, education to me, because we're not going to have a vaccine tomorrow or next week,

and we'll have better diagnostics before we're going to have vaccines and treatments. So I'm thinking education, guidelines, pamphlet, you know, with a sense of urgency into the physicians' offices. I don't know how many typical doctors right now have this information in their waiting room, but a lot of times we think we're invincible, and from what I'm hearing. So a couple of questions; do we have even an idea, a 25-year old woman who -- you know, she's got 15 years or longer to be in her childbearing years. How long if she's infected, so she gets the Zika virus, she's not pregnant. She waits X period of time. Is that one year, two years, 10 years, never? Do we have any idea?

Dr. Sheffield. So right now the guidance is if you travel to an area you're not pregnant, we're recommending people wait at least four weeks. The reason for that is the incubation period is about up to two weeks. The viremic time period where they could -- where the virus can cross to the placenta and then to the fetus is somewhere around seven to ten days.

Mr. Collins. Yes, but what I'm getting at is, okay, she's tested positive. She's not pregnant. How long would a woman who knows she's had the Zika virus, she was infected. Should she wait to consider having children? Is it never, or is it one or two years? Do we have any guidelines in that area?

Dr. Sheffield. We don't. Right now we're saying about four weeks, but that is based on, again, very, very limited data. That's where we desperately need information coming out of Brazil, and Colombia, and some of the U.S. studies that are -- -

Dr. Hotez. It'll be important to determine if Zika is going by the same play book as something like dengue where the virus is in your system for a couple of weeks, and then it's gone. And that's probably the likely scenario. There are -- there is evidence that, for instance, West Nile virus can sometimes persist in the kidneys for periods of months or years, but that appears to be an exception -- -

Mr. Collins. So even though someone may be antibody positive the virus, like you're saying with dengue, has cleared the bloodstream. You're saying then at that point it's to the best of your knowledge they would no longer be infecting a fetus?

Dr. Sheffield. To the best of our knowledge, yes.

Dr. Hotez. Right.

Mr. Collins. That's very good news, actually, if there's such a thing as good news here.

Dr. Hotez. It's about the only good news about this virus.

Mr. Collins. Yes. But if it clears, which is the difference in HIV and some others, because it doesn't clear. Yes, sir?

Mr. Gostin. The other thing to consider is for women who are considering getting pregnant but are not pregnant now, what we tell them, because they won't necessarily go to their physician, their physician's office. That's why in addition to education in the doctor's office, I think we need to do public health information campaigns to advise young women about what their risks are so that they can make well-informed decisions. And this is particularly important with the Rio Olympics that are looming, because although it will be the Southern Hemisphere's winter, there still will be active transmission. And they'll be coming then to the northern height of the summer where we could then see local transmissions here. So those are all kinds of things to consider in addition to the fact that, as you've all said, you have so much interchange between Puerto Rico, other U.S. territories --

Mr. Collins. So if there is one absolute I'm assuming the one absolute is a pregnant woman should not travel to those areas, in an absolute -- because you're saying they could be third trimester and we don't know. So would that at least be a fair absolute; you're pregnant. You just stay away?

Dr. Sheffield. I'm a physician. We never deal in absolute -- we never say --

Mr. Collins. Well, sometimes you need absolutes.

Dr. Sheffield. But we do strongly recommend they not travel.

Dr. Hotez. The problem will come and what happens in the summer when the Gulf Coast of Texas or Florida becomes an area where -- included in the travel ban zone, and then we're going to -- -

Mr. Collins. That would be a nightmare.

Dr. Hotez. That would be a nightmare.

Mr. Collins. Total nightmare.

Dr. Hotez. That's a real -- -

Mr. Collins. But thank you for your testimony. This education is absolutely critical for us, as well as the public. And I want to thank the Chairman for holding this hearing, and thank the witnesses for your testimony. I yield back.

Mr. Murphy. Thank you. Ms. Castor, going to recognize you for an additional couple of minutes here, five minutes.

Ms. Castor. Thank you very much.

In some of the countries experiencing outbreaks many do not have access to primary health services; that means limited access to family planning, as well. Dr. Hotez, it's fairly plain but would you explain to everyone why it is in the best interest of Americans and American families that we tackle the disease in Brazil, and in Puerto Rico, and other places in the Western Hemisphere?

Dr. Hotez. Well, thank you for that question. I think what's becoming clear is the Gulf Coast of the United States is part of the same eco zone that the Caribbean and Central America is. There's a homogeneity there, especially in our impoverished areas. I can take you through parts of the Fifth Ward of Houston and you might think you're in Port Au Prince or Tegucigalpa, and so we have to realize that what is happening in Haiti and happening in Central America is the same vulnerability as the Gulf Coast, and take that accordingly.

Ms. Castor. Dr. Gostin.

Mr. Gostin. Yes. It's a very good, actually, because one of the things we've learned with SARS, with Ebola, with so many novel infectious diseases, and it's more true, or at least as much true with Zika is that we can't just be defensive in the United States. You actually have to go to the source of the infection; that, in other words, to protect ourselves we also need to protect the people and the eco system, and the mosquito population -- -

Ms. Castor. So what should we be doing, what should the U.S. be doing to insure that women in these countries have access to family planning services during this crisis?

Mr. Gostin. Well, I believe that for health reasons and for moral reasons we should encourage it. I mean, there are particular countries that have told women not to become pregnant for a year, two years, and more. And as Pope Francis said, we need to give them the tools to be able to achieve that goal. And, of course, if they do have infants, then we need to give the mother maternal health care, we need to give the child services. I think it's very important. And, of course, it's important in Puerto Rico because Puerto Rico is going through a major financial crisis, bankruptcies. It's Medicaid system is in shambles. And part of the President's appropriation request is to support that and it seems to me that as a territory of the United States it's very important. But also because of the interchange of travel between people in Puerto Rico and the United States.

Ms. Castor. Dr. Sheffield, give us the practical advice of doctor to patient you would give on family planning in the impacted areas.

Dr. Sheffield. So practically speaking, I am a advocate of providing effective contraception in order to, as you mentioned, provide a tool to prevent pregnancy if the woman so desires, if she does have to travel to Zika-affected areas. So if I have a woman that is not pregnant and is not interested in becoming pregnant in the near future, we do talk contraception, particularly if she is traveling down to Zika-affected areas.

Ms. Castor. And then there's also been the discovery that Zika also poses a risk through sexual transmission, so it's not just women. We must also target communications and resources to men who may carry and spread the Zika virus. Dr. Sheffield, what guidance would you offer to men traveling to areas with active Zika transmission?

Dr. Sheffield. So we've also -- this has kind of thrown a wrench in it in our discussions over the last month or so. Now that sexual transmission has been confirmed and we are discovering more and more cases of sexual transmission, again all of them so far have been male to female transmission as was mentioned earlier. Our counseling right now is if you are a male who has a pregnant female partner, when you come back from travel from a Zika-affected area use condoms or actually abstain from sexual practice; however, if you don't abstain, use condoms. And we're using the word, you know, consistently and correctly use the condoms, and trying to prevent transmission. It may not be 100 percent

unless it's true abstinence, but it at least provides some protection.

Ms. Castor. It's a very important message for the millions, and millions, and millions of our neighbors who travel across the Americas and in the Western Hemisphere, so thank you all very much for your testimony today.

Mr. Murphy. Thank you. I want to follow-up with a couple of questions, as well. First of all, with regard to this -- so you're recommending, obviously, abstain from travel, abstain from other contact here. Does anyone know if airlines, and cruise ships, and travel agents are spreading that word, as well? Professor Gostin?

Mr. Gostin. They have not yet, but what we saw with Ebola was that even before governments were implementing policies, the airline industry was doing that. This is a -- it's a major financial issue for the industry, as well, particularly again because of the large travel to the Olympics and others, people canceling their flights, so I think it's very important for the United States Government and other governments to work with the airline industry to make sure that they follow the best public health advice.

Mr. Murphy. Certainly advise that. Mr. Conlon, with regard to this, many times people travel to areas and then go to a resort area. One would assume that there would be some different sort of vector control there versus another part of the community. Do you have any advice on that?

Mr. Conlon. In places in the Caribbean that do have vector control capabilities in the resort areas, it tends to be rather problematic, even more so than in the United States. I would recommend that people, and particularly males that are going into this area, utilize EPA registered repellants. They do work, they do work against all these mosquitoes, and they just need to follow label recommendations. But I would caution everyone to make sure they're EPA registered. There's a lot of mosquito repellant products out there that have rather iffy data sets supporting them, so EPA has taken into consideration that they're safe to use and they're effective at least four hours when utilized properly. What you do is you reduce human mosquito contact, no problem with the disease.

Mr. Murphy. So it isn't just the matter of looking at what islands and countries to avoid, but also -- I don't necessarily hear give with me confidence that even if it is a four or five star resort that they necessarily have full vector

control. And if you still go there, to use some sort of mosquito repellant, so there's multiple levels.

Mr. Conlon. Absolutely. And I would also say that if you're going to a resort that's got an 18-story hotel you can find Aedes aegypti at 18 stories. They go up through the elevator shafts.

Mr. Murphy. Okay. In your testimony you also noted the American Mosquito Control Association is currently developing guidelines specifically geared towards aegypti and albopictus. What will these guidelines focus on, and when will they be ready, and how do you see them being put to use?

Mr. Conlon. Well, hopefully, we're going to get them ready by about April, but one can never know when you're talking about dealing with volunteers. We're specifically going to try to shift our control paradigms and our recommendations from reactive, which is oftentimes larvicide. Larvicide are not going to be the answer with this mosquito, primarily because we generally use larvicide because the larvae are contained in a small area, they're easy to get at, they're easy to kill, and then they spread out as adults, and make it difficult for us to deal with them with regard to adulticides. In the case of this mosquito, though, larvicide are not going to be the answer because they're occurring in the same area where the adults are, so you might as well kill the adults in addition to. So we're going to focus more on the adulticide issues, we're going to focus more on trying to get community support, elicit community support to get rid of the habitat. This is a human problem. This not necessarily at Aedes aegypti problem. We're creating the problem, and we need to be conversant in creating the solution, as well.

Mr. Murphy. All right, thank you. Dr. Sheffield, what do we know currently about the risk of a Zika infection passing from an asymptomatic mother to a child during pregnancy? It can still happen?

Dr. Sheffield. We think it can. There haven't been excellent documented cases yet of an asymptomatic mother passing to an infant, or passing to her fetus. That being said, we are assuming that it could happen, and so the recommendations are the same whether you're symptomatic or asymptomatic.

Mr. Murphy. And, again, that's something the OB and the pediatricians should always in screening questions, where have you been? So how frequently should pregnant women who could have had an asymptomatic Zika infection

be tested for the virus?

Dr. Sheffield. So right now when a pregnant woman comes back from a Zika-affected area, we're doing the initial test. We're doing the PCR, RT PCR if she is symptomatic. If she is asymptomatic, we are doing the IGM and the plaque-reducing neutralizing antibody test. If that is negative, we still are following up the fetus with serial ultrasounds. If the ultrasound becomes abnormal, we will retest a mother that initially tested negative, and we will offer amniocentesis to test the fetus, also.

Mr. Murphy. And do we have the capacity to handle all those tests?

Dr. Sheffield. Right now we have not been turned down on a test. Maryland actually is able to do the test. It's the one of the states that's able to do the test. However, when we start rolling this out to all 50 states, I think that is a large question, is if every pregnant woman who travels needs to be tested at least once, do we have the capacity? And then you start looking at the asymptomatic, or the symptomatic men and testing. I think that is a concern.

Mr. Murphy. Is it possible also for the Zika virus to be transmitted through a breast-feeding mother to her infant?

Dr. Sheffield. So that's an excellent question. For breast-feeding mothers, we have found right -- so far they have found Zika RNA in the breast milk, so we know that at some point the virus has made it to the breast milk. That being said, there have been no cases of transmission from breast milk. There also have not been active virus identified from the breast milk, so we know that there's parts of virus there. That's why the PCR comes back positive. But as of right now we haven't found active virus in breast milk.

Mr. Murphy. Well, I want to thank this panel and the previous panel. This is very sobering and, quite frankly, very frightening stories we have heard today about a very real nightmare of the spread of Zika virus. And we don't have the answers yet, we don't have the tests yet, we don't have the solutions, and I don't even think we know all the consequences yet of what this does to adults, to infants, and what we'll see in the future with children, whether it is those who have been affected in utero with the virus, or those who may have been affected during early childhood, because we

don't know what that could do to the developing brain, as well. So we'll monitor this very closely.

We thank you and the other panelists for your information on this. So I'd like to thank the witnesses and the members who have attended today. Thank you, Ms. Castor, for stepping in here.

I remind all members they have 10 business days to submit questions for the record. I ask that the witnesses all agree to respond promptly to the questions. And with that, this hearing is adjourned. Thank you.

[Whereupon, at 12:56 p.m., the subcommittee was adjourned.]